Official Title: A Phase Ib/II Study Evaluating the Safety and Efficacy of Obinutuzumab in Combination With Idasanutlin and Venetoclax in Patients With Relapsed or Refractory Follicular Lymphoma and Obinutuzumab or Rituximab in Combination With Idasanutlin and Venetoclax in Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma

NCT Number: NCT03135262

Document Date: DAP Version 3: 02-April-2019

DATA ANALYSIS PLAN (DAP) MODULE 2

Title: Harmonized Specifications Document for the InHarmony studies

Protocol numbers: BO29561, BO29562, BO29563, GO29833, GO29834, BH29812, BH39147

Author:

[redacted], Study Statistician & [redacted] Date

Approver:

[redacted] * Date

*** The approver has ensured that key team members have been involved, contributed and reviewed the content of the List of Planned Outputs as described in the DAP Module 2 guideline.**

TABLE OF CONTENTS Page

LIST OF APPENDICES Page

1 Introduction

The purpose of this document is to define the specifications required for the analyses and output production for the InHarmony studies (BO29561, BO29562, BO29563, GO29833, GO29834, BH29812). This document should be referred to alongside the harmonized List of Planned Outputs (LoPO) spreadsheet.

2 Data Handling Specifications

2.1 Datacut

For primary CSR analyses, each study will have data cut based on the 'clinical cutoff date' (CCOD). Data collected on or before the CCOD will be included in.

For the datacut rules refer to the instructions for 'fixed-cutoff datacut' type on the Global Data Standards Repository (GDSR) Browser - Rules and Definitions for Analysis Data Cuts.

2.2 Treatment Definition

"Chemotherapy" (CT) is defined as at least one dose > 0 of Doxorubicin, Bendamustine, Cyclophosphamide, Vincristine or Prednisone/Prednisolone/Methylprednisolone (=steroids). Steroids are only counted as part of Chemotherapy if they were given as part of CHOP according to the study drug eCRF page (EX domain).

"Study treatment" is defined as at least one dose > 0 of any component of combination therapy (e.g. obinutuzumab, atezolizumab, polatuzumab vedotin, venetoclax, lenalidomide, idasanutlin) or chemotherapy.

2.2.1 Treatment Groups

The treatment arm labels to be included in the outputs are displayed as described below in following order:

Atezolizumab will be replaced by 'Atezo'

Obinutuzumab will be replaced by 'G'

Rituximab will be shown as 'R'

Polatuzumab vedotin will be replaced by 'P'

Venetoclax will be replaced by 'V'

Idasanutlin will be replaced by 'I'

Lenalidomide will be replaced by 'L'

Bendamustine will be replaced by 'B'

CHOP will be shown as 'CHOP'

We also should show dose levels after each treatment. So for illustration purposes, a treatment arm of "Obinutuzumab 1000mg + Polatuzumab vedotin 1mg/kg + Lenalidomide 10mg" would be shown as "G (1000MG) P (1MG/KG) L (10MG)", or "Obinutuzumab 1000mg + Atezolizumab 1mg + CHOP" would be shown as "Atezo (1MG) - G (1000MG) - CHOP".

2.2.2 New Anti-lymphoma Treatment

A new anti-lymphoma treatment (NALT) is defined as any treatment reported on the 'Follow-up New Anti-Lymphoma Therapy' or 'New Anti-Lymphoma Surgery and Procedure' eCRF pages.

If a patient has more than one, use the first date from any of the NALTs.

2.3 Patient Allocation to Reporting Periods

The following definitions will be used to allocate AEs and laboratory data to study periods. The same definitions will also be used in other cases where applicable, e.g. patient disposition. Adverse events are assigned to the study periods based on the AE onset date.

2.3.1 Study Day 1

Study day 1 is the day of first administration of any study treatment (see Section 2.2).

2.3.2 Before Therapy

Any AE that occurs before study day 1 is considered to have occurred before therapy unless the end date is after the date of first study drug intake and the most extreme intensity is higher than the initial intensity (see treatment emergent rules in Section 6.2.1). For handling of pre-dose laboratory assessments, see definition of baseline (Section 2.3.3).

2.3.3 Baseline

The baseline assessment is the last valid assessment in the 28 day window before first administration of a study treatment component (see Section 2.2 for study treatment definition). If no time is linked to a laboratory or vital sign assessment at study day 1, it is assumed that the assessment was done before the drug administration. For patients who never received study treatment, baseline is defined as the last valid assessment prior to or on the day of enrolment – note though that this is only applicable to parameters not being reported out using the safety population, as otherwise these patients are anyway excluded.

2.3.4 Study Periods

All periods below end at the study completion or early withdrawal visit. For all periods, NALT refers to the first occurrence of NALT post study-treatment.

If a patient is ongoing in any period at the time of reporting, then consider last known alive date as the period end date just for the purpose of duration calculations and to ensure events are still mapped to this period.

2.3.4.1 Treatment Period

The treatment period will be defined as the time between study day 1 and last administration of any component of the study treatment + 28 days or if a NALT starts within 28 days, then treatment period ends one day prior to the start of the NALT.

2.3.4.2 Induction Treatment Period

Only relevant for studies with a maintenance or consolidation treatment period: For patients receiving maintenance or consolidation therapy, the induction treatment period will be defined as the time between study day 1 and 1 second before the first dose of maintenance or consolidation therapy, or if a NALT starts prior to the start of maintenance or consolidation, the induction treatment period ends one day prior to the start of the NALT. For those not receiving maintenance or consolidation therapy, the induction treatment period follows the same rules as given above for the treatment period (see Section 2.3.4.1).

2.3.4.3 Maintenance or Consolidation Period

Only relevant for studies with a maintenance or consolidation treatment period: The maintenance or consolidation period starts on the day of the patient's first dose of any treatment in maintenance or consolidation and ends one day prior to the start of NALT or 28 days after the last dose of any maintenance or consolidation treatment.

Note: Safety outputs produced on the maintenance or consolidation period will only show the maintenance or consolidation treatment arm, and these outputs will only include those patients that enter the maintenance or consolidation period.

2.3.4.4 Post treatment Follow-up Period

The follow-up period refers to the phase of the study that is post study treatment. Only patients who have an induction treatment completion eCRF page completed (for patients without a dose of maintenance or consolidation treatment) and a maintenance/consolidation treatment completion eCRF page completed (for patients who received maintenance or consolidation treatment) will be included in the follow-up period.

The follow-up period starts the day after the end of the treatment period (see Section 2.3.4.1). The follow-up period ends at the date recorded on the post treatment follow-up phase completion eCRF page, or at the last recorded date in the eCRF for patients ongoing in the period.

2.3.4.5 Survival Follow-up

Survival follow-up starts the day after the follow-up period ends. Survival follow-up ends at the date recorded on the study completion/early discontinuation eCRF page, or at the last recorded date in the eCRF for patients ongoing in the period. For patients who withdrew from induction, post-induction or follow up phase due to PD, survival follow up starts the day after the date of study completion/early discontinuation.

2.3.5 Treatment Cycle

A treatment cycle starts on the day of the first administration of a study treatment component and ends the second before the start of the next cycle. For example, cycle 1 will start at the first valid cycle 1 study drug administration and will end at the start date of the cycle 2 dose (or cycle 3, or 4 etc. if cycle 2 dose is missing) minus 1 second. The last cycle ends when the treatment period ends.

2.3.6 Observation Time

Observation time is the time between enrolment date and the day of death or the last assessment in the database (=last known alive date, see Section 2.3.7).

2.3.7 Last known alive date

The last known alive date is derived from the latest of dates in the following CRF fields: AE start and end dates (including start and end dates of IRR symptoms), tumor response assessment dates, study drug exposure dates, lab assessment dates, vital signs assessment dates, ECG assessment dates, survival follow-up pages where the status is confirmed as 'ALIVE', death date, enrolment date and date of informed consent.

As per STREAM standard rules only partial dates from tumor response or death data are included. In this case missing day is replaced by 1st of the month if only month and year are given. Dates where month and/or year are missing are not imputed but excluded. For partial death dates STREAM applies the following additional rule: If month/year of last known alive date from all other dates* is equal to the month/year of partial death date then last known alive date is set to * + 1 day.

2.3.8 Study Drug Exposure Time

Study drug exposure time is defined as the last study treatment administration end date (where dose is > 0) minus the first study treatment administration date (where dose is >0) plus 1 day. This could be calculated individually by study drug or collectively for all study drugs.

2.3.9 General Rules

In the analysis of laboratory data by cycle, if there are several observations per cycle the last value is used. If there are two valid assessments per day and no time is available, the scheduled valid assessment will be taken. In the analysis of follow-up data by visit, patients will be assigned to visits using the clinical planned event (CPE).

All derivations of duration are initially done based on days and converted to months and years if needed using 30.4375 and 365.25, respectively, as denominator if not otherwise specified. Unless otherwise specified, months will be used in outputs.

Computation of durations: any duration in days is computed as end date minus start date + 1 day.

2.4 Handling of Missing and Incomplete Data

Laboratory values with either a '<' or '>' included in the lab result will have the inequality symbol removed and 0.001 will be either subtracted (when '<' is included) or added (when '>' is included) to the numeric value of the result for the purpose of summarizing (the original value will be displayed in listings). For example, laboratory values given as " <7" or ">7" are treated as follows:

Recorded data value	When reported as numerical value	When reported in a listing
<7	6.999	<7
>7	7.001	>7

Each AE is assigned to a time period, i.e. pre-treatment, during treatment (could be further split as induction/maintenance or consolidation) or follow-up (Section 2.3).

In listings AEs with partial dates will be shown by having a missing study day.

For AEs and concomitant treatment (not including NALTs), the following rules will be applied:

- Incomplete onset dates for AEs will be handled as follows:
    - in case the day is missing, it is replaced by the 1st of the month, unless a trial treatment exists within that month (not necessarily first treatment) then set to the date of that treatment
    - in case the day and month are missing, they are replaced by 1st of January, unless the first trial treatment exists within that year then set to the date of that treatment
    - in case imputation leads to the AE occurring before treatment, the onset date will be set to the treatment start date
    - resolution dates are checked to ensure imputed onset dates do not become later than the resolution date
- In case AE most extreme intensity is missing, it will be replaced by the initial intensity
- AEs with missing grades will be included in the summaries for grade 3 to 5 AEs
- AEs with missing relationship to trial medication are included in the summaries of related AEs
- AE with missing seriousness will be included in all summaries of serious adverse events (SAEs)

- For partial concomitant treatment start dates the 1st of the month will be imputed (if only day is missing) or 1st January will be imputed (if day and month are missing).

