Official Title: An Open-Label, Multinational, Multicenter, Phase IIIB Study to Assess Safety of Rituximab Following Subcutaneous Administration in Patients With CD20+ DLBCL or CD20+ Follicular NHL Grade 1 to 3A

NCT Number: NCT02406092

Document Date: SAP Version 1: 04-January-2022

STATISTICAL ANALYSIS PLAN

TITLE: **AN OPEN-LABEL, MULTINATIONAL, MULTICENTER, PHASE IIIB STUDY TO ASSESS SAFETY OF RITUXIMAB FOLLOWING SUBCUTANEOUS ADMINISTRATION IN PATIENTS WITH CD20+ DLBCL OR CD20+ FOLLICULAR NHL GRADE 1 TO 3A**

PROTOCOL NUMBER: ML28964

STUDY DRUG: Rituximab

VERSION NUMBER: 1.0

IND NUMBER: N/A

EUDRACT NUMBER: N/A

SPONSOR: Roche Algeria

PLAN PREPARED BY: [redacted]

SPARC Consulting (on behalf of IQVIA), Milan - Italy

DATE FINAL: See electronic date stamp below

DATE(S) AMENDED: N/A

STATISTICAL ANALYSIS PLAN APPROVAL

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STATISTICAL ANALYSIS PLAN HISTORY

Version	Date Release
0.1	15DEC2021
0.2	22DEC2021
1.0	04JAN2022

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LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
aaIPI	Age-adjusted International Prognostic Index
AAR	Administration-associated reaction
AE	Adverse Event
ALT (SGPT)	alanine aminotransferase
aPTT	Activated Partial Thromboplastin Time
AST (SGOT)	Aspartate Aminotransferase
BSA	body surface area
BUN	Blood Urea Nitrogen
CEC	Clinical Events Committee
CHO	Chinese hamster ovary
CHOP	cyclophosphamide, oncovine (vincristine), doxorubicin, prednisone/prednisolone
CHOP-21	CHOP given every 21 days
CHOP-14	CHOP given every 14 days
CHVP	cyclophosphamide, doxorubicin, etoposide, prednisone/prednisolone
CI	Confidence Interval
CLL	chronic lymphocytic leukaemia
CR	Complete Response
CRF	Case Report Form
CRu	complete response unconfirmed
CRO	contract research organization
CT	Computerised Tomography
CTCAE	Common Terminology Criteria for Adverse Events
C_{trough}	Minimal plasma concentration prior to next drug administration
CVP	cyclophosphamide, vincristine, prednisone/prednisolone
DFS	disease-free survival
DLBCL	diffuse large B-cell lymphoma
EC	Ethics Committee
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
EFS	event-free survival
EGSG	East German Study Group
EU	European Union
FC	Fludarabine, cyclophosphamide

Abbreviation	Definition
FC 28	FC given every 28 days
FDA	Food and Drug Administration
FDG-PET	[18F]deoxyglucose positron emission tomography
FFS	failure-free survival
FL	follicular lymphoma
FLIPI	Follicular Lymphoma International Prognostic Index
G-CSF	granulocyte colony-stimulating factor
GELA	Groupe d'Etude des Lymphomes de l'Adulte
GLSG	German Low-Grade Lymphoma Study Group
HACA	human antichimeric antibody
HAMA	human anti-mouse antibody
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
IB	Investigator's Brochure
ICF	informed consent form
ICH	International Council for Harmonisation
iDMC	Independent Data Monitoring Committee
IDSMB	Independent Data Safety Monitoring Board
IFN	interferon-α
IMP	Investigational Medicinal Product
INR	International Normalised ratio
IPI	International Prognostic Index
IRC	Independent Review Committee
IRF	Independent Review Facility
IRR	Infusion-related reaction
IIRR	infusion/injection-related reaction
ITT	Intent-to-treat
IV	Intravenous
IWG	International Working Group
LDH	Lactate Dehydrogenase
LPLV	last patient, last visit
MCP	mitoxantrone, chlorambucil, prednisone/prednisolone
MedDRA	Medical Dictionary for Regulatory Activities
MInT	MabThera international trial
MRI	Magnetic Resonance Imaging

Abbreviation	Definition
NCI	National Cancer Institute
NCI CTCAE	National Cancer Institute Common Terminology Criteria for Adverse Events
NHL	Non-Hodgkin's Lymphoma
NIMP	Non-investigational medicinal product
ORR	Objective Response Rate
OS	Overall Survival
PD	progressive disease (disease progression)
PD	pharmacodynamics
PET	positron emission tomography
PFS	progression-free survival
PK	Pharmacokinetic
PML	Progressive Multifocal Leukoencephalopathy
PR	Partial Response
PRP	patient-reported outcome
PT	Prothrombin Time
PT	Preferred Term
RBC	Red Blood Cells
RCR	Roche Clinical Repository
R-CHOP	rituximab plus CHOP chemotherapy
RCT	randomized controlled trial
R-CVP	rituximab plus CVP chemotherapy
R-CHVP	rituximab plus CHVP chemotherapy
R-FC	Rituximab plus FC chemotherapy
rHuPH20	recombinant human hyaluronidase
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System (software)
SC	subcutaneous(ly)
SD	Stable Disease
SEER	Surveillance, Epidemiology, and End Results
SOC	System Organ Class
SPD	sum of the products of the greatest diameters
SUSAR	Suspected Unexpected Serious Adverse Reactions
SWT	Satisfaction with Therapy
TLS	Tumour lysis syndrome
TNLT	time to next lymphoma treatment

Abbreviation	Definition
TTF	time to treatment failure
TTP	time to tumour progression
ULN	Upper Limit of Normal
WBC	White Blood Cells
WHO	World Health Organization

LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

1. BACKGROUND

The purpose of the analyses outlined in this Statistical Analysis Plan (SAP) is to evaluate the safety of Rituximab following subcutaneous administration in patients with CD20+ DLBCL or CD20+ follicular NHL grade 1 to 3A.

This SAP is based on Section 6 (Statistical considerations and analysis plan) of the study protocol version 3.1, signed on February 25 h, 2016.

2. STUDY DESIGN

This is an open-label, single-arm study to evaluate the safety of rituximab SC administered during first line treatment for FL (Induction and/or Maintenance), or DLBCL (treatment plus 24 months of follow-up).

This study will include adult patients with CD20+ DLBCL or CD20+ follicular NHL (grade 1 to 3a; NHL), who have already received at least one full dose of IV rituximab during induction or maintenance. Patients receiving Induction therapy must be able to receive at least 4 cycles of rituximab SC in addition to standard chemotherapy. FL Patients receiving Maintenance therapy must be able to receive at least 6 cycles of rituximab SC.

During administration of rituximab SC, patients will be assessed for safety and efficacy as detailed in the Schedule of Assessments (see Appendix 1 of Study Protocol). RASQ (see Appendix 6 of Study Protocol) will be applied to patients at the end of the study after rituximab administration. Healthcare Professional (HCP) Questionnaire (see Appendix 7 of study Protocol) will be applied at the end of the study to health care professionals.

Induction Therapy:

Patients receiving Induction therapy prior to entry into the study must be eligible to receive at least four further cycles of rituximab SC (i.e., 4 additional months of Induction treatment). Patients with follicular NHL who will continue into Maintenance therapy (after staging at the end of Induction) can continue to receive rituximab SC during Maintenance (see below).

Maintenance Therapy (patients with follicular NHL):

Patients receiving Maintenance therapy prior to entry into the study must be eligible to receive at least six further cycles of rituximab SC (i.e., 12 additional months of Maintenance treatment). Patients who are continuing into Maintenance therapy following at least four cycles of rituximab SC during Induction Therapy must also be eligible to

receive at least six cycles of rituximab SC (i.e. 12 additional months of Maintenance treatment).

Post-treatment Follow Up:

All patients will continue the study with 24 months of follow-up period.

2.1 PROTOCOL SYNOPSIS

The Protocol Synopsis is in Appendix 1. For additional details, see the Schedule of Assessments in Appendix 2.

2.2 OUTCOME MEASURES

This study will evaluate safety of Rituximab following subcutaneous administration in patients with CD20+ DLBCL or CD20+ follicular NHL grade 1 to 3A.

2.2.1 Safety Outcome Measures

Safety outcome measures will include AARs (defined as all related AEs occurring within 24 hours of rituximab SC administration, including IIRRs, injection-site reactions, administration site conditions and all symptoms thereof), grade $\geqslant$ 3 AEs and SAEs. Other safety assessments include routine safety laboratory tests, vital signs measurements, and changes in concomitant medications. All clinical AEs and SAEs as well as laboratory abnormalities will be recorded regardless of their intensity / grading. Grading will be completed according to the NCI CTCAE version 4.0 (see Appendix 5 of the protocol).

2.2.2 Efficacy Outcome Measures

The efficacy of rituximab will be evaluated at the end of induction treatment for FL patients and at the end of the last cycle for DLBCL patients in terms of EFS, PFS, OS, CR/CRu and DFS. The endpoints of EFS, PFS and OS will be defined and analysed twice using two different starting points for the time-to-event calculations. The first starting point will be first dose of rituximab IV and the second will be first dose of rituximab SC.

- EFS is defined as the time from first dose of rituximab (analysed using both first dose of IV and first dose of SC) to first occurrence of progression or relapse, according to the IWG response criteria (Cheson et al 1999, see Protocol Appendix 2) or other country standards, or initiation of a non–protocol- specified anti-lymphoma therapy or death, whichever occurs first.
- PFS is defined as the time from first dose of rituximab (analysed using both first dose of IV and first dose of SC) to the first occurrence of progression or relapse, according to the IWG response criteria (Cheson et al. 1999, see Protocol Appendix 2) or other country standards, or death from any cause.

- OS is defined as the time from first dose of rituximab (analysed using both first dose of IV and first dose of SC) until death from any cause.
- DFS will be assessed at the end of induction treatment in patients achieving CR/CRu and is defined as the period from the date of the initial CR/CRu until the date of relapse or death from any cause.
- CR/CRu: Response assessments 4 - 6 weeks after the last dose of Induction treatment will be based on the Investigator's assessment, completed according to the original International Working Group (IWG) response criteria for response assessment of lymphoma (Cheson et al. 1999; see Protocol Appendix 2).

Tumour assessments will be based on computed tomography (CT) scans of the neck, chest, abdomen and/or pelvis (if detectable by these techniques) or other diagnostic means (e.g., magnetic resonance imaging [MRI], PET/CT) where applicable. Other methods (e.g., MRI) are acceptable for patients in whom CT scans are contraindicated. The CT scan used for eligibility assessments may be performed up to 28 days prior to dosing.

2.2.3 Exploratory Outcome Measures

Not applicable.

2.2.4 Pharmacokinetic Outcome Measures

Not applicable.

2.3 DETERMINATION OF SAMPLE SIZE

A sample size of 110 patients is deemed sufficient for this study. In this study, all planned statistical analysis will be exploratory in nature as the study will not be powered to address any pre-defined statements and only descriptive statistical evaluations will be carried out primarily for safety (and efficacy) parameters. Additionally, no published reference is available on administration-associated reactions (AARs) following multiple doses of subcutaneous (SC) rituximab during induction and/or maintenance therapy in patients with CD20+ follicular non-Hodgkin's lymphoma (NHL) or CD20+ diffuse large B-cell lymphoma (DLBCL). However, with 110 patients a 95% Clopper-Pearson CI for the incidence of AARs will be no wider than +/- 9.7% . This width of interval is deemed sufficiently precise to draw valid conclusions around the incidence of ARRs. Additionally, enrolment of more than 110 patients within the specified indications could also be difficult in participating countries. Due to the fact of exploratory nature of the study, drop out patients will not be replaced.

2.3.1 Sample Size for the China Extension Period

Not applicable for this study.

2.4 ANALYSIS TIMING

This length of the study study is planned according to the type of lymphoma (either FL or DLBCL). Since assessments for FL patients are expected to be on-study longer, this portion of the study will be determinative for the length of the study. For FL patients the study is estimated to take approximately 6 years (68 months) based on an approximately 12 month of recruitment period, 8 months of induction and 24 months of maintenance treatment and 24 months of follow-up period.

On the other hand, DLBCL patients are expected to be on-study for a shorter period of time (approximately in 4 years), based on approximately 12 months recruitment, 8 months of treatment and 24 months follow up period with a recruitment period of approximately 18 months

The end of the study, defined as last patient last visit (LPLV), will occur 24 months after the last SC rituximab treatment for the last FL or DLBCL patient, whichever comes later.

The statistical analysis will be performed after all patients have completed the study.

An interim analysis in not planned.

2.4.1 Analysis Timing for the China Subgroup Analysis

Not applicable for this study.

3. STUDY CONDUCT

3.1 RANDOMIZATION

Not applicable. This is an open-label study, non-comparative single arm study.

3.2 INDEPENDENT REVIEW FACILITY

Not applicable for this study.

3.3 DATA MONITORING

Not applicable for this study.

4. STATISTICAL METHODS

This is not a hypothesis testing study but an exploratory study with predefined precision of estimates for key safety parameters for sample size determination; there are no formal statistical hypotheses tests to be tested, and there will be no adjustments for multiplicity of endpoints or within-subgroups comparisons.

Descriptive statistics will be provided in summary tables according to the type of variable using appropriate descriptive statistics.

Continuous variables will be summarized by descriptive statistics (number of cases, mean, standard deviation, median, minimum and maximum).

Categorical variables will be summarized using counts of patients and percentages; missing category will be displayed if appropriate.

Exposure to study treatment (rituximab) and chemotherapy, including the number of cycles administered, duration of treatment exposure (calculated from date of first treatment date to the last treatment date) and dosing information (e.g., dose interruptions, modifications and delays) will be summarized.

The number of patients who prematurely discontinue study treatment and the number of patients who withdrew from the study will be summarized and reasons for withdrawal will be displayed

All data collected will be presented in by-patient data listings.

All planned analyses identified in this Statistical Analysis Plan (SAP) will be performed by SPARC Consulting (Milan) on behalf of IQVIA following Sponsor Authorization of this SAP.

All statistical analyses and data processing will be performed using SAS® Software (release 9.4 or higher) under Windows 10 PRO operating system.

All medical history and AE terms will be assigned to a Low Level Term (LLT), Preferred Term (PT) and will be classified by the primary System Organ Class (SOC) according to the Medical Dictionary for Regulatory Activities (MedDRA) thesaurus, version 24.1, medications will be coded using the INN-1.0V Dictionary, and laboratory values converted in Standard Unit (SI) by TCS, Mumbai, India.

Unplanned visits have been foreseen in the study. Unplanned measurements will not be included in by-visit summaries. Listings will include planned and unplanned data.

4.1 ANALYSIS POPULATIONS

4.1.1 Randomized Population

Not applicable for this study.

4.1.2 Per Protocol Population

Not defined for this study.

4.1.3 Pharmacokinetic-Evaluable Population

Not applicable for this study.

4.1.4 Safety Population

The Safety data will be summarized based on the safety population (SAF), defined as all patients who have received at least one dose of rituximab.

4.1.5 Intent-To-Treat Population

The efficacy endpoints will be summarized based on the ITT population (ITT) defined as all patients enrolled into the study.

4.2 ANALYSIS OF STUDY CONDUCT

Enrolment, patients' disposition, and discontinuation from the study will be summarized for the ITT population overall and for patients with Diffuse Large B-Cell Lymphoma (DLBCL) and patients with follicular Non-Hodgkin's Lymphoma (FL), separately. The reasons for study drug discontinuation will also be tabulated. Protocol deviations, including major deviations with regards to the inclusion and exclusion criteria and major deviations due to Covid-19 pandemic, will be summarized by deviation category for the ITT population. A line listing with all protocol deviations reported over the study will be also provided.

Deviations from the protocol including violations of inclusion/exclusion criteria will be assessed definitely as "*minor*" or "*major*" by the study clinical team prior to closure of the study database.

4.2.1 Definition of Baseline

Baseline is defined as the screening visit. Thus, change from baseline to a specific timepoint of a study parameter is calculated as follows:

Change from baseline to time X = (value at time X) - (baseline value).

4.3 ANALYSIS OF TREATMENT GROUP COMPARABILITY

Demographic and other baseline characteristics (including age, sex, ethnicity, and baseline disease characteristics, e.g., DLBCL Diagnosis), as well as the demographic profile (height, weight, and BMI), IPI score (according to Shipp et al. 1993) and/or FLIPI score and serum pregnancy test at Screening/Baseline will be summarized using means, standard deviations, medians, and ranges for continuous variables and proportions for categorical variables, as appropriate.

Summaries will be presented overall and for patients with DLBCL and patients with FL separately for ITT population.

A summary analysis of the DLBCL and FL diagnosis will be presented for the SAF population.

The overall evaluation of a 12-lead ECG tracing at screening will be presented by means of a summary analysis on SAF population.

4.3.1 Medical History

Data from "*Medical History*" form will be summarized for ITT population with descriptive statistics.

All verbatim terms reported will be assigned to a PT and will be classified by the primary SOC.

Previous diseases are those reported in the "*Medical History*" form of the eCRF not flagged as "*Ongoing at study entry*".

Concomitant diseases are those flagged as "*Ongoing at study entry*".

The following data will be presented:

- A default frequency table showing the number and percentage of patients who exhibited at least one previous disease and the previous diseases by primary SOC and PT;
- A default frequency table showing the number and percentage of patients who exhibited at least one concomitant disease and the concomitant diseases by primary SOC and PT.

Any previous diseases as well as concomitant diseases will be listed.

4.3.2 Surgery and Procedures History

Data from "*Surgery and Procedures history (cancer and non-cancer related)*" form will be summarized for ITT population with descriptive statistics.

All verbatim terms reported will be assigned to a PT and will be classified by the primary SOC.

The following data will be presented:

- A default frequency table showing the number and percentage of patients who exhibited at least one surgery and the surgery by primary SOC and PT;

All surgery and procedures will be listed.

4.3.3 Physical Examination

Physical Examinations details for each body system will be summarized across each visit for safety population.

4.3.4 Previous and Concomitant Therapies

Data from "*Concomitant Medication*" form will be summarized for safety population with descriptive statistics.

Therapies will be coded using the INN-1.0V dictionary. New anti-lymphoma treatment (chemotherapy, radiotherapy, immunotherapy), initiated after the Baseline visit will be presented in summary tables.

Handling of partial dates for prior and concomitant therapies will be performed by TCS, Mumbai, India.

Previous therapy includes any medication stopped before exposure to study drug. The following data will be presented in a unique summary table for previous therapies:

- Total number of patients with at least one treatment (n,%)
- Total number of treatments (n)
- Total number of patients with at least one treatment by ATC class level 2 (n,%)
- Total number of treatments by ATC class level 2 (n)
- Treatments by ATC class level 2 (n,%)

Concomitant therapy consists of any medication taken during the study, including those started before but ongoing at first dose of study drug. The following data will be presented overall in a unique summary table for concomitant therapies:

- Total number of patients with at least one treatment (n,%)
- Total number of treatments (n)
- Total number of patients with at least one treatment by ATC class level 2 (n,%)
- Total number of treatments by ATC class level 2 (n)
- Treatments by ATC class level 2 (n,%)

All previous and concomitant therapies reported over the study will be listed.

4.3.5 Viral Serology

Viral serology at screening including HBcAb, HBsAg, HCV antibody, and HIV antibody will be summarized for SAF population with descriptive statistics.

4.4 EFFICACY ANALYSIS

The efficacy analysis will be performed in the ITT analysis set.

Efficacy endpoints include EFS, PFS, OS, DFS, and CR/CRu rate.

Summaries will be presented overall and for patients with DLBCL and patients with FL separately.

Response assessments will be based on the Investigator's assessment, completed according to the IWG response criteria (Cheson et al 1999, see Appendix 2 of Study Protocol) or other country standards. The endpoints of EFS, PFS and OS will be defined and analyzed twice using two different starting points for the time-to-event calculations. The first starting point will be first dose of rituximab IV and the second will be first dose of rituximab SC.

The analysis of endpoints measured as a time-to-event (e.g., EFS, PFS, OS and DFS) is based on the survivor function, which is the probability of remaining event free beyond a certain point in time.

The survivor function will be estimated using Kaplan-Meier methodology and summarized using the range, the 25th and 75th percentiles and median survival along their 95% confidence interval.

Patients who have experienced none of these events at the time of analysis (clinical cut-off) and patients who are lost to follow up will be censored at their last clinical assessment date. Patients without post-baseline tumour assessments will be censored at the time of their baseline visit except if death occurs prior to their first scheduled tumour assessment.

The survivor function will be displayed graphically using a Kaplan-Meier curve.

The number and percentage of the patients with event or censored will be also presented. Analysis will be performed using the SAS procedure Proc Lifetest.

4.4.1 Primary Efficacy Endpoint

Not applicable.

4.4.2 Secondary Efficacy Endpoints

Event-Free Survival (EFS)

EFS is defined as the time from first dose of rituximab (analysed using both first dose of IV and first dose of SC) to first occurrence of progression or relapse, according to the IWG response criteria (Cheson et al 1999, see Appendix 2 of Study Protocol) or other country standards, or initiation of a non-protocol-specified anti-lymphoma therapy or death, whichever occurs first. Time will be calculated in months as follow:

EFS = (date of event/censor – date of first dose + 1) / 30.4375

Progression-Free Survival (PFS)

PFS is defined as the time from first dose of rituximab (analysed using both first dose of IV and first dose of SC) to the first occurrence of progression or relapse, according to the IWG response criteria (Cheson et al 1999, see Appendix 2 of Study Protocol) or other country standards, or death from any cause. Time will be calculated in months as follow:

PFS = (date of event/censor – date of first dose + 1) / 30.4375

Overall Survival (OS)

OS is defined as the time from first dose of rituximab (analysed using both first dose of IV and first dose of SC) until death from any cause. Time will be calculated in months as follow:

OS = (date of event/censor – date of first dose + 1) / 30.4375

Disease-Free Survival (DFS)

DFS will be assessed in patients achieving CR/CRu and is defined as the period from the date of the initial CR/CRu until the date of relapse or death from any cause. Time will be calculated in months as follow:

DFS = (date of event/censor – date of initial CR/CRu + 1) / 30.4375

Complete Response rate (CR)/Complete Response unconfirmed (CRu)

CR/CRu rate at 4-6 weeks after the last dose of Induction treatment will be summarized and presented with the corresponding 95% two-sided Pearson-Clopper CI by treatment group and overall.

Endpoints resulting in an incidence rate (e.g., CR/CRu) will be summarised with a 95% Clopper-Pearson confidence interval.

4.4.3 Exploratory Efficacy Endpoints

Not applicable.

4.4.4 Sensitivity Analyses

Not applicable.

4.4.5 Subgroup Analyses

Demographics and baseline characteristics (age, ethnicity, height, weight, BMI, IPI score, FLIPI score and Surgery/Procedure History) will be also presented stratified by gender (Male, Female).

a) PFS and OS results will be reported for the following l subgroups, in addition to the analysis populations described in the document: Gender (Female, Male)

b) FLIPI score (Low risk, Intermediate risk/High risk) for FL patients only

c) Grade of FL (1, 2, 3a)

4.5 PHARMACOKINETIC AND PHARMACODYNAMIC ANALYSES

Not applicable.

4.6 PATIENT-REPORTED OUTCOME ANALYSES

Patient satisfaction with administration of treatment will be evaluated using the Rituximab Administration Questıonnaıre (RASQ) for safety population.

The RASQ is a 20-item questionnaire measuring the impact of the mode of treatment administration on five domains: Physical Impact, Psychological Impact, Impact on Activities of Daily Living, Convenience, and Satisfaction. The Physical Impact domain comprises of 3 items (Pain, swelling, and redness (Q2) , Pain experience (Q3), Side effects as expected (Q4)), the Psychological Impact domain contains 5 items (Anxious about injection/IV (Q5), Worry condition will get worse (Q6), Anxious thinking about disease (Q7), Confidence the injection/IV treating disease (Q8), Feeling restricted by injection/IV (Q9)), the Impact on Activities of Daily Living domain contains 3 items (Interference with usual/daily activities (Q14a), Limit daily activities (Q14b), Lost/gained time(Q15)), the Convenience domain contains 3 items (Is it convenient to get injection/IV

(Q10), Length of time to get injection/IV as expected (Q12), Bothered by the amount of time to get injection/IV (Q13)) and the Satisfaction domain includes 2 items (How satisfied or dissatisfied are you with the injection/IV (Q1), Would you recommend the way you received the treatment (Q19). All 16 RASQ items included in the above domains have five response options. Reverse-coded response values will be created for eight of the RASQ items (Q2, Q3, Q5, Q6, Q7, Q9, Q14a, and Q14b).

