Statistical Analysis Plan

Study Title

A prospective, multi-centre, phase IV clinical trial to assess the safety and efficacy of Acalabrutinib capsules in Indian adult Patients with chronic lymphocytic leukaemia and relapsed and refractory mantle cell lymphoma

Protocol/ Study Number	:	D8220C00022
Sponsor Name	:	AstraZeneca Pharma India Limited
Sponsor Addre s	:	AstraZeneca Pharma India Limited Block N1, 12th Floor, Manyata Embassy Business Park Rachenahalli, Outer Ring Road, Bangalore-560045
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Designation	:	Biostatistician

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LIST OF ABBREVIATION

AE	Adverse Event
AESI	AEs of special interest
ALT	Alanine Aminotransferase
ANC	Absolute Neutrophil Count
BID	Twice daily
BTK	Bruton Tyrosine Kinase
CLL	Chronic Lymphocytic Leukaemia
CMV	Cytomegalovirus
CNS	Central Nervous System
CR	Complete Remission
CT	Computed Tomography
CTCAE	Common Terminology Criteria for Adverse Event
ECG	Electrocardiography
ECOG	Eastern Cooperative Oncology Group
EORTC QLQC30	European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire
Hb	Haemoglobin
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
ICH	International Conference on Harmonisation
IGHV	Immunoglobulin Variable Heavy Chain
iwCLL	International Workshop on Chronic Lymphocytic Leukaemia
LDT	Lymphocyte Doubling Time
MCL	Mantle Cell Lymphoma
MedDRA	Medical Dictionary for Regulatory Activities
MRI	Magnetic Resonance Imaging
PI	Prescribing Information
PR	Partial Remission
PRL	Partial Response with Treatment-Induced Lymphocytosis
PRO	Patients-reported outcome
SAE	Serious Adverse Event
SLL	Small Lymphocytic Lymphoma
SoA	Schedule of Activities

1. INTRODUCTION

The purpose of this document is to provide a description of the statistical methods and procedures to be implemented for the analysis of data from D8220C00022 study. This document is based on protocol version 1.0 Dated 01-SEP-2020. The statistical planning and conduct of analysis of the data from this study will follow the principles defined in relevant ICH-E9 guidelines. Any change from the planned analysis as described in the protocol, are detailed here, and any differences described here supersede the analysis as presented in the protocol.

2. Study Objective and Design

2.1 Study Objective

2.1.1 Primary Objective

- To investigate the safety of Acalabrutinib among Patients with treatment naïve and R/R CLL/ SLL, and relapsed & refractory MCL in Indian Patient

2.1.2 Secondary Objective

- To assess the efficacy of Acalabrutinib in Patients of CLL/SLL and relapsed & refractory MCL in Indian Patients.
- Patient-reported outcome (PRO)

2.2 Study Description

2.2.1 Study Design

The study is a phase IV, open-label, single-arm, multi-centre, prospective study to be conducted in India. The study will evaluate the safety and efficacy of Acalabrutinib in Indian adult Patients with CLL/SLL and Patients with MCL who have received at least one prior therapy. The Investigator will be trained on the locally approved Prescribing Information (PI) before the enrolment of the first Patient at their site to ensure compliance and proper dosing of the study drug. Patients will be monitored throughout the study period for AEs /SAEs/AESI of Acalabrutinib.

Patients with CLL/SLL and MCL who are eligible to receive Acalabrutinib treatment as per locally approved PI and ratified by an independent clinical judgment of treating physician will be evaluated for inclusion into the current phase IV trial. To enrol approximately 100 Patients (90 Patients of TN & R/R CLL and 10 R/R MCL Patients) into the study, it is expected that approximately 150 Patients will need to be screened.

The study will be initiated after approval by the Ethics Committee. Patients will undergo the following phases: Screening/Enrolment Phase, Treatment Phase, and Follow-up Phase.

The decision of Patients to participate in this study must not, in any way, impact the standard of care they are receiving or any benefits to which they are otherwise entitled. Prior to data collection, all Patients must sign an Informed Consent Form (ICF), allowing for data collection and source data verification to be performed in accordance with local requirements and Sponsor policy.

Two cohorts of Patients will be included in the current study (a) Patients with CLL/SLL who are treatment naïve or have received at least one prior therapy (N= 90) and (b) Patients with MCL who have received at least one prior therapy (N= 10). Potential Patients will undergo screening phase within 07 days prior to the first dose. Patients who meet the protocol-defined inclusion/exclusion criteria will be prospectively enrolled in the study.

Acalabrutinib capsules 100 mg are administered twice daily (BID) for 06 cycles, starting from Cycle 1, Day 1, and continuing up to Cycle 6, Day 28; or until study drug discontinuation due to either disease progression or, unacceptable toxicity, or other reasons, whichever occurs earlier.

Acalabrutinib will be provided by the Sponsor to Patients in the Treatment Phase. The Sponsor shall also conduct laboratory investigations for safety and efficacy evaluations, including haematology, biochemistry, radiology, and electrocardiography (ECG), as mentioned in the SoA table.

2.2.2 Inclusion Criteria

1. Men and Women aged 18yrs or more.
2. Eastern Cooperative Oncology Group (ECOG) performance status of 0,1, or 2
3. Able to receive all outPatient treatments, all laboratory monitoring, and all radiologic evaluations.
4. The following laboratory parameters:
   a. Absolute neutrophil count (ANC) ≥750 cells/µL or ≥500 cells/µL in Patients with documented bone marrow involvement, and independent of growth factor support 07 days before the assessment
   b. Platelet count ≥50,000 cells/µL or ≥30,000 cells/µL in Patients with documented bone marrow involvement, and without transfusion support 07 days before the assessment
   c. Aspartate transaminase (AST) and Alanine transaminase (ALT) ≤2.0 x ULN
   d. Total bilirubin ≤1.5 x ULN
   e. Estimated creatinine clearance of ≥30 mL/min
5. Refractory disease defined as achieving less than partial response with the most recent treatment within 6 months before study entry
6. Provision of signed, written and dated informed consent prior to any study-specific Procedures
7. The Patients of either CLL or MCL:

   a. CLL Patients:

i. Treatment naïve or ≥1 prior systemic therapy for CLL

ii. Diagnosis of CD20+ CLL that meets published diagnostic criteria (Hallek et al. 2018)

iii. An active disease that meets ≥1 of the following iwCLL 2018 criteria for requiring treatment:

1) Evidence of progressive marrow failure as manifested by the development of, or worsening of, anaemia and/or thrombocytopenia. Cut-off levels of Hb <10 g/dL or platelet counts <100 × 109/L are generally regarded as an indication for treatment. However, in some Patients, platelet counts <100 × 109/L may remain stable over a long period; this situation does not automatically require therapeutic intervention.
2) Massive (i.e., ≥6 cm below the left costal margin) or progressive or symptomatic splenomegaly.
3) Massive nodes (i.e., ≥10 cm in longest diameter) or progressive or symptomatic lymphadenopathy.
4) Progressive lymphocytosis with an increase of ≥50% over a 2-month period or Lymphocyte Doubling Time (LDT) in <6 months. LDT can be obtained by linear regression extrapolation of absolute lymphocyte counts obtained at intervals of 2 weeks over an observation period of 2 to 3 months; Patients with initial blood lymphocyte counts <30 × 109/L may require a longer observation period to determine the LDT. Factors contributing to lymphocytosis other than CLL (e.g., infections, steroid administration) should be excluded.
5) Autoimmune complications, including anaemia or thrombocytopenia poorly responsive to corticosteroids.
6) Symptomatic or functional extra-nodal involvement (e.g., skin, kidney, lung, spine).
7) Disease-related symptoms as defined by any of the following:

   a) Unintentional weight loss of ≥10% within the previous 06 months.