Partial dates of NALT will be imputed as follows, in order to use the most conservative (i.e. earliest) date without shortening the treatment period:

- If only the year is available then the difference between 1st January of the year and the last administration date of any component of study treatment will be checked: if the difference is >28 days then 1st January will be imputed; otherwise, if the difference is ≤28 days then the date of the last study drug administration* + 29 days will be imputed.
- If the month and year are both available then the difference between the 1st of the month and last study drug administration will be checked: if the difference is >28 days then the 1st of the month will be imputed; otherwise, if the difference is ≤28 then the date of the last study drug administration* +29 days will be imputed. However, if this leads to the imputed date having the month following the month in the partial date, then the last day of the partial date month will be imputed.

*For B-cell and Immunoglobulin outputs, use the last antibody administration date; for other outputs use the last of all study medication dates.

Partial study drug administration dates will not be imputed. A valid study drug administration record is one with a complete begin date and a >0 actual dose for antibody or chemotherapy. Only valid records should be used for all analyses where information of study drug administration is used.

Handling of partial or missing dates for other assessments are discussed within their corresponding sections.

3 Subgroups

Definitions of potential subgroups are included in this section. Please refer to LOPO to determine which analyses these subgroups are applied to.

3.1 ABC/GCB subtypes for DLBCL patients

DLBCL cell-of-origin (COO) prognostic subgroups (ABC and GCB), defined using gene expression profiling, have been associated with different clinical outcomes in patients receiving R-CHOP for DLBCL, with GCB subgroups demonstrating a better prognosis than ABC. DLBCL patients will be classified as having the ABC or GCB cell of origin subtypes.

3.2 BCL-2 subgroups for DLBCL patients

BCL-2 overexpression has been shown to have prognostic value in DLBCL. DLBCL patients will be classified as having high/low BCL-2 expression.

3.3 Double hit subgroup (FISH) for DLBCL patients

Approximately 9%–17% of patients with newly diagnosed DLBCL harbor an underlying *MYC* rearrangement, and these patients are at high risk of treatment failure with R-CHOP. A subset of patients with *MYC*-positive DLBCL also harbors an additional *BCL2* rearrangement. These "double-hit" lymphomas are associated with a very poor outcome Subgroup of 'Double hit' DLBCL patients vs. rest of DLBCL patients will be set up.

3.4 Double positive subgroup (IHC) for DLBCL patients

Overexpression of BCL-2 and Myc in DLBCL has also been observed in the absence of translocation. This "double-positive" DLBCL status is also associated with worse prognosis. Therefore subgroup of double positive (IHC) DLBCL patients will be set up.

Cell of Origin (COO) and BCL-2 for DLBCL patients: COO and BCL-2 based subgroups will be set up for DLBCL patients: ABC-BCL-2 high, ABC-BCL-2 low, GCB-BCL-2 high, GCB-BCL-2 low**.**

Cell of Origin (COO) and Myc for DLBCL patients: COO and Myc based subgroups will be set up for DLBCL patients: ABC-BCL-2 positive-MYC positive, GCB-BCL-2 positive-MYC positive.

3.5 IPI / FLIPI

For FL patients FLIPI based subgroups may be created. For DLBCL patients IPI based subgroups may be created.

Applicable for Study	BO29563 Atezo-G-B	BO29563 Atezo-G/R-CHOP	BO29562	BO29561	GO29833	GO29834	BH29812
ABC/GCB		x		x			x
BCL-2		x		x			x
Double hit		x		x			x
Double positive		x		x			x
COO&Myc		x		x			x
MRD	x	x	x	x			x
IPI/FLIPI	x	x	x	x			x
p53							x
CD8	x	x	x	x			
PDL1	x	x	x	x			
CD58		x					
CD79				x			

4 Demographics, Baseline Disease Characteristics and Prognostic Markers

4.1 Demographics

Demographics are collected at enrollment and generally may include:

- Gender
- Age at BL
- Race
- Ethnicity
- Weight
- Height
- BMI (= body mass index)
- BSA (= body surface area)
- ECOG Performance score at BL

4.2 Baseline Disease Characteristics and Prognostic Markers

Baseline Disease Characteristics and Prognostic Markers are baseline conditions specifically related to the indication under study. These may include:

- Histology/ pathologic diagnosis
- Ann Arbor stage
- Time since first histologic or pathologic diagnosis
- Biomarker status from tumor tissue or blood samples at BL
    - COO
    - BCL-2
    - MYC
    - COO and BCL-2
    - BCL-2 and MYC(FISH)
    - BCL-2 and MYC(IHC)
    - COO and BCL-2 and MYC

    - P53 (in studies with idasanutlin)

- IPI
- FLIPI
- Follicular Lymphoma Grade
- Any B symptoms at BL
- Individual B-symptoms, i.e. fever, weight loss, night sweats, at BL
- Bulky disease (threshold 70 mm) at BL
- Number of Indicator Lesions at BL
- Number of non-Indicator Lesions at BL
- Spleen Assessment at BL: Palpable yes/no or >13 cm in vertical length vs. <=13 cm (r/r DLBCL/FL)
- Liver Assessment at BL : Palpable yes/no
- SPD of Indicator Lesions at BL
- Number of prior anti-lymphoma therapies
- Prior radiotherapies
- Prior surgeries or procedures
- Serum LDH at BL(>normal vs. <=normal)
- Extranodal Involvement at BL yes/no
- If yes, Number of extranodal sites at BL
- Bone Marrow Involvement
- Status (relapsed/refractory or previously untreated) (BO29563)
- PET score at BL
- Presence of FDG avid lesions representing lymphoma at BL yes/no (detected by PET scan)
- Evidence of FDG avid disease in bone marrow at BL yes/no (detected by PET scan)

5 Efficacy Analyses

The efficacy analyses will be performed on the efficacy evaluable population, which includes all patients who received at least one dose of any components of the combination during the expansion

phase. Patients who received any study drugs at the RP2D during the dose-escalation/safety run-in phase may be pooled with the efficacy evaluable population depending on protocol.

For studies which have specific definition of the efficacy population, refer to protocol for the definition. For example, Study BH29812: The primary and secondary efficacy analyses will include all patients enrolled in the expansion phase.

5.1 Analysis of Primary Endpoint

The primary efficacy endpoint is the proportion of patients achieving a CR at EOI, as determined by the IRC on the basis of PET-CT scans according to modified Lugano 2014 criteria. Point estimates will be presented, along with the corresponding 90% Clopper-Pearson exact CIs. Patients without a post-baseline tumor assessment will be considered non-responders.

5.2 Analysis of Secondary Endpoints

The secondary efficacy analyses will be estimation of the proportion of patients who achieve each of the following endpoints:

- CR at EOI, as determined by the investigator on the basis of PET-CT scans
- CR at EOI, as determined by the IRC and by the investigator on the basis of CT scans alone
- Objective response (defined as a CR or PR) at EOI, as determined by the IRC and by the investigator on the basis of PET-CT scans
- Objective response (defined as a CR or PR) at EOI, as determined by the IRC and by the investigator on the basis of CT scans alone
- Best response of CR or PR during the study, as determined by the investigator on the basis of CT scans alone

Study BO29563:

- CR at EOI, as determined by the investigator on the basis of PET-CT scans using modified Lugano 2014 criteria
- CR at EOI, as determined by the IRC and by the investigator on the basis of PET-CT and CT scans using modified Cheson 2007 criteria
- Objective response (defined as a CR or PR) at EOI, as determined by the IRC and by the investigator using modified Lugano 2014 criteria and modified Cheson 2007 criteria
- Best objective response (defined as a CR or PR) during the study (including all tumor assessments), as determined by the investigator using modified Cheson 2007

Point estimates will be presented, along with the corresponding two-sided 90% Clopper-Pearson exact CIs. Patients without a post-baseline tumor assessment will be considered non-CRs and non-responders, respectively.

5.3 Analysis of Exploratory Endpoints

Exploratory efficacy analyses will include estimation of the proportion of patients achieving each of the following endpoints:

- For patients who have positive PET scans at EOI: CR at 12 months, as determined by the IRC and by the investigator on the basis of PET-CT scans
- CR at 12 months, as determined by the investigator on the basis of CT scans alone (BO29561)
- CR at 12, 24, and 30 months in patients with previously untreated FL, as determined by the investigator using modified Cheson 2007 criteria (BO29563)
- Additional descriptive analysis based on TP53 status will be performed on the following endpoint: CR at EOI, as determined by the IRC on the basis of PET-CT scans (BH29812)

Point estimates will be presented, along with the corresponding two-sided 90% Clopper-Pearson exact CIs. Patients without a post-baseline tumor assessment will be considered non-CRs and non-responders, respectively.

Exploratory efficacy analyses will also be performed on the following endpoints:

- PFS, defined as the time from initiation of study treatment to first occurrence of disease progression or relapse, as determined by investigator on the basis of CT scans alone, or death from any cause
- EFS, defined as the time from initiation of study treatment to any treatment failure, including disease progression or relapse, as determined by investigator on the basis of CT scans alone, initiation of new anti-lymphoma therapy, or death from any cause, whichever occurs first
- DFS, defined, among patients achieving a CR, as the time from the first occurrence of a documented CR to relapse, as determined by the investigator on the basis of CT scans alone, or death from any cause, whichever occurs first
- DOR, defined as the time from the initial response to disease progression or death among patients who have experienced a CR or PR during study (Study BO29561/BO29562).
- OS, defined as the time from initiation of study treatment to death from any cause

PFS, EFS, DFS, DOR, and OS will be summarized descriptively using the Kaplan-Meier method (Kaplan and Meier 1958). For the PFS, EFS, and DFS analyses, data for patients without an event of interest will be censored at the date of the last tumor assessment. For the PFS and EFS analyses, data for patients without post-baseline tumor assessments will be censored at the date of initiation of study treatment plus 1. For the DFS analysis, data for patients without a tumor assessment after the first CR will be censored at the date of first CR tumor assessment + 1 day. For the DOR analysis, data for patients without a tumor assessment after the Objective Response (OR) of CR or PR will be censored at the date of OR tumor assessment +1 day. For the OS analysis, data for patients who have not died will be censored at the date the patient was last known to be alive. Where medians are reached, the corresponding estimated median will be provided, along with the 95% CI using the method of

Brookmeyer and Crowley (1982). In addition, landmark estimates of the proportion of patients who are event free at 6 months, 9 months, 1 year, and 2 years will be provided, along with 95% asymptotic CIs using Greenwood's formula for standard errors.

5.4 Interim Analyses

It is anticipated that at least one interim analysis will be conducted during the expansion phase of the study, when at least 15 patients in one treatment arm have been evaluated for PET-CT–defined CR at the EOI.

6 Safety Analyses

Safety analyses will be based on all patients who received at least 1 component of study medication. For safety analyses, patients will be reported by the treatment actually received. Patients who only received certain treatments from a combination group, but not all, will be reported by the planned treatment group.