In addition, there are 4 descriptive questions that are not part of the above domains and are scored separately.

For each domain, if there are no missing responses, the domain will be scored using the formula:

Domain score = [(Sum of completed item responses / Number of completed items) - 1] x 100 / (Maximum possible item response value – Minimum possible item response value)

However, if there are any missing responses within a domain then the domain will not be scored (i.e., a missing value is assigned to the domain).

Since the maximum possible item response value is 5 and the minimum possible response value is 1 for all RASQ items, a simpler way to represent the above formula for the RASQ domains is:

RASQ domain score = (Mean of completed item responses – 1) x 25

Descriptive statistics will be computed for the RASQ questions assessing patient responses regarding convenience, satisfaction and preference for rituximab SC as compared to rituximab IV. Specifically, frequencies and percentages will be presented by question and timepoint, for the total sample and for patients with DLBCL and patients with FL separately.

In addition, descriptive statistics will be computed by domain (Physical Impact domain, Psychological Impact domain, Impact on Activities of Daily Living domain, Convenience domain and Satisfaction domain) and timepoint overall and for patients with DLBCL and patients with FL separately.

Listings will present by patient data for individual responses and domain scores.

4.7 HEALTHCARE PROFESSIONAL REPORTED OUTCOME ANALYSES

Healthcare Professional (HCP) Questionnaire will be evaluated with descriptive statistics. Frequencies and percentages will be presented.

All data reported in Healthcare Professional (HCP) Questionnaire will be listed.

4.8 SAFETY ANALYSES

All safety analyses will be presented for the Safety population overall and for patients with DLBCL and patients with FL separately.

Safety will be assessed by AEs, AEs of grade $\geqslant$ 3, SAEs, AARs including IIRRs, AEs within the MedDRA SMQ ”Anaphylactic reactions” (wide), safety laboratory parameters, vital signs, concomitant medications, premature withdrawal from the study and from study medication due to AEs and ECOG performance status. All clinical AEs and SAEs as well as laboratory abnormalities will be recorded and graded according to the NCI-CTCAE version 4.0.

4.8.1 Exposure of Study Medication

Exposure to study treatment (rituximab) and chemotherapy, including the number of cycles administered in induction and maintenance phases, duration of treatment exposure (calculated from date of first treatment date to the last treatment date) and dosing information (e.g., dose interruptions, modifications and delays) will be summarized for the safety population.

New anti-lymphoma treatment (chemotherapy, radiotherapy, immunotherapy), initiated after baseline visit will be presented in summary tables.

Summary analysis will be presented overall and for patients with DLBCL and patients with FL separately.

4.8.2 Adverse Events

The analysis of AEs will focus on treatment-emergent adverse events (TEAEs), i.e., AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose. Non-treatment emergent AEs (i.e., those occurring before commencement of study medication) will only be listed. Adverse events will be coded using the Medical Dictionary for Regulatory Activities (MedDRA version 24.1).

Handling of partial dates for AEs will be performed by TCS, Mumbai, India. Where an AE start date is partially or fully missing, and it is unclear as to whether AE started after of the study, it will be assumed to be TEAE (worst case).

The incidence of AARs, AEs, AEs leading to premature discontinuation or interruption of study treatment, SAEs, grade $\geqslant$ 3 AEs will be computed with 95% Confidence Interval (calculated using either the Clopper-Pearson methodology, or the Poisson distribution, for frequencies below 10%). The incidence of each AE will be summarized according to the primary System Organ Class and by Preferred Term. The incidence of cutaneous and soft tissue AARs will additionally be summarised for those that are defined as localized and those that are defined as non-localized. The incidence of deaths and cause of deaths will be listed and summarized.

Counts and percentages will be presented, by primary SOC and PT, overall and for patients with DLBCL and patients with FL separately.

A patient having more than one adverse event with the same PT will be counted only once in the incidence calculation for that PT. Similarly, if a patient has more than one AE in the same SOC, the patient will be counted only once in the total number of patients with an AE for that SOC.

Where AEs are summarized by relationship or by maximum CTC grade, each patient's maximum CTC grade will be used in the summary. If a patient experiences the same adverse event at more than one CTC grade level, or with more than one relationship to study drug, the most severe rating or the stronger causal relationship to study drug will be used.

Any missing CTC grade, casualty, or outcome will not be imputed but classified as unknown for listing purpose and the worst case will be considered for summarization purpose.

If the severity is missing for a TEAE, the TEAE will be considered as Severe.

If the relationship to study treatment is missing for a TEAE, the TEAE will be considered as related to study treatment.

If CTG grade is missing, the worst CRT grade will be considered.

An overview of number of patients with at least one Treatment Emergent Adverse Event (TEAE), at least one serious TEAE, at least one AE of special interest (AESI), at least one Administration Associated Reaction (AARs), at least one cutaneous and soft tissue AARs (localized), at least one cutaneous and soft tissue AARs (non-localized), at least one grade $\geqslant$ 3 TEAEs, at least one grade $\geqslant$ 3 serious TEAEs, at least one grade $\geqslant$ 3 AARs, at least one grade $\geqslant$ 3 infusion/injection related reactions, number of TEAEs leading to Rituximab drug interrupted/drug delayed, number of TEAEs leading to Rituximab dose discontinuation, number of TEAEs leading to chemotherapy dose modification, number of TEAEs leading to chemotherapy dose discontinuation and number of TEAEs leading to death will be provided.

The following summary statistical tables including frequencies and percentages, along with the 95% CI of the observed proportions (calculated using either the Clopper-Pearson methodology, or the Poisson distribution, for frequencies below 10%) will be provided:

- Proportion of all TEAEs by Primary SOC and PT;
- Proportion of serious TEAEs by Primary SOC and PT;

- Proportion of localized AARs by Primary SOC and PT;
- Proportion of non-localized AARs by Primary SOC and PT;
- Proportion of grade ⩾ 3 TEAEs by Primary SOC and PT;
- Proportion of grade ⩾ 3 serious TEAEs by Primary SOC and PT;
- Proportion of grade ⩾ 3 AARs by Primary SOC and PT;
- Proportion of TEAEs leading to Rituximab drug interrupted/drug delayed by Primary SOC and PT;
- Proportion of TEAEs leading to Rituximab dose discontinuation by Primary SOC and PT;
- Proportion of TEAEs leading to chemotherapy dose modification by Primary SOC and PT;
- Proportion of TEAEs leading to chemotherapy dose discontinuation by Primary SOC and PT;
- Proportion of TEAEs leading to death by Primary SOC and PT.

The following groups of adverse events will be summarized:

- All TEAEs;
- All Treatment-Emergent SAEs;
- All AESI;
- All AARs;
- All IRRs;
- Grade ⩾ 3 TEAEs;
- Grade ⩾ 3 Treatment-Emergent SAEs;
- Grade ⩾ 3 AESI;
- Grade ⩾ 3 AARs;
- Grade ⩾ 3 IIRRs;
- TEAEs within the MedDRA SMQ “Anaphylactic reactions” (wide);
- TEAEs leading to dose modification of Rituximab;
- TEAEs leading to dose modification of chemotherapy;
- TEAEs leading to discontinuation of chemotherapy;
- TEAEs leading to death;
- Cutaneous and soft tissue AARs (localized);
- Cutaneous and soft tissue AARs (non-localized);

- TEAEs with an incidence ⩾ 5 %;
- TEAEs by maximum severity;
- Non TEAEs by strongest relationship;
- Non serious TEAEs with an incidence ⩾ 5 %.

These groups will be summarized using the following factors by System Organ Class and Preferred Term:

- total
- event related to Rituximab
- event related to chemotherapy

The following individual data listings will be produced:

- A listing of all AEs;
- A listing of all serious AEs;
- A listing of all AESI;
- A listing of all AARs;
- A listing of all AEs related to Rituximab;
- A listing of grade ⩾ 3 AEs;
- A listing of all AEs leading to Rituximab drug interruption/drug delay;
- A listing of all AEs leading to Rituximab drug discontinuation;
- A listing of all AEs leading to chemotherapy dose modification;
- A listing of all AEs leading to chemotherapy dose discontinuation;
- A listing of all AEs within the MedDRA SMQ “Anaphylactic reactions”;
- A listing of all Cutaneous and soft tissue AARs (localized);
- A listing of all Cutaneous and soft tissue AARs non-(localized);
- A listing of death
- A listing of all pre-treatment AE.

AEs of special interest (AESI) include AARs, hepatotoxicity (elevated ALT or AST in combination with either an elevated bilirubin or clinical jaundice, as defined in Section 5.3.5.6 of Study Protocol) and suspected transmission of an infectious agent by the study drug (see Section 5.2.3 of Study Protocol).

4.8.3 Laboratory Data

Summary analysis will be performed in the safety population overall and for patients with DLBCL and patients with FL separately.

Actual values and the changes from baseline to each time-point in hematology, biochemistry, coagulation test parameters will be summarized using descriptive statistics.

Shift tables of NCI CTCAE grade at baseline against worst grade recorded during the treatment period will be presented for all laboratory parameters.

A list of laboratory assessments to be included:

- Haematology: hemoglobin, RBC count, WBC count and differential count (neutrophils, eosinophils, basophils, monocytes, lymphocytes, other cells) and platelet count;
- Biochemistry at Screening: sodium, potassium, ALT/SGPT, AST/SGOT, total bilirubin, serum creatinine, alkaline phosphatase, albumin, blood urea nitrogen (BUN), C-reactive protein and LDH. Biochemistry at any further timepoint: sodium, potassium, ALT/SGPT, AST/SGOT, total bilirubin, and serum creatinine;
- Coagulation: International Normalized Ratio (INR), Prothrombin Time (PT), Activated Partial Thromboplastin Time (aPTT).

For each laboratory parameter, where appropriate, the reported values will be converted into SI units and if needed boundary values for reference ranges will be converted.

4.8.4 Vital Signs

Analysis of vital signs will be performed in the safety population overall and for patients with DLBCL and patients with FL separately.

Vital signs will include measurements of heart rate, systolic and diastolic blood pressure, and body temperature.

A summary of actual values and changes from baseline over the study will be provided for each vital sign with default descriptive statistics at each time-point.

4.8.5 ECOG Performance Status

Eastern Cooperative Oncology Group (ECOG) performance status (Grade 0 – Grade 5) will be summarized by frequency tables over time for the safety population overall and for patients with DLBCL and patients with FL separately.

4.9 MISSING DATA

Imputed values will be included in the analysis set(s), but will not change the original clinical database (rawdata).

Missing data in safety parameters will not be replaced except for relationship to study medications and severity of AE and partial date in AE and prior/concomitant treatments (Sections 4.3.4 and 4.8.2).

In all efficacy analyses, missing data handling is specific to the efficacy endpoint and details are given within Section 4.4 for all efficacy endpoints.

For analysis of change from baseline endpoints if no baseline value exists for a patient at a specific time-point, then the patient will be excluded from the analysis of that time-point.

4.10 INTERIM ANALYSES

No interim analyses are planned.

5. CHINA SUBGROUP ANALYSIS

Not applicable.

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Clinical Study Protocol ML28964, version 3.1, 07 February 2016.

Appendix 1 - Protocol Synopsis

TITLE:	**AN OPEN-LABEL, MULTINATIONAL, MULTICENTER, PHASE IIIB STUDY TO ASSESS SAFETY OF RITUXIMAB FOLLOWING SUBCUTANEOUS ADMINISTRATION IN PATIENTS WITH CD20+ DLBCL OR CD20+ FOLLICULAR NHL GRADE 1 TO 3A**
PROTOCOL NUMBER:	ML28964
VERSION NUMBER:	3.1
EUDRACT NUMBER:	{Number}
IND NUMBER:	N/A
TEST PRODUCT:	Rituximab (RO 45-2294)
PHASE:	IIIb
INDICATION:	CD20+ diffuse large B-cell lymphoma or CD20+ follicular non-Hodgkin's lymphoma grade 1 to 3a
SPONSOR:	Roche Algeria,

Objectives

Primary Objective

- To evaluate the incidence of administration-associated reactions (AARs) following multiple doses of subcutaneous (SC) rituximab during Induction and/or Maintenance therapy in patients with CD20+ follicular non-Hodgkin's lymphoma (NHL) or CD20+ diffuse large B-cell lymphoma (DLBCL) who have previously received at least one dose of intravenous (IV) rituximab.
- AARs are defined as all adverse events (AEs) occurring within 24 hours of rituximab SC administration and which are considered related to study drug. AARs include infusion/injection-related reactions (IIRRs), injection-site reactions, administration site conditions and all symptoms thereof.

Secondary Objectives

- To evaluate patient-reported outcomes in terms of Rituximab Administration Questionnaire (RASQ)
- To further evaluate the safety of rituximab SC in terms of:
  - Grade ≥ 3 AEs
  - Grade ≥ 3 AARs
  - Serious adverse events (SAEs)
- To evaluate the efficacy of rituximab SC in terms of:
  - event-free survival (EFS)
  - progression-free survival (PFS)
  - Overall survival (OS).
  - disease-free survival (DFS)
  - complete response (CR) rate, including complete response unconfirmed (CRu), 4 weeks after the last dose of Induction treatment
- To evaluate healthcare professional outcomes in terms of:
  - HCP (Healthcare Professional) Questionnaire

Other Objectives

Not applicable

Study Design

Description of Study

This is an open-label, single-arm study to evaluate the safety of rituximab SC administered during

first line treatment for FL (Induction and/or Maintenance therapy plus 24 months of follow up), or DLBCL (treatment plus 24 months of follow-up).

This study will include adult patients with CD20+ DLBCL or CD20+ follicular NHL (grade 1 to 3a; NHL), who have already received at least one full dose of IV rituximab during first-line treatment, induction or maintenance.

During administration of rituximab SC, patients will be assessed for safety and efficacy as detailed in the **Schedule of Assessments** (see **Appendix 1**). The Rituximab Administration Questionnaire (RASQ, **Appendix 6**) will be applied to patients and Healthcare Professional (HCP) Questionnaire (see **Appendix 7**) will be applied to health care professionals at the end of the study.

Induction Therapy:

NHL patients receiving Induction therapy prior to entry into the study must be eligible to receive at least four further cycles of rituximab SC (i.e. 4 additional months of Induction treatment). Patients with follicular NHL who will continue into Maintenance therapy (after staging at the end of Induction) can continue to receive rituximab SC during Maintenance (see below).

Maintenance Therapy (patients with follicular NHL):

NHL patients receiving Maintenance therapy prior to entry into the study must be eligible to receive at least six further cycles of rituximab SC (i.e. 12 additional months of Maintenance treatment).
Patients who are continuing into Maintenance therapy following at least 4 (four) cycles of rituximab SC during Induction Therapy must also be eligible to receive at least six cycles of rituximab SC (i.e. 12 additional months of Maintenance treatment).

Figure 1 Study duration: Patients with CD20+ Follicular NHL

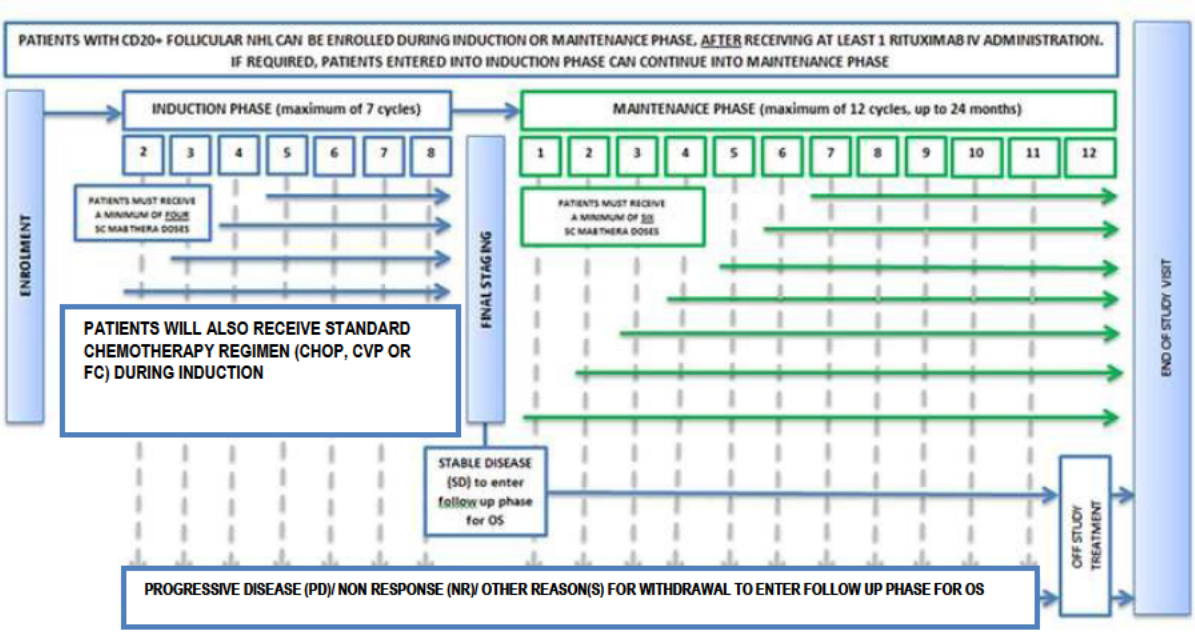
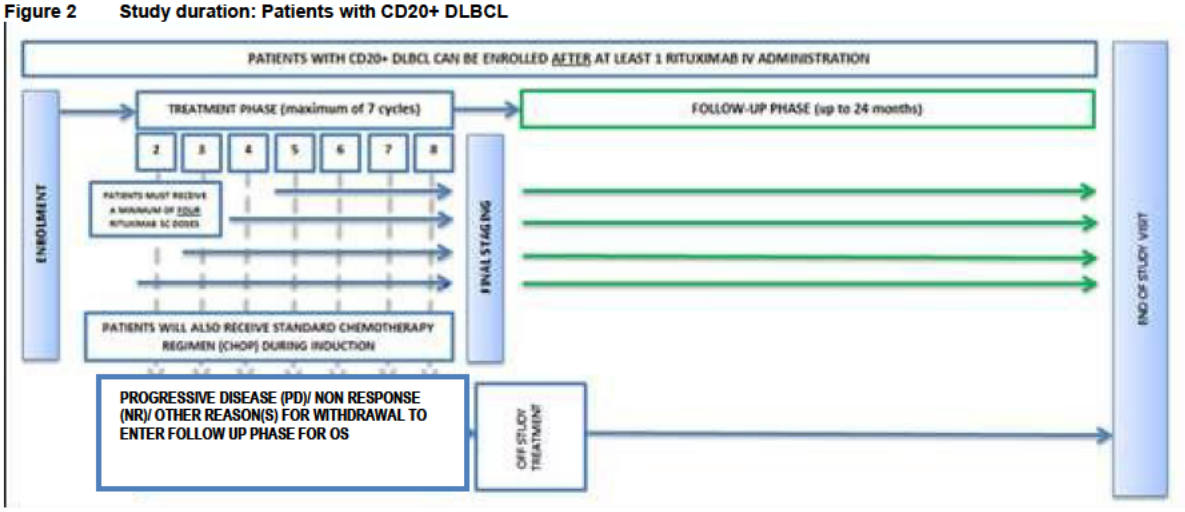


Figure 2 Study duration: Patients with CD20+ DLBCL



Number of Patients

A sample size of 110 patients is deemed sufficient for this study. In this study, all planned statistical analysis will be exploratory in nature as the study will not be powered to address any pre-defined statements and only descriptive statistical evaluations will be carried out primarily for safety (and efficacy) parameters. Additionally, no published reference is available on administration-associated reactions (AARs) following multiple doses of subcutaneous (SC) rituximab during induction and/or maintenance therapy in patients with CD20+ follicular non-Hodgkin's lymphoma (NHL) or CD20+ diffuse large B-cell lymphoma (DLBCL). However, with 110 patients a 95% Clopper-Pearson CI for the incidence of AARs will be no wider than +/- 9.7% . This width of interval is deemed sufficiently precise to draw valid conclusions around the incidence of ARRs. Additionally, enrolment of more than 110 patients within the specified indications could also be difficult in participating countries.
Due to the fact of exploratory nature of the study, drop out patients will not be replaced.

Target Population

The target population will consist of adults with CD20+ DLBCL or CD20+ follicular NHL grade 1 to 3a, according to the World Health Organization (WHO) classification system.

Inclusion Criteria

Patients must meet the following criteria for study entry:

1. Signed, written informed consent form
2. Age ≥ 18 and ≤ 80 years at time of enrolment
3. Histologically confirmed, CD20+ DLBCL or CD20+ follicular NHL grade 1 to 3a, according to the WHO classification system
4. Currently being treated with rituximab IV in the Induction or Maintenance setting, having received at least one full dose of rituximab IV, defined as standard full dose of rituximab IV 375 mg/m^2 administered without interruption or early discontinuation because of tolerabilityissues
5. Expectation and current ability for the patient to receive at least four additional cycles of treatment during the Induction phase and six additional cycles of treatment during the Maintenance phase (patients with follicular NHL)
6. Induction only: An International Prognostic Index (IPI) score of 1-4 or IPI score of 0 with bulky disease, defined as one lesion ≥ 7.5 cm, or Follicular Lymphoma International Prognostic Index (FLIPI) (low, intermediate or high risk) (see **Appendix 3**)
7. Induction only: At least one bi-dimensionally measurable lesion defined as ≥ 1.5 cm in its largest dimension on computed tomography (CT) scan
8. Eastern Cooperative Oncology Group (ECOG) performance status ≤ 3 (see **Appendix 3**)
9. Patients with CD20+ DLBCL eligible for R-CHOP regimen
10. Patients with LVEF ≥55%

Exclusion Criteria

Patients who meet any of the following criteria will be excluded from study entry:

Cancer-Related Criteria

1. Transformed lymphoma (i.e., histologic evidence of transformation to a Burkitt lymphoma) or follicular lymphoma (FL) Grade IIIB
2. Primary central nervous system lymphoma, primary effusion lymphoma, primary mediastinal DLBCL, DLBCL of the testis, or primary cutaneous DLBCL
3. History of other malignancy that could affect compliance with the protocol or interpretation of results. This includes a malignancy that has been treated but not with curative intent, unless the malignancy has been in remission without treatment for ≥ 5 years prior to dosing. Note: Patients with a history of curatively treated basal or squamous cell carcinoma or melanoma of the skin or in situ carcinoma of the cervix are eligible for the study.

Prior or Concomitant Treatments

4. On-going corticosteroid use > 30 mg/day of prednisone or equivalent. Note: patients receiving corticosteroid treatment with ≤ 30 mg/day of prednisone or equivalent must be documented to be on a stable dose of at least 4 weeks' duration prior to dosing.