   b) Significant fatigue (i.e., ECOG performance scale 02 or worse; cannot work or unable to perform usual activities).

   c) Fever ≥100.5°F or 38.0°C for 02 or more weeks without evidence of infection.

   d) Night sweats for ≥1 month without evidence of infection.

b. MCL Patients:

i. Confirmed MCL with translocation t(11;14) (q13;q32) and/or overexpressed cyclin D1

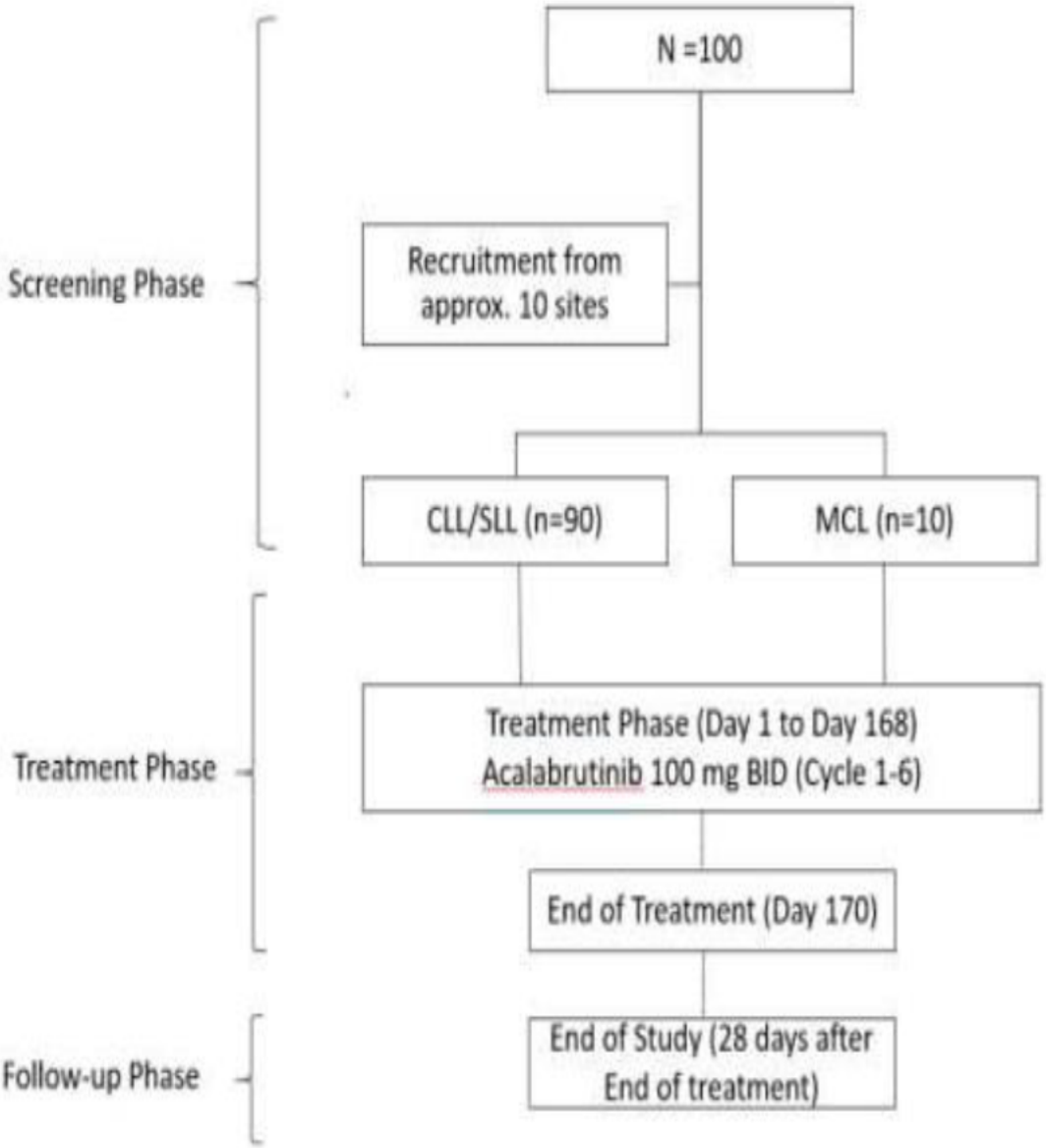
ii. Measurable nodal disease (one or more lesions measuring ≥2 cm in the longest diameter)

iii. Relapsed after, or were refractory to, 1-5 previous treatments.

2.2.3 Exclusion Criteria

1. Known prolymphocytic leukaemia, Central Nervous System (CNS) lymphoma or leukaemia; or known history of (or currently suspected) Richter's syndrome
2. Treatment with chemotherapy, external beam radiation therapy, anticancer antibodies, or investigational drug within 30 days of the first dose of study drug
3. Prior radio-conjugated or toxin-conjugated antibody therapy
4. Anticoagulation therapy (e.g., warfarin or equivalent vitamin K antagonists) within 07 days of the first dose of study drug.
5. Major surgery ≤30 days before the first dose of study drug
6. History of stroke or intracranial haemorrhage ≤6 months before the first dose of study drug.
7. History of bleeding diathesis
8. Prior exposure to a B-cell lymphoma-2 (Bcl-2) inhibitor or B-cell receptor inhibitor like BTKs
9. Active Cytomegalovirus (CMV) infection or serologic status reflecting active Hepatitis B or C infection or known history of infection with Human Immunodeficiency Virus (HIV), or any uncontrolled active systemic infection.
10. Significant cardiovascular disease such as uncontrolled or symptomatic arrhythmias, Congestive Heart Failure, or Myocardial Infarction within 06 months of screening, or any Class 3 or 4 cardiac diseases as defined by the New York Heart Association Functional Classification, or QTcB >480 msec at screening.
11. Requiring treatment with proton-pump inhibitors (e.g., Omeprazole, Esomeprazole, Lansoprazole, Dexlansoprazole, Rabeprazole, or Pantoprazole).
12. Breastfeeding or pregnant.
13. Current life-threatening illness, medical condition, or organ/system dysfunction which, in the Investigator's opinion, could have compromised the Patient's safety or put the study at risk.
14. Concurrent participation in another therapeutic clinical trial.

2.2.4 Study Flow Chart



2.2.5 Study Plan

Study Phase	Screening Phase	Treatment Phase [a]		Follow-up Phase
Cycle		Cycles 1-6	EOT	EOS
Visit No.	1	2-7 (Day 1 of each cycle)	8	
Study Days	-6 to 0	1-168 (28 days per cycle)	170	28 days post-EOT
Screening/Enrolment visit				
Informed consent [$]	X			
Eligibility Criteria	X			
Demographics/ Review medical history	X			
ECOG Performance Status	X	X	X	
General Physical examination [b]	X	Symptom-directed physical examination only		
Concomitant medication recording	Continuous from the time of ICF until 28 days after the last Acalabrutinib dose in the treatment phase.			
Study Drug Administration				
Acalabrutinib dosing		The recommended dose is Acalabrutinib 100 mg capsules BID, starting on Day 1 Cycle 1, until disease progression or unacceptable toxicity. Each cycle of treatment is 28 days.		
Disease Evaluations (Disease characteristics will be performed as per routine clinical practice)				
Baseline Disease Characteristics	X			
Safety Evaluations (baseline and each treatment visit) [*]				
Physical examination [b]	X	Symptom-directed physical examination only		
Vital parameters [c]	X	X	X	
Adverse event monitoring	Continuous from the time of ICF until 28 days after last study dose of Acalabrutinib.			