Study data will be summarized separately for each phase. Data from the dose-escalation/safety run-in phase will be summarized by cohort (assigned dose level). Data from the expansion phase will be summarized by histological subtype (i.e., FL or DLBCL) and treatment group if applicable.

6.1 Exposure

Exposure summaries will be done by study period, i.e. there will be separate outputs for induction and post-induction phase. Exposure summaries will also be done by cycle if necessary.

6.1.1 Extent of Exposure to Study Drug

At least one component of study treatment (i.e. obinutuzumab, rituximab, atezolizumab, polatuzumab vedotin, venetoclax, lenalidomide, idasanutlin or chemotherapy as defined in section 2.2) per cycle requires a received dose of >0 to be considered as a received cycle.

6.1.2 Dose Intensity

The dose intensity will be calculated based on the total received dose as compared to total planned dose (based on planned dose of first intake). Patients who withdrew prematurely from one study drug component but are still receiving other components of the study drug will be included in the calculation of the dose intensity up until the last day on which they received any study drug component.

E.g a patient in Atezo-G-Benda arm in BO29563 in induction had 5 doses of G with last dose on Cycle 3 Day 1, and 7 doses of Bendamustine with last dose on Cycle 4 Day 1. Number of expected doses for G would be 6, dose intensity for G would be 5 * 1000 mg / 6 * 1000 mg.

The intensity categories are: <60%, 60 - <80%, 80 - <90%, >=90%, Missing. Summary statistics (mean, s.d., median, range) will also be used to summarize the dose intensity.

Dose intensity will be summarized separately for the induction and post-induction phase. For drugs in Prednisone category in BO29563, i.e. Methylprednisolone, Prednisone, Prednisolone and Dexamethasone, dose intensity is calculated for the whole category as number of actually received doses divided by number of expected doses up to the last time point any component of study drug was received.

6.2 Adverse Events

6.2.1 General AE Reporting

Listings will include all AEs. A flag will indicate to which study period an AE is assigned to: before treatment, initial/induction treatment, maintenance/consolidation treatment or follow up.

Study periods are as defined in Section 2.3.4. An AE is assigned to a period using the AE onset date, Unless otherwise specified, AE and SAE summary tables will be restricted to those that are treatment emergent, defined as starting on or after the day of first dose of any drug. For summary tables on the follow-up period, no upper time window is implemented, that is, all AEs from start of follow-up onwards will be included.

Generally AE will be summarized by study period.

In addition selected adverse events and AESI (see categories in subsequent tables) may be summarized by treatment cycle. An AE will be assigned to a cycle based on the AE onset day relative to cycle start day. Cycle start day is the first day on which any study medication was administered. AEs with onset on cycle start day will be included in the respective cycle.

In studies BO29561, BO29562 and BO29563 AESI based on tickbox in CRF page and on causality to any study drug will be reported separately .

6.2.2 Selected AEs and AE of Special Interest (AESI)

Selected AE and AESI were defined based on the clinical experience with study treatment components that represent an IMP. Also anticipated potentially overlapping toxicities as specified in respective study protocols need to be taken into account.

Definitions for selected AE and AESI are provided in subsequent tables.

Selected AE Category	Definition	BO29563	BO29562	BO29561	BH29812	BH39147	GO29833	GO29834
Thrombocytopenia	SMQ "HAEMATOPOIETIC THROMBOCYTOPENIA narrow" (20000031n)	x	x	x	x	x	x	x
Hepatitis B reactivation/newly occurring	PT 'HEPATITIS B'	x	x	x	x	x	x	x
Cardiac AE	SOC "CARDIAC DISORDERS"	x	x	x	x	x	x	x
Infusion Related Reaction (IRR)	PT 'INFUSION RELATED REACTION' and related to at least one component of study treatment and event occurred within 24 hours or during infusion and tickbox 'Systemic Infusion Reaction' ticked (This definition was applied in BO29563- study lead BioStats/SPA please check if this is valid for your study)	x	x	x	x	x	x	x
Infections	SOC 'INFECTIONS AND INFESTATIONS'	x	x	x	x	x	x	x
Neutropenia	Roche Standard AEGT "NEUTROPENIA AND ASSOCIATED COMPLICATIONS" (for BO29561-3:including late onset and prolonged neutropenia) (SMQ Haematopoietic leukopenia narrow for GO29833/834)	x	x	x	x	x	x	x

Selected AE Category	Definition	BO29563	BO29562	BO29561	BH29812	BH39147	GO29833	GO29834
Prolonged neutropenia	Initial ANC < 1.0 × 109/L that is still present 28 days after treatment with GA101				x	x		
Late onset Neutropenia	ANC < 1.0 × 109/L occurring>=28 days after ga101 infusion has been completed/stopped				x	x		
Gastrointestinal perforation	SMQ "GASTROINTESTINAL PERFORATION" (20000107 narrow).	x	x	x	x	x	x	x
Peripheral Neuropathy (motor/and or sensory)	SMQ Peripheral neuropathy wide			x			x	x
Dose Limiting Toxicity	CRF tickbox				x			
Drug-drug interactions	Single PT		x					

AE of Special Interest	Definition	BO29563	BO29562	BO29561	BH29812	BH39147	GO29833	GO29834
Drug induced liver injury	~~Respective tickbox for AESI on CRF page ticked~~				x	x	x	x
Suspected transmission of infectious agent	~~Respective tickbox for AESI on CRF page ticked~~				x	x	x	x
Grade 4 thrombocytopenia	SMQ "HAEMATOPOIETIC THROMBOCYTOPENIA narrow" (20000031n)						x	
Grade ≥ 3 infection	SOC						x	
Grade ≥ 3 thrombocytopenia or Grade 2 thrombocytopenia if associated with hemorrhage/bleeding	?				x	x		
Grade ≥ 2 diarrhea	?				x	x		
Grade ≥ 3 neutropenia, including febrile neutropenia	SMQ HAEMATOPOIETIC LEUKOPENIA (narrow)				x	x		
Grade ≥ 2 C. difficile infection	?				x	x		
Immune-related Pneumonitis	SMQ INTERSTITIAL LUNG DISEASE (narrow)	x	x	x				
Immune-related Colitis	HLT COLITIS (excluding infective)	x	x	x				
Immune-related Adrenal insufficiency	AEGT Atezolizumab comprehensive adrenal insufficiency search - 22 Jul 2015	x	x	x				
Immune-related Diabetes Mellitus	AEGT Atezolizumab Diabetes/DKA (excludes Hyperglycemia)	X	X	X				

AE of Special Interest	Definition	BO29563	BO29562	BO29561	BH29812	BH39147	GO29833	GO29834
Immune-related Pancreatitis	ATEZOLIZUMAB PANCREATITIS AEGT	x	x	x				
Immune-related hypothyroidism	Hypothyroidism SMQ (wide)	x	x	x				
Immune-related hyperthyroidism	Hyperthyroidism SMQ (narrow)	x	x	x				
Immune-related Hepatitis	HEPATIC FAILURE, FIBROSIS AND CIRRHOSIS AND OTHER LIVER DAMAGE-RELATED CONDITIONS SMQ (narrow); HEPATITIS NON-INFECTIOUS SMQ (narrow); LIVER RELATED INVESTIGATIONS, SIGNS AND SYMPTOMS SMQ (narrow)	x	x	x				
Immune-related Guillain-Barré syndrome	GUILLAIN-BARRE SMQ (narrow)	x	x	x				
Immune-related Myasthenia gravis	HLT MYASTHENIA GRAVIS AND RELATED CONDITIONS	x	x	x				
Immune-Related Nephritis	HLT glomerulonephritis and nephrotic syndrome or HLT nephritis NEC	x	x	x				
Immune-related Meningitis	Noninfectious meningitis SMQ (narrow	x	x	x				
Immune related Encephalitis	Noninfectious encephalitis SMQ (narrow)	x	x	x				
Immune-related myositis	HLT muscle infections and inflammations; HLT muscular autoimmune disorders	x	x	x				

AE of Special Interest	Definition	BO29563	BO29562	BO29561	BH29812	BH39147	GO29833	GO29834
Immune-related Rhabdomyolysis	SMQ Rhabdomyolysis / myopathy (narrow)	x	x	x				
Immune-related Rash	AEGT EGFR Associated Skin Reactions	x	x	x				
~~IRR/Hypersensitivity~~ Infusion Related Reactions	~~AEGT Kadcyla specific AEGT Infusion Related reactions/Hypersensitivity (type 1) 14 Feb 2013~~ PTs 'Infusion Related Reaction' , 'Cytokine Release Syndrome' Only AE with onset on same day or within 1 day of Atezo infusion are flagged	x	x	x				
Systemic immune Activation	Systemic Immune Activation (PT) , Cytokine Release Syndrome (PT)	x	x	x				
Immune Related Ocular Inflammatory Toxicity	AEGT ATEZOLIZUMAB OCULAR INFLAMMATION TOXICITY)	X	X	X				
Immune-related Vasculitis	Vasculitis (SMQ) narrow	x	x	x				
Immune-related Hypophysitis	hypothalamic and pituitary disorders NEC (HLT)	x	x	x				
Immune-related Myocarditis	~~Noninfectious myocarditis (HLT), Noninfectious pericarditis(HLT), Cardiac failure (SMQ) narrow~~ AEGT Atezolizumab Myocarditis Immune Related	x	x	x				

AE of Special Interest	Definition	BO29563	BO29562	BO29561	BH29812	BH39147	GO29833	GO29834
Immune-related Severe Cutaneous Reaction	Severe cutaneous adverse reactions (SMQ) narrow	x	x	x				
Secondary malignancy	"Malignant or Unspecified Tumours"(2000009w), starting 6 months after the first study drug intake or later	x	x	x	x	x	x	x
Tumor Lysis Syndrome	PT: 'TUMOUR LYSIS SYNDROME'	x	x	x	x	x	x	x
Auto-Immune Hemolytic Anaemia	Haemolytic Disorders (SMQ) narrow	x	x	x				

PT = Preferred Term , HLT = High Level Term , HLGT = High Level Group Term , SOC = System Organ class, SMQ=Standard MedDRA Queries

For Atezo specific AESI (i.e. all categories of AESI listed in table except secondary malignancy and TLS) only AE with causality to Atezo suspected and onset on or after start of cycle 2 are considered.

6.3 Concomitant Medications

Outputs for concomitant medications will include any treatment reported on the "Concomitant Medications" form eCRF pages, with additional pages included as required per study. Prophylactic medication and premedication, such as anti-coagulant agents including aspirin and LMWHs, will be summarized separately.

6.3.1 Corticosteroids

For any analyses requiring identification of corticosteroids we will use the company standard 'corticosteroids' drug basket created by the Drug Basket Committee (DBC) at: http://we2.collaboration.roche.com/team/2012137a/SitePages/Default.aspx. We will use the full list of terms from this basket.