Laboratory Assessments at Screening

5. Inadequate renal function, defined as:
   - Creatinine > 1.5 times the upper limit of normal (ULN) (unless normal creatinine clearance), or calculated creatinine clearance < 40 mL/min (using the Cockcroft-Gault formula)
6. Inadequate hematologic function, defined as:
   - Hemoglobin < 9 g/dL
   - Absolute neutrophil count < 1.5 x 109/L
   - Platelet count < 75 x 109/L

7. Inadequate hepatic function, defined as:
   - Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) > 2.5 x ULN
   - Total bilirubin ≥ 1.5 x ULN. Note: patients with documented Gilbert disease may be enrolled if total bilirubin is ≤ 3.0 x ULN

Other Prior or Current Medical Conditions or Treatments

8. History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies or known sensitivity or allergy to murine products
9. For patients with FL and DLBCL - Contraindication to any of the individual components of CHOP (cyclophosphamide, vincristine, doxorubicin and prednisone), including prior receipt of anthracyclines
10. Other serious underlying medical conditions, which, in the Investigator's judgment, could impair the ability of the patient to participate in the study (e.g., significant cardiovascular disease, uncontrolled diabetes mellitus, gastric ulcers, active autoimmune disease)
11. Recent major surgery (within 4 weeks prior to dosing, other than for diagnosis
12. Active and/or severe bacterial, viral, fungal, mycobacterial, parasitic, or other infection (excluding fungal infections of nail beds) or any major episode of infection requiring treatment with IV antibiotics or hospitalization (relating to the completion of the course of antibiotics except if for tumour fever) within 4 weeks prior to dosing
13. Active hepatitis B virus (HBV) or active hepatitis C virus (HCV) infection (must be ruled out during Screening)
14. History of human immunodeficiency virus (HIV) seropositive status

General Criteria

15. Inability to provide informed consent and comply with protocol requirements.
16. Life expectancy of less than 6 months
17. A positive serum pregnancy test in women of childbearing potential within 7 days prior to dosing or within 14 days if with a confirmatory urine pregnancy test within 7 days prior to dosing. Women of childbearing potential are defined as pre-menopausal women or women who are < 2 years after the onset of menopause and are not surgically sterile.
18. Fertile men or women of childbearing potential who do not agree to use a highly effective measure of contraception (such as oral contraceptives, intrauterine device or barrier method of contraception in conjunction with spermicidal jelly or surgically sterile) throughout the study and for at least 12 months after the last dose of rituximab.

Length of Study

Assessments of this study will be performed according to the type of lymphoma (either FL or DLBCL). Since assessments for FL patients are expected to be on-study longer, this portion of the study will be determinative for the length of the study. For FL patients the study is estimated to take approximately 6 years (68 months) based on an approximately 12 month of recruitment period, 8 months of induction and 24 months of maintenance treatment and 24 months of follow-up period.
On the other hand, DLBCL patients are expected to be on-study for a shorter period of time (approximately in 4 years), based on approximately 12 month recruitment, 8 months of treatment and 24 months follow up period.

End of Study

The end of the study, defined as last patient last visit (LPLV), will occur 24 months after the last SC rituximab treatment for the last FL or DLBCL patient, whichever comes later.

- FL patients who complete induction treatment will then enter the maintenance phase. Following the last SC rituximab administration, FL patients will be followed up for 24 months.
- DLBCL patients who receive their last SC rituximab treatment will then enter the post- treatment follow-up phase.
- Patients with SD or PD at staging will be withdrawn from study treatment and will only be followed AEs and for survival until the end of the study.
- Patients who do not complete the Induction treatment per protocol will undergo end-of-treatment assessment within 4 weeks after the last dose of Induction treatment and will be followed until the end of the whole study according to local practice for AEs, tumour response / progression (if PD not yet documented), survival, and documentation of any new anti-lymphoma treatment.

- Patients who complete the study or discontinue from the study early will be asked to return to the clinic (after 28 days or at least 5 half-lives of any non-rituximab IMPs, whichever longer) after the last dose of study drug for a follow-up visit.

Safety Outcome Measures

Safety outcomes will include AARs (defined as all related AEs occurring within 24 hours of rituximab SC administration including IIRRs, administration site conditions and all symptoms thereof), grade ≥ 3 AEs, and SAEs. Other safety assessments include routine safety laboratory tests, vital signs measurements and changes in concomitant medications. All clinical AEs and SAEs as well as laboratory abnormalities will be recorded regardless of their intensity / grading. Grading will be completed according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

Efficacy Outcome Measures

Tumour assessments will be done according to the protocol schedule of assessments (See Appendix 1-Appendix 2).

Tumour assessments will be based on CT scans of the neck, chest, abdomen and/or pelvis (if detectable by these techniques) or other diagnostic means (e.g. magnetic resonance imaging [MRI]) where applicable. Other methods (e.g. MRI) are acceptable for patients in whom CT scans are contraindicated. The CT scan used for eligibility assessments may be performed up to 28 days prior to dosing.

Response assessments 4-6 weeks after the last dose of Induction treatment will be based on the Investigator's assessment, completed according to the International Working Group (IWG) response criteria (Cheson et al. 1999, see **Appendix 2**).

The efficacy of rituximab SC will be evaluated during Induction and/or Maintenance in terms of EFS, PFS, OS, CR/CRu, and DFS.

The endpoints of EFS, PFS and OS will be defined and analysed twice using two different starting points for the time-to-event calculations. The first starting point will be first dose of rituximab IV and the second will be first dose of rituximab SC.

EFS is defined as the time from first dose of rituximab (analysed using both first dose of IV and first dose of SC) to first occurrence of progression or relapse, according to the IWG response criteria (Cheson et al. 1999, see **Appendix 2**) or initiation of a non–protocol-specified anti-lymphoma therapy or death, whichever occurs first.

PFS is defined as the time from first dose of rituximab (analysed using both first dose of IV and first dose of SC) to the first occurrence of progression or relapse, according to the IWG response criteria (Cheson et al. 1999, see **Appendix 2**) or death from any cause.

OS is defined as the time from first dose of rituximab (analysed using both first dose of IV and first dose of SC) to death from any cause.

DFS will be assessed in patients achieving CR/CRu and is defined as the period from the date of the initial CR/CRu until the date of relapse or death from any cause.

CR/CRu is complete response or complete response unconfirmed and is measured 4 weeks after the last dose of Induction treatment.

Exploratory Outcome Measures

Not applicable

Pharmacodynamic and Pharmacokinetic Outcome Measures

Not applicable

Pharmacoeconomic Outcome Measures

Not applicable

Patient-Reported Outcome Measures

Patient satisfaction with administration of treatment will be evaluated using the RASQ (see **Appendix 6**) after the rituximab IV administration,after last Rituximab SC in induction and after last Rituximab SC in maintenance. The RASQ will be completed immediately after rituximab administration and before chemotherapy administration in case the patient will receive chemotherapy. Patients prematurely discontinuing treatment during the study should complete the questionnaire at time of

discontinuation, as long as they had been administered at least one dose of treatment via both administration routes.

Healthcare Professional Reported Outcome Measures

At the end of the study, healthcare professional (HCP) questionnaire (see Appendix 7) will be applied to healthcare professionals such as hematologists, internists, nurses or other healthcare professionals who administered rituximab SC.

Study Drug and Study Treatment

The term "study drug" will be used throughout the protocol to refer to rituximab SC. The term "study treatment" will be used to refer to protocol-mandated treatment (also including background chemotherapy and/or other pre-medications).

Investigational Medicinal ProductsTest Product

Rituximab SC - The rituximab SC dose is 1400 mg for all patients, independent of patient body surface area (BSA). This translates into an injection volume of 11.7 mL.

Each administration will consist of a single SC injection of rituximab 1400 mg independent of BSA.

Induction therapy: rituximab SC will always be administered **prior** to the selected chemotherapy regimen (with the exception of the corticosteroid component in CHOP regimens), on average of once a month for a minimum of four cycles.

Maintenance therapy (patients with follicular NHL): rituximab SC will be administered at 2-month intervals for a minimum of six cycles, according to local standards of care.

Comparator

Not applicable.

Non-Investigational Medicinal Products

Background therapy: Commercially available chemotherapy will be used in combination with rituximab SC, as per standard local practice. For further details, see the local prescribing information for CHOP, CVP or FC.

Concomitant therapy: Patients should receive full supportive care, such as granulocyte colony-stimulating factor (G-CSF) support, transfusions of blood and blood products, prophylactic antiviral medication, antibiotics, anti-emetics, or local application of radiotherapy for consolidation after induction, as applicable and according to institutional standards. Mesna (2-Mercapto Ethane Sulfonate sodium) may be used as prophylaxis of haemorrhagic cystitis.

Pre-medication: In order to reduce the incidence and severity of IIRRs, it is recommended that all patients receive the following premedication administered 30-60 minutes prior to each rituximab administration:

- paracetamol (acetaminophen)
- diphenhydramine hydrochloride or alternative antihistamine.

Tumor Lysis Syndrome Prophylaxis: TLS prevention may include hydration and prophylactic rasburicase (recombinant urate oxidase) in high-risk patients, hydration plus allopurinol or rasburicase for intermediate-risk patients, and close monitoring of electrolyte abnormalities for low- risk patients. Primary management of established TLS involves similar recommendations, with the addition of aggressive hydration and diuresis, plus allopurinol or rasburicase for hyperuricemia.

Statistical Methods

The analysis of this study will be exploratory and will primarily make use of descriptive statistical methods. In addition, exploratory statistical testing and modeling will be used to highlight interesting aspects of the data. All tests will be two-sided and carried out with a 5% α-error rate without correction for multiplicity.

All enrolled patients who receive at least one dose of study medication will be included in the Safety Population, which will be the primary analysis population for safety parameters. All enrolled patients will be included in the Intent-to-Treat Population, which will be the primary analysis population for efficacy parameters. Other analysis populations may be defined based on more restrictive criteria, such as fulfillment of eligibility criteria or a minimum duration of the observation period.

Endpoint and Analysis

Safety will be assessed on the following safety parameters: AARs, including IIRRs, AEs, AEs of grade ≥ 3, SAEs, routine laboratory parameters, vital signs, concomitant medications, premature withdrawal from the study and from study medication due to AEs or ECOG performance status.

The incidence of AARs AEs, AEs leading to premature discontinuation or interruption of study treatment, SAEs, grade ≥ 3 AEs will be estimated with 95%-Clopper-Pearson confidence intervals. The incidence of each AE will be summarized by the primary system-organ class and by preferred term. The incidence of deaths and cause of deaths will be listed and summarized.

Laboratory parameters will be summarized and selected laboratory parameters may also be displayed graphically.

Vital signs will be summarized over time.

ECOG performance status will be summarized by frequency tables over time and percentage of patients in different categories will be presented by bar charts at different time points.

Concomitant medication will be coded according to the WHO DRUG dictionary and tabulated in summary tables.

All safety analyses will be based on the Safety population.

The analysis of endpoints measured as a time to event (EFS, PFS, OS and DFS) is based on the survivor function, which is the probability of remaining event-free beyond a certain point in time. The survivor function will be estimated using Kaplan-Meier methodology and summarized using the range, the 25th and 75th percentiles and median survival along with a 95% confidence interval for median survival.

Endpoints resulting in an incidence rate (e.g., CR/CRu) will be summarized with a 95% Clopper- Pearson confidence interval.

Determination of Sample Size

A sample size of 110 patients is deemed sufficient for this study. In this study, all planned statistical analysis will be exploratory in nature as the study will not be powered to address any pre-defined statements and only descriptive statistical evaluations will be carried out primarily for safety (and efficacy) parameters. Additionally, no published reference is available on administration-associated reactions (AARs) following multiple doses of subcutaneous (SC) rituximab during induction and/or maintenance therapy in patients with CD20+ follicular non-Hodgkin's lymphoma (NHL) or CD20+ diffuse large B-cell lymphoma (DLBCL). However, with 110 patients a 95% Clopper-Pearson CI for the incidence of AARs will be no wider than +/- 9.7%. This width of interval is deemed sufficiently precise to draw valid conclusions around the incidence of ARRs. Additionally, enrolment of more than 110 patients within the specified indications could also be difficult in participating countries. Due to the fact of exploratory nature of the study, drop out patients will not be replaced.

Interim Analyses

Not applicable

Study procedures

See **Schedule of Assessments**, **Appendix 1** and **Appendix 2**.

Appendix 2 - Schedule of Assessments

SCHEDULE OF ASSESSMENTS FOR PATIENTS WITH CD20+ FOLLICULAR NHL

Study Period / Visit	Screening / Baseline	Induction (cycles)								Maintenance (cycles)												EOT	F/UP	End of Study Visit
Timing / Assessments	D -28 to D -1	1[a]	2	3	4	5	6	7	8	Final Staging	1	2	3	4	5	6	7	8	9	10	11	12	• 4-6w after last dose of SC Rit	Every 3m (year 1) • Every 6m (year 2)	
Written informed consent [b]	X																								
Demographic data	X																								
Medical history	X																								
Follicular NHL diagnosis and WHO Classification [c]	X																								
Documentation of/testing for HIV, active hepatitis and other infections [d]	X																								
Tumour evaluation [e]	X									X													X	X	X
Physical examination, infection assessment, vital signs [f]	X X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Height and weight	X									X															
12-lead ECG	X																								
FLIPI score [g]	X																								
ECOG performance status [h]	X																								
Serum pregnancy test [i]	X																								
Laboratory: Haematology, Biochemistry, Coagulation tests [j]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Study Period / Visit	Screening / Baseline	Induction (cycles)								Final Staging	Maintenance (cycles)												EOT	F/UP	End of Study Visit
Timing / Assessments	D -28 to D -1	1[a]	2	3	4	5	6	7	8		1	2	3	4	5	6	7	8	9	10	11	12	• 4-6w after last dose of SC Rit	Every 3m (year 1) • Every 6m (year 2)	
Study Treatment (minimum doses)	X					X	X	X	X								X	X	X	X	X	X			
Adverse event recording [k]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant treatments & therapies	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
RASQ [l]	X									X													X		
HCP Questionnaire [m]																							X		
Survival										X													X	X	X

a. Patients must have previously received at least one cycle of IV rituximab before enrolment. All Screening/Baseline assessments could have been performed at the IV cycle visit.
b. Signed informed consent must be obtained prior to any study-required Screening/Baseline assessments.
c. Diagnosis of follicular NHL before treatment must have included histological diagnosis and initial CD20 expression confirmation.
d. Patients known to have active hepatitis C, active hepatitis B, history of HIV seropositive status, or signs or symptoms of other active and/or severe infection must not be included in the study. Serology should be performed according to clinical judgment before and during treatment with rituximab. Local guidelines for patient consent to viral testing must be adhered to.
e. CT and MRI are currently the best available and most reproducible methods for measuring target lesions selected for response assessment. Conventional CT or MRI should be performed according to institutional standards. Tumour assessment will be based on CT scans of the neck, chest, abdomen and pelvis, as applicable. CT scan with contrast is the recommended technique. However, MRIs of the chest, abdomen, and pelvis with a non-contrast CT scan may be used in patients for whom CT scans with contrast are contraindicated (i.e., patients with contrast allergy or impaired renal clearance). Owing to the global nature of this study, and due to limited availability of FDG-PET scanners, an FDG-PET scan cannot be mandated. The CT scan used for eligibility assessment may be performed up to 28 days before first dose of study medication. The end-of-treatment response assessment including radiology/imaging report must be obtained 4 weeks after the last dose of Induction treatment. Response should be determined on the basis of radiographic and clinical evidence of disease according the IWG guidelines (Cheson *et al*. 1999; see **Appendix 2**), or if not applicable, institutional standards should be used for tumour evaluation. Disease progression will be evaluated by the Investigator according to the IWG response criteria for NHL (Cheson *et al*. 1999; see **Appendix 2**) or other country standards until PD. Subsequent bone marrow assessments are required to confirm any suspected CR in patients with bone marrow involvement at baseline.
f. As part of physical exam, SC injection sites will be checked at every treatment visit. As part of tumour assessments, physical examinations should also include the evaluation of the presence and degree of enlarged lymph nodes, hepatomegaly, and splenomegaly. Patients should be assessed for presence of active infections throughout the treatment periods. Vital signs assessment includes resting heart rate, body temperature and blood pressure.
g. FLIPI score determined at Baseline (prior to Cycle 1). Where possible, the baseline FLIPI score should be calculated from the patient notes. Missing FLIPI scores will not preclude enrolment. See **Appendix 3**.
h. ECOG performance status needs to be ≤ 3 for inclusion of the patient into the study. See **Appendix 3**.

i. Women of childbearing potential (defined as pre-menopausal women or women who are < 2 years after the onset of menopause and not surgically sterile) must undergo serum pregnancy test within 7 days prior to first dose or within 14 days if with a confirmatory urine pregnancy test within 7 days prior to dosing.
j. Haematology parameters will include haemoglobin, RBC, WBC count and differential, and platelet count. Biochemistry parameters at Screening will include sodium, potassium, ALT/SGPT, AST/SGOT, total bilirubin, serum creatinine, alkaline phosphatase, albumin, BUN, C-reactive protein and LDH. Biochemistry parameters at any further timepoint during the study will include sodium, potassium, ALT/SGPT, AST/SGOT, total bilirubin, and serum creatinine. Coagulation tests will include: INR, PT, and aPTT. The results from the safety laboratory assessments must be available on treatment days, prior to the rituximab administrations.
k. After informed consent has been obtained but prior to dosing, only SAEs caused by a protocol-mandated intervention should be reported (e.g. SAEs related to invasive procedures such as biopsies). All clinical and laboratory AEs reported during the study will be documented and graded using the NCI CTCAE criteria, version 4.0. Special attention should be given to any acute infusion-related toxicities. After initiation of study drug, all AEs/SAEs, regardless of relationship to study drug, will be reported until study closure.
l. Patient reported outcomes: All patients will be required to complete the Rituximab Administration Questionnaire (RASQ, see **Appendix 6**) at the end of the study. Patients prematurely discontinuing study treatment should complete the questionnaire at time of discontinuation, as long as they had taken at least one dose via each treatment route (IV and SC) post-randomization. RASQ will be completed immediately after rituximab administration and before chemotherapy administration.
m. Healthcare Professional (HCP) Questionnaire (see **Appendix 7**) will be completed at the end of the study by healthcare professionals such as haematologists, internists, nurses or other healthcareprofessionals who administered rituximab SC during the study.

SCHEDULE OF ASSESSMENTS FOR PATIENTS WITH CD20+ DLBCL

Study Period	Screening / Baseline	Treatment (cycles)							Final Staging	Post-Treatment Follow-Up						End of Study Visit
Visit																
Timing / Assessments	D -28 to D -1	1[a]	2	3	4	5	6	7	8		1-3	3-6	6-9	9-122	12-18	18-24	
Written informed consent [b]	X																
Demographic data	X																
Medical history	X																
DLBCL diagnosis and WHO Classification [c]	X																
Documentation of/testing for HIV, active hepatitis and other infections [d]	X																
Tumour evaluation [e]	X									X	X	X	X	X	X	X	X
Physical examination, infection assessment, vital signs [f]	X X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Height and weight	X X									X							
12-lead ECG	X																
IPI score [g]	X																
ECOG performance status [h]	X									X							
Serum pregnancy test [i]	X																
Laboratory: Haematology, Biochemistry, Coagulation tests [j]	X X	X	X	X	X	X	X	X	X	X	X	X	X	X			X
Study Treatment						X	X	X	X								
Adverse event recording [k]	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X

Study Period	Screening / Baseline	Treatment (cycles)							Final Staging	Post-Treatment Follow-Up						End of Study Visit
Visit																
Timing / Assessments	D -28 to D -1	1[a]	2	3	4	5	6	7	8		1-3	3-6	6-9	9-122	12-18	18-24	
Concomitant treatments & therapies	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
RASQ [l]	X									X							
HCP Questionnaire [m]										X							
Survival										X	X	X	X	X	X	X	X

a. Patients must have previously received at least one cycle of IV rituximab before enrolment. All Screening/Baseline assessments could have been performed at the IV cycle visit.
b. Signed informed consent must be obtained prior to any study-required Screening/Baseline assessments.
c. Diagnosis of diffuse large B-cell lymphoma before treatment must have included histological diagnosis and initial CD20 expression confirmation.
d. Patients known to have active hepatitis C, active hepatitis B, history of HIV seropositive status, or signs or symptoms of other active and/or severe infection must not be included in the study. Serology should be performed according to clinical judgment before and during treatment with rituximab. Local guidelines for patient consent to viral testing must be adhered to.
e. CT and MRI are currently the best available and most reproducible methods for measuring target lesions selected for response assessment. Conventional CT or MRI should be performed according to institutional standards. Tumour assessment will be based on CT scans of the neck, chest, abdomen and pelvis, as applicable. CT scan with contrast is the recommended technique. However, MRIs of the chest, abdomen, and pelvis with a non-contrast CT scan may be used in patients for whom CT scans with contrast are contraindicated (i.e., patients with contrast allergy or impaired renal clearance). Owing to the global nature of this study, and due to limited availability of FDG-PET scanners, an FDG-PET scan cannot be mandated. The CT scan used for eligibility assessment may be performed up to 28 days before first dose of study medication. The end-of-treatment response assessment including radiology/imaging report must be obtained 4 weeks after the last dose of Induction treatment. Response should be determined on the basis of radiographic and clinical evidence of disease according the IWG guidelines (Cheson *et al*. 1999; see **Appendix 2**), or if not applicable, institutional standards should be used for tumour evaluation. Screening/Baseline bone marrow examinations should include biopsy and aspirate for morphology (flow studies are optional) for staging purposes unless it has been performed within 1 month prior to dosingand was done for the purpose of diagnosis and staging of DLBCL. Subsequent bone marrow assessments are required to confirm any suspected CR in patients with bone marrow involvement at baseline.
f. As part of physical exam, SC injection sites will be checked at every treatment visit. As part of tumour assessments, physical examinations should also include the evaluation of the presence and degree of enlarged lymph nodes, hepatomegaly, and splenomegaly. Patients should be assessed for presence of active infections throughout the treatment periods. Vital signs assessment includes resting heart rate, body temperature and blood pressure.
g. IPI (according to Shipp *et al*. 1993) score determined at Baseline (prior to Cycle 1). Where possible, the baseline IPI score should be calculated from the patient notes. Missing IPI scores will not preclude enrolment. See **Appendix 3**.
h. ECOG performance status needs to be ≤ 3 for inclusion of the patient into the study. See **Appendix 3**.
i. Women of childbearing potential (defined as pre-menopausal women or women who are < 2 years after the onset of menopause and not surgically sterile) must undergo serum pregnancy test within 7 days prior to first dose or within 14 days if with a confirmatory urine pregnancy test within 7 days prior to dosing.
j. Haematology parameters will include haemoglobin, RBC, WBC count and differential, and platelet count. Biochemistry parameters at Screening will include sodium, potassium, ALT/SGPT, AST/SGOT, total bilirubin, serum creatinine, alkaline phosphatase, albumin, BUN, C-reactive protein and LDH. Biochemistry parameters at any

further timepoint during the study will include sodium, potassium, ALT/SGPT, AST/SGOT, total bilirubin, and serum creatinine. Coagulation tests will include: INR, PT, andaPTT. The results from the safety laboratory assessments must be available on treatment days, prior to the rituximab administrations.

k. After informed consent has been obtained but prior to dosing, only SAEs caused by a protocol-mandated intervention should be reported (e.g. SAEs related to invasive procedures such as biopsies). All clinical and laboratory AEs reported during the study will be documented and graded using the NCI CTCAE criteria, version 4.0. Specialattention should be given to any acute infusion-related toxicities. After initiation of study drug, all AEs/SAEs, regardless of relationship to study drug, will be reported until study closure.

l. Patient reported outcomes: All patients will be required to complete the Rituximab Administration Questionnaire (see **Appendix 6**) at the end of the study. Patients prematurely discontinuing study treatment should complete the questionnaire at time of discontinuation, as long as they had taken at least one dose via each treatmentroute (IV and SC) post-randomization. RASQ will be comleted immediately after rituximab administration and before chemotherapy administration.

m. Healthcare Professional (HCP) Questionnaire (see **Appendix 7**) will be completed at the end of the study by healthcare professionals such as haematologists, internists,nurses or other healthcareprofessionals who administered rituximab SC during the study.

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Appendix 3 - Table and Listing Shells

TABLE 14.1.1) ENROLLED BY COUNTRY AND SITE (ITT POPULATION)

	All Patients (N=xxx)
Country	
Algeria	xx (x.x%)
Morocco	xx (x.x%)
Tunisia	xx (x.x%)
Site	
Site #1	xx (x.x%)
Site #2	xx (x.x%)
Site #3	xx (x.x%)
Site …	xx (x.x%)
Site n	xx (x.x%)

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.2) SUMMARY OF PATIENT DISPOSITION (ITT POPULATION)

	Statistic	All Patients (N=xx)	DLBCL (N=xx)	FL (N=xx)
Intent-to-treat Population	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Safety Population	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Discontinuation treatment				
Progression of Disease	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Adverse Event	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Pregnancy	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Patient request/Withdraw consent	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Investigator decision	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Lack of compliance	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Lost to Follow-up	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Death	n (%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Number of subjects who Continued to Maintenance Phase	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note(s): Percentages for the reasons for discontinuation are based on the number of subjects who discontinued. Other percentages are calculated based on number of subjects in ITT population.