Study Phase	Screening Phase	Treatment Phase *		Follow-up Phase
Cycle		Cycles 1-6	EOT	EOS
Visit No.	1	2-7 (Day 1 of each cycle)	8	
Study Days	-6 to 0	1-168 (28 days per cycle)	170	28 days post-EOT
12-lead ECG	X	X	X	
Lymph node biopsy [d]	X			
Next-generation sequencing (NGS)-CLL panel [e]	X			
Haematology [f] & Biochemistry [g]	X	X	X	
Urinalysis [h]	X	X	X	
Pregnancy Test [i]	X	X	X	
Chest X-ray [j]	X	X	X	
Efficacy Evaluations (once in 3 months)				
CT/MRI [k]	X	X	X	
EORTC QLQ-C30 Questionnaire	X	X	X	

$ Patients must sign the informed consent form before any study-specific procedures are performed.

* Procedures conducted as part of the Patient's routine clinical management (e.g., blood count) and obtained before signing of the Informed Consent Form (ICF) may be utilised for screening or baseline purposes provided the procedures meet the protocol-specified criteria and were performed within the time frame (-6 to 0 day)

a. Treatment phase from Day 1 to Day 168. The treatment with Acalabrutinib will be continued until disease progression or unacceptable drug-related toxicity, whichever occurs earlier.

b. The screening physical examination will include, at a minimum, the general appearance of the Patient, height (screening only) and weight, and examination of the skin, eyes, ears, nose, throat, lungs, heart, abdomen, extremities, musculoskeletal system, lymphatic system, and nervous system. Symptom-directed physical examination, including tumour assessments by palpation, are done thereafter.

c. Vital signs (blood pressure, heart rate, and temperature) will be assessed after the Patient has rested in the sitting position.

d. Lymph node biopsy will be conducted in Patients with lymphadenopathy. However, a report of previous lymph node biopsy performed within 06 months before the study enrolment could be considered if the Patient did not receive any medication during that period

Study Phase	Screening Phase	Treatment Phase [a]		Follow-up Phase
Cycle		Cycles 1-6	EOT	EOS
Visit No.	1	2-7 (Day 1 of each cycle)	8	
Study Days	-6 to 0	1-168 (28 days per cycle)	170	28 days post-EOT

e. Next-generation sequencing will be conducted to understand the genetic profile in Indian settings. Molecular cytogenetics (FISH) for del(13q), del(11q), del(17p), trisomy 12 in peripheral blood lymphocytes; TP53 mutation; immunoglobulin variable heavy chain (IGHV) mutational status will be assessed before the start of treatment in CLL/SLL-naïve Patients, or CLL/SLL Patients who did not have their report. However, MCL Patients are Relapsed/Refractory and their previous report data will be used. A six months old report can be considered for both the conditions.

f. Haematology will include a complete blood cell count [white blood cell count, haemoglobin (Hb), haematocrit, reticulocyte, and platelet count] and differential leukocyte count, including both percent and an absolute number of lymphocytes. Haematology need not be repeated on Cycle 1 Day 1if screening haematology was within 5 days.

2.3 Randomization

Not Applicable

2.4 Blinding and Un-Blinding

Not Applicable

2.5 Interim Analysis

Interim analyses is planned for first 50 subjects who completes the study. All the primary safety analysis will be produced for the interim analysis.

3. Population Analysis Set

3.1 Full Analysis Set

The Full Analysis Set (FAS) will consist of all enrolled Patients who received at least one dose of Acalabrutinib.

The FAS will be used for all analyses of safety and efficacy.

4. Sample Size and Power Calculations

The primary endpoint of the trial is to demonstrate the safety profile of Acalabrutinib in routine clinical practice as assessed by the incidence of adverse events (AEs) (Serious and Non-serious AEs) observed during the trial. As per the Health Authority requirement, the total sample size of the study will be approximately 100.

5. Patient Characteristics and Study Conduct Summaries

5.1 General Considerations

Statistical Analysis will be performed using SAS (version 9.4 or higher) software (SAS Institute Inc USA). Categorical variables will be summarized with the frequency and percentage of Patients in each category. Continuous variables will be summarized descriptively with the number of Patients, mean, standard deviation, minimum, median and maximum values.

5.2 Decimal Point

Unless otherwise noted, means, median, will be presented to one decimal place more than the measured value, the same decimal as the measured value, percentages and confidence intervals will be presented to two decimal places and p-value will be presented to three decimal place. Percentages after zero counts will not be displayed and percentages equating to 100% will be presented as 100%, without any decimal places.

5.3 Disposition of Patients

Patient disposition table will be based on all enrolled Patients who consented to participate in the study. The following summaries will be included in the disposition table: total number of Patients screened in the study, number and percentage of Patients who failed screening, number and percentage of Patients who completed the study, and number and percentage of Patients who discontinued from the study with reason for discontinuation.

5.4 Demographic and Baseline Characteristics

Demographic and baseline characteristics will be summarized based on the Full Analysis Set.

Descriptive summaries will be provided for the demographic and baseline characteristics. Demographic characteristics and baseline characteristics such as Age, Gender, Height, Race, etc. will be summarized and tabulated for Full Anlyssis set.

All the continuous variables (i.e., age, height etc.) will be summarized by n, mean, standard deviation, minimum, median and maximum values. All the categorical variables will be summarized as counts and percentages.

6. Efficacy Analysis Strategy

6.1 Efficacy Endpoints

6.1.1 Primary Endpoint

- Adverse Events (AEs), Serious Adverse Events (SAEs), and AEs of Special Interest (AESI) including Arrhythmias (Atrial Fibrillation), Anaemia, Hypertension, Bleeding, Infections, Reasons for discontinuation and second primary malignancies

6.1.2 Secondary Endpoint

- Objective response to treatment.
- Health related quality of life (EORTC QLQC30 Questionnaire)

6.2 Efficacy Hypothesis

Not Applicable

6.3 Statistical Methods for Efficacy Analysis

All primary and secondary efficacy endpoints will be summarized by Full Analysis Set.

Categorical data will be summarized using frequencies and percentages. Continuous data will be summarized with descriptive statistics, including mean, standard deviation, median, minimum, and maximum.

6.3.1 Primary Endpoint Analysis

Primary Endpoint evaluations will include adverse event monitoring, physical examinations, ECG monitoring, clinical laboratory investigations (haematology and biochemistry), vital sign measurements, ECOG performance status and death as observed by the Investigator.

Adverse Events (AEs), Serious Adverse Events (SAEs), and AEs of Special Interest (AESI) will be summarized using frequencies and percentages.

Physical examination will be collected as per visit scheduled. Physical examination results (normal /abnormal) from scheduled visits will be summarized for each body system. A listing will be provided for the Normal/abnormal physical examination parameters.

A 12-lead electrocardiogram (ECG) will be performed as per visit scheduled. ECG results (normal, abnormal clinically insignificant, abnormal clinically significant) will be summarized as counts and percentage.

Laboratory investigations (haematology and biochemistry) data will be collected as per visit scheduled. Laboratory values will be presented using the International System of Units (SI units). Observed values will be summarized descriptively (n, mean, median, standard deviation, minimum, and maximum values). A listing will be provided which contains data for each laboratory parameter.

Vital signs will be performed as per visit scheduled. Vital signs parameters include Systolic Blood Pressure, Diastolic Blood Pressure, Heart Rate, Respiratory rate and Temperature. Descriptive summaries (n, mean, median, standard deviation, minimum and maximum values) of observed values in each vital sign parameter at each assessment visit will be presented. A listing will be provided for all vital signs parameters assessments.