For atezolizumab contained studies, impact of steroids on atezolizumab and IRR prevention will be explored.

6.4 Laboratory Data

Laboratory data that have been obtained will be converted to System International (SI) units. Grading system will be from NCI-CTC version 4. Where normal ranges are required to be converted, the Roche References Ranges will be used (cf. gcp_spt000144). The grading will be defined as follows:

Project-specific Gradings:

Parameter	SI Unit	Grade 4 Low	Grade 3 Low	Grade 2 Low	Grade 1 Low
LYMPH	10**9/L	< 0.2	0.2 to < 0.5	0.5 to < 0.8	0.8 to < 1
NEUTR	10**9/L	< 0.5	0.5 to < 1	1 to < 1.5	1.5 to < 1.8
CRCL	mL/min	< 15	15 to < 30	30 to < 60	60 to < LLN

Parameter	SI Unit	Grade 1 High	Grade 2 High	Grade 3 High	Grade 4 High
LYMPH	10**9/L	-	> 4 to 20	> 20	-
NEUTR	10**9/L	-	-	-	-
CRCL	mL/min	-	-	-	-

6.4.1 Hematology and Chemistry Laboratory Data

Summary tables will be produced for the hematology and chemistry laboratory parameters (LBCAT=HEMATOLOGY, LBCAT=CHEMISTRY).

6.4.2 General Derivation Rules on Absolute Counts/Percentages

The laboratory parameters such as lymphocytes, eosinophils, basophils and monocytes might be recorded as absolute count or percentage in the eCRF. If on the same day and time, the absolute count

of the laboratory parameter is missing but the percentage is not missing, then the absolute count will be derived from the percentage to absolute count as follows:

ABSOLUTE_COUNT = PERCENTAGE x WBC, where WBC is white blood cell (LBTESTCD=WBC) and expressed as cells per microliter (LBSTRESU = 10^9/L, or 10^3/uL). Note that WBC values collected on the same date and time will be used in the derivation of absolute count. If the WBC value is missing on the same day and time then the absolute count of the laboratory parameter will also be missing.

Note: If a patient has multiple values of the same assessment on the same day and at the same time, the minimum values recorded will be retained for the calculation of the absolute counts.

6.4.3 Absolute Neutrophil Counts

Neutrophil count recovery is defined as absolute neutrophil count ANC $\geq 1.0 \times 10^9$/L, given ANC was collected after the patient has had his last dose of antibody, and ANC $< 1.0 \times 10^9$/L at the last previous visit before EOT. Neutrophil count recovery (ANC $\geq 1.0 \times 10^9$/L) should not be immediately followed by ANC $< 1.0 \times 10^9$/L, or a missing assessment, but only by ANC $\geq 1.0 \times 10^9$/L at the next visit.

VISIT 1	VISIT 2	VISIT 3	VISIT 4	OUTCOME
$< 1.0 \times 10^9$/L	$\geq 1.0 \times 10^9$/L	missing	missing	Not RECOVERED
$< 1.0 \times 10^9$/L	$\geq 1.0 \times 10^9$/L	$\geq 1.0 \times 10^9$/L	$< 1.0 \times 10^9$/L	RECOVERED
$< 1.0 \times 10^9$/L	$\geq 1.0 \times 10^9$/L	$< 1.0 \times 10^9$/L	$< 1.0 \times 10^9$/L	NOT RECOVERED
$< 1.0 \times 10^9$/L	$\geq 1.0 \times 10^9$/L	missing	$< 1.0 \times 10^9$/L	NOT RECOVERED

Time to neutrophil count recovery is defined as the number of days between the date of last dose of antibody and the date of single recovery. In case a patient was not depleted at last dose of antibody, no time to single recovery will be calculated. Where no ANC value occurs at the last drug intake, the next valid ANC assessment will be taken. For instance, ANC values at the EOT visit might be used instead if there is no ANC assessment on the day of the last dose of the antibody. If there are multiple ANC records at a visit, the last ANC assessment will be retained provided there is a valid identifier. If a study does not have a valid identifier, the lowest ANC value at the visit will be used instead.

6.4.4 Serum Creatinine Clearance

Serum creatinine clearance will be derived using the Cockcroft-Gault formula (where needed).

6.4.5 Hy's Law Cases

Patients with ALT > 3x BL OR AST > 3x BL AND Total Bilirubin >2xULN within 14 days, at any time for post baseline measurement, will be investigated for potential Hy's Law cases in a patient listing.

A summary table showing the proportion of patients with elevated ALT, AST, ALP and Total Bilirubin will also be produced.

6.4.6 B-Cell Depletion and Recovery

B-cell depletion is defined as CD19 B-cell count < $0.07x10^9$/L and can only occur after at least one dose of antibody has been administered.

Time to depletion is defined as the number of days between the first intake of study drug and the date of first depletion (assessments at study day 1 after start of the infusion are considered as after baseline).

Note that CD19 B-cells with no time record are assumed to be collected before the first treatment dose. Hence B-cells with no associated time that are collected on the same day as the last dose of the antibody will be assumed to be pre-dose.

6.4.6.1 B-cell recovery

B-cell recovery is defined as CD19 B-cell count >= 0.07x109/L, and B-cell was collected after LAA, the patient's B-cells were previously depleted and recovery is not followed exclusively by further depletion, i.e. B-cell recovery at a visit cannot be immediately followed by B-cell depletion, or a missing assessment, but only by recovery at the next visit. Assuming the situation 4 B-cell assessments at 4 visits:

VISIT 1	VISIT 2	VISIT 3	VISIT 4	OUTCOME
DEPLETED	RECOVERED	missing	missing	Not RECOVERED
DEPLETED	RECOVERED	RECOVERED	DEPLETED	RECOVERED
DEPLETED	RECOVERED	DEPLETED	DEPLETED	NOT RECOVERED
DEPLETED	RECOVERED	missing	DEPLETED	NOT RECOVERED

Time to B-cell recovery is defined as the number of days between the date of LAA and the date of single recovery. In case a patient was not depleted at last dose of antibody, no time to single recovery will be calculated. Where no CD19 value occurs at LAA, the next valid CD19 assessment will be taken. For instance, CD19 values at the EOT visit might be used instead if there is no CD19 assessment on the day of LAA. If there are multiple CD19 records at a visit, the last CD19 assessment will be retained provided there is a valid identifier. If a study does not have a valid identifier, the lowest CD19 value at the visit will be used instead.

The Nadir is the lowest absolute CD19 value for the patient across all visits after baseline (assessment at study day 1 after start of the infusion is considered as after baseline). The time to nadir is the study

day of the earliest occurrence of the nadir value. In case of consecutive visits with the same value, the earliest date of assessments will be used. The time to nadir will be calculated as the study day of the earliest occurrence of the nadir value.

The parameters to be summarized will be CD19 + B-cell depletion and recovery over time, time to depletion, duration of depletion, time to recovery, and time to follow up without recovery.

Disease progression will be taken into account in the summary of B-cell recovery: patients with PD before B-cell recovery or PD within 45 days after recovery will be accounted for in 'Recovery with PD'; other patients will accounted for in 'Recovery without PD'. Time to B-cell recovery will be summarized separately for all patients and for patients who were in response at the time of recovery (no PD before or within 45 days from recovery). Patients with PD before recovery or within 45 days after recovery will be censored at the minimum of progressive disease date and B-cell recovery date.

B-cell depletion and recovery will be assessed up to the first day of NALT. Missing CD19 values might be recorded as "NOT DONE" or ".".

6.4.7 T cell and NK cell counts

The summary of the mean (+/-SD) for the T cell (CD3, CD4, CD8) and NK cell counts (CD16 and CD56) will be shown over time in a figure where T-cell and NK-cell data are available.

6.4.8 PD-L1 (CD274), PD-1, B7-1(CD80)

The appropriate outputs, summary or listing, will be produced for studies with atezolizumab.

6.4.9 Pharmacokinetik Samples, HAHA, HACAand ATA

PK serum concentration of obinutuzumab, atezolizumab, lenalidomide, polatuzumab vedotin, venetoclax, Idasanutlin will be analysed. Immunogenicity to obinutuzumab, atezolizumab, Rituximab and polatuzumab vedotin will be explored analytically based on the immune response relative to the HAHA, HACA or ATA prevalence at baseline.

6.4.10 Immunoglobulins

6.4.10.1 Immunoglobulin Depletion and Recovery

Immunoglobulin depletion and recovery during follow up will be derived according to the following:

Lower immunoglobulin thresholds:

- IgA: 0.5 g/L
- IgM: 0.3 g/L
- IgG: 5 g/L

- **Depletion after Baseline:**
    - YES = (Lab value < Lower Threshold)
    - NO = (Lab value >= Lower Threshold)

- **Recovery:**
    - YES = (Lab value >= Lower Threshold), and the lab value was collected after the last dose of antibody and patient was previously depleted
    - NO = (Lab value < Lower Threshold) and the lab value was collected after the last dose of antibody and patient was previously depleted (only displayed for last value in patient listing)

Recovery (single) is the first recovery based on definition above which is not followed exclusively by further depletion i.e. recovery at a visit cannot be immediately followed by depletion, or a missing assessment, but only by recovery at the next visit. Time to single recovery is defined as the number of days between the date of last dose of antibody and date of single recovery. In case a patient was not depleted at the last dose of antibody no time to single recovery will be calculated. Where no immunoglobulin value occurs at the last dose of antibody, the next valid immunoglobulin assessment will be taken. If there are multiple immunoglobulin records at a visit, the last immunoglobulin assessment will be retained provided there is a valid identifier. If a study does not have a valid identifier, the lowest immunoglobulin value at the visit will be used instead. Recovery will be assessed up to the first day of NALT.

Analysis will be done separately for IgA, IgM and IgG. No time windows will be applied. Only visits with a valid date and non-missing values will be considered for the derivation of immunoglobulin recovery and depletion. Immunoglobulins with no associated time that are collected on the same day as the last dose of the antibody will be assumed to be pre-dose.

Descriptive statistics (n, mean, sd, median, range) will be produced at each timepoint where immunoglobulin values are available to describe the course of IgA, IgG and IgM.

An output will be produced to look at the proportion of patients with low immunoglobulin levels at each timepoint where immunoglobulin values are available.

7 Pharmacokinetic Analyses

PK analyses will be defined in a separate analysis plan.

8 Protocol Deviations

Major protocol deviations will be taken from the PDMS system. All major deviations from PDMS will be listed and summarized and will be reported in the CSR.

9 References

10 Output Template

This section will contain all output templates, including those produced by STREAM.