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.3) SUMMARY OF PROTOCOL DEVIATIONS (ITT POPULATION)

Category Subcategory	Statistic	All Patients (N=xxx)		DLBCL (N=xx)		FL (N=xx)	
Number of patients with at least one Protocol Deviation	n (%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Protocol Deviations	n (%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Reason 1	n (%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Reason 2	n (%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Reason 3	n (%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Number of patients with at least one major Protocol Deviation	n (%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Major Protocol Deviations	n (%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Reason 1	n (%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Reason 2	n (%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Reason 3	n (%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Number of patients with at least one COVID-19 related Protocol Deviation	n (%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
COVID-19 Protocol Deviations	n (%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Reason 1	n (%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Reason 2	n (%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Reason 3	n (%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)

Note(s): Percentages for the protocol deviations are based on the number of patients in ITT population in each group.
Patients with multiple protocol deviations within the same category are counted only once under those categories.
The same patient experiencing multiple protocol deviation criterion are counted under each criterion.

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.4) SUMMARY OF DEMOGRAPHICS (ITT POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xx)	FL (N=xx)
Age (Years)				
	n	xxx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.xx	xx.xx	x.xx
	Minimum	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x
Sex				
Male	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity				
Hispanic (latino)	n (%)	xx (x.x%)	xx (x.x%)	xx (x.x%)
Not Hispanic (non-latino)	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Applicable as per local regulations	n (%)	xx (x.x%)	xx (x.x%)	xx (x.x%)
Other	n (%)	xx (x.x%)	xx (xx.x%)	xx (x.x%)
Childbearing potential				
Yes	n (%)	xx (x.x%)	xx (x.x%)	xx (x.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Source: xxx.sas Run DDMMMYYYY

Programming note:
This table (age and ethnicity variables) to be repeated stratified by sex (Male, Female).

TABLE 14.1.5) SERUM PREGNANCY TEST AT SCREENING (SAFETY POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Was the serum pregnancy test performed?				
No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Pregnancy test result#				
Negative	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Positive	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in SAF population.
Percentages are calculated relative to the total number of SAF patients who performed a serum pregnancy test at screening visit.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.1.6) SUMMARY OF BASELINE CHARACTERISTICS – PART #1 (ITT POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xx)	FL (N=xx)
Height (cm)				
	n	xxx	xx	xx
	Mean	xxx.x	xxx.x	xxx.x
	SD	x.xx	x.xx	x.xx
	Minimum	xxx.x	xxx.x	xxx.x
	Median	xxx.x	xxx.x	xxx.x
	Maximum	xxx.x	xxx.x	xxx.x
Weight (Kg)				
	n	xxx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Maximum	xxx.x	xxx.x	xxx.x
BMI (Kg/m^2)				
	n	xxx	xx	xx
	Mean	xx.x	xx.x	xx.x
	SD	x.xx	x.xx	x.xx
	Minimum	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x

Source: xxx.sas Run DDMMMYYYY

Programming note:
This table to be repeated stratified by sex (Male, Female).

TABLE 14.1.7) SUMMARY OF BASELINE CHARACTERISTICS – PART #2 (ITT POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xx)	FL (N=xx)
IPI Score				
Low risk	n (%)	xx (xx.x%)	xx (xx.x%)	
Low intermediate risk	n (%)	xx (x.x%)	xx (xx.x%)	
High intermediate risk	n (%)	xx (xx.x%)	xx (xx.x%)	
High risk	n (%)	xx (x.x%)	xx (xx.x%)	
FLIPI Score				
Low risk	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Intermediate risk	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High risk	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Surgery/Procedure History				
General	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lymphoma related	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Both	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reproductive Status				
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note(s): Percentages for reproductive status are based on the number of female patients in that particular group.

Source: xxx.sas Run DDMMMYYYY

Programming note:
This table (IPI Score, FLIPI Score, Surgery/Procedure history variables) to be repeated stratified by sex (Male, Female).

TABLE 14.1.8) DLBCL DIAGNOSIS (SAFETY POPULATION)

	Statistic	DLBCL (N=xxx)
How was the histological diagnosis obtained?		
Fine needle aspiration	n (%)	xxx (xx.x%)
Core needle biopsy	n (%)	xxx (xx.x%)
Excisional/incisional biopsy of peripheral lymph node	n (%)	xxx (xx.x%)
CD20+ expression#		
Negative	n (%)	xxx (xx.x%)
Positive	n (%)	xxx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in SAF population.
Percentages are calculated relative to the number of patients with a diagnosis obtained by means of a Fine Needle Aspiration method.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.1.9) FOLLICULAR LYMPHOMA DIAGNOSIS (SAFETY POPULATION)

	Statistic	FL (N=xxx)
How was the histological diagnosis obtained?		
Fine needle aspiration	n (%)	xxx (xx.x%)
Core needle biopsy	n (%)	xxx (xx.x%)
Excisional/incisional biopsy of peripheral lymph node	n (%)	xxx (xx.x%)
Grade of FL		
Grade 1	n (%)	xxx (xx.x%)
Grade 2	n (%)	xxx (xx.x%)
Grade 3a	n (%)	xxx (xx.x%)
CD20+ expression		
Negative	n (%)	xxx (xx.x%)
Positive	n (%)	xxx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in SAF population.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.1.10) SUMMARY OF BONE MARROW AT BASELINE (ITT POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xx)	FL (N=xx)
Bone marrow assessment done				
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Bone marrow assessment using aspirate				
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Bone marrow assessment using aspirate result				
Positive	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Bone marrow assessment using biopsy				
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Bone marrow assessment using biopsy result				
Positive	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in ITT population.

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.11) LEAD ECG AT SCREENING (SAFETY POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Was 12-lead ECG performed?				
No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Overall evaluaton of ECG tracing#				
Normal	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Abnormal, NCS	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Abnormal, CS	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Note:
CS = Clically Significant.
NCS = Not Clinically Significant.
Percentages are calculated relative to the total number of patients in SAF population.
Percentages are calculated relative to the total number of SAF patients who performed ECG at screening visit.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.1.12) VIRAL SEROLOGY AT SCREENING (SAFETY POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Was the viral serology sample collected?				
No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Hepatitis B core antibody (HBcAb)				
Negative	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Positive	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Not done	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Hepatitis B surface antigen (HBsAg)				
Negative	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Positive	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Not done	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
HCV antibody				
Negative	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Positive	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Not done	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
HCV antibody				
Negative	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Positive	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Not done	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Does the patient have an active viral infection with hepatitis B virus (HBV) or hepatitis C virus (HCV)?				
No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in SAF population.
Percentages are calculated relative to the total number of SAF patients who performed a viral serology test at screening visit.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.1.13) SUMMARY OF PREVIOUS DISEASE (ITT POPULATION)

System Organ Class MedDRA Preferred Term	All Patients (N=xxx)	DLBCL (N=xx)	FL (N=xx)
Number of patients with at least one previous disease	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<Primary SOC>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<Primary SOC>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in the ITT population.
Medical History terms were coded using MedDRA thesaurus version 24.1.
Previous diseases are those not flagged as “Ongoing at study entry” in the CRF form.
Patients can have more than one previous disease.

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.14) SUMMARY OF CONCOMITANT DISEASE (ITT POPULATION)

System Organ Class MedDRA Preferred Term	All Patients (N=xxx)	DLBCL (N=xx)	FL (N=xx)
Number of patients with at least one concomitant disease	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<Primary SOC>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<Primary SOC>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<Primary SOC>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)
<PT>	xx (xx.x%)	xx (xx.x%)	x (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in the ITT population.
Medical History terms were coded using MedDRA thesaurus version 24.1.
Concomitant diseases are those flagged as "Ongoing at study entry" in the CRF form.
Patients can have more than one concomitant disease.

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.15) SUMMARY OF PHYSICAL EXAMINATION (SAFETY POPULATION)

Visit	Body System	All Patients (N=xxx)	DLBCL (N=xx)	FL (N=xx)
xxx	Head Ears Eyes Nose Throat			
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal, not clinically significant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal, clinically significant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not applicable	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Cardiovascular system			
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal, not clinically significant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal, clinically significant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not applicable	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Dermatological			
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal, not clinically significant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal, clinically significant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not applicable	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Musculoskeletal system			
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal, not clinically significant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal, clinically significant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not applicable	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Respiratory system			
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal, not clinically significant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal, clinically significant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not applicable	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Genitourinary system			
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Gastrointestinal system			
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Nervous system			
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Other			
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note(s): Percentages are based on the number of patients in safety population at the specific visit.

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.16) SUMMARY OF PREVIOUS THERAPIES (SAFETY POPULATION)

ATC Class Level 2 Other Treatment	Statistic	All Patients (N=xxx)	FL (N=xxx)	DLBCL (N=xxx)
Total number of patients with at least one treatment	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total number of treatments	n	xxx	xxx	xxx
Class 1				
Total number of patients with at least one treatment	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total number of treatments	n	xxx	xxx	xxx
Other treatment 1	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other treatment 2	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				
Class 2				
Total number of patients with at least one treatment	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total number of treatments	n	xxx	xxx	xxx
Other treatment 1	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				

Notes:
Treatments are coded using the INN-1.0V dictionary.
Treatments can appear under multiple classes.
Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Likewise, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
For frequency counts in “Total number of treatments”, multiple uses of the same medication for a patient were counted separately.
Patients can have more than one previous therapy. Previous therapy includes any medication stopped before exposure to study drug.

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.17) SUMMARY OF CONCOMITANT THERAPIES (SAFETY POPULATION)

ATC Class Level 2 Other Treatment	Statistic	All Patients (N=xxx)	FL (N=xxx)	DLBCL (N=xxx)
Total number of patients with at least one treatment	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total number of treatments	n	xxx	xxx	xxx
Class 1				
Total number of patients with at least one treatment	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total number of treatments	n	xxx	xxx	xxx
Other treatment 1	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other treatment 2	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				
Class 2				
Total number of patients with at least one treatment	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Total number of treatments	n	xxx	xxx	xxx
Other treatment 1	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				

Notes:
Treatments are coded using the INN-1.0V dictionary.
Treatments can appear under multiple classes.
Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Likewise, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
For frequency counts in "Total number of treatments", multiple uses of the same medication for a patient were counted separately.
Patients can have more than one concomitant therapy. Concomitant therapy consists of any medication taken during the study, including those started before but ongoing at first dose of study drug.

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.18) SUMMARY OF PREVIOUS IV RITUXIMAB DOSE FOR DLBCL (SAFETY POPULATION)

	Statistic	DLBCL (N=xxx)
Number of previous IV rituximab treatment cycles		
One	n (%)	xxx (xx.x%)
Two	n (%)	xxx (xx.x%)
Three	n (%)	xxx (xx.x%)
Four	n (%)	xxx (xx.x%)
Dose of most recent IV rituximab cycle		
	n	xxx
	Mean (SD)	xx.x (xx.x)
	Median	xx.x
	Min,Max	xx,xx

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.19) SUMMARY OF PREVIOUS IV RITUXIMAB DOSE FOR FL (SAFETY POPULATION)

	Statistic	FL (N=xxx)
What phase of IV Rituximab was the patient on for their most recent IV cycle?		
Induction phase	n (%)	xxx (xx.x%)
Maintenance phase	n (%)	xxx (xx.x%)
Number of previous IV rituximab treatment cycles		
One	n (%)	xxx (xx.x%)
Two	n (%)	xxx (xx.x%)
Three	n (%)	xxx (xx.x%)
Four	n (%)	xxx (xx.x%)
Five	n (%)	xxx (xx.x%)
Six	n (%)	xxx (xx.x%)
Seven	n (%)	xxx (xx.x%)
Eight	n (%)	xxx (xx.x%)
Dose of most recent IV rituximab cycle		
	n	xxx
	Mean (SD)	xx.x (xx.x)
	Median	xx.x
	Min,Max	xx,xx
Which treatment phase is the subject eligible to enter the study?		
Induction phase	n (%)	xxx (xx.x%)
Maintenance phase	n (%)	xxx (xx.x%)

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.20) EXPOSURE TO RITUXIMAB SC – ADMINISTRATION SUMMARY (SAFETY POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xx)	FL (N=xx)
Induction Cycle*				
Induction Cycle 1	n (%)	x (x.x%)		x (x.x%)
Induction Cycle 2	n (%)	x (x.x%)		x (x.x%)
Induction Cycle …	n (%)	x (x.x%)		x (x.x%)
Induction Cycle n	n (%)	x (x.x%)		x (x.x%)
Maintenance Cycle*				
Maintenance Cycle 1	n (%)	x (x.x%)		x (x.x%)
Maintenance Cycle 2	n (%)	x (x.x%)		x (x.x%)
Maintenance Cycle …	n (%)	x (x.x%)		x (x.x%)
Maintenance Cycle n	n (%)	x (x.x%)		x (x.x%)
Treatment Cycle*				
Treatment Cycle 1	n (%)	x (x.x%)	x (x.x%)	
Treatment Cycle 2	n (%)	x (x.x%)	x (x.x%)	
Treatment Cycle …	n (%)	x (x.x%)	x (x.x%)	
Treatment Cycle n	n (%)	x (x.x%)	x (x.x%)	
Total number of cycles				
	n	xxx	xx	xx
	Mean	x.x	x.x	x.x
	SD	x.xx	x.xx	x.xx
	Minimum	x.x	x.x	x.x
	Median	x.x	x.x	x.x
	Maximum	xx.x	x.x	x.x

Note(s): *Number of Rituximab SC cycles exposure.
Denominator for calculating the percentage is N (Safety population).

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.21) EXPOSURE TO RITUXIMAB SC – ADMINISTRATION DETAILS (SAFETY POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xx)	FL (N=xx)
Full Doses				
Overall	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Full Doses in Induction Cycle				
Induction Cycle 1	n (%)	x (x.x%)		x (x.x%)
Induction Cycle 2	n (%)	x (x.x%)		x (x.x%)
Induction Cycle …	n (%)	x (x.x%)		x (x.x%)
Induction Cycle n	n (%)	x (x.x%)		x (x.x%)
Full Doses in Maintenance Cycle				
Maintenance Cycle 1	n (%)	x (x.x%)		x (x.x%)
Maintenance Cycle 2	n (%)	x (x.x%)		x (x.x%)
Maintenance Cycle …	n (%)	x (x.x%)		x (x.x%)
Maintenance Cycle n	n (%)	x (x.x%)		x (x.x%)
Full Doses in Treatment Cycle				
Treatment Cycle 1	n (%)	x (x.x%)	x (x.x%)	
Treatment Cycle 2	n (%)	x (x.x%)	x (x.x%)	
Treatment Cycle …	n (%)	x (x.x%)	x (x.x%)	
Treatment Cycle n	n (%)	x (x.x%)	x (x.x%)	

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.22) EXPOSURE TO RITUXIMAB SC – ADMINISTRATION DETAILS (SAFETY POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xx)	FL (N=xx)
Duration of Injection				
	n	xxx	xxx	xxx
	Mean	x.x	x.x	x.x
	SD	x.xx	x.xx	x.xx
	Minimum	x.x	x.x	x.x
	Median	x.x	x.x	x.x
	Maximum	xx.x	xx.x	xx.x
Dose Injected				
xxxx mg	n (%)	xxxx (xx.x%)	xxx (xx.x%)	xxxx (xx.x%)
xxxx mg	n (%)	xxxx (xx.x%)	xxx (xx.x%)	xxxx (xx.x%)
xxxx mg	n (%)	xxxx (xx.x%)	xxx (xx.x%)	xxxx (xx.x%)
Interruption Duration* #				
	n	xxx	xxx	xxx
	Mean	x.x	x.x	x.x
	SD	x.xx	x.xx	x.xx
	Minimum	x.x	x.x	x.x
	Median	x.x	x.x	x.x
	Maximum	xx.x	xx.x	xx.x

Note(s): #Interruption due to Serious Adverse Event/ Adverse Event of Special Interest.

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.23) TYPE OF CHEMOTHERAPY (SAFETY POPULATION)

Type of chemotherapy	Statistic	All Patients (N=xxx)	DLBCL (N=xx)	FL (N=xx)
CHOP-14 X 6	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
CHOP-14 X 8	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
CHOP-21 X 6	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
CHOP-21 X 8	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
CVP-21 X 8	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
FC-28 X 6	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
Other	n (%)	x (x.x%)	x (x.x%)	x (x.x%)

Note(s): Denominator for calculating the percentage is N (Safety population).

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.24) EXPOSURE TO CHEMOTHERAPY (SAFETY POPULATION)

Type		Statistic	All Patients (N=xxx)	DLBCL (N=xx)	FL (N=xx)
CHOP-14 X 6	Induction Cycle				
	1 Induction Cycle	n (%)	x (x.x%)		x (x.x%)
	2 Induction Cycles	n (%)	x (x.x%)		x (x.x%)
	n Induction Cycles	n (%)	x (x.x%)		x (x.x%)
	Total number of cycles				
		n	xx		xx
		Mean	x.x		x.x
		SD	x.xx		x.xx
		Minimum	x.x		x.x
		Median	x.x		x.x
		Maximum	x.x		x.x

Note(s): Denominator for calculating the percentage is N (Safety population).

Source: xxx.sas Run DDMMMYYYY

Programming note:
This table should be also presented for all chemotherapy regimen patient is taking.

TABLE 14.1.25) EXPOSURE TO NEW ANTI - LYMPHOMA TREATMENT CHEMO/IMMUNO THERAPY (SAFETY POPULATION)

Type		Statistic	All Patients (N=xxx)	DLBCL (N=xx)	FL (N=xx)
Chemo/Immuno Therapy	Total Number of Cycles				
	1 Cycle	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
	2 Cycles	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
	n Cycles	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
	Total number of cycles				
		n	xx	xx	xx
		Mean	x.x	x.x	x.x
		SD	x.xx	x.xx	x.xx
		Minimum	x.x	x.x	x.x
		Median	x.x	x.x	x.x
		Maximum	xx.x	x.x	xx.x
	Duration of Exposure (days)				
		n	xx	xx	xx
		Mean	xx.x	xx.x	xxx.x
		SD	xx.xx	xx.xx	xx.xx
		Minimum	x.x	x.x	xx.x
		Median	xx.x	xx.x	xxx.x
		Maximum	xxx.x	xxx.x	xxx.x
	Response				
	CR	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
	CRu	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
	PR	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
	SD	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
	PD	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
	Unable to assess	n (%)	x (x.x%)	x (x.x%)	x (x.x%)

Note(s): Denominator for calculating the percentage is N (Safety population).

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.26) INITIAL CHOP REGIMEN DOSAGE (SAFETY POPULATION)

Study Treatment	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Cyclophosphamide (mg/m^2)				
	n	xxx	xxx	xxx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min,Max	xx,xx	xx,xx	xx,xx
Doxorubicin (mg/m^2)				
	n	xxx	xxx	xxx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min,Max	xx,xx	xx,xx	xx,xx
Vincristine (mg/m^2)				
	n	xxx	xxx	xxx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min,Max	xx,xx	xx,xx	xx,xx
Prednisone/prednisolone (mg/m^2)				
	n	xxx	xxx	xxx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min,Max	xx,xx	xx,xx	xx,xx

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.27) INITIAL CVP REGIMEN DOSAGE (SAFETY POPULATION)

Study Treatment	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Cyclophosphamide (mg/m^2)				
	n	xxx	xxx	xxx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min,Max	xx,xx	xx,xx	xx,xx
Vincristine (mg/m^2)				
	n	xxx	xxx	xxx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min,Max	xx,xx	xx,xx	xx,xx
Prednisone/prednisolone (mg/m^2)				
	n	xxx	xxx	xxx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min,Max	xx,xx	xx,xx	xx,xx

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.28) INITIAL FLUDARABINE DOSAGE (SAFETY POPULATION)

Study Treatment	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Fludarabine (mg/m^2)				
	n	xxx	xxx	xxx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min,Max	xx,xx	xx,xx	xx,xx
Cyclophosphamide (mg/m^2)				
	n	xxx	xxx	xxx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x
	Min,Max	xx,xx	xx,xx	xx,xx

Source: xxx.sas Run DDMMMYYYY

TABLE 14.1.29) EXPOSURE TO NEW ANTI - LYMPHOMA TREATMENT RADIOTHERAPY (SAFETY POPULATION)

Type			Statistic	All Patients (N=xxx)	DLBCL (N=xx)	FL (N=xx)
Radiotherapy	Irradiation Site					
		Neck	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
		Chest	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
		Abdomen	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
		Pelvis	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
		Other	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
	Cumulative Dose of Radiation (Gy)					
		xx.xx Radiation	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
		xx.xx Radiation	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
		xx.xx Radiation	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
		xx.xx Radiation	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
	Cumulative Dose of Radiation (Gy)					
			n	xx	xx	xx
			Mean	xx.xx	xx.xx	xx.xx
			SD	x.xx	x.xx	x.xx
			Minimum	xx.xx	xx.xx	xx.xx
			Median	xx.xx	xx.xx	xx.xx
			Maximum	xx.xx	xx.xx	xx.xx
	Duration of Exposure (days)					
			n	xx	xx	xx
			Mean	xx.x	xx.x	xx.x
			SD	x.xx	x.xx	x.xx
			Minimum	xx.x	xx.x	xx.x
			Median	xx.x	xx.x	xx.x
			Maximum	xx.x	xx.x	xx.x
	Response					
		CR	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
		CRu	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
		PR	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
		SD	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
		PD	n (%)	x (x.x%)	x (x.x%)	x (x.x%)
		Unable to assess	n (%)	x (x.x%)	x (x.x%)	x (x.x%)

Note(s): Denominator for calculating the percentage is N (Safety population).

Source: xxx.sas Run DDMMMYYYY

TABLE 14.2.1) OVERALL SUMMARY OF PATIENTS EXPERIENCING EACH CLASS OF TREATMENT EMERGENT ADVERSE EVENT (SAFETY POPULATION)

Events	Statistic	All Patients (N=xxx)	DLBCL (N=xx)	FL (N=xx)
Treatment Emergent Adverse Events	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Treatment Emergent Serious Adverse Events	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Adverse Events of Special Interest	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Administration Associated Reactions	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Cutaneous and soft tissue AARs (Localized)	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Cutaneous and soft tissue AARs (Non-Localized)	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade >=3+ Treatment-Emergent Adverse Events	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade >=3+ Treatment-Emergent Serious Adverse Events	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade >=3+ Administration Associated Reactions	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Grade >=3+ Infusion/Injection-Related Reactions	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
TEAEs leading to rituximab drug interrupted/drug delayed	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
TEAEs leading to rituximab dose discontinuation	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
TEAEs leading to chemotherapy dose modification	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
TEAEs leading to chemotherapy dose discontinuation	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
TEAEs leading to death	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note(s): A patient experiencing multiple occurrences of an adverse event was counted, at most, once per Event.
TEAE = Treatment-Emergent Adverse Event.