ECOG will be performed as per visit scheduled. ECOG performance status will be summarized as counts and ercentage.

6.3.2 Secondary Endpoint Analysis

Secondary Endpoint evaluations will be assessed based on iwCLL 2018 criteria for CLL/SLL and for MCL . Efficacy will be based on objective response [Complete Remission (CR) + Partial Remission (PR) and Partial response with lymphocytosis (PRL)] via Computed Tomography (CT) scans or Magnetic Resonance Imaging (MRI). The sum of complete response and partial responses and Partial response with lymphocytosis (PRL)] will be summarized using frequencies, percentage and 95% CI will be calculated using Clopper Pearson confidence interval method.

Health related quality of life (EORTC QLQC30 Questionnaire) summarized using frequencies and percentage.

7. References

- D8220C00022 Protocol, Version No: 01, AstraZeneca Pharma India Limited, Block N1, 12th Floor, Manyata Embassy, Business Park, Rachenahalli, Outer Ring Road, Bangalore-560045
- ICH E3 Guideline
- ICH E9; STATISTICAL PRINCIPLES FOR CLINICAL TRIALS.

8. Mock Tables

Table 14.1.1. Patient Disposition in the Study

	CLL/SLL (N=xx)	MCL (N=xx)	Total (N=xx)
	n (%)	n (%)	n (%)
Patients Screened	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Screen Failures	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Patients Completed the study	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Patients Discontinued the study	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Reason for Discontinuation			
Patient Decision	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Adverse Event	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Severe non-compliance to study protocol	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Initiation of alternative anticancer therapy including another investigational agent	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Disease progression	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Pregnancy or intent to become pregnant	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Other	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Other 1	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Other 2	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)

- The Capital "N" in the column header represents the total number of all Enrolled Patients.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages in the “Patients Screened”, “Screen Failures”, “Patient completed the study” and “Patients Dicontinued the study” rows are based on the number of Patient in each group.
- Percentages in the “Reasons for Discontinuation” rows are based on the number of Patients Discontinued study in each group.
- Note: Screened Patients are those who signed the informed consent
- Source :Listing 16.2.1.1, listing 16.2.1.2

Table 14.1.2. Summary of Demographic and Baseline Characteristics

Demographic and Baseline Variables	CLL/SLL (N=xx)	MCL (N=xx)	Total (N=xx)
Age (Years)			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
Gender			
Male	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Female	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Missing	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Race			
Asian	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Other	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Other 1	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Other n	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Height (cm)			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages are based on number of patient in each group.
- SD = Standard Deviation, min=minimum, max=maximum
- Source :Listing 16.2.2.

Table 14.1.3. Summary of Medical and Surgical History

System Organ Class /Preferred Term	CLL/SLL (N=xx)	MCL (N=xx)	Total (N=xx)
	n (%)	n (%)	n (%)
Patient with any medical history	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
System Organ Class 1	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Preferred Term 1	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Preferred Term 2	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
System Organ Class 2	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Preferred Term 1	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Preferred Term 2	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
System Organ Class 3	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Preferred Term 1	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Preferred Term 2	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
System Organ Class 4	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Preferred Term 1	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Preferred Term 2	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
System Organ Class 5	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Preferred Term 1	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Preferred Term 2	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages in the "Patient with any medical history" rows are based on number of patient in each group.
- Percentages in the "System Organ Class" and "Preferred Term" rows are based on number of Patient with any medical history in each group.
- Medical histories were coded using MedDRA Ver23.0
- Source :Listing 16.2.6

Table 14.1.4. Summary of Concomitant Medication

	CLL/SLL (N=xx)	MCL (N=xx)	Total (N=xx)
	n (%)	n (%)	n (%)
Visit 1			
Any concomitant medication given during visit			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Any prior therapy received for Chronic Lymphocytic Leukemia/ Mantle Cell Lymphoma			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Patient refractory to the Therapy			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Visit x			
Any New Concomitant medication given Since Last Visit			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages are based on number of patient in each group.
- Programme Note: Visit x- Visit 2 up to Visit 8.
- Source :Listing 16.2.19

Table 14.1.5. Summary of Baseline Disease Characteristics

	CLL/SLL (N=xx)	MCL (N=xx)	Total (N=xx)
	n (%)	n (%)	n (%)
Clinical Staging (Rai Staging) of Chronic Lymphocytic Leukaemia			
Stage 0	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Stage I	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Stage II	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Stage III	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Stage IV	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Characteristics			
Only Blood abnormality	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Blood abnormality with lymphadenopathy	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Blood abnormality with organomegaly	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
CLL-IPI Score			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
Mantle Cell Lymphoma			
Relapsed	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Refractory	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Clinical Staging (Ann Arber)			
Stage I	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Stage II	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Stage IE	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Stage IIE	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Stage III	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Stage IIIS	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Stage IIIE	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Stage IV	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Genomic alteration			
Translocation t(11;14) (q13;q32)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Overexpressed cyclin D1	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
MIPI Score			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages are based on number of patient in each group.
- SD = Standard Deviation, min=minimum, max=maximum
- Source :Listing 16.2.3.

Table 14.1.6. Summary of Lymph Node Biopsy

	CLL/SLL (N=xx)	MCL (N=xx)	Total (N=xx)
	n (%)	n (%)	n (%)
Lymph node enlarged			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Size of Lymph node (mm)			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
Lymph node biopsy performed within 6 months before study enrolment			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Method of Biopsy			
Fine-needle aspiration biopsy	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Core needle biopsy	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Open (surgical) biopsy	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages are based on number of patient in each group.
- SD = Standard Deviation, min=minimum, max=maximum
- Source :Listing 16.2.4.

Table 14.1.7. Summary of Next Generation Sequencing_CLL

	(N=xx)
	n (%)
Genomic sample collected for molecular cytogenetics (FISH)	
Yes	xx (xx.xx)
No	xx (xx.xx)
NA	xx (xx.xx)
Any genomic alteration observed	
Yes	xx (xx.xx)
No	xx (xx.xx)
If Yes	
11q deletion	xx (xx.xx)
13q deletion	xx (xx.xx)
17p deletion	xx (xx.xx)
12 addition	xx (xx.xx)
TP53 mutation	xx (xx.xx)
IGHV mutation	xx (xx.xx)
Other	xx (xx.xx)
Other 1	xx (xx.xx)
Other n	xx (xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages in the “Genomic sample collected for molecular cytogenetics” and “Any Genomic alteration observed” rows are based on number of patient in each group.
- Percentages in the “If yes” rows are based on number of Patient Any genomic alteration observed.
- Source :Listing 16.2.5.

Table 14.1.8. Summary of Chest X-Ray

	CLL/SLL (N=xx)	MCL (N=xx)	Total (N=xx)
	n (%)	n (%)	n (%)
Visit x			
Patient have any sign and symptom of Pneumonia			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Views			
Posteroranterior	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Anteroposterior	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Lateral	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Assessment Result			
Normal	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Abnormal	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
If abnormal			
Unilateral	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Bilateral	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
If Unilateral			
Unilobar	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Bilobar	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- Percentage in the “Patient have any Sign and Symptoms of Pneumonia” rows are based on number of patient in each group
- Percentage in the “Views” rows are based on the Number of Patient have any Sign and Symptoms of Pneumonia in each group.
- Programmer Note Visit x: Visit 1 up to Visit 8
- Source :Listing 16.2.8.