10.1 Output 1 Enrollment by Country and Investigator

Country, Investigator Number / Name	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Country 1	nn (xx.x%)	nn (xx.x%)
xxxxx / LastName, FirstName	nn (xx.x%)	nn (xx.x%)
xxxxx / LastName, FirstName	nn (xx.x%)	nn (xx.x%)
…		
Country 2	nn (xx.x%)	nn (xx.x%)
xxxxx / LastName, FirstName	nn (xx.x%)	nn (xx.x%)
…		

Programming notes:

1. Analysis population: ITT
2. Template ID: ENT02
3. Program name: T_EN

10.2 Output 2 Patient Disposition

Status	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Alive on Induction Phase	nn (xx.x%)	nn (xx.x%)
Alive on Maintenance/Consolidation Phase	nn (xx.x%)	nn (xx.x%)
Alive in follow-up	nn (xx.x%)	nn (xx.x%)
Discontinued study	nn (xx.x%)	nn (xx.x%)
Reason 1	nn (xx.x%)	nn (xx.x%)
Reason 2	nn (xx.x%)	nn (xx.x%)
Reason 3	nn (xx.x%)	nn (xx.x%)
Reason 4	nn (xx.x%)	nn (xx.x%)
…	nn (xx.x%)	nn (xx.x%)

Programming notes:

1. Analysis population: ITT
2. Template ID: DST01
3. Program name: T_DS
4. CRF: Study Drug Administration, Maintenance Phase Completion, Consolidation Phase Completion, Study Drug Discontinuation
5. Alive on induction phase: subject took at least one dose of study medicine and was on induction phase (at least one study treatment Induction Phase Completion or discontinuation was **not** recorded AND study treatment discontinuation was **not** recorded on eCRF)
6. Alive on maintenance/consolidation phase: subject took at least one dose of study medicine on maintenance/consolidation phase and was on maintenance/consolidation phase (at least one maintenance study treatment discontinuation was **not** recorded and study discontinuation was **not** recorded on eCRF)
7. Alive in follow-up: all study treatment discontinuation was recorded but study discontinuation was **not** recorded on eCRF
8. Discontinued study: study discontinuation was recorded on eCRF
9. For BH29812, no maintenance/consolidation for DLBCL patients

10.3 Output 3 Analysis Populations

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
ITT (Enrolled Population)		
Safety Evaluable Population		
Total Exclusions		
Reason 1		
Reason 2		
Efficacy Evaluable Population		
Total Exclusions		
Reason 1		
Reason 2		

10.4 Output 4 Listing of Patients Excluded from Analysis Populations

Center/ Patient ID	Age/Sex/Race	Population Excluded From	Reason
[redacted]	[redacted]		

10.5 Output 5 Study Drug Completion Status and Reasons of Withdrawals from Study Drug

Status	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Induction Phase		
Discontinued study drug 1	nn (xx.x%)	nn (xx.x%)
Reason 1	nn (xx.x%)	nn (xx.x%)
Reason 2	nn (xx.x%)	nn (xx.x%)
Reason 3	nn (xx.x%)	nn (xx.x%)
Reason 4	nn (xx.x%)	nn (xx.x%)
…	nn (xx.x%)	nn (xx.x%)
Discontinued study drug 2	nn (xx.x%)	nn (xx.x%)
Reason 1	nn (xx.x%)	nn (xx.x%)
Reason 2	nn (xx.x%)	nn (xx.x%)
…	nn (xx.x%)	nn (xx.x%)
…		
Maintenance/Consolidation Phase		
Discontinued study drug 1	nn (xx.x%)	nn (xx.x%)
Reason 1	nn (xx.x%)	nn (xx.x%)
Reason 2	nn (xx.x%)	nn (xx.x%)
…	nn (xx.x%)	nn (xx.x%)

Programming notes:

1. Analysis population: Safety
2. Template ID: DST01
3. Program name: T_DS_DRG
1. CRF: Study Drug Administration

10.6 Output 6 Duration on Treatment and Follow-up

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Duration on Treatment (months)		
n	nnn	nnn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min–max	xx–xx	xx–xx
Duration of Study Period (months)		
n	nnn	nnn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min–max	xx–xx	xx–xx

Duration on Treatment was calculated as time from the first dose date until the last dose date + 1 day. Patients without any study medication were excluded.
Duration of Study Period was calculated as time from the first dose date to the last dates the patients were known to be alive or their death dates if died + 1 day.
Programing notes:

1. Analysis population: Safety
2. Template ID: DMT01
3. Program name: T_DS_DUR
4. Use descriptive method
5. CRF: Study Drug Administration
6. Duration of study period: Patients for whom no death is captured on the clinical database use the date they were known to be alive (see Section 2.3.7).

Output 7 Listing of Patients Who Discontinued Early from Study Drug

Center/ Patient ID	Age/Sex/Race	Drug*	Date of First Study Drug Administration	Day of Last Study Drug Administration	Day of Study Discontinuation*	Reason for Discontinuation from study drug*	Reason for Discontinuation from study
[redacted]		Treatment1	[redacted]	12	14	Adverse event	Adverse event
		Treatment2		36	65	Lost to follow-up	Lost to follow-up
		Treatment3		36	65	Lost to follow-up	Lost to follow-up

Programing notes:

1. Analysis population: Safety
2. Template ID: DSL02
3. Program name: L_DS_DRG
4. Reason for Discontinuation from study: leave blank if a patient discontinued from study drug but not discontinued from study
5. Date of first study drug administration: use the first date of any drug
6. Day of last study drug administration: use the day for the certain drug
7. *：one line for each drug

10.8 Output 8 Major Protocol Deviations

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)			
Total number of patients with at least one major Protocol Deviation	nn (xx.x%)	nn (xx.x%)			
Total number of major protocol deviations	nn	nn			
Inclusion Criteria					
Age criteria	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Exclusion Criteria					
Pregnancy criteria	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Sodium > 180mg	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)
Procedural					
Incorrect dose	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)	nn (xx.x%)

Programing notes:

1. Analysis population: ITT
2. Template ID: PDT01
3. Program name: T_DV

10.9 Output 9 Listing of Major Protocol Deviations

Center/ Patient ID	Age/Sex/Race	Category	Subcategory
[redacted]			
…			

Programing notes:

1. Analysis population: ITT
2. Program name: L_DV

10.10 Output 10 Demographics and Baseline Characteristics

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Age (yr)		
n	nnn	nnn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min–max	xx–xx	xx–xx
Age group (yr)		
n	nnn	nnn
18–40	nn (xx.x%)	nn (xx.x%)
41–64	nn (xx.x%)	nn (xx.x%)
≥65	nn (xx.x%)	nn (xx.x%)
Sex		
n	nnn	nnn
Male	nn (xx.x%)	nn (xx.x%)
Female	nn (xx.x%)	nn (xx.x%)
Weight (kg) at baseline		
n	nnn	nnn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min–max	xx–xx	xx–xx
Height (cm) at baseline		
n	nnn	nnn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min–max	xx–xx	xx–xx
ECOG Category at baseline		
n	nnn	nnn
0	nn (xx.x%)	nn (xx.x%)
>=1	nn (xx.x%)	nn (xx.x%)
...		
...		

Programming notes:

1. Analysis population: ITT
2. Template ID: DMT01
3. Program name: T_DM
4. CRF: Demographics, ECOG Performance Status, Vital Signs
5. See section 4.1 for identifying further variables that may be included in this output.

10.11 Output 11 Baseline Disease Characteristics and Prognostic Markers

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Duration since initial diagnosis* (months)		
n	nn	nn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min–max	xx–xx	xx–xx
Ann Arbor Stage at initial diagnosis		
n	nn	nn
Stage 1	nn (xx.x%)	nn (xx.x%)
Stage 2	nn (xx.x%)	nn (xx.x%)
Stage 3	nn (xx.x%)	nn (xx.x%)
Stage 4	nn (xx.x%)	nn (xx.x%)
Initial FL grade**		
n	nn	nn
Grade 1	nn (xx.x%)	nn (xx.x%)
Grade 2	nn (xx.x%)	nn (xx.x%)
Grade 3a	nn (xx.x%)	nn (xx.x%)
Ungraded	nn (xx.x%)	nn (xx.x%)
Duration since diagnosis at study entry* (months)		
n	nn	nn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min–max	xx–xx	xx–xx
Ann Arbor Stage at study entry		
n	nn	nn
Stage 1	nn (xx.x%)	nn (xx.x%)
Stage 2	nn (xx.x%)	nn (xx.x%)
Stage 3	nn (xx.x%)	nn (xx.x%)
Stage 4	nn (xx.x%)	nn (xx.x%)
FL Grade at study entry**		
n	nn	nn
Grade 1	nn (xx.x%)	nn (xx.x%)
Grade 2	nn (xx.x%)	nn (xx.x%)
Grade 3a	nn (xx.x%)	nn (xx.x%)
Ungraded	nn (xx.x%)	nn (xx.x%)
Prior anti-lymphoma therapy		
N	nn	nn

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Yes	nn (xx.x%)	nn (xx.x%)
No	nn (xx.x%)	nn (xx.x%)
Lines of prior anti-lymphoma therapy		
N	nn	nn
1	nn (xx.x%)	nn (xx.x%)
2	nn (xx.x%)	nn (xx.x%)
>=3	nn (xx.x%)	nn (xx.x%)
Prior anti-CD20 agents		
N	nn	nn
Yes	nn (xx.x%)	nn (xx.x%)
No	nn (xx.x%)	nn (xx.x%)
Prior autologous stem cell transplant		
N	nn	nn
Yes	nn (xx.x%)	nn (xx.x%)
No	nn (xx.x%)	nn (xx.x%)
Prior cancer radiotherapy		
N	nn	nn
Yes	nn (xx.x%)	nn (xx.x%)
No	nn (xx.x%)	nn (xx.x%)
Total number of risk factors for IPI at initial Diagnosis (DLBCL)***		
N	nn	nn
Low (0 to 2)	nn (xx.x%)	nn (xx.x%)
High (3 to 5)	nn (xx.x%)	nn (xx.x%)
Total number of risk factors for IPI at study entry (DLBCL)***		
N	nn	nn
Low (0 to 2)	nn (xx.x%)	nn (xx.x%)
High (3 to 5)	nn (xx.x%)	nn (xx.x%)
Total number of risk factors for FLIPI at initial Diagnosis (FL)**		
N	nn	nn
Low (0 or 1)	nn (xx.x%)	nn (xx.x%)
Intermediate (2)	nn (xx.x%)	nn (xx.x%)
High (3 to 5)	nn (xx.x%)	nn (xx.x%)
Total number of risk factors for FLIPI at study entry (FL)***		