Source: xxx.sas Run DDMMMYYYY

TABLE 14.2.2) PROPORTION OF TREATMENT EMERGENT ADVERSE EVENT BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	Statistic		All Patients (N=xxx)		DLBCL (N=xxx)		FL (N=xxx)	
Number of patients with Treatment Emergent Adverse Event	n (%)		xxx (xx.x%)		xxx (xx.x%)		xxx (xx.x%)	
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%

Note(s): MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
N = number of patients, % = Observed percentage, E = number of events, CI = Confidence Interval.
Percentages are calculated relative to the total number of patients in the SAF population.
95% CI of the observed percentage calculated using the Clopper-Pearson methodology, or the Poisson distribution for frequencies below 10%.
Each patient is counted at most once within each SOC and PT.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.3) PROPORTION OF SERIOUS TREATMENT EMERGENT ADVERSE EVENT BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	Statistic		All Patients (N=xxx)		DLBCL (N=xxx)		FL (N=xxx)	
Number of patients with serious Treatment Emergent Adverse Event	n (%)		xxx (xx.x%)		xxx (xx.x%)		xxx (xx.x%)	
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%

Note(s): MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
N = number of patients, % = Observed percentage, E = number of events, CI = Confidence Interval.
Percentages are calculated relative to the total number of patients in the SAF population.
95% CI of the observed percentage calculated using the Clopper-Pearson methodology, or the Poisson distribution for frequencies below 10%.
Each patient is counted at most once within each SOC and PT.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.4) PROPORTION OF LOCALIZED ADMINISTRATION ASSOCIATED REACTIONS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	Statistic		All Patients (N=xxx)		DLBCL (N=xxx)		FL (N=xxx)	
Number of patients with Localized AARs	n (%)		xxx (xx.x%)		xxx (xx.x%)		xxx (xx.x%)	
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%

Note(s): MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
N = number of patients, % = Observed percentage, E = number of events, CI = Confidence Interval.
Percentages are calculated relative to the total number of patients in the SAF population.
95% CI of the observed percentage calculated using the Clopper-Pearson methodology, or the Poisson distribution for frequencies below 10%.
Each patient is counted at most once within each SOC and PT.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.5) PROPORTION OF NON-LOCALIZED ADMINISTRATION ASSOCIATED REACTIONS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Number of patients with Non-localized AARs	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<Primary SOC>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<Primary SOC>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<Primary SOC>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%

Note(s): MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
N = number of patients, % = Observed percentage, E = number of events, CI = Confidence Interval.
Percentages are calculated relative to the total number of patients in the SAF population.
95% CI of the observed percentage calculated using the Clopper-Pearson methodology, or the Poisson distribution for frequencies below 10%.
Each patient is counted at most once within each SOC and PT.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.6) PROPORTION OF TREATMENT-EMERGENT ADVERSE EVENTS WITH GRADE >=3+ AES BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	Statistic		All Patients (N=xxx)		DLBCL (N=xxx)		FL (N=xxx)	
Number of patients with grade >=3+ TEAEs	n (%)		xxx (xx.x%)		xxx (xx.x%)		xxx (xx.x%)	
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%

Note(s): MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
N = number of patients, % = Observed percentage, E = number of events, CI = Confidence Interval.
Percentages are calculated relative to the total number of patients in the SAF population.
95% CI of the observed percentage calculated using the Clopper-Pearson methodology, or the Poisson distribution for frequencies below 10%.
Each patient is counted at most once within each SOC and PT.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.7) PROPORTION OF TREATMENT-EMERGENT ADVERSE EVENTS WITH GRADE >=3+ SAES BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	Statistic		All Patients (N=xxx)		DLBCL (N=xxx)		FL (N=xxx)	
Number of patients with grade >=3+ serious TEAEs	n (%)		xxx (xx.x%)		xxx (xx.x%)		xxx (xx.x%)	
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%

Note(s): MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
N = number of patients, % = Observed percentage, E = number of events, CI = Confidence Interval.
Percentages are calculated relative to the total number of patients in the SAF population.
95% CI of the observed percentage calculated using the Clopper-Pearson methodology, or the Poisson distribution for frequencies below 10%.
Each patient is counted at most once within each SOC and PT.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.8) PROPORTION OF TREATMENT-EMERGENT ADVERSE EVENTS WITH GRADE >=3+ AARS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	Statistic		All Patients (N=xxx)		DLBCL (N=xxx)		FL (N=xxx)	
Number of patients with grade >=3+ AARs	n (%)		xxx (xx.x%)		xxx (xx.x%)		xxx (xx.x%)	
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<Primary SOC>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E	95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%

Note(s): MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
N = number of patients, % = Observed percentage, E = number of events, CI = Confidence Interval.
Percentages are calculated relative to the total number of patients in the SAF population.
95% CI of the observed percentage calculated using the Clopper-Pearson methodology, or the Poisson distribution for frequencies below 10%.
Each patient is counted at most once within each SOC and PT.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.9) PROPORTION OF TREATMENT-EMERGENT ADVERSE EVENTS LEADING TO RITUXIMAB DRUG INTERRUPTED/DRUG DELAYED BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Number of patients with TEAE leading to drug Interruption/drug delayed	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<Primary SOC>				
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<Primary SOC>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<Primary SOC>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%

Note(s): MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
N = number of patients, % = Observed percentage, E = number of events, CI = Confidence Interval.
Percentages are calculated relative to the total number of patients in the SAF population.
95% CI of the observed percentage calculated using the Clopper-Pearson methodology, or the Poisson distribution for frequencies below 10%.
Each patient is counted at most once within each SOC and PT.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.10) PROPORTION OF TREATMENT-EMERGENT ADVERSE EVENTS LEADING TO RITUXIMAB DOSE DISCONTINUATION BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	Statistic	All Patients (N=xxx)		DLBCL (N=xxx)		FL (N=xxx)	
Number of patients with TEAE leading to dose discontinuation	n (%)	xxx (xx.x%)		xxx (xx.x%)		xxx (xx.x%)	
<Primary SOC>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<Primary SOC>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<Primary SOC>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%

Note(s): MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
N = number of patients, % = Observed percentage, E = number of events, CI = Confidence Interval.
Percentages are calculated relative to the total number of patients in the SAF population.
95% CI of the observed percentage calculated using the Clopper-Pearson methodology, or the Poisson distribution for frequencies below 10%.
Each patient is counted at most once within each SOC and PT.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.11) PROPORTION OF TREATMENT-EMERGENT ADVERSE EVENTS LEADING TO CHEMOTHERAPY DOSE MODIFICATION BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Number of patients with TEAE leading to chemotherapy dose modification	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
<Primary SOC>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<Primary SOC>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<Primary SOC>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%

Note(s): MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
N = number of patients, % = Observed percentage, E = number of events, CI = Confidence Interval.
Percentages are calculated relative to the total number of patients in the SAF population.
95% CI of the observed percentage calculated using the Clopper-Pearson methodology, or the Poisson distribution for frequencies below 10%.
Each patient is counted at most once within each SOC and PT.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.12) PROPORTION OF TREATMENT-EMERGENT ADVERSE EVENTS LEADING TO CHEMOTHERAPY DOSE DISCONTINUATION BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Number of patients with TEAE leading to chemotherapy dose discontinuation	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<Primary SOC>				
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<Primary SOC>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<Primary SOC>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%	xxx (xx.x%) xxx xx.x%-xx.x%

Note(s): MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
N = number of patients, % = Observed percentage, E = number of events, CI = Confidence Interval.
Percentages are calculated relative to the total number of patients in the SAF population.
95% CI of the observed percentage calculated using the Clopper-Pearson methodology, or the Poisson distribution for frequencies below 10%.
Each patient is counted at most once within each SOC and PT.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.13) PROPORTION OF TREATMENT-EMERGENT ADVERSE EVENTS LEADING TO DEATH BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	Statistic	All Patients (N=xxx)		DLBCL (N=xxx)		FL (N=xxx)	
Number of patients with TEAE leading to death	n (%)	xxx (xx.x%)		xxx (xx.x%)		xxx (xx.x%)	
<Primary SOC>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<Primary SOC>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<Primary SOC>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%
<PT>	n (%) E 95% CI	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%	xxx (xx.x%) xxx	xx.x%-xx.x%

Note(s): MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
N = number of patients, % = Observed percentage, E = number of events, CI = Confidence Interval.
Percentages are calculated relative to the total number of patients in the SAF population.
95% CI of the observed percentage calculated using the Clopper-Pearson methodology, or the Poisson distribution for frequencies below 10%.
Each patient is counted at most once within each SOC and PT.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.14) SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

	All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
System Organ Class Preferred Term	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy
Number of patients with Treatment-Emergent Adverse Events	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.15) SUMMARY OF SERIOUS TREATMENT-EMERGENT ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	All Patients (N=xxx) n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy	DLBCL (N=xx) n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy	FL (N=xx) n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy
Number of patients with serious Treatment-Emergent Adverse Events	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.16) SUMMARY OF ADVERSE EVENTS OF SPECIAL INTEREST BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class / Preferred Term	All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
		Number of Events				Number of Events				Number of Events		
	n(%)	Total	TR Rituximab	TR Chemotherapy	n(%)	Total	TR Rituximab	TR Chemotherapy	n(%)	Total	TR Rituximab	TR Chemotherapy
Number of patients with Adverse Event of Special interest	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.17) SUMMARY OF ADMINISTRATION ASSOCIATED REACTIONS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
		Number of Events				Number of Events				Number of Events		
	n(%)	Total	TR Rituximab	TR Chemotherapy	n(%)	Total	TR Rituximab	TR Chemotherapy	n(%)	Total	TR Rituximab	TR Chemotherapy
Number of patients with Administration Associated Reactions	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.18) SUMMARY OF INFUSION/INJECTION-RELATED REACTIONS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
		Number of Events				Number of Events				Number of Events		
	n(%)	Total	TR Rituximab	TR Chemotherapy	n(%)	Total	TR Rituximab	TR Chemotherapy	n(%)	Total	TR Rituximab	TR Chemotherapy
Number of patients with Infusion/Injection-Related Reaction	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.19) SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS WITH GRADE >=3+ AES BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

	All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
System Organ Class Preferred Term	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy
Number of patients with grade >=3+ Treatment Emergent Adverse Event	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.20) SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS WITH GRADE >=3+ SAES BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

	All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
System Organ Class Preferred Term	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy
Number of patients with grade >=3+ Treatment-Emergent Serious Adverse Events	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.21) SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS WITH GRADE >=3+ AESI BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

	All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
System Organ Class Preferred Term	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy
Number of patients with grade >=3+ Treatment-Emergent AESI	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.22) SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS WITH GRADE >=3+ AARS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
		Number of Events				Number of Events				Number of Events		
	n(%)	Total	TR Rituximab	TR Chemotherapy	n(%)	Total	TR Rituximab	TR Chemotherapy	n(%)	Total	TR Rituximab	TR Chemotherapy
Number of patients with grade >=3+ Treatment-Emergent AARS	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.23) SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS WITH GRADE >=3+ IIRRS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

	All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
System Organ Class Preferred Term	n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy	n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy	n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy
Number of patients with grade >=3+ Treatment-Emergent IIRRS	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.24) SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS WITHIN THE MEDDRA SMQ `ANAPHYLACTIC REACTIONS' (WIDE) BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

	All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
System Organ Class Preferred Term	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy
Number of patients with SMQ Anaphylactic reactions	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.25) SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS LEADING TO RITUXIMAB DRUG INTERRUPTED/DRUG DELAYED BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

	All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
System Organ Class Preferred Term	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy
Number of patients with Treatment-Emergent Adverse Event Leading to Rituximab Drug interrupted/delayed	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.26) SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS LEADING TO RITUXIMAB DOSE DISCONTINUATION BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

	All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
System Organ Class Preferred Term	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy
Number of patients with Treatment-Emergent Adverse Event Leading to Rituximab Dose discontinuation	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.27) SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS LEADING TO CHEMOTHERAPY DOSE MODIFICATION BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
		Number of Events				Number of Events				Number of Events		
	n(%)	Total	TR Rituximab	TR Chemotherapy	n(%)	Total	TR Rituximab	TR Chemotherapy	n(%)	Total	TR Rituximab	TR Chemotherapy
Number of patients with Treatment-Emergent Adverse Event Leading to Chemotherapy Dose modification	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.28) SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS LEADING TO CHEMOTHERAPY DOSE DISCONTINUATION BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

	All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
System Organ Class Preferred Term	n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy	n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy	n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy
Number of patients with Treatment-Emergent Adverse Event Leading to Chemotherapy Dose discontinuation	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.29) SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS LEADING TO DEATH BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

	All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
System Organ Class Preferred Term	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy
Number of patients with Treatment-Emergent Adverse Event Leading to death	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.30) SUMMARY OF CUTANEOUS AND SOFT TISSUE AARS (LOCALIZED) BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	All Patients (N=xxx) n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy	DLBCL (N=xx) n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy	FL (N=xx) n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy
Number of patients with Cutaneous and soft tissue AARS localized	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.31) SUMMARY OF CUTANEOUS AND SOFT TISSUE AARS (NON-LOCALIZED) BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	All Patients (N=xxx) n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy	DLBCL (N=xx) n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy	FL (N=xx) n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy
Number of patients with Cutaneous and soft tissue AARS non-localized	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.32) SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS WITH AN INCIDENCE OF >=5% BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
		Number of Events				Number of Events				Number of Events		
	n(%)	Total	TR Rituximab	TR Chemotherapy	n(%)	Total	TR Rituximab	TR Chemotherapy	n(%)	Total	TR Rituximab	TR Chemotherapy
Number of patients with Treatment-Emergent Adverse Events with Incidence >=5%	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.33) SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM AND MAXIMUM SEVERITY (SAFETY POPULATION)

		All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
Maximum Severity	System Organ Class Preferred Term	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy
Grade x	Number of patients with Treatment-Emergent Adverse Event (Max Grade)	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Grade x	Number of patients with Treatment-Emergent Adverse Event (Max Grade)	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.34) SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM AND STRONGEST RELATIONSHIP (SAFETY POPULATION)

		All Patients (N=xxx)				DLBCL (N=xx)				FL (N=xx)			
Strongest relationship	System Organ Class Preferred Term	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy	n(%)	Number of Events Total	TR Rituximab	TR Chemotherapy
Yes	Number of patients with Treatment-Emergent Adverse Event (Max Grade)	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
No	Number of patients with Treatment-Emergent Adverse Event (Max Grade)	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
	< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.35) SUMMARY OF NON-SERIOUS TREATMENT-EMERGENT ADVERSE EVENTS WITH AN INCIDENCE OF >=5% BY SYSTEM ORGAN CLASS AND PREFERRED TERM (SAFETY POPULATION)

System Organ Class Preferred Term	All Patients (N=xxx) n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy	DLBCL (N=xx) n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy	FL (N=xx) n(%)	Number of Events Total	 TR Rituximab	 TR Chemotherapy
Number of patients with Treatment-Emergent Adverse Events with Incidence >=5%	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
Primary SOC>	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx
< PT >	xx (xx.x%)	xxx	xxx	xxx	xx (xx.x%)	xxx	xxX	xxx	xx (xx.x%)	xxx	xxx	xxx

Note(s): n=number of patients with an event. TR=treatment related.
MedDRA = Medical Dictionary for Regulatory Activities. SOC and PT are from the MedDRA dictionary, version 24.1.
A patient experiencing multiple occurrences of an adverse event was counted, at most, once per System Organ Class and Preferred Term.

TEAEs are AEs occurring on the day of or after the first administration of study drug and up to 28 days after the last dose.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.2.36) SUMMARY OF PATIENTS DEAD OVER THE STUDY (SAFETY POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Total number of patients dead	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Primary cause of death				
Progression of disease	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Adverse event	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Unknown	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Other	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
If cause of death is AE, was the underlying cancer a contributing factor#?				
Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Is there reasonable suspected casual relationship to study medication?				
Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Was an autopsy performed?				
Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in the SAF population.
Percentages are calculated relative to the total number of patients with primary cause of death = “AE”.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.**3**.1) SUMMARY OF HEMATOLOGY PARAMETERS OVER THE STUDY (SAFETY POPULATION)

Hemoglobin (g/L)		All Patients (N=xxx)		DLBCL (N=xx)		FL (N=xx)	
	Statistic	Value	Change from Screening	Value	Change from Screening	Value	Change from Screening
Screening Visit	n	xxx		xx		xx	
	Mean (SD)	xxx.x (xx.xx)		xxx.x (xx.xx)		xxx.x (xx.xx)	
	Median	xxx.x		xxx.x		xxx.x	
	Min/Max	xx.x/xxx.x		xx.x/xxx.x		xx.x/xxx.x	
Cycle 1 Induction	n	xx	xx			xx	xx
	Mean (SD)	xxx.x (xx.xx)	x.x (x.xx)			xxx.x (xx.xx)	x.x (x.xx)
	Median	xxx.x	x.x			xxx.x	x.x
	Min/Max	xxx.x/xxx.x	xx.x/x.x			xxx.x/xxx.x	xx.x/x.x
Cycle 2 Induction	n	xx	xx			xx	xx
	Mean (SD)	xxx.x (xx.xx)	x.x (xx.xx)			xxx.x (xx.xx)	x.x (xx.xx)
	Median	xxx.x	x.x			xxx.x	x.x
	Min/Max	xx.x/xxx.x	xx.x/xx.x			xx.x/xxx.x	xx.x/xx.x
...							
Cycle x Induction	n	xx	xx			xx	xx
	Mean (SD)	xxx.x (xx.xx)	x.x (xx.xx)			xxx.x (xx.xx)	x.x (xx.xx)
	Median	xxx.x	x.x			xxx.x	x.x
	Min/Max	xx.x/xxx.x	xx.x/xx.x			xx.x/xxx.x	xx.x/xx.x

Notes:
Change from Screening values includes only those patients with both a screening value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table to be repeated for all hematology parameters for each visit of induction and maintenance phases.
Data must be presented according to the International System of Units (SI).

TABLE 14.3.2) SUMMARY OF BLOOD CHEMISTRY PARAMETERS OVER THE STUDY (SAFETY POPULATION)

Sodium (mmol/L)		All Patients (N=xxx)		DLBCL (N=xx)		FL (N=xx)	
	Statistic	Value	Change from Screening	Value	Change from Screening	Value	Change from Screening
Screening Visit	n	xxx		xx		xx	
	Mean (SD)	xxx.x (xx.xx)		xxx.x (xx.xx)		xxx.x (xx.xx)	
	Median	xxx.x		xxx.x		xxx.x	
	Min/Max	xx.x/xxx.x		xx.x/xxx.x		xx.x/xxx.x	
Cycle 1 Induction	n	xx	xx			xx	xx
	Mean (SD)	xxx.x (xx.xx)	x.x (x.xx)			xxx.x (xx.xx)	x.x (x.xx)
	Median	xxx.x	x.x			xxx.x	x.x
	Min/Max	xxx.x/xxx.x	xx.x/x.x			xxx.x/xxx.x	xx.x/x.x
Cycle 2 Induction	n	xx	xx			xx	xx
	Mean (SD)	xxx.x (xx.xx)	x.x (xx.xx)			xxx.x (xx.xx)	x.x (xx.xx)
	Median	xxx.x	x.x			xxx.x	x.x
	Min/Max	xx.x/xxx.x	xx.x/xx.x			xx.x/xxx.x	xx.x/xx.x
...							
Cycle x Induction	n	xx	xx			xx	xx
	Mean (SD)	xxx.x (xx.xx)	x.x (xx.xx)			xxx.x (xx.xx)	x.x (xx.xx)
	Median	xxx.x	x.x			xxx.x	x.x
	Min/Max	xx.x/xxx.x	xx.x/xx.x			xx.x/xxx.x	xx.x/xx.x

Notes:
Change from Screening values includes only those patients with both a screening value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table to be repeated for all blood chemistry parameters for each visit of induction and maintenance phases.
Data must be presented according to the International System of Units (SI).

TABLE 14.3.3) SUMMARY OF COAGULATION TESTS OVER THE STUDY (SAFETY POPULATION)

PT (sec)		All Patients (N=xxx)		DLBCL (N=xx)		FL (N=xx)	
	Statistic	Value	Change from Screening	Value	Change from Screening	Value	Change from Screening
Screening Visit	n	xxx		xx		xx	
	Mean (SD)	xxx.x (xx.xx)		xxx.x (xx.xx)		xxx.x (xx.xx)	
	Median	xxx.x		xxx.x		xxx.x	
	Min/Max	xx.x/xxx.x		xx.x/xxx.x		xx.x/xxx.x	
Cycle 1 Induction	n	xx	xx			xx	xx
	Mean (SD)	xxx.x (xx.xx)	x.x (x.xx)			xxx.x (xx.xx)	x.x (x.xx)
	Median	xxx.x	x.x			xxx.x	x.x
	Min/Max	xxx.x/xxx.x	xx.x/x.x			xxx.x/xxx.x	xx.x/x.x
Cycle 2 Induction	n	xx	xx			xx	xx
	Mean (SD)	xxx.x (xx.xx)	x.x (xx.xx)			xxx.x (xx.xx)	x.x (xx.xx)
	Median	xxx.x	x.x			xxx.x	x.x
	Min/Max	xx.x/xxx.x	xx.x/xx.x			xx.x/xxx.x	xx.x/xx.x
...							
Cycle x Induction	n	xx	xx			xx	xx
	Mean (SD)	xxx.x (xx.xx)	x.x (xx.xx)			xxx.x (xx.xx)	x.x (xx.xx)
	Median	xxx.x	x.x			xxx.x	x.x
	Min/Max	xx.x/xxx.x	xx.x/xx.x			xx.x/xxx.x	xx.x/xx.x

Notes:
Change from Screening values includes only those patients with both a screening value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table to be repeated for all blood chemistry parameters for each visit of induction and maintenance phases.
Data must be presented according to the International System of Units (SI).

TABLE 14.**3.4)** SHIFT TABLE OF HEMATOLOGY PARAMETERS ACCORDING TO NCI CTCAE WORST GRADE RECORDED DURING THE TREATMENT PERIOD (SAFETY POPULATION)

			NCI CTCAE Worst Grade During Treatment Period					
		Statistic	Grade 1	Grade 2	Grade 3	Grade 4	Not Done	All
DLBCL	Screening							
	Grade 1	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 2	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 3	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 4	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Not Done	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	All	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
FL	Screening							
	Grade 1	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 2	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 3	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 4	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Not Done	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	All	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
All Patients	Screening							
	Grade 1	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 2	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 3	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 4	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Not Done	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	All	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Notes:
Percentage are calculated relative to the total number of patients in the SAF population (row percentages).

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table to be repeated for all hematology parameters.

TABLE 14.3.5) SHIFT TABLE OF BLOOD CHEMISTRY PARAMETERS ACCORDING TO NCI CTCAE WORST GRADE RECORDED DURING THE TREATMENT PERIOD (SAFETY POPULATION)

			NCI CTCAE Worst Grade During Treatment Period					
		Statistic	Grade 1	Grade 2	Grade 3	Grade 4	Not Done	All
DLBCL	Screening							
	Grade 1	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 2	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 3	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 4	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Not Done	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	All	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
FL	Screening							
	Grade 1	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 2	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 3	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 4	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Not Done	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	All	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
All Patients	Screening							
	Grade 1	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 2	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 3	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 4	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Not Done	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	All	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Notes:
Percentage are calculated relative to the total number of patients in the SAF population (row percentages).

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table to be repeated for all blood chemistry parameters.

TABLE 14.3.6) SHIFT TABLE OF COAGULATION TESTS ACCORDING TO NCI CTCAE WORST GRADE RECORDED DURING THE TREATMENT PERIOD (SAFETY POPULATION)

			NCI CTCAE Worst Grade During Treatment Period					
		Statistic	Grade 1	Grade 2	Grade 3	Grade 4	Not Done	All
DLBCL	Screening							
	Grade 1	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 2	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 3	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 4	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Not Done	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	All	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
FL	Screening							
	Grade 1	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 2	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 3	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 4	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Not Done	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	All	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
All Patients	Screening							
	Grade 1	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 2	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 3	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Grade 4	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Not Done	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	All	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Notes:
Percentage are calculated relative to the total number of patients in the SAF population (row percentages).

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table to be repeated for all coagulation tests.

TABLE 14.3.7) SUMMARY OF VITAL SIGNS OVER THE STUDY (SAFETY POPULATION)

Heart Rate (bpm)		All Patients (N=xxx)		DLBCL (N=xx)		FL (N=xx)	
	Statistic	Value	Change from Screening	Value	Change from Screening	Value	Change from Screening
Screening Visit	n	xxx		xx		xx	
	Mean (SD)	xxx.x (xx.xx)		xxx.x (xx.xx)		xxx.x (xx.xx)	
	Median	xxx.x		xxx.x		xxx.x	
	Min/Max	xx.x/xxx.x		xx.x/xxx.x		xx.x/xxx.x	
Cycle 1 Induction	n	xx	xx			xx	xx
	Mean (SD)	xxx.x (xx.xx)	x.x (x.xx)			xxx.x (xx.xx)	x.x (x.xx)
	Median	xxx.x	x.x			xxx.x	x.x
	Min/Max	xxx.x/xxx.x	xx.x/x.x			xxx.x/xxx.x	xx.x/x.x
Cycle 2 Induction	n	xx	xx			xx	xx
	Mean (SD)	xxx.x (xx.xx)	x.x (xx.xx)			xxx.x (xx.xx)	x.x (xx.xx)
	Median	xxx.x	x.x			xxx.x	x.x
	Min/Max	xx.x/xxx.x	xx.x/xx.x			xx.x/xxx.x	xx.x/xx.x
...							
Cycle x Induction	n	xx	xx			xx	xx
	Mean (SD)	xxx.x (xx.xx)	x.x (xx.xx)			xxx.x (xx.xx)	x.x (xx.xx)
	Median	xxx.x	x.x			xxx.x	x.x
	Min/Max	xx.x/xxx.x	xx.x/xx.x			xx.x/xxx.x	xx.x/xx.x

Notes:
Change from Screening values includes only those patients with both a screening value and a value for summarized time period.
n represents number of patients contributing to summary statistics.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table to be repeated for Systolic Blood Pressure, Diastolic Blood Pressure, Body Weight and Body Temperature.