Table 14.1.9. Summary of urine Pregnancy Test

	CLL/SLL (N=xx)	MCL (N=xx)	Total (N=xx)
	n (%)	n (%)	n (%)
Visit x			
Urine Pregnancy Test Performed			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Result			
Positive	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Negative	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- Programmer Note Visit x: Visit 1 up to Visit 8.
- Percentage in the “Urine Pregnanacy Test” row based on number of patient in each group.
- Percentages in the “Result” row are based on the number of Patient with urine Pregnancy Test performed in each group.
- Source :Listing 16.2.18.1

Table 14.2.1. Analysis of Objective Response

	CLL/SLL (N=xx) n (%)	MCL (N=xx) n (%)	Total (N=xx) n (%)
Visit 5			
Response Assessment			
Complete Response (CR)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Partial Response (PR)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Partial Response with lymphocytosis (PR-L)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Objective response	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
95 % CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Visit 8			
Response Assessment			
Complete Response (CR)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Partial Response (PR)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Partial Response with lymphocytosis (PR-L)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Objective response	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
95 % CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)

- Objective response =Complete Response (CR) + Partial Response (PR) + Partial Response with lymphocytosis (PRL)
- Percentage in the "Reponse Assessment"are based on number of patient in each group.
- 95 % CI will be calculated based on clopper Pearson confidence interval method
- Source :Listing 16.2.9.2

Table 14.2.2. Summary of QLQ-C30 Questionnaire

	CLL/SLL (N=xx)	MCL (N=xx)	MCL (N=xx)
	n (%)	n (%)	n (%)
Visit x			
Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Do you have any trouble taking a long walk			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Do you have any trouble taking a short walk outside of the house			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Do you need to stay in bed or a chair during the day			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Do you need help with eating, dressing, washing yourself or using the toilet			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Were you limited in doing either your work or other daily activities			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Were you limited in pursuing your hobbies or other leisure time activities			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Were you short of breath			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Have you had pain			

1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Did you need to rest			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Have you had trouble sleeping			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Have you felt weak			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Have you lacked appetite			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Have you felt nauseated			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Have you vomited			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Have you been constipated			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Have you had diarrhea			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Were you tired			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)

3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Did pain interfere with your daily activities			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Have you had difficulty in concentrating on things, like reading a newspaper or watching television			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Did you feel tense			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Did you worry			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Did you feel irritable			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Did you feel depressed			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Have you had difficulty remembering things			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Has your physical condition or medical treatment interfered with your family life			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Has your physical condition or medical treatment interfered with your social activities			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)

3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Has your physical condition or medical treatment caused you financial difficulties			
1 (Not at all)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2 (A little)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3 (Quite a bit)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4 (Very much)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
How would you rate your overall health during the past week			
1 (Very Poor)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
5	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
6	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
7 (Excellent)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
How would you rate your overall quality of life during the past week			
1 (Very Poor)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
5	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
6	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
7 (Excellent)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Total Score			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- Programmer Note Visit x: Visit 1, Visit 5 and Visit 8
- Percentage are based on number of patient in each group.
- Source :Listing 16.2.10.

Table 14.3.1. Summary of Adverse Event

	CLL/SLL (N=xx)	MCL (N=xx)	Total (N=xx)
	n (%)	n (%)	n (%)
Patient Experience Any Adverse Event			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
CTCAE grade			
Mild	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Moderate	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Severe	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Life – Threatening or disabling	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Death	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Investigator's causality rating against the Investigational Product			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Action Taken			
None	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Non-drug treatment required	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Hospitalization/ prolonged hospitalization	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Diagnostic or clinical test(s) conducted	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Drug Withdrawn	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Patient Withdrawn			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Treatment taken			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Outcome			
Recovered without sequelae	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Recovered with sequelae	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Not recovered/ Not resolved	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Recovering/ resolving	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Unknown	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Fatal	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages in the "Patient Experience Any Adverse Event" rows are based on number of patient in each group.
- Percentages in the "CTCAE grade, Investigator's causality rating against the Investigational Product, Action Taken, Patient Withdrawn, Treatment taken and Outcome" rows are based on number of Patient Experience Any Adverse Event in each group.
- Source :Listing 16.2.11.1, Listing 16.2.11.2

Table 14.3.2. Summary of Physical examination

	CLL/SLL (N=xx)	MCL (N=xx)	Total (N=xx)
	n (%)	n (%)	n (%)
Visit x			
Physical examination performed			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
System x			
Normal	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Abnormal NCS	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Abnormal CS	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- Percentages in the “Physical Examination performed” rows are based on number of patient in each group.
- Percentages in the “System x” rows are based on number of Patient Physical Examination performed in each group.
- Programmer Note: Generate summaries for the following System x :General Appearance, Skin, Eyes, Ears, Nose, Throat, Lungs, Heart, Abdomen, Extermities, Musculoskeletal System, Lymphatic System, Nervous System, Liver, Spleen and Other.
- NCS= Non-clinically significant
- CS= clinically significant
- Programme Note: Visit x- Visit 1 up to Visit 8
- Source :Listing 16.2.13

Table 14.3.3. Summary of Electrocardiogram

	CLL/SLL (N=xx)	MCL (N=xx)	Total (N=xx)
Visit x			
ECG Performed			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Heart rate (bpm)			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
QRS (ms)			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
PR (ms)			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
RR (ms)			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
QT (ms)			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
QTcB (ms)			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- SD = Standard Deviation, min=minimum, max=maximum
- Visit x: Visit 1 up to Visit 8
- Source :Listing 16.2.14

Table 14.3.4.1. Summary of Laboratory assessment for Haematology

	CLL/SLL (N=xx)	MCL (N=xx)	Total (N=xx)
Visit x			
Sample Collected			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Haematology Parameter x			
n	Xx	Xx	Xx
Missing	Xx	Xx	Xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- SD = Standard Deviation, min=minimum, max=maximum
- Percentages in the “Sample collected” rows are based on number of patient in each group.
- Programmer Note: Generate summaries for the following Haematology parameters x: Haematocrit (%), Haemoglobin (g/dL), Neutrophils (%), Basophils (%), Eosinophils (%), Monocytes(%), Absolute Lymphocytes Count(thou/µL), Percentage Lymphocytes (%), Reticulocyte (%), Absolute Neutrophils Count (thou/µL), Platelet Count (thou/µL), Total leukocyte count(thou/µL).
- Programmer Note Visit x: Visit 1 up to Visit 8
- Source :Listing 16.2.15.1

Table 14.3.4.2. Summary of Laboratory assessment for Biochemistry

	CLL/SLL (N=xx)	MCL (N=xx)	Total (N=xx)
Visit x			
Sample Collected			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Biochemistry Parameter x			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- SD = Standard Deviation, min=minimum, max=maximum
- Percentages in the “Sample collected” rows are based on number of patient in each group.
- Programmer Note: Generate summaries for the following parameters x – Albumin (g/dL), Glucose (mg/dL), Amylase (U/L), Lipase (U/L), Alkaline phosphatase (U/L), Lactate dehydrogenase (U/L), Alanine aminotransferase (U/L), Aspartate aminotransferase (U/L), Potassium (mmol/L), Bicarbonate (mmol/L), Sodium (mmol/L), Calcium (mg/dL), Total bilirubin (mg/dL), Chloride(mmol/L), Total Protein (g/dL), Creatinine (mL/min/1.73m^2), Urea (mg/dL), Blood Urea Nitrogen (mg/dL), Gamma-glutamyltransferase (U/L), Magnesium (mg/dL), Haptoglobin (g/L) and b2-microglobulin(ng/ML).
- Programmer Note Visit x: Visit 1 up to Visit 8.
- Source :Listing 16.2.15.2