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
N	nn	nn
Low (0 or 1)	nn (xx.x%)	nn (xx.x%)
Intermediate (2)	nn (xx.x%)	nn (xx.x%)
High (3 to 5)	nn (xx.x%)	nn (xx.x%)
Total number of risk factors for FLIPI2 at initial Diagnosis (FL)**		
N	nn	nn
Low (0 or 1)	nn (xx.x%)	nn (xx.x%)
Intermediate (2)	nn (xx.x%)	nn (xx.x%)
High (3 to 5)	nn (xx.x%)	nn (xx.x%)
Total number of risk factors for FLIPI2 at study entry (FL)***		
N	nn	nn
Low (0 or 1)	nn (xx.x%)	nn (xx.x%)
Intermediate (2)	nn (xx.x%)	nn (xx.x%)
High (3 to 5)	nn (xx.x%)	nn (xx.x%)
B-Symptom: unexplained fever greater than 38 degree C		
N	nn	nn
Yes	nn (xx.x%)	nn (xx.x%)
No	nn (xx.x%)	nn (xx.x%)
B-Symptom: night sweats		
N	nn	nn
Yes	nn (xx.x%)	nn (xx.x%)
No	nn (xx.x%)	nn (xx.x%)
B-Symptom: unexplained weight loss greater than 10% in less than or equal 6 months		

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
N	nn	nn
Yes	nn (xx.x%)	nn (xx.x%)
No	nn (xx.x%)	nn (xx.x%)
SPD		
n	nnn	nnn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min–max	xx–xx	xx–xx
Bulk Disease		
n	nnn	nnn
Yes	nn (xx.x%)	nn (xx.x%)
No	nn (xx.x%)	nn (xx.x%)
LDH		
n	nnn	nnn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min–max	xx–xx	xx–xx
Bone marrow involvement		
n	nnn	nnn
Yes	nn (xx.x%)	nn (xx.x%)
No	nn (xx.x%)	nn (xx.x%)

Programming notes:

1. Analysis population: ITT
2. Template ID: DMT01
3. Program name: T_DM_HIS
4. *Duration since initial diagnosis : time from date of initial histological diagnosis to date of first study drug
5. *Duration since diagnosis at study entry : time from date of diagnosis at study entry to date of first study drug
6. Generate this output for DLBCL and FL respectively (**: only applicable for FL groups, ***: only applicable for DLBCL groups)
7. Lines of prior anti-lymphoma chemotherapy: maximum lines of anti-lymphoma therapy
8. CRF: NHL history, NHL prognostic factors, prior anti-lymphoma therapy, prior anti-CD20 agents, prior autologous stem cell transplant, prior anti-lymphoma radiotherapy
9. Further variables that may be included here are listed in section 4.2

Note: For FLIPI/IP category, follow study SMT instruction if different from the mockup.

10.12 Output 12 Peripheral Neuropathy History

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Patients with history of peripheral neuropathy		
n	nn	nn
Status of peripheral neuropathy		
n	nn	nn
Resolved	nn (xx.x%)	nn (xx.x%)
Ongoing with treatment	nn (xx.x%)	nn (xx.x%)
Ongoing without treatment	nn (xx.x%)	nn (xx.x%)
Type of peripheral neuropathy		
n	nn	nn
Sensory only	nn (xx.x%)	nn (xx.x%)
Motor only	nn (xx.x%)	nn (xx.x%)
Sensory and motor	nn (xx.x%)	nn (xx.x%)
Unable to determine	nn (xx.x%)	nn (xx.x%)

Programming notes:

1. Analysis population: ITT
2. Template ID: DMT01
3. Program name: T_PN
4. CRF: Peripheral Neuropathy Medical History and Baseline Conditions
5. Status of PN: If a patient had more than one record, the status will be determined according to the sequence: Ongoing with treatment, ongoing without treatment, and then resolved.
6. Type of PN: If a patient had more than one record, the type of PN should include all the types which were presented in each record.
7. **This output is only applied to studies with polatuzumab or lenalidomide.**

10.13 Output 13 Medical History

MedDRA System Organ Class MedDRA Preferred Term	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Total number of patients with at least one condition	nn (xx.x%)	nn (xx.x%)
Overall total number of conditions	nn	nn
VASCULAR DISORDERS		
Total number of patients with at least one condition	nn (xx.x%)	nn (xx.x%)
HYPERTENSION	nn (xx.x%)	nn (xx.x%)
VARICOSE VEINS	nn (xx.x%)	nn (xx.x%)
…		
Total number of conditions	nn	nn
…		

Investigator text for medical history conditions coded using MedDRA version xx.x.
Percentages are based on N in the column headings.

Programming notes:

1. Analysis population: ITT
2. Template ID: MHT01
3. Program name: T_MH
4. CRF: General Medical History and Baseline Conditions

10.14 Output 14 Listing of Previous Systemic Anti-lymphoma Therapy

Center/ Patient ID	Age/Sex/Race	Line of Therapy	Chemotherapy Regimen	Chemotherapy Cycles	First Agent Day	Last Agent Day	Best Response	PD	Anti-CD20 Agent	Abti-CD20 Dose	Autologous Stem Cell Transplant
[redacted]		1st	CHOP	6			CR	YES	Rituximab		YES

Programming notes:

1. Analysis population: ITT
2. Program name: l_cm
3. CRF: Prior anti-lymphoma therapy, prior anti-CD20 agents, prior autologous stem cell transplant

10.15 Output 15 Previous Systemic Anti-lymphoma Therapy

Total number of patients with at least one treatment	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Anti-lymphoma Therapy Backbone		
Total number of patients with at least one treatment	nn (xx.x%)	nn (xx.x%)
Total number of treatments	nnn	nnn
XXXXXXX	nn (xx.x%)	nn (xx.x%)
YYYYYYY	nn (xx.x%)	nn (xx.x%)
ZZZZZZZZ	nn (xx.x%)	nn (xx.x%)
…		
Anti-CD20 as Induction Treatment		
Total number of patients with at least one treatment	nn (xx.x%)	nn (xx.x%)
Total number of treatments	nnn	nnn
XXXXXXX	nn (xx.x%)	nn (xx.x%)
YYYYYYY	nn (xx.x%)	nn (xx.x%)
ZZZZZZZZ	nn (xx.x%)	nn (xx.x%)
…		
Anti-CD20 as Induction and Maintenance Treatment		
Total number of patients with at least one treatment	nn (xx.x%)	nn (xx.x%)
Total number of treatments	nnn	nnn
XXXXXXX	nn (xx.x%)	nn (xx.x%)
YYYYYYY	nn (xx.x%)	nn (xx.x%)
ZZZZZZZZ	nn (xx.x%)	nn (xx.x%)
Autologous Stem Cell Transplant		
Total number of patients with at least one treatment	nn (xx.x%)	nn (xx.x%)
Total number of treatments	nnn	nnn
Autologous Stem Cell Transplant	nn (xx.x%)	nn (xx.x%)

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.

Programming notes:

1. Analysis population: ITT
2. Program name: T_PALT
3. CRF: Prior anti-lymphoma therapy, prior anti-CD20 agents, prior autologous stem cell transplant

10.16 Output 16 Response to Previous Systemic Anti-lymphoma Therapy

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Lines of prior anti-lymphoma therapy		
n	nn	nn
Mean (SD)	x.x (x.x)	x.x (x.x)
Median	x.x	x.x
25th-75th	x.x-x.x	x.x-x.x
Min-Max	x-x	x-x
Refractory to last prior anti-CD20 agents*		
n	nn (xx.x%)	nn (xx.x%)
Yes	nn (xx.x%)	nn (xx.x%)
No	nn (xx.x%)	nn (xx.x%)
Refractory to last prior anti-lymphoma therapy**		
n	nn (xx.x%)	nn (xx.x%)
Yes	nn (xx.x%)	nn (xx.x%)
No	nn (xx.x%)	nn (xx.x%)
Time from last prior anti-lymphoma therapy (days)***		
n	nn	nn
Mean (SD)	x.x (x.x)	x.x (x.x)
Median	x.x	x.x
25th-75th	x.x-x.x	x.x-x.x
Min-Max	x-x	x-x

* Defined as no response or progression on or relapse within 6 months of last anti-lymphoma therapy among patients whose last prior regimen contained anti-CD20

** Defined as no response or progression on or relapse within 6 months of last anti-lymphoma therapy

*** Defined as time from end date of last anti-lymphoma therapy to first dose date

Programming notes:

1. Analysis population: ITT
2. Program name: T_PALT_R

10.17 Output 17 Listing of Follow-up New Anti-lymphoma Therapy

Center/ Patient ID	Age/Sex/Race	Line of Therapy	Regimen	Last Study Dose Day	First Agent Day	Last Agent Day	Anti-CD20 Agent	Surgery/Procedure description	Site	Surgery/Procedure Day
[redacted]		1st	CHOP				Rituximab			

Programming notes:

1. Analysis population: Safety
2. Program name: L_PALT
3. CRF: Follow-up New Anti-Lymphoma Therapy, Regimen

10.18 Output 18 Follow-up New Anti-lymphoma Therapy

Total number of patients with at least one treatment	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Chemotherapy		
Total number of patients with at least one treatment	nn (xx.x%)	nn (xx.x%)
Total number of treatments	nnn	nnn
XXXXXXX	nn (xx.x%)	nn (xx.x%)
YYYYYYY	nn (xx.x%)	nn (xx.x%)
ZZZZZZZZ	nn (xx.x%)	nn (xx.x%)
…		
Anti-CD20		
Total number of patients with at least one treatment	nn (xx.x%)	nn (xx.x%)
Total number of treatments	nnn	nnn
XXXXXXX	nn (xx.x%)	nn (xx.x%)
YYYYYYY	nn (xx.x%)	nn (xx.x%)
ZZZZZZZZ	nn (xx.x%)	nn (xx.x%)
…		
Autologous Stem Cell Transplant		
Total number of patients with at least one treatment	nn (xx.x%)	nn (xx.x%)
Total number of treatments	nnn	nnn
Autologous Stem Cell Transplant	nn (xx.x%)	nn (xx.x%)

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.

Programming notes:

1. Analysis population: Safety
2. Program name: T_NALT
3. CRF: Follow-up New Anti-Lymphoma Therapy, Regimen
4. Provide two separate outputs if necessary: Anti-Lymphoma Treatments Administered Before Progression and Anti-Lymphoma Treatments Administered After Progression

10.19 Output 19 Concomitant Medication

Class Other Treatment	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Total number of patients with at least one treatment	nn (xx.x%)	nn (xx.x%)
Total number of treatments	nnn	nnn
CORTICOSTEROIDS		
Total number of patients with at least one treatment	nn (xx.x%)	nn (xx.x%)
PREDNISONE	nn (xx.x%)	nn (xx.x%)
PREDNISOLONE	nn (xx.x%)	nn (xx.x%)
…		
Total number of treatments	nnn	nnn

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.