TABLE 14.3.8) ECOG PERFORMANCE STATUS (SAFETY POPULATION)

		All Patients (N=xxx)		DLBCL (N=xx)		FL (N=xx)	
Cycle/Visit	ECOG-PS	n	%	n	%	n	%
Screening Visit	Grade 1	xxx	x.x	xx	x.x	xx	x.x
	Grade 2	xxx	x.x	xx	x.x	xx	x.x
	Grade 3	xxx	x.x	xx	x.x	xx	x.x
	Grade 4	xxx	x.x	xx	x.x	xx	x.x
	Grade 5	xxx	x.x	xx	x.x	xx	x.x
	Missing	xxx	x.x	xx	x.x		x.x
Final Staging	Grade 1	xxx	x.x	xx	x.x	xx	x.x
	Grade 2	xxx	x.x	xx	x.x	xx	x.x
	Grade 3	xxx	x.x	xx	x.x	xx	x.x
	Grade 4	xxx	x.x	xx	x.x	xx	x.x
	Grade 5	xxx	x.x	xx	x.x	xx	x.x
	Missing	xxx	x.x	xx	x.x	xx	x.x

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.4.1) TARGET LESION ASSESSMENT AT SCREENING (PART #1) (SAFETY POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Were any target lesions identified?				
No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Location of lesion				
Neck	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Chest	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Abdomen	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Pelvis	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Other	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
CT with contrast				
No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
CT result				
Negative	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Positive	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Not assessed	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
CT without contrast				
No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
CT w/o contrast result				
Negative	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Positive	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Not assessed	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
MRI				
No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
MRI result				
Negative	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Positive	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Not assessed	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in SAF population.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.4.2) TARGET LESION ASSESSMENT AT SCREENING (PART #2) (SAFETY POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Clinical assessment				
No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Clinical assessment result				
Negative	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Positive	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Not assessed	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
FDG-PET				
No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
FDG-PET result				
Negative	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Positive	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Not assessed	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Other assessment				
No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Other assessment				
Negative	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Positive	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Not assessed	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Notes:
Percentages are calculated relative to the total number of patients in SAF population.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.4.3) POST-SCREENING TARGET LESION ASSESSMENT (PART #1) (SAFETY POPULATION)

		Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Study Visit <XXX>	Was a target lesions assessment done at this visit?				
	No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Were there any changes in the Target Lesions since the previous visit assessment?				
	No				
	Yes				
	Not applicable				
	Location of lesion				
	Neck	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Chest	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Abdomen	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Pelvis	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Other	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	CT with contrast				
	No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	CT result				
	Increased	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Decreased	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	No change	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	CT without contrast				
	No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	CT w/o contrast result				
	Increased	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Decreased	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	No change	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	MRI				
	No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	MRI result				
	Increased	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Decreased	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	No change	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Note:
Percentages are calculated relative to the total number of patients in SAF population performing the study visit.

Programming note:
This table should be also presented for all post-screening visits.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.4.4) POST-SCREENING TARGET LESION ASSESSMENT (PART #2) (SAFETY POPULATION)

		Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Study Visit <XXX>	Clinical assessment				
	No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Clinical assessment result				
	Increased	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Decreased	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	No change	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	FDG-PET				
	No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	FDG-PET result				
	Increased	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Decreased	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	No change	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Other assessment				
	No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Other assessment				
	Increased	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Decreased	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	No change	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Change in lesion since first assessed /previous visit				
	Enlarged	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	No change	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Reduced in size	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Not visible/too small	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Not applicable	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Note:
Percentages are calculated relative to the total number of patients in SAF population performing the study visit.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table should be also presented for all post-screening visits.

TABLE 14.4.5) OVERALL LESION ASSESSMENT (SAFETY POPULATION)

		Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Study Visit <XXX>	Response of target lesions				
	Complete response (CR)	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Complete response unconfirmed (CRu)	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Partial response (PR)	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Stable disease (SD)	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Progressive disease (PD)	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Unable to assess (UA)	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Not applicable	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Are there any new lesions?				
	No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Investigator's overall assessment of response at this visit				
	Complete response (CR)	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Complete response unconfirmed (CRu)	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Partial response (PR)	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Stable disease (SD)	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Progressive disease (PD)	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Unable to assess (UA)	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Not applicable	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Note:
Percentages are calculated relative to the total number of patients in SAF population performing the study visit.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table should be also presented for all post-screening visits.

TABLE 14.5.1) OVERALL SURVIVAL FROM FIRST DOSE OF RITUXIMAB IV (ITT POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Time to event (months)	25th (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
	Median (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
	75th (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Number of patients				
Events	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Censored	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Notes:
Percentages are calculated on the number of patients in the ITT population.
Overall survival(months) was estimated using Kaplan-Meier method.
Patients who are not reported as having died at the time of analysis will be censored at the last contact date.
Patients who do not have post-baseline information will be censored at the date of initiation of study treatment.
Patients enrolled but not treated will be assigned time = 0.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table should be also presented from the first dose of Rituximab SC.
This table should be also presented stratified by:

a) Gender (Female, Male)

b) FLIPI score (Low risk, Intermediate risk/High risk) for FL patients only

c) Grade of FL (1, 2, 3a)

TABLE 14.5.2) OVERALL SURVIVAL FROM FIRST DOSE OF RITUXIMAB IV: DISTRIBUCTION FUNCTION (ITT POPULATION)

Time (months)	Censoring Indicator	Distribution Function Estimate	Failure	Survival Standard Error	Number Failed	SDF Lower Confidence Limit	SDF Upper Confidence Limit
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
..	..	..	..	..	..	..	..
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx

Note:
Data derived from Kaplan-Meier curve.

Source: XXXX.SAS, Run on DDMMMYYYY

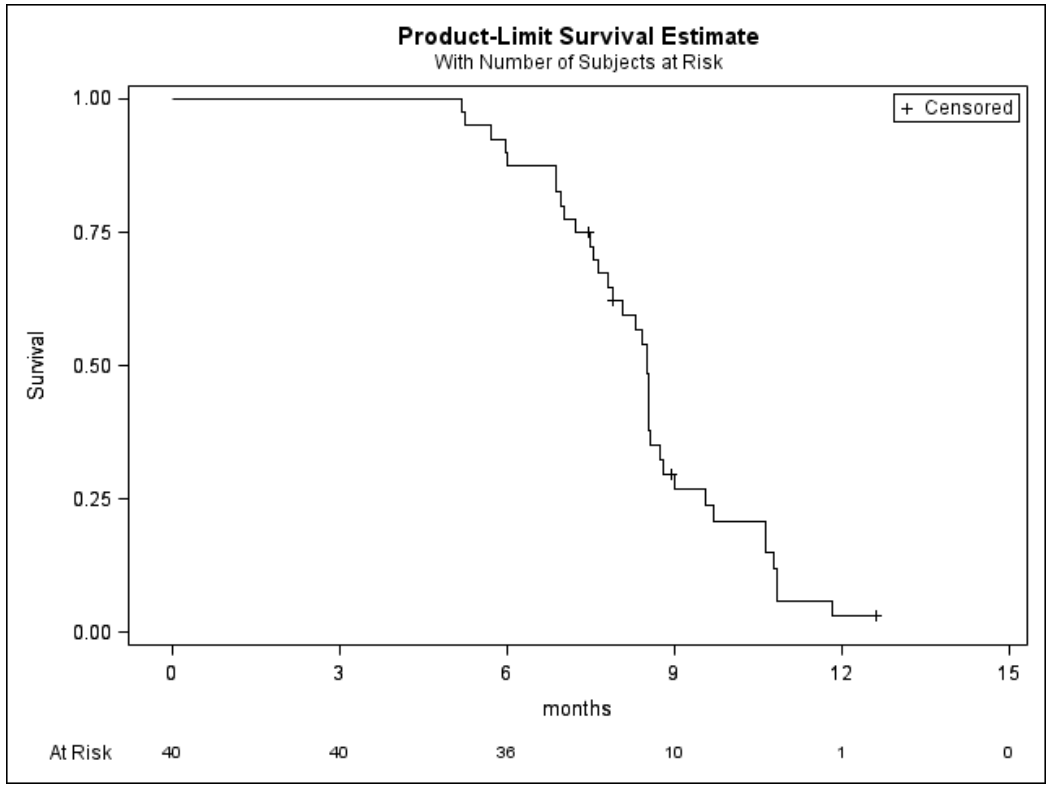
Programming note:
This table should be presented for All Patients, DLBCL and FL groups.
This table should be also presented from the first dose of Rituximab SC.
This table should be also presented stratified by:

a) Gender (Female, Male)

b) FLIPI score (Low risk, Intermediate risk/High risk) for FL patients only

c) Grade of FL (1, 2, 3a)

TABLE 14.5.3) OVERALL SURVIVAL FROM FIRST DOSE OF RITUXIMAB IV: DISTRIBUCTION FUNCTION CURVE FOR ALL SUBJECTS (ITT POPULATION)



Note:
Data derived from Kaplan-Meier curve.

Source: XXXX.SAS, Run on DDMMMYYYY

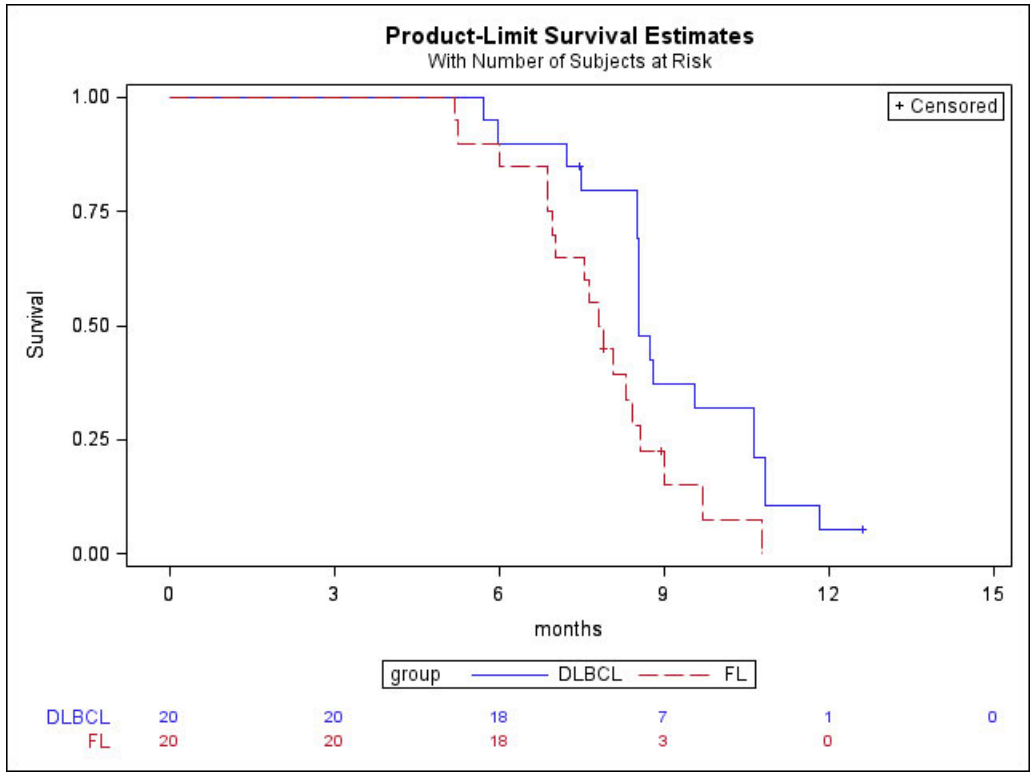
Programming note:
This table should be also presented from the first dose of Rituximab SC.
This table should be also presented stratified by:

a) Gender (Female, Male)

b) FLIPI score (Low risk, Intermediate risk/High risk) for FL patients only

c) Grade of FL (1, 2, 3a)

TABLE 14.5.4) OVERALL SURVIVAL FROM FIRST DOSE OF RITUXIMAB IV: DISTRIBUCTION FUNCTION CURVE BY TYPE OF LYMPHOMA (ITT POPULATION)



Note:
Data derived from Kaplan-Meier curve.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table should be also presented from the first dose of Rituximab SC.
This table should be also presented stratified by:

a) **Gender (Female, Male)**
b) **FLIPI score (Low risk, Intermediate risk/High risk) for FL patients only**
c) **Grade of FL (1, 2, 3a)**

TABLE 14.5.5) PROGRESSION FREE SURVIVAL FROM FIRST DOSE OF RITUXIMAB IV (ITT POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Time to event (months)	25th (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
	Median (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
	75th (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Number of patients				
Events	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Censored	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Notes:
Percentages are calculated on the number of patients in the ITT population.
PFS (months) was estimated using Kaplan-Meier method.
PFS is defined as the time from first dose of rituximab to the first occurrence of progression or relapse, or death from any cause, whichever occurs first.
Patients who have not experienced disease progression or death at the time of analysis and patients who are lost to follow up will be censored at their last clinical assessment date. Patients without post-baseline tumour assessments will be censored at the time of their baseline visit except if death occurs prior to their first scheduled tumour assessment.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table should be also presented from the first dose of Rituximab SC.
This table should be also presented stratified by:

d) Gender (Female, Male)

e) FLIPI score (Low risk, Intermediate risk/High risk) for FL patients only

f) Grade of FL (1, 2, 3a)

TABLE 14.5.6) PROGRESSION FREE SURVIVAL FROM FIRST DOSE OF RITUXIMAB IV: DISTRIBUCTION FUNCTION (ITT POPULATION)

Time (months)	Censoring Indicator	Distribution Function Estimate	Failure	Survival Standard Error	Number Failed	SDF Lower Confidence Limit	SDF Upper Confidence Limit
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
..	..	..	..	..	..	..	..
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx

Note:
Data derived from Kaplan-Meier curve.

Source: XXXX.SAS, Run on DDMMMYYYY

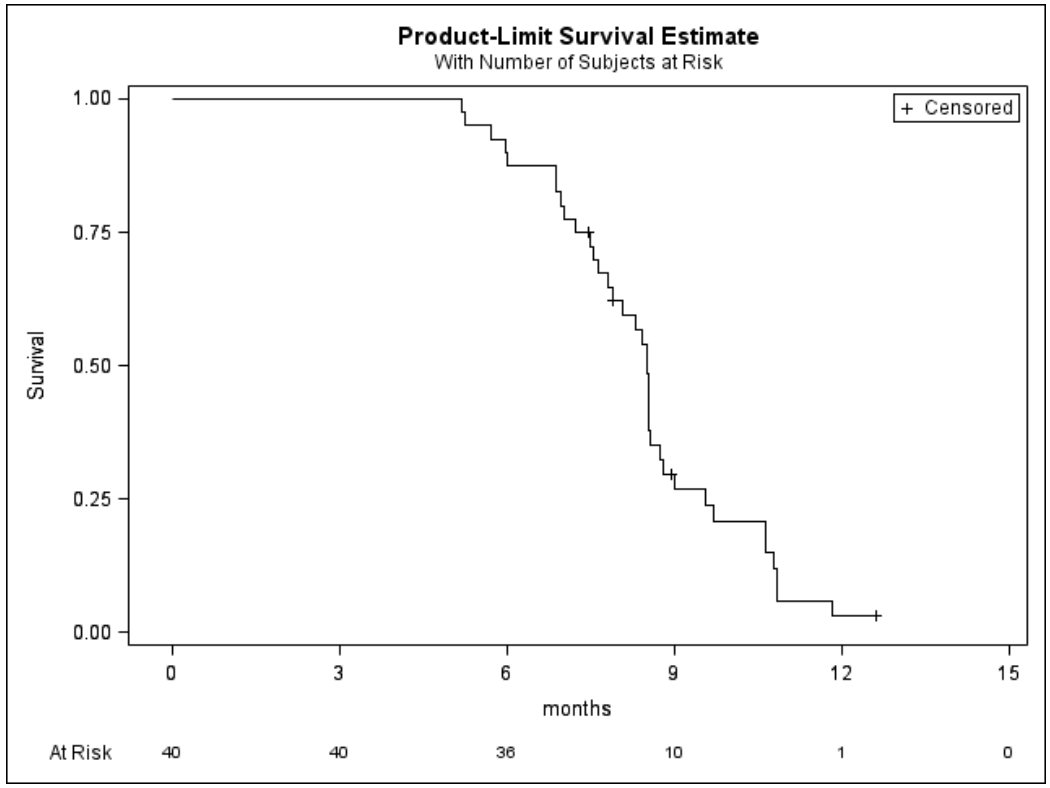
Programming note:
This table should be presented for All Patients, DLBCL and FL groups.
This table should be also presented from the first dose of Rituximab SC.
This table should be also presented stratified by:

a) Gender (Female, Male)

b) FLIPI score (Low risk, Intermediate risk/High risk) for FL patients only

c) Grade of FL (1, 2, 3a)

TABLE 14.5.7) PROGRESSION FREE SURVIVAL FROM FIRST DOSE OF RITUXIMAB IV: DISTRIBUCTION FUNCTION CURVE FOR ALL SUBJECTS (ITT POPULATION)



Note:
Data derived from Kaplan-Meier curve.

Source: XXXX.SAS, Run on DDMMMYYYY

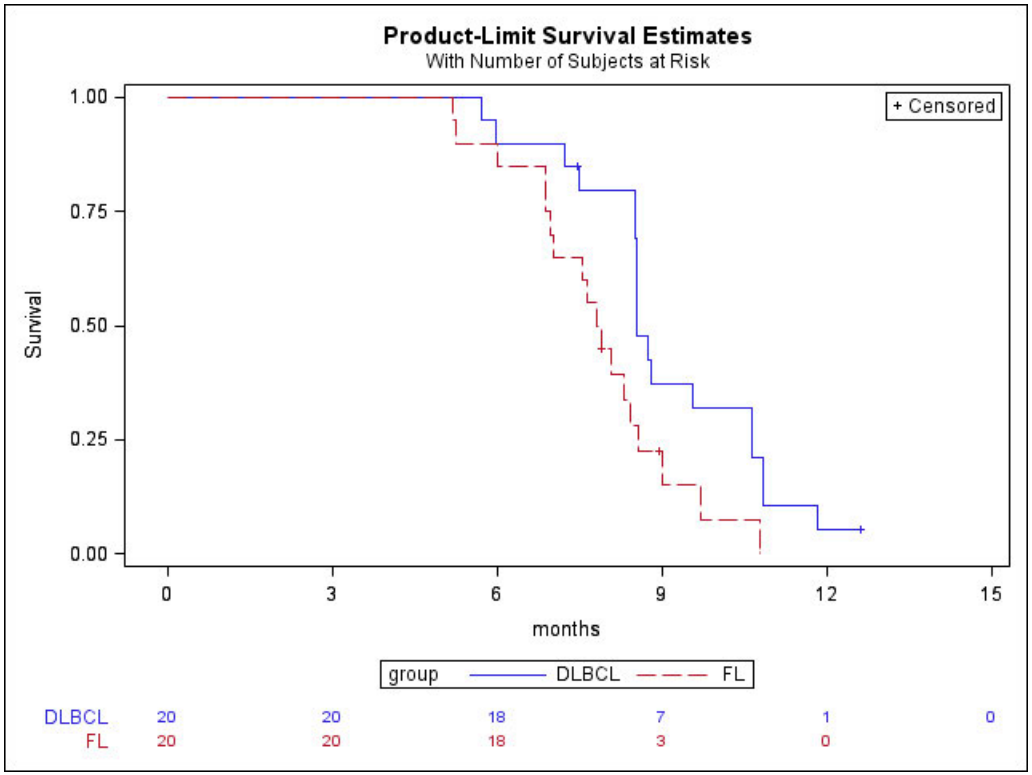
Programming note:
This table should be also presented from the first dose of Rituximab SC.
This table should be also presented stratified by:

a) Gender (Female, Male)

b) FLIPI score (Low risk, Intermediate risk/High risk) for FL patients only

c) Grade of FL (1, 2, 3a)

TABLE 14.5.8) PROGRESSION FREE SURVIVAL FROM FIRST DOSE OF RITUXIMAB IV: DISTRIBUCTION FUNCTION CURVE by TYPE OF LYMPHOMA (ITT POPULATION)



Note:
Data derived from Kaplan-Meier curve.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table should be also presented from the first dose of Rituximab SC.
This table should be also presented stratified by:

a) Gender (Female, Male)

b) FLIPI score (Low risk, Intermediate risk/High risk) for FL patients only

c) Grade of FL (1, 2, 3a)

TABLE 14.5.9) DISEASE FREE SURVIVAL (ITT POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Time to event (months)	25th (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
	Median (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
	75th (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Number of patients				
Events	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Censored	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Notes:
Percentages are calculated on the number of patients in the ITT population.
DFS (months) was estimated using Kaplan-Meier method.
DFS will be assessed in patients achieving CR/CRu and is defined as the period from the date of the initial CR/CRu until the date of relapse or death from any cause.
Patients who have not experienced disease progression or death at the time of analysis and patients who are lost to follow up will be censored at their last clinical assessment date.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.5.10) DISEASE FREE SURVIVAL: DISTRIBUCTION FUNCTION (ITT POPULATION)

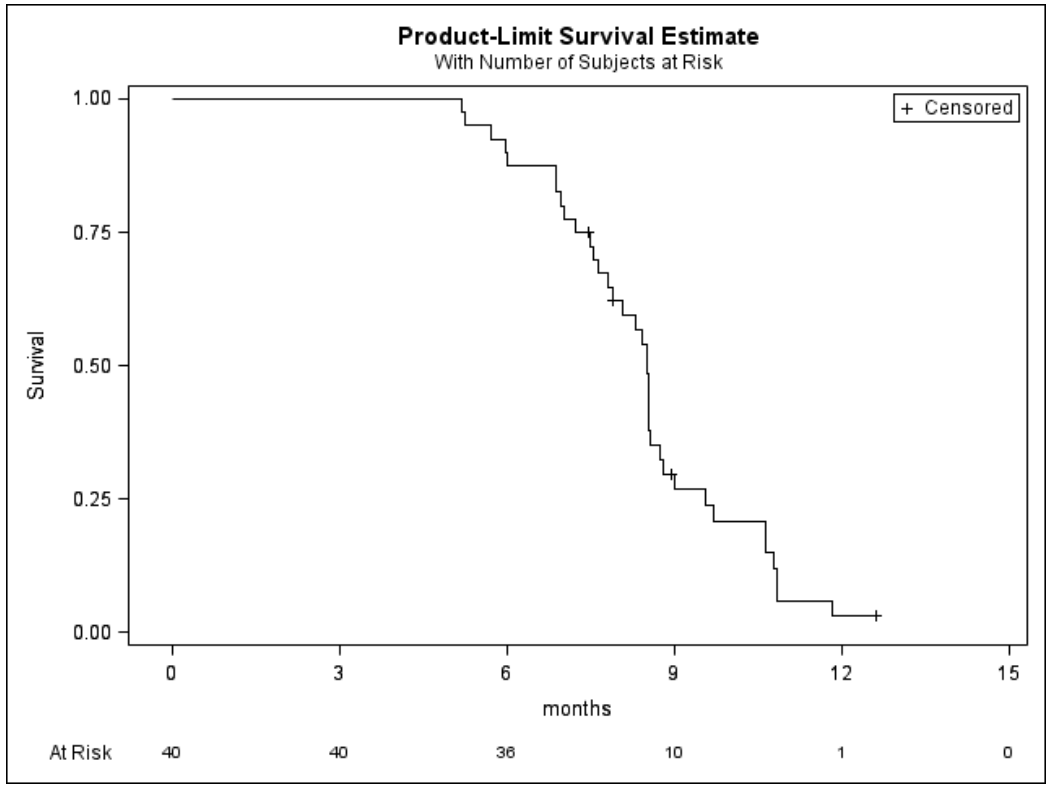
Time (months)	Censoring Indicator	Distribution Function Estimate	Failure	Survival Standard Error	Number Failed	SDF Lower Confidence Limit	SDF Upper Confidence Limit
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
..	..	..	..	..	..	..	..
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx

Note:
Data derived from Kaplan-Meier curve.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table should be presented for All Patients, DLBCL and FL groups.