Table 14.3.4.3. Summary of Laboratory assessment for Serology

	CLL/SLL (N=xx)	MCL (N=xx)	Total (N=xx)
	n (%)	n (%)	n (%)
Sample Collected			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
HIV			
Positive	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Negative	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Active Cytomegalovirus (CMV) infection			
Positive	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Negative	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Hepatitis B surface antigen (HBsAg)			
Positive	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Negative	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Hepatitis B surface antibody (HBsAb)			
Positive	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Negative	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Anti-HBc antibody			
Positive	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Negative	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Anti-HCV antibody			
Positive	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Negative	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- Percentage rows are based on number of patient in each group
  Percentage in the "HIV", "Active Cytomegalovirus (CMV) infection"," Hepatitis B surface antigen (HBsAg)"," Hepatitis B surface antibody (HBsAb)"," Anti-HBc antibody" and "Anti-HCV antibody" rows are based on /nuber of Patient Sample Collected.
- Source :Listing 16.2.15.4

Table 14.3.5. Summary of Vital Signs

	CLL/SLL (N=xx)	MCL (N=xx)	Total (N=xx)
Visit x			
Vital Signs Collected			
Yes	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
No	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Weight (Kg)			
n	Xx	Xx	Xx
Missing	Xx	Xx	Xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
Heart rate (bpm)			
n	Xx	Xx	Xx
Missing	Xx	Xx	Xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
Respiratory rate (Breaths/min)			
n	Xx	Xx	Xx
Missing	Xx	Xx	Xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
Systolic Blood Pressure (mmHg)			
n	Xx	Xx	Xx
Missing	Xx	Xx	Xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
Diastolic Blood Pressure (mmHg)			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)
Temperature (F)			
n	xx	xx	xx
Missing	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
(min, max)	(xx.xx, xx.xx)	(xx.xx, xx.xx)	(xx.xx, xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- SD = Standard Deviation, min=minimum, max=maximum ;Percentage rows are based on the number of Full Analysis Set.
- Visit x: Visit 1 up to Visit 8 ; Source :Listing 16.2.16

Table 14.3.6. Summary of ECOG

ECOG performed	CLL/SLL (N=xx)	MCL (N=xx)	Total (N=xx)
	n (%)	n (%)	n (%)
Visit x			
ECOG Grade			
0	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
1	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
2	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
3	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
4	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
5	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)

- The Capital "N" in the column header represents the total number Full Analysis Set.
- The small "n" in summary statistics represents the total number of Patients.
- Percentage rows are based on number of patient in each group.
- Programme Note: Visit x- Visit 1 up to Visit 8.
- Source :Listing 16.2.17

Listing 16.2.1.1. Listing of Patient Informed Consent Details

Patient Number	Patient Group	Informed consent	Date and Time for Informed Consent
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM

Listing 16.2.1.2. Listing of Patient Study Completion

Patient Number	Patient Group	Patient completed the study	Date of study completion/discontinuation	Primary reason for withdrawal	Other, specify
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY	Xxxx	Xxxx
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY	Xxxx	Xxxx
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY	xxxx	xxxx
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY	xxxx	xxxx
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY	xxxx	xxxx

Listing 16.2.2. Listing of Patient Demographics

Patient Number	Patient Group	Age/Gender	Date of Birth	Height (cm)	Race	Other, Specify
xx-xxxx	(CLL/SLL)/(MCL)	xx/xxx	DD-MMM-YYYY	xxx	xxxx	xxxx
xx-xxxx	(CLL/SLL)/(MCL)	xx/xxx	DD-MMM-YYYY	xxx	xxxx	xxxx
xx-xxxx	(CLL/SLL)/(MCL)	xx/xxx	DD-MMM-YYYY	xxx	xxxx	xxxx
xx-xxxx	(CLL/SLL)/(MCL)	xx/xxx	DD-MMM-YYYY	xxx	xxxx	xxxx
xx-xxxx	(CLL/SLL)/(MCL)	xx/xxx	DD-MMM-YYYY	xxx	xxxx	xxxx

Listing 16.2.3. Listing of Patient Baseline Disease characteristics

Patient Number	Patient Group	Date of Diagnosis	Clinical Staging of Chronic Lymphocytic Leukaemia	Characteristics	CLL-IPI Score	Mantle Cell Lymphoma	Clinical Staging	Genomic Alteration	MIPI Score
xx-xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	xx	xxxx	xxxx	Relapsed / Refractory	xxxx	xxxx	xxxx
xx-xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	xx	xxxx	xxxx	Relapsed / Refractory	xxxx	xxxx	xxxx
xx-xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	xx	xxxx	xxxx	Relapsed / Refractory	xxxx	xxxx	xxxx
xx-xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	xx	xxxx	xxxx	Relapsed / Refractory	xxxx	xxxx	xxxx
xx-xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	xx	xxxx	xxxx	Relapsed / Refractory	xxxx	xxxx	xxxx

Listing 16.2.4. Listing of Patient Lymph Node Biopsy

Patient Number	Patient Group	lymp node enlarged	Lymp node (mm)	lymph node biopsy required	lymph node biopsy performed within 6 months before study enrolment	Date of biopsy	Patient receive any medication for the study indication from day of biopsy till date	Method of Biopsy
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	Yes/No	Yes/No	DD-MMM-YYYY	Yes/No	Xxxx
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	Yes/No	Yes/No	DD-MMM-YYYY	Yes/No	Xxxx
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	Yes/No	Yes/No	DD-MMM-YYYY	Yes/No	Xxxx
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	Yes/No	Yes/No	DD-MMM-YYYY	Yes/No	Xxxx
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	Yes/No	Yes/No	DD-MMM-YYYY	Yes/No	xxxx

Listing 16.2.5. Listing of Patient Next Generation Sequencing-CLL

Patient Number	Genomic sample collected for molecular cytogenetics (FISH)	Date of sample	Any genomic alteration observed	Specify the alterations	Other, specify
xx-xxxx	Yes/No/NA	DD-MMM-YYYY	Yes/No	xxxx	xxxx
xx-xxxx	Yes/No/NA	DD-MMM-YYYY	Yes/No	xxxx	xxxx
xx-xxxx	Yes/No/NA	DD-MMM-YYYY	Yes/No	xxxx	xxxx
xx-xxxx	Yes/No/NA	DD-MMM-YYYY	Yes/No	xxxx	xxxx
xx-xxxx	Yes/No/NA	DD-MMM-YYYY	Yes/No	xxxx	xxxx

Listing 16.2.6. Listing of Patient Medical or Surgical History

Patient Number	Patient Group	Patient have any medical or Surgical History	Seq. No	Medical/Surgical History Description	System Organ Class	Preferred Term	Start Date	Stop Date	Ongoing	Received Treatment
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	xx	xxxx	xxxx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	Yes/No
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	xx	xxxx	xxxx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	Yes/No
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	xx	xxxx	xxxx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	Yes/No
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	xx	xxxx	xxxx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	Yes/No
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No	xx	xxxx	xxxx	xxxx	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	Yes/No

Listing 16.2.7.1. Listing of Patient Acalabrutinib dosing (Part I)

Patient Number	Visit	Patient Group	Capsule Acalabrutinib dispensed for cycle 1	Number of Capsule dispensed	IP kit Number	Acalabrutinib administered at the visit
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xx	xxxxxx	Yes/No
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xx	xxxxxx	Yes/No
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xx	xxxxxx	Yes/No
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xx	xxxxxx	Yes/No
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xx	xxxxxx	Yes/No