Programming notes:

1. Analysis population: Safety
2. Template ID: CMT01
3. Program name: T_CM
4. CRF: Concomitant medication
5. Concomitant treatments are defined as any medication starting on or after the first day of study treatment

10.20 Output 20 Previous-Concomitant Medications

Programming notes:

1. Analysis population: Safety
2. Template ID: CMT01
3. Program name: T_PCM
4. CRF: Concomitant medication
5. Previous-Concomitant treatments are any medication started before study treatment start and ending after the start of study treatment

10.21 Output 21 Previous Medications

Programming notes:

1. Analysis population: Safety
2. Template ID: CMT01
3. Program name: T_PM
4. CRF: Concomitant medication
5. Previous treatments are defined as all treatments with an end date occurring before date of first study treatment.

10.22 Output 22 Surgery and Procedure History

Class Other Treatment	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Total number of patients with at least one surgery and procedure	nn (xx.x%)	nn (xx.x%)
Total number of surgery and procedure	nnn	nnn
Total number of patients with at least one surgery and procedure	nn (xx.x%)	nn (xx.x%)
XXXXXXXX	nn (xx.x%)	nn (xx.x%)
XXXXXXXX	nn (xx.x%)	nn (xx.x%)
…		
Total number of surgery and procedure	nnn	nnn

Programming notes:

1. Analysis population: Safety
2. Template ID: CMT01
3. Program name: T_XP
4. CRF: Surgery and Procedure History

10.23 Output 23 Glossary of Superclass terms, Preferred Terms and Verbatim Terms for Concomitant Medications

Medication Class	Standardized Term	Verbatim Term
XXXXXXXXXXXXX		
	XXXXXXXXXXXX	XXXXXXXXXXXX
		XXXXXXXXXXXX
	XXXXXXXXXXXX	XXXXXXXXXXXX
	XXXXXXXXXXXX	XXXXXXXXXXXX
	XXXXXXXXXXXX	XXXXXXXXXXXX
		XXXXXXXXXXXX
		XXXXXXXXXXXX
	XXXXXXXXXXXX	XXXXXXXXXXXX
		XXXXXXXXXXXX
	XXXXXXXXXXXX	XXXXXXXXXXXX
XXXXXXXXXXXXX		
	XXXXXXXXXXXX	XXXXXXXXXXXX
	XXXXXXXXXXXX	XXXXXXXXXXXX

Programming notes:

1. Template ID: AEL01
2. Program name: L_CM
3. CRF: Concomitant medication
4. Including previous, previous-concomitant, and concomitant medications

10.24 Output 24 Listing of Study Drug Exposure

Center/ Patient ID	Age/Sex/Race	Date of First Study Drug Administration	Cycle	Treatment	Start Day	End Day	Dose	Unit	Reason for Dose Adjustment
[redacted]			1	Study drug 1	x	x	xx	xx	Adverse event
				Study drug 2	x	x	xx	xx	
				Study drug 3	x	x	xx	xx	
			n	xx	nn	nn	xx	xx	

Programming notes:

1. Analysis population: Safety
2. Program name: L_EX
3. CRF: study drug administration
4. For BO29563 and BO29561 display visit label instead of Cycle

10.25 Output 25 Study Drug Exposure during Induction Phase

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Study Drug 1		
Treatment duration (months)		
n	nnn	nnn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min–max	xx–xx	xx–xx
Number of cycles		
n	nnn	nnn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min–max	xx–xx	xx–xx
Treatment duration (Cycles)		
n	nnn	nnn
1–6	nn (xx.x%)	nn (xx.x%)
7-12	nn (xx.x%)	nn (xx.x%)
13-18	nn (xx.x%)	nn (xx.x%)
19-24	nn (xx.x%)	nn (xx.x%)
>=25	nn (xx.x%)	nn (xx.x%)
Total number of dose		
n	nnn	nnn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx	xx
Min–max	xx–xx	xx–xx
Total cumulative dose (mg)		
n	nnn	nnn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min–max	xx–xx	xx–xx
Dose intensity (%) adjusted for dose modification and delay		
n	nnn	nnn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min–max	xx–xx	xx–xx
Study Drug 2		
Study Drug 3		

Treatment duration is the date of the last dose of study medication minus the date of the first dose plus 1 day.

Dose intensity (%) is the cumulative total dose actually received up to the last cycle actually received divided by the expected dose up to the last time point when any component of study medication was actually received.

Programming notes:

1. Analysis population: Safety
2. Template ID: EXT01
3. Program name: T_EX_IN
4. Treatment duration (days)=(date of last dose-date of first dose)+**1**
5. Treatment cycles: based on the actual cycles
6. Exposure by Cycle is optional

10.26 Output 26 Study Drug Exposure During Maintenance/Consolidation Phase

Programming notes:

1. Analysis population: Safety
2. Template ID: EXT01
3. Program name: T_EX_MC
4. Treatment duration (days)=(date of last dose-date of first dose)+**1**
5. Treatment cycles: based on the actual cycles
6. Exposure by Cycle is optional.

10.27 Output 27 Glossary of Adverse Event Preferred Terms and Investigator-Specified Terms

MedDRA System Organ Class	MedDRA Preferred Term	Investigator-Specified Adverse Event Term
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA NOS	ANAEMIA
		ANEMIA
	LEUCOCYTOSIS NOS	LEUKOCYTOSIS
	LEUCOPENIA NOS	LEUKOPENIA
	LYMPHADENOPATHY	NECROTIC LYMPH NODE
		SWOLLEN GLANDS IN THROAT
		SWOLLEN THROAT GLANDS
	FEBRILE NEUTROPENIA	FEBRILE NEUTROPENIA
		NEUTROPENIC FEVER
	NEUTROPENIA	NEUTROPENIA
CARDIAC DISORDERS	CARDIOMYOPATHY NOS	CARDIOMYOPATHY
	CONGESTIVE (DILATED) CARDIOMYOPATHY	DILATED CARDIOMYOPATHY
	ANGINA PECTORIS	ANGINA PECTORIS

Programming notes:

1. Template ID: AEL01
2. Program name: L_AE_PT

10.28 Output 28 Listing of Adverse Events

Center/Patient ID- Age/Sex/Race MedDRA Preferred Term	Date of First Study Drug Administration	Study Day of Onset	AE Duration in Days	Most Extreme CTC Grade	Outcome (1)	Treatment for AE	Relation to Study drug	Action with Study drug (2)	Reason Classified as Serious (3)
nnnnnn/nnnnn-nn/x/x xxxxxxxxxxx*	nnxxxnnnn	nn	12	4	2	xxx	A:No, G:No, V:Yes	A:3, G:2, V:3	n

*: SAE (1) Outcome: 1 = fatal; 2 = not recovered/not resolved; 3 = recovered/resolved; 4 = recovered/resolved with sequelae; 5 = recovering/resolving; 6 = unknown.

(2) Action taken with study drug: 1 = dose not changed; 2 = dose reduced; 3 = drug interrupted; 4 = drug withdrawn; 5 = not applicable; 6 = unknown.

(3) Reason classified as serious: 1 = resulted in death; 2 = life threatening; 3 = required prolonged in patient hospitalization; 4= disabling; 5 = a congenital anomaly/birth defect in offspring of study subject; 6 = does not meet any of the above serious criteria, but may jeopardize the subject, and may require medical or surgical intervention to prevent one of the outcomes listed above.

Relation to Study Drug & Action with Study drug: A = Atezolizumab; G = GA101; V = Venetoclax;

Programming notes:

1. Analysis population: Safety
2. Template ID: AEL02
3. Program name: L_AE
4. The final footnote is dependent on which study drugs are given

10.29 Output 29 Listing of Serious Adverse Events

Programming notes:

1. Analysis population: Safety
2. Template ID: AEL02
3. Program name: L_AES

10.30 Output 30 Listing of Grade 3, 4, 5 Adverse Events

Programming notes:

1. Analysis population: Safety
2. Template ID: AEL02
3. Program name: L_AE345

10.31 Output 31 Listing of Adverse Events Leading to Discontinuation of Any Study Drug

Programming notes:

1. Analysis population: Safety
2. Template ID: AEL02
3. Program name: L_AEW

10.32 Output 32 Listing of Adverse Events Leading to Dose Modification or Interruption of Any Study Drug

Programming notes:

1. Analysis population: Safety
2. Template ID: AEL02
3. Program name: L_AEM

10.33 Output 33 Listing of Adverse Events Leading to Death

Programming notes:

1. Analysis population: Safety
2. Template ID: AEL02
3. Program name: L_AED

10.34 Output 34 Listing of Potential Adverse Events of Special Interest

Programming notes:

1. Analysis population: Safety
2. Template ID: AEL02
3. Program name: L_AESI
4. Definition: see Table in 6.2.2 Selected AEs and Potential AE of Special Interest

Note: For BO29561-3 an additional listing based on AESI ticked on eCRF AESI page will be created. AESI will be summarized by tickbox categories. Only AESI with causality to Atezo suspected and onset >= cycle 2 start will be included.

10.35 Output 35 Listing of Selected Adverse Events

Programming notes:

1. Analysis population: Safety
2. Template ID: AEL02
3. Program name: L_AESE
4. Definition of selected AE (see table in section 6.2.2)

Note: listing 34 and 35 may be combined depending on individual studies. The title becomes "Listing of Adverse Events of Selected and Special Interest"

10.36 Output 36 Safety Summary

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Total number of AEs	nn	nn
Total number of patients with at least one		
AE	nn (xx.x%)	nn (xx.x%)
Grade 5 AE	nn (xx.x%)	nn (xx.x%)
Grade 3-5 AE	nn (xx.x%)	nn (xx.x%)
Serious AE	nn (xx.x%)	nn (xx.x%)
AE leading to any study treatment discontinuation	nn (xx.x%)	nn (xx.x%)
AE leading to dose reductions		
AE leading to drug interruptions		
AE leading to study discontinuation	nn (xx.x%)	nn (xx.x%)
Related to Drug 1 AE	nn (xx.x%)	nn (xx.x%)
Related to Drug 1 Grade 3-5AE	nn (xx.x%)	nn (xx.x%)
Related to Drug 1 SAE	nn (xx.x%)	nn (xx.x%)
Related to Drug 2 AE	nn (xx.x%)	nn (xx.x%)
Related to Drug 2 Grade 3-5 AE	nn (xx.x%)	nn (xx.x%)
Related to Drug 2 SAE	nn (xx.x%)	nn (xx.x%)
Related AE (to at least one treatment) leading to study treatment discontinuation (of all treatments)	nn (xx.x%)	nn (xx.x%)
~~Related AE (to at least one treatment) leading to study discontinuation~~	~~nn (xx.x%)~~	~~nn (xx.x%)~~