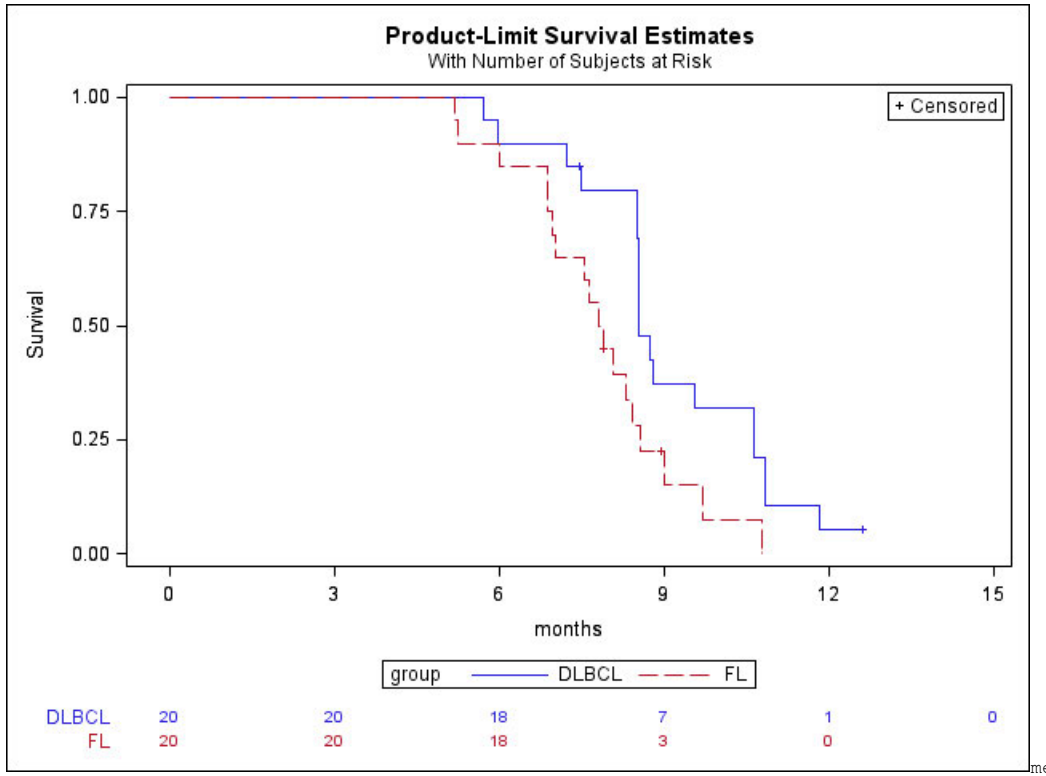
TABLE 14.5.11) DISEASE FREE SURVIVAL: DISTRIBUCTION FUNCTION CURVE FOR ALL SUBJECTS (ITT POPULATION)



Note:
Data derived from Kaplan-Meier curve.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.5.12) DISEASE FREE SURVIVAL: DISTRIBUCTION FUNCTION CURVE BY TYPE OF LYMPHOMA (ITT POPULATION)



Note:
Data derived from Kaplan-Meier curve.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.5.13) EVENT FREE SURVIVAL FROM FIRST DOSE OF RITUXIMAB IV (ITT POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Time to event (months)	25th (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
	Median (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
	75th (95% CI)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)	xxx.x (xxx.x,xxx.x)
Number of patients				
Events	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Censored	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Notes:
Percentages are calculated on the number of patients in the ITT population.
EFS (months) was estimated using Kaplan-Meier method.
EFS is defined as the time from first dose of rituximab to first occurrence of progression or relapse, or initiation of a non-protocol-specified anti-lymphoma therapy or death, whichever occurs first.
Patients who have not experienced disease progression or relapse or initiation of a non-protocol-specified anti-lynphoma therapy or death at the time of analysis and patients who are lost to follow up will be censored at their last clinical assessment date.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table should be also presented from the first dose of Rituximab SC.

TABLE 14.5.14) EVENT FREE SURVIVAL FROM FIRST DOSE OF RITUXIMAB IV: DISTRIBUCTION FUNCTION (ITT POPULATION)

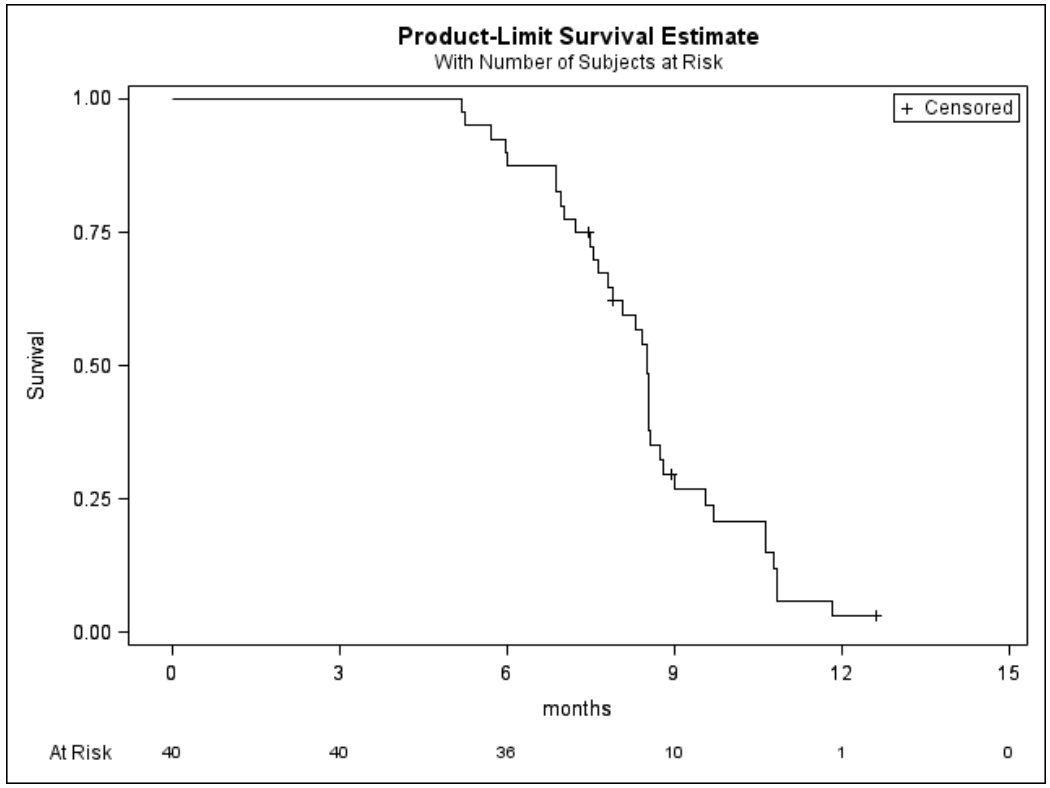
Time (months)	Censoring Indicator	Distribution Function Estimate	Failure	Survival Standard Error	Number Failed	SDF Lower Confidence Limit	SDF Upper Confidence Limit
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx
..	..	..	..	..	..	..	..
xxx	x	x.xxxx	x	x.xxxx	xxx	x.xxxx	x.xxxx

Note:
Data derived from Kaplan-Meier curve.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table should be presented for All Patients, DLBCL and FL groups.
This table should be also presented from the first dose of Rituximab SC.

TABLE 14.5.15) EVENT FREE SURVIVAL FROM FIRST DOSE OF RITUXIMAB IV: DISTRIBUCTION FUNCTION CURVE FOR ALL SUBJECTS (ITT POPULATION)

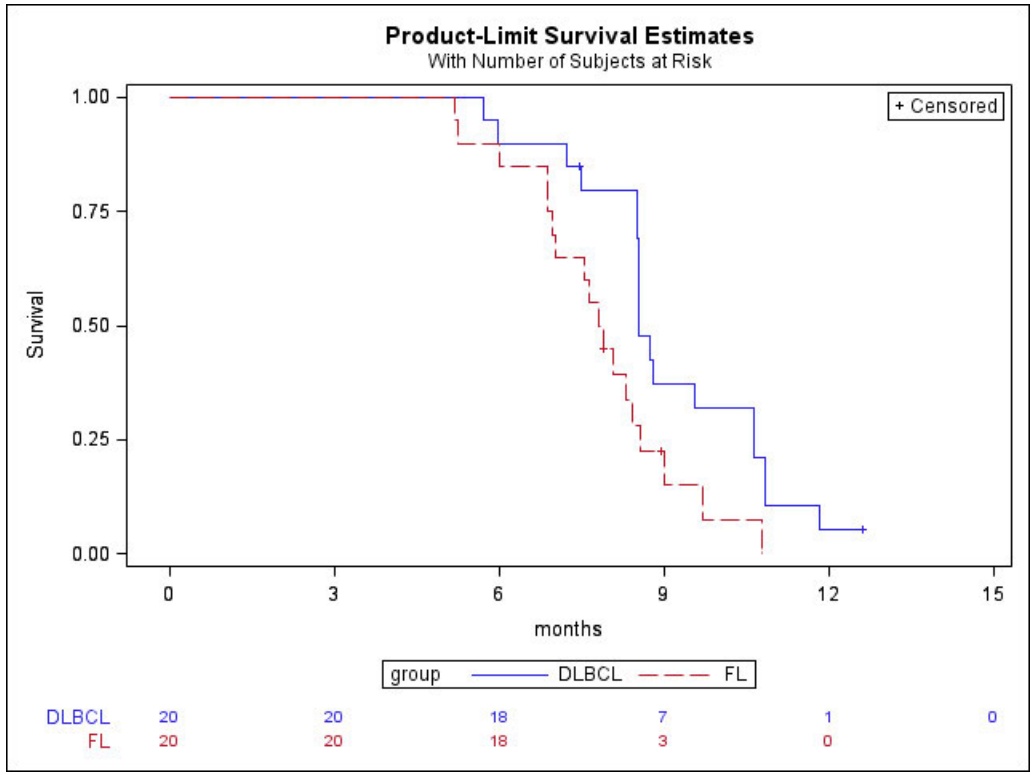


Note:
Data derived from Kaplan-Meier curve.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table should be also presented from the first dose of Rituximab SC.

TABLE 14.5.16) EVENT FREE SURVIVAL FROM FIRST DOSE OF RITUXIMAB IV: DISTRIBUCTION FUNCTION CURVE BY TYPE OF LYMPHOMA (ITT POPULATION)



Note:
Data derived from Kaplan-Meier curve.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
This table should be also presented from the first dose of Rituximab SC.

TABLE 14.5.17) SUMMARY OF COMPLETE RESPONSE OR COMPLETE RESPONSE UNCONFIRMED (ITT POPULATION)

	Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
CR	n/N1 (%) - 95% CI	xx/XXX (xx.x%) - xx.x,xx.x	xx/XXX (xx.x%) - xx.x,xx.x	xx/XXX (xx.x%) - xx.x,xx.x
CRu (unconfirmed)	n/N1 (%) - 95% CI	xx/XXX (xx.x%) - xx.x,xx.x	xx/XXX (xx.x%) - xx.x,xx.x	xx/XXX (xx.x%) - xx.x,xx.x
CR/CRu	n/N1 (%) - 95% CI	xx/XXX (xx.x%) - xx.x,xx.x	xx/XXX (xx.x%) - xx.x,xx.x	xx/XXX (xx.x%) - xx.x,xx.x

Notes:
CR = Complete Response. CRu = Complete Response Unconfirmed.
N1=Number of patients have evaluable overall lesion assessment data.
Two-sided Clopper-Pearson confidence interval.
Tumour assessment measured four weeks after the end of the Induction treatment.
Number of patients performing the tumour assessment was used as denominator.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.6.1) RITUXIMAB IV ADMINISTRATION SATIFICATION QUESTIONNAIRE - ITEMS FREQUENCY ANALYSIS (SAFETY POPULATION)

		Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Study Visit <xxx>	Was the RASQ questionnaire completed?				
	No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	1.Thinking about the Rituximab IV infusion, how satisfied or dissatisfied are you with the IV infusion?				
	Very satisfied	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Satisfied	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Neither satisfied nor dissatisfied	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Dissatisfied	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Very dissatisfied	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Patient did not answer question	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	2.Thinking about the Rituximab IV infusion, how do you rate the pain, swelling or redness you experienced at the site of the drug infusion?				
	None	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Mild	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Moderate	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Severe	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Very severe	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Patient did not answer question	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	…				

Note:
Percentages are calculated relative to the total number of patients in SAF population performing the RASQ questionnaire for Rituximab IV administration.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
All items of RASQ questionnaire for Rituximab IV administration must be presented.

TABLE 14.6.2) RITUXIMAB SC ADMINISTRATION SATIFICATION QUESTIONNAIRE - ITEMS FREQUENCY ANALYSIS (SAFETY POPULATION)

		Statistic	All Patients (N=xxx)	DLBCL (N=xxx)	FL (N=xxx)
Study Visit <xxx>	Was the RASQ questionnaire completed?				
	No	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Yes	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	1.Thinking about the Rituximab SC injection, how satisfied or dissatisfied are you with the SC injection?				
	Very satisfied	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Satisfied	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Neither satisfied nor dissatisfied	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Dissatisfied	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Very dissatisfied	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Patient did not answer question	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	2.Thinking about the Rituximab SC injection, how do you rate the pain, swelling or redness you experienced at the site of the drug infusion?				
	None	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Mild	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Moderate	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Severe	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Very severe	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	Patient did not answer question	n (%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
	…				

Note:
Percentages are calculated relative to the total number of patients in SAF population performing the RASQ questionnaire for Rituximab SC administration.

Source: XXXX.SAS, Run on DDMMMYYYY

Programming note:
All items of RASQ questionnaire for Rituximab SC administration must be presented.

TABLE 14.6.3) SUMMARY OF RITUXIMAB ADMINISTRATION SATISFACTION QUESTIONNAIRE IV MEAN SCORES (SAFETY POPULATION)

Physical Impact domain	Statistic	All Patients (N=xx)	DLBCL (N=xx)	FL (N=xx)
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.6.4) SUMMARY OF RITUXIMAB ADMINISTRATION SATISFACTION QUESTIONNAIRE IV MEAN SCORES (SAFETY POPULATION)

Psychological Impact domain	Statistic	All Patients (N=xx)	DLBCL (N=xx)	FL (N=xx)
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.6.5) SUMMARY OF RITUXIMAB ADMINISTRATION SATISFACTION QUESTIONNAIRE IV MEAN SCORES (SAFETY POPULATION)

Impact on Activities of Daily Living domain

	Statistic	All Patients (N=xx)	DLBCL (N=xx)	FL (N=xx)
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.6.6) SUMMARY OF RITUXIMAB ADMINISTRATION SATISFACTION QUESTIONNAIRE IV MEAN SCORES (SAFETY POPULATION)

Convenience domain

	Statistic	All Patients (N=xx)	DLBCL (N=xx)	FL (N=xx)
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.6.7) SUMMARY OF RITUXIMAB ADMINISTRATION SATISFACTION QUESTIONNAIRE IV MEAN SCORES (SAFETY POPULATION)

Satisfaction domain	Statistic	All Patients (N=xx)	DLBCL (N=xx)	FL (N=xx)
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.6.8) SUMMARY OF RITUXIMAB ADMINISTRATION SATISFACTION QUESTIONNAIRE SC MEAN SCORES (SAFETY POPULATION)

Physical Impact domain

	Statistic	All Patients (N=xx)	DLBCL (N=xx)	FL (N=xx)
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.6.9) SUMMARY OF RITUXIMAB ADMINISTRATION SATISFACTION QUESTIONNAIRE SC MEAN SCORES (SAFETY POPULATION)

Psychological Impact domain	Statistic	All Patients (N=xx)	DLBCL (N=xx)	FL (N=xx)
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.6.10) SUMMARY OF RITUXIMAB ADMINISTRATION SATISFACTION QUESTIONNAIRE SC MEAN SCORES (SAFETY POPULATION)

Impact on Activities of Daily Living domain

	Statistic	All Patients (N=xx)	DLBCL (N=xx)	FL (N=xx)
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.6.11) SUMMARY OF RITUXIMAB ADMINISTRATION SATISFACTION QUESTIONNAIRE SC MEAN SCORES (SAFETY POPULATION)

Convenience domain

	Statistic	All Patients (N=xx)	DLBCL (N=xx)	FL (N=xx)
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.6.12) SUMMARY OF RITUXIMAB ADMINISTRATION SATISFACTION QUESTIONNAIRE SC MEAN SCORES (SAFETY POPULATION)

Satisfaction domain	Statistic	All Patients (N=xx)	DLBCL (N=xx)	FL (N=xx)
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x
Visit xx	n	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.x/xx.x	xx.x/xx.x	xx.x/xx.x

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.6.13) HEALTHCARE PROFESSIONAL QUESTIONNAIRE (PART #1)

	Statistic	All Healthcare Professionals (N=xxx)
Was the HCP questionnaire completed?		
No	n (%)	xxx (xx.x%)
Yes	n (%)	xxx (xx.x%)
1.Did you personally administer the SC Rituximab in the study?		
Always	n (%)	xxx (xx.x%)
Sometimes	n (%)	xxx (xx.x%)
Never	n (%)	xxx (xx.x%)
1a. If never, who did administer the SC Rituximab in the study?		
Other hematologist	n (%)	xxx (xx.x%)
Other internist	n (%)	xxx (xx.x%)
Oncology/chemo nurse	n (%)	xxx (xx.x%)
Other	n (%)	xxx (xx.x%)
2.How many minutes preparation time was required after receiving the Rituximab vial from the pharmacy?		
<5	n (%)	xxx (xx.x%)
6-10	n (%)	xxx (xx.x%)
11-15	n (%)	xxx (xx.x%)
16-20	n (%)	xxx (xx.x%)
>20	n (%)	xxx (xx.x%)
Not sure	n (%)	xxx (xx.x%)
3.How many minutes in total did it usually take to administer the Rituximab subcutaneously using the hand held syringe?		
<5	n (%)	xxx (xx.x%)
6-15	n (%)	xxx (xx.x%)
16-30	n (%)	xxx (xx.x%)
31-60	n (%)	xxx (xx.x%)
61-90	n (%)	xxx (xx.x%)
>90	n (%)	xxx (xx.x%)
Not sure	n (%)	xxx (xx.x%)
4.How long do you think the SC sessions usually lasted from patients' arrival until departure		
<2 hours	n (%)	xxx (xx.x%)
>2 but <3 hours	n (%)	xxx (xx.x%)
>3 but <4 hours	n (%)	xxx (xx.x%)
5.How anxious do you think the SC treatment made patients feel?		
Not al all	n (%)	xxx (xx.x%)
Fairly	n (%)	xxx (xx.x%)
Very	n (%)	xxx (xx.x%)

Note:
Percentages are calculated relative to the total number of healthcare professional performing the HCP questionnaire.

Source: XXXX.SAS, Run on DDMMMYYYY

TABLE 14.6.14) HEALTHCARE PROFESSIONAL QUESTIONNAIRE (PART #2)

	Statistic	All Healthcare Professionals (N=xxx)
6.How reliable was using the hand held syringe to give Rituximab subcutaneously?		
Not at all	n (%)	xxx (xx.x%)
Fairly	n (%)	xxx (xx.x%)
Very	n (%)	xxx (xx.x%)
Extremely	n (%)	xxx (xx.x%)
7.Overall how easy did you/your staff find giving Rituximab subcutaneously using the hand held syringe?		
Not at all	n (%)	xxx (xx.x%)
Fairly	n (%)	xxx (xx.x%)
Very	n (%)	xxx (xx.x%)
Extremely	n (%)	xxx (xx.x%)
8.How likely would you be to offer or recommend SC administration of Rituximab via a hand held syringe to your patients in the future?		
Not at all	n (%)	xxx (xx.x%)
Fairly	n (%)	xxx (xx.x%)
Very	n (%)	xxx (xx.x%)
Extremely	n (%)	xxx (xx.x%)
9.In general how would you describe your experience regarding the Rituximab SC treatment?		
Satisfactory	n (%)	xxx (xx.x%)
Unsatisfactory	n (%)	xxx (xx.x%)

Note:
Percentages are calculated relative to the total number of healthcare professional performing the HCP questionnaire.

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.1)1. ANALYSIS SETS

Patient	Site	Intent-To-Treat Population	Safety Population	Reason for Exclusion from Safety Population	Type of Lymphoma
xxxx	xxxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.1)2. INCLUSION/EXCLUSION CRITERIA VIOLATED

Patient	Type of Lymphoma	Failed Criteria
xxxx	xxxx	xxx
xxxx	xxxx	xxx
xxxx	xxxx	xxx
xxxx	xxxx	xxx

Note:
Only I/E criteria failed are reported in this line listing.