Listing 16.2.7.2. Listing of Patient Acalabrutinib dosing (Part II)

Patient Number	Visit	Patient Group	Capsule Acalabrutinib dispensed for cycle 2	Capsule Acalabrutinib dispensed for cycle 3	Capsule Acalabrutinib dispensed for cycle 4	Capsule Acalabrutinib dispensed for cycle 5	Capsule Acalabrutinib dispensed for cycle 6	Number of Capsule dispensed	IP kit Number	Acalabrutinib administered at the visit
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	xx	xxxxxx	Yes/No
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	xx	xxxxxx	Yes/No
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	xx	xxxxxx	Yes/No
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	xx	xxxxxx	Yes/No
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	xx	xxxxxx	Yes/No

Listing 16.2.7.3. Listing of Patient Treatment Compliance

Patient Number	Visit	Patient Group	Any change from the dosing schedule	If Yes, comment	Patient 100% compliant with the treatment medication in last treatment cycle
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	Xxxx	Yes/No
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	Xxxx	Yes/No
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxxx	Yes/No
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	Xxxx	Yes/No
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxxx	Yes/No

Listing 16.2.8. Listing of Patient Chest X-ray

Patient Number	Visit	Patient Group	Patient have any Sign and Symptom of Pneumonia	Date and Time for Image	Views	Assessment Result	If abnormal	If Unilateral
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	Normal/Abnormal	Unilateral/Bilateral	Unilobar/Bilobar
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	Normal/Abnormal	Unilateral/Bilateral	Unilobar/Bilobar
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	Normal/Abnormal	Unilateral/Bilateral	Unilobar/Bilobar
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	Normal/Abnormal	Unilateral/Bilateral	Unilobar/Bilobar
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM	xxxx	Normal/Abnormal	Unilateral/Bilateral	Unilobar/Bilobar

Listing 16.2.9.1. Listing of Patient CT Scan and MRI

Patient Number	Visit	Patient Group	CT Scan or MRI performed	Date and Time for Image	Type of Image	Size of spleen Length (cm)	Anteroposterior diameter (cm)	Thickness (cm)	Size of the Liver (cm)	Volume of Liver (ml)	Sum of Product diameter (mm)	Percentage change from visit 1 (%)
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM	CT Scan/MRI	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM	CT Scan/MRI	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM	CT Scan/MRI	xxxx	xxxx	xxxx	xxxx	xxxx	Xxxx	Xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM	CT Scan/MRI	xxxx	xxxx	xxxx	xxxx	xxxx	Xxxx	Xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM	CT Scan/MRI	xxxx	xxxx	xxxx	xxxx	xxxx	Xxxx	Xxxx

Listing 16.2.9.2. Listing of Patient Response Assessment

Patient Number	Visit	Patient Group	Response Assessment
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	xxxx

Listing 16.2.10. Listing of Patient QLP-C30 Questionnaire

Patient Number	Visit	Patient Group	Date of Assessment	Questionnaire	Score	Total Score
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	xxxx	xxxx
				Do you have any trouble taking a long walk?	xxxx	
				Do you have any trouble taking a short walk outside of the house?	xxxx	
				Do you need to stay in bed or a chair during the day?	xxxx	
				Do you need help with eating, dressing, washing yourself or using the toilet?	xxxx	
				Were you limited in doing either your work or other daily activities?	xxxx	
				Were you limited in pursuing your hobbies or other leisure time activities?	xxxx	
				Were you short of breath?	xxxx	
				Have you had pain?	xxxx	
				Did you need to rest?	xxxx	
				Have you had trouble sleeping?	xxxx	
				Have you felt weak?	xxxx	
				Have you lacked appetite?	xxxx	
				Have you felt nauseated?	xxxx	
				Have you vomited?	xxxx	
				Have you been constipated?	xxxx	
				Have you had diarrhea?	xxxx	
				Were you tired?	xxxx	
				Did pain interfere with your daily activities?	xxxx	
				Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	xxxx	
				Did you feel tense?	xxxx	
				Did you worry?	xxxx	
				Did you feel irritable?	xxxx	
				Did you feel depressed?	xxxx	
				Have you had difficulty remembering things?	xxxx	

					Has your physical condition or medical treatment interfered with your family life?	xxxx	
					Has your physical condition or medical treatment interfered with your social activities?	xxxx	
					Has your physical condition or medical treatment caused you financial difficulties?	xxxx	
					How would you rate your overall health during the past week?	xxxx	
					How would you rate your overall quality of life during the past week?	xxxx	
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY		Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	xxxx	xxxx
					Do you have any trouble taking a long walk?	xxxx	
					Do you have any trouble taking a short walk outside of the house?	xxxx	
					Do you need to stay in bed or a chair during the day?	xxxx	
					Do you need help with eating, dressing, washing yourself or using the toilet?	xxxx	
					Were you limited in doing either your work or other daily activities?	xxxx	
					Were you limited in pursuing your hobbies or other leisure time activities?	xxxx	
					Were you short of breath?	xxxx	
					Have you had pain?	xxxx	
					Did you need to rest?	xxxx	
					Have you had trouble sleeping?	xxxx	
					Have you felt weak?	xxxx	
					Have you lacked appetite?	xxxx	
					Have you felt nauseated?	xxxx	
					Have you vomited?	xxxx	
					Have you been constipated?	xxxx	
					Have you had diarrhea?	xxxx	
					Were you tired?	xxxx	
					Did pain interfere with your daily activities?	xxxx	
					Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	xxxx	
					Did you feel tense?	xxxx	
					Did you worry?	xxxx	

Did you feel irritable?	xxxx
Did you feel depressed?	xxxx
Have you had difficulty remembering things?	xxxx
Has your physical condition or medical treatment interfered with your family life?	xxxx
Has your physical condition or medical treatment interfered with your social activities?	xxxx
Has your physical condition or medical treatment caused you financial difficulties?	xxxx
How would you rate your overall health during the past week?	xxxx
How would you rate your overall quality of life during the past week?	xxxx

Listing 16.2.11.1. Listing of Patient Adverse event log (Part I)

Patient Number	Visit	Patient Group	Patient experience Any Adverse event	Seq. No	Event Description	System Organ Class	Preferred Term	Start Date and Start Time	End Date and End Time
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xx	xxxx	xxxx	xxxx	DD-MMM-YYYY/HH:MM	DD-MMM-YYYY/HH:MM
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xx	xxxx	xxxx	xxxx	DD-MMM-YYYY/HH:MM	DD-MMM-YYYY/HH:MM
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xx	xxxx	xxxx	xxxx	DD-MMM-YYYY/HH:MM	DD-MMM-YYYY/HH:MM
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xx	xxxx	xxxx	xxxx	DD-MMM-YYYY/HH:MM	DD-MMM-YYYY/HH:MM
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xx	xxxx	xxxx	xxxx	DD-MMM-YYYY/HH:MM	DD-MMM-YYYY/HH:MM

Listing 16.2.11.2. Listing of Patient Adverse event log (Part II)

Patient Number	Visit	Patient Group	Ongoing	CTCAE grade	Investigator's causality rating against the Investigational Product	Action Taken	Patient Withdrawn	Treatment Taken	Outcome
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	xxxx	xxxx	Yes/No	xxxx	Yes/No	Yes/No	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	xxxx	xxxx	Yes/No	xxxx	Yes/No	Yes/No	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	xxxx	xxxx	Yes/No	xxxx	Yes/No	Yes/No	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	xxxx	xxxx	Yes/No	xxxx	Yes/No	Yes/No	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	xxxx	xxxx	Yes/No	xxxx	Yes/No	Yes/No	xxxx

Listing 16.2.12.1. Listing of Patient SAE (Part I)

Patient Number	SAE Term	Patient Group	Date of AE met Criteria for SAE	Date of Investigator became aware of serious AE	Patient Hospitalised due to SAE	Date of Hospitalisation/ Date of Discharge	System Organ Class/ Preferred Term	Seriousness Criteria	Date of Event Onset
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xxxx	DD-MMM-YYYY
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xxxx	DD-MMM-YYYY
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xxxx	DD-MMM-YYYY
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xxxx	DD-MMM-YYYY
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	DD-MMM-YYYY	Yes/No	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xxxx	DD-MMM-YYYY

Listing 16.2.12.2. Listing of Patient SAE (Part II)

Patient Number	Patient Group	Causality assessment in relation to study procedure	Causality assessment in relation to Other medication	Outcome	Outcome Date	Autopsy performed	Date of Autopsy
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No/NA	xxxx	xxxx	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No/NA	xxxx	xxxx	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No/NA	xxxx	xxxx	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No/NA	xxxx	xxxx	DD-MMM-YYYY	Xxxx	DD-MMM-YYYY
xx-xxxx	(CLL/SLL)/(MCL)	Yes/No/NA	xxxx	xxxx	DD-MMM-YYYY	xxxx	DD-MMM-YYYY

Listing 16.2.13. Listing of Patient Physical Examination

Patient Number	Visit	Patient Group	Physical examination performed	Date of Examination	Seq. No.	System	Result
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY	xx	xxxx	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY	xx	xxxx	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY	xx	xxxx	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY	xx	xxxx	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY	xx	xxxx	xxxx

Listing 16.2.14. Listing of Patient ECG Performed.

Patient Number	Visit	Patient Group	ECG performed	Date and Time for ECG performed	Parameter	Result	Unit	Finding
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx

Listing 16.2.15.1. Listing of Patient Haematology

Patient Number	Visit	Patient Group	Blood Sample collected	No, Specify Reason	Date and Time for Blood Sample collected	Parameter	If Other Parameter	Result	Unit	Finding
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx	xxx

Listing 16.2.15.2. Listing of Patient Biochemistry

Patient Number	Visit	Patient Group	Blood Sample collected	No Specify Reason	Date and Time for Blood Sample collected	Parameter	If, Other Parameter	Result	Unit	Finding
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx	xxx

Listing 16.2.15.3. Listing of Patient Urinalysis

Patient Number	Visit	Patient Group	Urin Sample collected	No Specify Reason	Date and Time for Urin Sample collected	Parameter	Result	Unit	Finding
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	xxx	DD-MMM-YYYY/HH:MM	xxx	xxx	xxx	xxx

Listing 16.2.15.4. Listing of Patient Serology

Patient Number	Blood Sample Collected	Patient Group	No Specify Reason	Date and Time for blood sample collected	HIV	Active Cytomegalovirus (CMV) infection	HbsAg	HBsAb	Anti-HBc antibody	Anti-HCV antibody
xx-xxxx	Yes/No	(CLL/SLL)/(MCL)	Xxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xx-xxxx	Yes/No	(CLL/SLL)/(MCL)	Xxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xx-xxxx	Yes/No	(CLL/SLL)/(MCL)	Xxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xx-xxxx	Yes/No	(CLL/SLL)/(MCL)	Xxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xx-xxxx	Yes/No	(CLL/SLL)/(MCL)	Xxx	DD-MMM-YYYY/HH:MM	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx

Listing 16.2.16. Listing of Patient Vital Signs

Patient Number	Visit	Patient Group	Vital Signs Collected	Date of Vital Signs Collected	Parameters	Result	Unit	Finding	If, Abnormal CS
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY	xxx	xxx	xxx	Xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY	xxx	xxx	xxx	Xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY	xxx	xxx	xxx	Xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY	xxx	xxx	xxx	xxx	xxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	DD-MMM-YYYY	xxx	xxx	xxx	xxx	xxx

Listing 16.2.17. Listing of Patient ECOG

Patient Number	Visit	Patient Group	Date of ECOG	ECOG Grade
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	Xx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	Xx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	Xx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	Xx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	Xx

Listing 16.2.18.1. Listing of Patient Urine Pregnancy test

Patient Number	Visit	Patient Group	Urine Pregnancy test performed	No, Specify Reason	Date and Time of Assessment	Result
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No/NA	xxx	DD-MMM-YYYY/HH:MM	Positive/Negative
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No/NA	xxx	DD-MMM-YYYY/HH:MM	Positive/Negative
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No/NA	xxx	DD-MMM-YYYY/HH:MM	Positive/Negative
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No/NA	xxx	DD-MMM-YYYY/HH:MM	Positive/Negative
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No/NA	xxx	DD-MMM-YYYY/HH:MM	Positive/Negative

Listing 16.2.18.2. Listing of Patient Pregnancy From

Patient Number	Visit	Patient Group	Date of pregnancy conformed	Date of last menstrual period	Estimated Date of Delivery	Outcome of pregnancy	If Live Birth, provide the Birth Outcome
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY	xxxx	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	xxxx
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY	Xxxx	xxxx

Listing 16.2.19. Listing of Patient Concomitant Medications

Patient Number	Visit	Patient Group	Any Concomitant medication given during Visit	Any New Concomitant medication given Since Last Visit	Any prior therapy received for Chronic Lymphocytic Leukemia / Mantle Cell Lymphoma	therapy	Dose per Administration	Unit	Route of Administration	Patient Refractory to the Therapy
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	Yes/No	Yes/No	xx	xx	Xx	xx	Yes/No
xx-xxxx	Xxxx	(CLL/SLL)/(MCL)	Yes/No	Yes/No	Yes/No	xx	xx	Xx	xx	Yes/No
xx-xxxx	Xxxx	(CLL/SLL)/(MCL)	Yes/No	Yes/No	Yes/No	xx	xx	Xx	xx	Yes/No
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	Yes/No	Yes/No	xx	xx	Xx	xx	Yes/No
xx-xxxx	xxxx	(CLL/SLL)/(MCL)	Yes/No	Yes/No	Yes/No	xx	xx	Xx	xx	Yes/No

Listing 16.2.20. Listing of Patient Prior and Concomitant medication

Patient Number	Patient Group	Patient receive any prior/ concomitant medications	Seq. NO	Medication Name	Preferred Term/ System Organ Class	Start Date/ End Date	Ongoing	Indication Description	Dosage Form	Dose/ Unit	Route/ Frequency
xx-xxxx	(CLL/SLL)/ (MCL)	Yes/No	xx	xxxx/xxxx	xxxx/xxxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xx	xxxx	xxxx/ xxxx	xxxx/xxxx
xx-xxxx	(CLL/SLL)/ (MCL)	Yes/No	xx	xxxx/xxxx	xxxx/xxxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xx	xxxx	xxxx/ xxxx	xxxx/xxxx
xx-xxxx	(CLL/SLL)/ (MCL)	Yes/No	xx	xxxx/xxxx	xxxx/xxxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xx	xxxx	xxxx/ xxxx	xxxx/xxxx
xx-xxxx	(CLL/SLL)/ (MCL)	Yes/No	xx	xxxx/xxxx	xxxx/xxxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xx	xxxx	xxxx/ xxxx	xxxx/xxxx
xx-xxxx	(CLL/SLL)/ (MCL)	Yes/No	xx	xxxx/xxxx	xxxx/xxxx	DD-MMM-YYYY/ DD-MMM-YYYY	xxxx	xx	xxxx	xxxx/ xxxx	xxxx/xxxx