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.2)1. MAJOR PROTOCOL DEVIATIONS

Patient	Type of Lymphoma	Category	Description of Deviation
xxxx	xxxx	xxxxx xxxxx	xxxxx xxxxx
xxxx	xxxx	xxxxx	xxxxx
xxxx	xxxx	xxxxx	xxxxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.2)2. MINOR PROTOCOL DEVIATIONS

Patient	Type of Lymphoma	Category	Description of Deviations
xxxx	xxxx	xxxxx xxxxx	xxxxx xxxxx
xxxx	xxxx	xxxxx	xxxxx
xxxx	xxxx	xxxxx	xxxxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.2)3. COVID-19 RELATED PROTOCOL DEVIATIONS

Patient	Type of Lymphoma	Category	Description of Deviations
xxxx	xxxx	xxxxx xxxxx	xxxxx xxxxx
xxxx	xxxx	xxxxx	xxxxx
xxxx	xxxx	xxxxx	xxxxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.3)1. STUDY DRUG DISCONTINUATION

Patient	Type of Lymphoma	Study Drug Discontinued?	Date of Trt Discontinuation	Primary Reason for trt Discontinuation	If Other, Specify	Date of Last Rituximab Dose	Date of Last Chemotherapy Dose	Will the Patient Proceed the FUP?
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	DDMMMYYYY	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	DDMMMYYYY	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	DDMMMYYYY	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	DDMMMYYYY	DDMMMYYYY	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.4)1. INFORMED CONSENT & DEMOGRAPHY

Patient	Type of Lymphoma	Was IC Obtained?	Date of Consent	Date of Birth	Age (yrs)	Sex	If Female, Childbearing Potential	Ethnicity	If Other, Specify	Derived Age from Birth Year and ICF Date	Height (cm)	Weight (Kg)	BMI (Kg/m^2)
xxxx	xxxx	xxxx	DDMMMYYYY	DDMMMYYYY	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	DDMMMYYYY	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	DDMMMYYYY	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	DDMMMYYYY	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.4)2. MEDICAL HISTORY

Patient	Type of Lymphoma	No.	Medical History Term	LLT	PT	SOC	Start Date (DDMMMYYYY)	Stop Date (DDMMMYYYY)	Ongoing at Study Entry?
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	DDMMMYYYY	xxxxxx
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	DDMMMYYYY	xxxxxx
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	DDMMMYYYY	xxxxxx
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	DDMMMYYYY	xxxxxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.4)3. SURGERY AND PROCEDURES HISTORY (CANCER AND NON-CANCER RELATED)

Patient	Type of Lymphoma	No.	Has patient Any Cancer or Non-Cancer Surgeries?	History Type	Surgery/Procedure	Date of Surgery/Procedure
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	DDMMMYYYY

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.4)4. DLBCL DIAGNOSIS

Patient	Type of Lymphoma	Date of Histological Diagnosis	How Was Histological Diagnosis Obtained?	If Fine Needle Aspiration, Provide Details	CD20+ Expression
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxxxxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxxxxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxxxxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxxxxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.4)5. FOLLICULAR LYMPHOMA DIAGNOSIS

Patient	Type of Lymphoma	Date of Histological Diagnosis	How Was Histological Diagnosis Obtained?	If Fine Needle Aspiration, Provide Details	Grade of FL	CD20+ Expression
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxxxxx	xxxxxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxxxxx	xxxxxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxxxxx	xxxxxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxxxxx	xxxxxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.4)6. ECOG PERFORMANCE STATUS, FLIPI AND IPI SCORE

Patient	Type of Lymphoma	Date of Assessment of ECOG PS	ECOG PS	Date of Assessment of FLIPI Score	FLIPI Score	Date of Assessment of IPI Score	IPI Score
xxxx	xxxx	DDMMMYYYY	xxx	DDMMMYYYY	xxx	DDMMMYYYY	xxx
xxxx	xxxx	DDMMMYYYY	xxx	DDMMMYYYY	xxx	DDMMMYYYY	xxx
xxxx	xxxx	DDMMMYYYY	xxx	DDMMMYYYY	xxx	DDMMMYYYY	xxx
xxxx	xxxx	DDMMMYYYY	xxx	DDMMMYYYY	xxx	DDMMMYYYY	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.4)7. VIRAL SEROLOGY AT SCREENING

Patient	Type of Lymphoma	Was Viral Serology Sample Collected?	Date of Sample Collection	HBcAb	HbsAg	HCV Antibody	HIV Antibody	Viral Infection with HBV or HCV?
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.4)8. CONCOMITANT MEDICATIONS

Patient	Type of Lymphoma	No.	Medication Name	PT	SOC	Reason for Medication	If Other, Specify	Indication	Start Date (DDMMMYYYY)	Dose	Dose Unit	Freq.	Route	If Other, Specify	Stop Date (DDMMMYYYY)	Ongoing
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxx	xxx	xxx	DDMMMYYYY	xxx	xxx	xxx	xxxxxx	xxxxxx	DDMMMYYYY	xxxxxx
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxx	xxx	xxx	DDMMMYYYY	xxx	xxx	xxx	xxxxxx	xxxxxx	DDMMMYYYY	xxxxxx
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxx	xxx	xxx	DDMMMYYYY	xxx	xxx	xxx	xxxxxx	xxxxxx	DDMMMYYYY	xxxxxx
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxx	xxx	xxx	DDMMMYYYY	xxx	xxx	xxx	xxxxxx	xxxxxx	DDMMMYYYY	xxxxxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.5)1. PREVIOUS IV RITUXIMAB DOSE – DLBCL

Patient	Type of Lymphoma	No. of Previous IV Rituximab Treatment Cycles	Dose of Most Recent IV Rituximab Cycle	Date of 1st Rituximab IV Administration	Wich Treatment Cycle is the Subject's First on-Study Cycle?
xxxx	xxxx	xxx	xxx	DDMMMYYYY	xxx
xxxx	xxxx	xxx	xxx	DDMMMYYYY	xxx
xxxx	xxxx	xxx	xxx	DDMMMYYYY	xxx
xxxx	xxxx	xxx	xxx	DDMMMYYYY	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.5)2. PREVIOUS IV RITUXIMAB DOSE – FL

Patient	Type of Lymphoma	Phase of IV Rituximab	No. of Cycles of IV Rituximab Recived Previously	Date of 1st Rituximab IV Administration	Dose of Most Recent IV Rituximab Cycle	Eligible Phase to Enter the Study	Wich Treatment Cycle is the Subject's First on-Study Cycle?
xxxx	xxxx	xxx	xxx	DDMMMYYYY	xxx	xxx	xxx
xxxx	xxxx	xxx	xxx	DDMMMYYYY	xxx	xxx	xxx
xxxx	xxxx	xxx	xxx	DDMMMYYYY	xxx	xxx	xxx
xxxx	xxxx	xxx	xxx	DDMMMYYYY	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.5)3. INITIAL CHOP

Patient	Type of Lymphoma	Start Date of CHOP	Cyclophosphamide Fixed Unit (mg/m^2)	Doxorubicin Fixed Unit (mg/m^2)	Vincristine Fixed Unit (mg/m^2)	Prednisone/Prednisolone Fixed Unit (mg/m^2)
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.5)4. SUBSEQUENT CHOP

Patient	Type of Lymphoma	Cycle	If Patient Receiving Same Regimen as in the Previous Cycle?	Start Date	If No, Specify Regimen Moved Onto
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.5)5. SUBSEQUENT CVP

Patient	Type of Lymphoma	Cycle	If Patient Receiving Same Regimen as in the Previous Cycle?	Start Date	If No, Specify Regimen Moved Onto
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.5)6. SUBSEQUENT FLUDARABINE

Patient	Type of Lymphoma	Cycle	If Patient Receiving Same Regimen as in the Previous Cycle?	Start Date	If No, Specify Regimen Moved Onto
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.5)7. SUBSEQUENT CHEMOTHERAPY

Patient	Type of Lymphoma	Cycle	If Patient Receiving Same Regimen as in the Previous Cycle?	Start Date	If No, Specify Regimen Moved Onto
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx
		xxxx	xxxx	DDMMMYYYY	xxx
		xxxx	xxxx	DDMMMYYYY	xxx
		xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx
		xxxx	xxxx	DDMMMYYYY	xxx
		xxxx	xxxx	DDMMMYYYY	xxx
		xxxx	xxxx	DDMMMYYYY	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.5)8. INITIAL CVP

Patient	Type of Lymphoma	Start Date of CVP	Cyclophosphamide Fixed Unit (mg/m^2)	Vincristine Fixed Unit (mg/m^2)	Prednisone/Prednisolone Fixed Unit (mg/m^2)
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.5)9. INITIAL FLUDARABINE

Patient	Type of Lymphoma	Start Date	Fludarabine Fixed Unit (mg/m^2)	Cyclophosphamide Fixed Unit (mg/m^2)
xxxx	xxxx	DDMMMYYYY	xxx	xxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.5)10. OTHER CHEMOTHERAPY

Patient	Type of Lymphoma	Chemotherapy Agent	Regimen Start Date	Dose	Unit	Regimen Stop Date
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	DDMMMYYYY
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	DDMMMYYYY
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	DDMMMYYYY
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	DDMMMYYYY

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.5)11. STUDY DRUG ADMINISTRATION

Patient	Type of Lymphoma	Visit	Was Rituximab Administered?	Start Date	Start Time	Stop Date	Stop Time	Intended Total Dose	Actual Total Dose	Was Full Dose Given?	If No, Provide Reason	If Other, Specify	If AE, is Grade 3-4 IIRR?	Drug Administered on time per Schedule	If No, Specify
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	hh:mm	DDMMMYYYY	hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxxx	xxxx	DDMMMYYYY	hh:mm	DDMMMYYYY	hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxxx	xxxx	DDMMMYYYY	hh:mm	DDMMMYYYY	hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxxx	xxxx	DDMMMYYYY	hh:mm	DDMMMYYYY	hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	hh:mm	DDMMMYYYY	hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxxx	xxxx	DDMMMYYYY	hh:mm	DDMMMYYYY	hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxxx	xxxx	DDMMMYYYY	hh:mm	DDMMMYYYY	hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxxx	xxxx	DDMMMYYYY	hh:mm	DDMMMYYYY	hh:mm	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.5)12. ANTI-LYMPHOMA CHEMO/IMMUNO THERAPY TREATMENT

Patient	Type of Lymphoma	New Chemo/Immuno Therapy for FL	Seq.	Drug Name	Cumulative Dose	Unit	No. Cycles	Start Date	End Date	Response
xxxx	xxxx	xxxxx	xxx	xxx	xxx	xxx	xxx	DDMMMYYYY	DDMMMYYYY	xxx
xxxx	xxxx	xxxxx	xxx	xxx	xxx	xxx	xxx	DDMMMYYYY	DDMMMYYYY	xxx
xxxx	xxxx	xxxxx	xxx	xxx	xxx	xxx	xxx	DDMMMYYYY	DDMMMYYYY	xxx
xxxx	xxxx	xxxxx	xxx	xxx	xxx	xxx	xxx	DDMMMYYYY	DDMMMYYYY	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.5)13. ANTI-LYMPHOMA RADIOTHERAPY TREATMENT

Patient	Type of Lymphoma	New Radiotherapy for FL	Seq.	Irradiation Site	If Other, Specify	Cumulative Dose	Unit	Start Date	End Date	Response
xxxx	xxxx	xxxxx	xxx	xxx	xxx	xxx	xxx	DDMMMYYYY	DDMMMYYYY	xxx
xxxx	xxxx	xxxxx	xxx	xxx	xxx	xxx	xxx	DDMMMYYYY	DDMMMYYYY	xxx
xxxx	xxxx	xxxxx	xxx	xxx	xxx	xxx	xxx	DDMMMYYYY	DDMMMYYYY	xxx
xxxx	xxxx	xxxxx	xxx	xxx	xxx	xxx	xxx	DDMMMYYYY	DDMMMYYYY	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.5)14. ANTI-LYMPHOMA TREATMENT

Patient	Type of Lymphoma	New Non-Protocol Specified Anti-Lymphoma Treatment	Start Date	Anti-Lymphoma Treatment	Radiotherapy	Chemo-Immuno Therapy
xxxx	xxxx	x	DDMMMYYYY	xxxxx	xxxxx	xxxxx
xxxx	xxxx	x	DDMMMYYYY	xxxxx	xxxxx	xxxxx
xxxx	xxxx	x	DDMMMYYYY	xxxxx	xxxxx	xxxxx
xxxx	xxxx	x	DDMMMYYYY	xxxxx	xxxxx	xxxxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.5)15. CHEMOTHERAPY SELECTION

Patient	Type of Lymphoma	Chemotherapy Regiment	If Other, Specify
xxxx	xxxx	xxxxx	xxxxx
xxxx	xxxx	xxxxx	xxxxx
xxxx	xxxx	xxxxx	xxxxx
xxxx	xxxx	xxxxx	xxxxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.6)1. PRE-TREATMENT ADVERSE EVENTS

Patient	Type of Lymphoma	No.	Description	LLT	PT	SOC	Start Date (DDMMMYYYY)	SAE	Initial Intensity	AESI	AAR	Extreme Intensity	Relation to Chemotherapy	Action Taken with Chemotherapy	AE Required Treatment	Outcome	End Date (DDMMMYYYY)
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY

Note:
ARR = Administration-associated reaction.

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.6)2. ADVERSE EVENTS

Patient	Type of Lymphoma	No.	Description	LLT	PT	SOC	Start Date (DDMMMYYYY)	SAE	Initial Intensity	AESI	AAR	Extreme Intensity	Relation to Rituximab	Action Taken with Rituximab	Relation to Chemotherapy	Action Taken with Chemotherapy	AE Required Treatment	Outcome	End Date (DDMMMYYYY)
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY

Note:
ARR = Administration-associated reaction.

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.6)3. SERIOUS ADVERSE EVENTS

Patient	Type of Lymphoma	No.	Description	LLT	PT	SOC	Start Date (DDMMMYYYY)	SAE	Initial Intensity	AESI	AAR	Extreme Intensity	Relation to Rituximab	Action Taken with Rituximab	Relation to Chemotherapy	Action Taken with Chemotherapy	AE Required Treatment	Outcome	End Date (DDMMMYYYY)
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY

Note:
ARR = Administration-associated reaction.

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.6)4. ADVERSE EVENTS OF SPECIAL INTEREST (AESI)

Patient	Type of Lymphoma	No.	Description	LLT	PT	SOC	Start Date (DDMMMYYYY)	SAE	Initial Intensity	AESI	AAR	Extreme Intensity	Relation to Rituximab	Action Taken with Rituximab	Relation to Chemotherapy	Action Taken with Chemotherapy	AE Required Treatment	Outcome	End Date (DDMMMYYYY)
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY

Note:
ARR = Administration-associated reaction.

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.6)5. ADMINISTERED ASSOCIATED REACTIONS

Patient	Type of Lymphoma	No.	Description	LLT	PT	SOC	Start Date (DDMMMYYYY)	SAE	Initial Intensity	AESI	AAR	Extreme Intensity	Relation to Rituximab	Action Taken with Rituximab	Relation to Chemotherapy	Action Taken with Chemotherapy	AE Required Treatment	Outcome	End Date (DDMMMYYYY)
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY

Note:
ARR = Administration-associated reaction.

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.6)6. GRADE 3+ ADVERSE EVENTS

Patient	Type of Lymphoma	No.	Description	LLT	PT	SOC	Start Date (DDMMMYYYY)	SAE	Initial Intensity	AESI	AAR	Extreme Intensity	Relation to Rituximab	Action Taken with Rituximab	Relation to Chemotherapy	Action Taken with Chemotherapy	AE Required Treatment	Outcome	End Date (DDMMMYYYY)
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY

Note:
ARR = Administration-associated reaction.

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.6)7. ADVERSE EVENTS LEADING TO RITUXIMAB DRUG INTERRUPTION OR DRUG DELAYED

Patient	Type of Lymphoma	No.	Description	LLT	PT	SOC	Start Date (DDMMMYYYY)	SAE	Initial Intensity	AESI	AAR	Extreme Intensity	Relation to Rituximab	Action Taken with Rituximab	Relation to Chemotherapy	Action Taken with Chemotherapy	AE Required Treatment	Outcome	End Date (DDMMMYYYY)
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY

Note:
ARR = Administration-associated reaction.

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.6)8. ADVERSE EVENTS LEADING TO CHEMOTHERAPY DOSE MODIFICATION

Patient	Type of Lymphoma	No.	Description	LLT	PT	SOC	Start Date (DDMMMYYYY)	SAE	Initial Intensity	AESI	AAR	Extreme Intensity	Relation to Rituximab	Action Taken with Rituximab	Relation to Chemotherapy	Action Taken with Chemotherapy	AE Required Treatment	Outcome	End Date (DDMMMYYYY)
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY

Note:
ARR = Administration-associated reaction.

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.6)9. ADVERSE EVENTS LEADING TO CHEMOTHERAPY DISCONTINUATION

Patient	Type of Lymphoma	No.	Description	LLT	PT	SOC	Start Date (DDMMMYYYY)	SAE	Initial Intensity	AESI	AAR	Extreme Intensity	Relation to Rituximab	Action Taken with Rituximab	Relation to Chemotherapy	Action Taken with Chemotherapy	AE Required Treatment	Outcome	End Date (DDMMMYYYY)
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY

Note:
ARR = Administration-associated reaction.

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.6)10. ADVERSE EVENTS WITHIN THE MEDDRA SMQ ANAPHYLACTIC REACTIONS

Patient	Type of Lymphoma	No.	Description	LLT	PT	SOC	Start Date (DDMMMYYYY)	SAE	Initial Intensity	AESI	AAR	Extreme Intensity	Relation to Rituximab	Action Taken with Rituximab	Relation to Chemotherapy	Action Taken with Chemotherapy	AE Required Treatment	Outcome	End Date (DDMMMYYYY)
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxx	DDMMMYYYY

Note:
ARR = Administration-associated reaction.

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.6)11. INJECTION SITE REACTIONS

Patient	Type of Lymphoma	Visit	Was an Infection Assessment Done?	Active Infection	Was a Rituximab SC Injection Site Examination Done?	Date of Assessment	Examination Result
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	x	Xxxxxxx	xxxx	xxxx	DDMMMYYYY	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.6)12. DEATH

Patient	Type of Lymphoma	Date of Death	Primary Cause of Death	If cause is AE, was Undelying Cancer a Contributing Factor?	If Other, Specify	Suspected Causal Realationship to Study Medication	Was Autopsy Performed?	If Yes, Summarize Findings
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx
xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.7.1) HEMATOLOGY

Patient	Type of Lymphoma	Age (yrs)	Gender	Visit	Collection Date (DDMMMYYYY)	Parameter	Original unit				SI	
							Value	NRLL	NRUL	Reference to Normal Range	Value	Unit
xxxx	xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
		xxxx	xxxx	xxxx	DDMMMYYYY	xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
		xxxx	xxxx	xxxx	DDMMMYYYY	xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
xxxx	xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx

Note:
NRLL: Normal range lower limit. NRUL: Normal range upper limit.

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.7.2) BIOCHEMISTRY

							Original unit				SI	
Patient	Type of Lymphoma	Age (yrs)	Gender	Visit	Collection Date (DDMMMYYYY)	Parameter	Value	NRLL	NRUL	Reference to Normal Range	Value	Unit
xxxx	xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
		xxxx	xxxx	xxxx	DDMMMYYYY	xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
		xxxx	xxxx	xxxx	DDMMMYYYY	xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
xxxx	xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx	xxxxxx	xxxxxx

Note:
NRLL: Normal range lower limit. NRUL: Normal range upper limit.

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.7.3) COAGULATION TESTS

Patient	Type of Lymphoma	Age (yrs)	Gender	Visit	Collection Date (DDMMMYYYY)	Parameter	Value	NRLL	NRUL	Reference to Normal Range
xxxx	xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxxxxx	xxxx	xxxx	xxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx
		xxxx	xxxx	xxxx	DDMMMYYYY	xxxxxx	xxxx	xxxx	xxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx
		xxxx	xxxx	xxxx	DDMMMYYYY	xxxxxx	xxxx	xxxx	xxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx
xxxx	xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxxxxx	xxxx	xxxx	xxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx
						xxxxxx	xxxx	xxxx	xxxx	xxxxxx

Note:
NRLL: Normal range lower limit. NRUL: Normal range upper limit.

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.8.1) VITAL SIGNS & BODY WEIGHT

Patient	Type of Lymphoma	Visit	Was Vital Signs Performed?	Date of Assessment	Pulse (bpm)	SBP (mmHg)	DBP (mmHg)	Body Temperature (°C)	Body Weight (Kg)
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx
		xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx
		xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx
		xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx
		xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx
		xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx
		xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.8.2) SERUM PREGNANCY TEST

Patient	Type of Lymphoma	Was Serum Pregnancy Test Performed?	Date of Assessment	Test Result
xxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.8.3) URINE PREGNANCY TEST

Patient	Type of Lymphoma	Was Urine Pregnancy Test Performed?	Date of Urine Pregnancy Test	Test Result
xxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.8.4) PHYSICAL EXAMINATION

Patient	Type of Lymphoma	Visit	Date of Assessment (DDMMMYYYY)	Body System	Result
xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx
				xxxx	xxxx
				xxxx	xxxx
				xxxx	xxxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx
				xxxx	xxxx
				xxxx	xxxx
				xxxx	xxxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx
				xxxx	xxxx
				xxxx	xxxx
				xxxx	xxxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.8.5) 12-LEAD ECG

Patient	Type of Lymphoma	ECG Performed?	ECG Date (DDMMMYYYY)	ECG Result
xxxx	xxxx	xxx	DDMMMYYYY	xxxxxxx
xxxx	xxxx	xxx	DDMMMYYYY	xxxxxxx
xxxx	xxxx	xxx	DDMMMYYYY	xxxxxxx
xxxx	xxxx	xxx	DDMMMYYYY	xxxxxxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.8.6) TARGET LESION ASSESSMENT AT SCREENING (PART #1)

Patient	Type of Lymphoma	Were Target Lesions Identified?	Location	If Other, Specify	CT with Contrast	Date of CT Scan	CT Scan Result	CT w/o Contrast	Date of CT Scan	Result	MRI	Date of MRI	MRI Result
xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	DDMMMYYYY	xxx	xxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	DDMMMYYYY	xxx	xxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	DDMMMYYYY	xxx	xxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	DDMMMYYYY	xxx	xxx	DDMMMYYYY	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.8.7) TARGET LESION ASSESSMENT AT SCREENING (PART #2)

Patient	Type of Lymphoma	Clinical Assessment?	Date of Assessment	Result	FDG-PET	Date of Scan	Result	Other	If Other, Specify	Date of Scan	Result
xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	xxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	xxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	xxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	xxx	DDMMMYYYY	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.8.8) TARGET LESION ASSESSMENT SUBSEQUENT (PART #1)

Patient	Type of Lymphoma	Visit	Were Any Changes?	Location	If Other, Specify	CT with Contrast	Date of CT Scan	CT Scan Result	CT w/o Contrast	Date of CT Scan	Result	MRI	Date of MRI	MRI Result
xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	DDMMMYYYY	xxx	xxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	DDMMMYYYY	xxx	xxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	DDMMMYYYY	xxx	xxx	DDMMMYYYY	xxx
xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	DDMMMYYYY	xxx	xxx	DDMMMYYYY	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.8.9) TARGET LESION ASSESSMENT SUBSEQUENT (PART #2)

Patient	Type of Lymphoma	Clinical Assessment?	Date of Assessment	Result	FDG-PET	Date of Scan	Result	Other	If Other, Specify	Date of Scan	Result	Change in Lesion Since First Assessed or Previous Visit
xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	xxx	DDMMMYYYY	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	xxx	DDMMMYYYY	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	xxx	DDMMMYYYY	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	DDMMMYYYY	xxxx	xxxx	xxx	DDMMMYYYY	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.8.10) OVERALL LESION ASSESSMENT

Patient	Type of Lymphoma	Date of Assessment	Response of Target Lesions	New Lesions?	Inv.'s Overall Assessment of Response at This Visit	Date of Progression
xxxx	xxxx	DDMMMYYYY	xxxx	xxx	xxx	DDMMMYYYY
xxxx	xxxx	DDMMMYYYY	xxxx	xxx	xxx	DDMMMYYYY
xxxx	xxxx	DDMMMYYYY	xxxx	xxx	xxx	DDMMMYYYY
xxxx	xxxx	DDMMMYYYY	xxxx	xxx	xxx	DDMMMYYYY

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.8.11) SURVIVAL STATUS

Patient	Type of Lymphoma	Was Survival Assessment Performed?	Date of Assessment	Survival Status	Date of Last Contact	Has the Patient Started New Lymphoma Treatment Since Last Contact?	Start Date
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	DDMMMYYYY	xxx	DDMMMYYYY
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	DDMMMYYYY	xxx	DDMMMYYYY
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	DDMMMYYYY	xxx	DDMMMYYYY
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	DDMMMYYYY	xxx	DDMMMYYYY

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.8.12) BONE MARROW ASSESSMENT

Patient	Type of Lymphoma	Was Bone Marrow Assesment Done?	Date of BM assessment	Was BM Assessment Done Using Aspirate?	Result	Was BM Assessment Done Using Biopsy?	Result
xxxx	xxxx	x	DDMMMYYYY	xxxxx	xxxxx	xxxxx	xxxxx
xxxx	xxxx	x	DDMMMYYYY	xxxxx	xxxxx	xxxxx	xxxxx
xxxx	xxxx	x	DDMMMYYYY	xxxxx	xxxxx	xxxxx	xxxxx
xxxx	xxxx	x	DDMMMYYYY	xxxxx	xxxxx	xxxxx	xxxxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.8.13) RASQ FOR IV ADMINISTRATION

Patient	Type of Lymphoma	Was RASQ Completed?	Date of Assessment	Item #1	Item 1a	..	Item 20	Physical impact domain value	Psychological impact domain value	Impact on ADL Domain value	Convenience domain value	Satisfaction Domain value
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY

LISTING 16.2.8.14) RASQ FOR SC ADMINISTRATION

Patient	Type of Lymphoma	Was RASQ Completed?	Date of Assessment	Item #1	Item 1a	..	Item 20	Physical impact domain value	Psychological impact domain value	Impact on ADL Domain value	Convenience domain value	Satisfaction Domain value
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

LISTING 16.2.8.15) HEALTHCARE PROFESSIONAL QUESTIONNAIRE

Site	Healthcare professional	Was HPQ Completed?	Date of Assessment	Item #1	Item 1a	..	Item 10
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx
xxxx	xxxx	xxxx	DDMMMYYYY	xxx	xxx	xxx	xxx

Source: XXXX.SAS, Run on DDMMMYYYY