Investigator text for AEs encoded using MedDRA version xx.x. Percentages are based on N in the column headings. Includes AEs with onset from first dose of study drug through XX days after last dose of study drug

Programming notes:

1. Analysis population: Safety
2. Template ID: AET01
3. Program name: T_AE_OSAFE
4. Reporting period: All adverse events will be reported until XX days (study specific) after the last dose of study treatment. An exception is Grade 3 and 4 infections (both related and unrelated), which should be reported until up to 2 years after the last dose of study treatment. *Study BO29562:* An exception is secondary malignancies (both related and unrelated), which should be reported until up to 6months after the last dose of lenalidomide.
5. **All the following safety outputs will be produced by study phase**

10.37 Output 37 Adverse Events

MedDRA System Organ Class MedDRA Preferred Term	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Total number of patients with at least one AE	nn (xx.x%)	nn (xx.x%)
Overall total number of AEs	nn	nn
SOC 1		
Total number of patients with at least one AE event	nn (xx.x%)	nn (xx.x%)
PT 1	nn (xx.x%)	nn (xx.x%)
PT 2	nn (xx.x%)	nn (xx.x%)
PT 3	nn (xx.x%)	nn (xx.x%)
PT 4	nn (xx.x%)	nn (xx.x%)
Total number of events	nn	nn
SOC 2		
Total number of patients with at least one AE	nn (xx.x%)	nn (xx.x%)
PT 1	nn (xx.x%)	nn (xx.x%)
PT 2	nn (xx.x%)	nn (xx.x%)
PT 3	nn (xx.x%)	nn (xx.x%)
PT 4	nn (xx.x%)	nn (xx.x%)
Total number of events	*nn*	nn
…		

Investigator text for AEs encoded using MedDRA version **xx.x**. Percentages are based on N in the column headings. Includes AEs with onset from first dose of study drug through xx days after last dose of study drug

Programming notes:

1. Analysis population: Safety
2. Template ID: AET02
3. Program name: T_AE

10.38 Output 38 Grade 3, 4, 5 Adverse Events

Programing notes:

1. Analysis population: Safety
2. Template ID: AET02
3. Program name: T_AE345

10.39 Output 39 Serious Adverse Events

Programing notes:

1. Analysis population: Safety
2. Template ID: AET02
3. Program name: T_AES

10.40 Output 40 Adverse Events Leading to Discontinuation of Any Study Drug

Programing notes:

1. Analysis population: Safety
2. Template ID: AET02
3. Program name: T_AEW

10.41 Output 41 Potential Adverse Events of Special Interest

Programing notes:

1. Analysis population: Safety
2. Template ID: AET02
3. Program name: T_AESPECIAL
4. Summarized by AESI category (see table 6.2.2)

Note: "Adverse events of special interest" may be combined with "Selected Adverse Events".

Note: For BO29561-3 an additional summary based on AESI ticked on eCRF AESI page will be created. AESI will be summarized by tickbox categories. Only AESI with causality to Atezo suspected and onset >= cycle 2 will be included.

10.42 Output 42 Selected Adverse Events

Programing notes:

1. Analysis population: Safety
2. Template ID: AET02
3. Program name: T_AESELECT
4. Summarized by AESI category (SMQ) and Preferred Term

Note: "Adverse events of special interest" may be combined with "Selected Adverse Events".

10.43 Output 43 Categorical Summary of Adverse Events of Special Interest

	Treatment Group 1 (N = xx)
No. of patients with at least one AE	xx (xx %)
No. of patients with grade 1 AEs	xx (xx %)
No. of patients with grade 2 AEs	xx (xx %)
No. of patients with grade 3 AEs	xx (xx %)
No. of patients with grade 4 AEs	xx (xx %)
No. of patients with grade 5 AEs	xx (xx %)
No. of patients with missing grade AEs	xx (xx %)
No. of patients with serious AE	xx (xx %)
Total No. of AEs	xx
No. of grade 1 AEs	xx
No. of grade 2 AEs	xx
No. of grade 3 AEs	xx
No. of grade 4 AEs	xx
No. of grade 15 AEs	xx
No. of AEs with missing grade	xx
No. of serious AEs	xx
No. of AEs with missing seriousness	xx
Total No. of patients with at least one AE:	xx
No. of patients with ant body dose interrupted due to AE	xx (xx %)
No. of patients with ant body withdrawn due to AE	xx (xx %)
No. of patients with atezolizumab interrupted due to AE	xx (xx %)
No. of patients with atezolizumab withdrawn due to AE	xx (xx %)
	xx (xx %)
No. of patients with chemotherapy dose reduced due to AE	xx (xx %)
No. of patients with chemotherapy interrupted due to AE	xx (xx %)
No. of patients with chemotherapy withdrawn due to AE	xx (xx %)
	xx (xx %)
No. of patients with any treatment dose reduced due to AE	xx (xx %)
No. of patients with any treatment interrupted due to AE	xx (xx %)
No. of patients with any treatment withdrawn due to AE	xx (xx %)
No. of patients with at least one AE unresolved or ongoing	xx (xx %)
No. of patients with treatment received for AE	xx (xx %)
No. of patients without treatment received for AE	xx (xx %)

Percentages are based on the number of patients with at least one AE (except the first block of the output where the percentages are based on N).

When calculating the number of patients with AEs of a specific grade only the highest AE grade per patient is taken into account.

All occurrences of the same adverse event in one patient are counted separately.

Investigator text for AEs encoded using MedDRA vxx.x.

Programing notes:

1. Analysis population: Safety
2. Program name: T_AE_C_AESPECIAL
3. Definition: see Table in 6.2.2 Selected AEs and Potential AE of Special Interest
4. 'Chemotherapy' can be replaced by the actual study chemotherapy term, e.g. Bendamustine

~~10.44 Output 44 Categorical Summary of Selected Adverse Events~~

~~Programing notes:~~

~~1. Analysis population: Safety~~
~~2. Program name: T_AE_C_AESELECT~~
~~3. Definition: see Table in 6.2.2 Selected AEs and Potential AE of Special~~ Interest

10.45 Output 45 Adverse Events by Cycle

Treatment Cycles	Treatment Group 1 (N = xx)
Cycle 1	
Patients with at least one AE	xx (xx%)
Number of AEs	xx
Number of grade 3-4 AEs	xx
Number of fatal AEs	xx
Number of serious AEs	xx
Number of AEs leading to ant body withdrawal	xx
Number of AEs leading to atezolizumab withdrawal	xx
Number of AEs leading to chemotherapy withdrawal	xx
n	xx
Cycle 2	
Patients with at least one AE	xx (xx%)
Number of AEs	xx
Number of grade 3-4 AEs	xx
Number of fatal AEs	xx
Number of serious AEs	xx
Number of AEs leading to ant body withdrawal	xx
Number of AEs leading to atezolizumab withdrawal	xx
Number of AEs leading to chemotherapy withdrawal	xx
n	xx
Cycle x	

Investigator text for AEs encoded using MedDRA vxx.x.
n is a number of patients received study drug at each cycle.
Percentages are based on n.
Multiple occurrences of the same adverse event in one individual counted only once for each cycle.

Programing notes:

1. Analysis population: Safety
2. Program name: T_AE_C_AECYC
3. 'Chemotherapy' can be replaced by the actual study chemotherapy term, e.g. Bendamustine

10.46 Output 46 Potential Adverse Events of Special Interest by Cycle

Programing notes:

1. Analysis population: Safety
2. Program name: T_AESI_C_AECYC
3. 'Chemotherapy' can be replaced by the actual study chemotherapy term, e.g. Bendamustine

10.47 Output 47 Selected Adverse Events by Cycle

Programing notes:

1. Analysis population: Safety
2. Program name: T_AESE_C_AECYC
3. 'Chemotherapy' can be replaced by the actual study chemotherapy term, e.g. Bendamustine

10.48 Output 48 Adverse Events by Highest NCI CTCAE Grade

MedDRA System Organ Class and Preferred Term	Grade	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
- Any adverse events -	-Any Grade-	nn	nn
	1	nn	nn
	2	nn	nn
	3	nn	nn
	4	nn	nn
	5	nn	nn
BLOOD AND LYMPHATIC SYSTEM DISORDERS			
- Overall -	-Any Grade-	nn	nn
	1	nn	nn
	2	nn	nn
	3	nn	nn
	4	nn	nn
	5	nn	nn
NEUTROPENIA	-Any Grade-	nn	nn
	1	nn	nn
	2	nn	nn
	3	nn	nn
	4	nn	nn
	5	nn	nn

Investigator text for AEs encoded using MedDRA version xx.x. Multiple occurrences of the same AE in one individual are counted once at the maximum intensity for this term. The Any Intensity rows present the number of AEs reported at any intensity across all patients. Patients experiencing > 1 event (different PTs) within a SOC will have all unique events contributing to this count. Includes AEs with onset from first dose of study drug through **xx** days after last dose of study drug

Programing notes:

1. Analysis population: Safety
2. Template ID: AET04
3. Program name: T_AE_CTC

10.49 Output 49 Most Common Adverse Event with Incidence ≥ 5% by Preferred Term

Programing notes:

1. Analysis population: Safety
2. Template ID: AET08
3. Program name: T_AE_PT_P5
4. Display only by preferred term, not by SOC

10.50 Output 50 Most Common Grade 3, 4, 5 Adverse Event with Incidence ≥ 5% by Preferred Term

Programing notes:

1. Analysis population: Safety
2. Template ID: AET08
3. Program name: T_AE345_PT_P5

10.51 Output 51 Duration from First Study Treatment Date to Onset of Peripheral Neuropathy

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Duration from first study treatment to onset of PN (months)		
n	nnn	nnn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min–max	xx–xx	xx–xx
Duration from first study treatment to onset of grade 2 or higher PN (months)		
n	nnn	nnn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min–max	xx–xx	xx–xx

Programing notes:

1. Analysis population: Safety
2. Template ID: NA
3. Program name: T_DUR_PN
4. Use univariate variable analysis
5. **This output is applied to studies with polatuzumab**

10.52 Output 52 Listing of Deaths

Center/ Patient ID	Age/Sex/Race	Date of First Study Drug Administration	Day of Last Study Drug Administration	Day of Death	Associated SAE Preferred Term	Autopsy Performed?	Cause of Death
[redacted]			12	62	Myocardial infarction	Yes	xxxxxx
			36	37	Ischemic Stroke	No	xxxxxx

Programming notes:

1. Analysis population: Safety
2. Template ID: AEL04
3. Program name: L_DD

10.53 Output 53 Deaths

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
All deaths	xx (xx.x%)	xx (xx.x%)
Adverse Events	xx (xx.x%)	xx (xx.x%)
Disease Progression	xx (xx.x%)	xx (xx.x%)
No. of deaths during treatment		
Cause of death		
Adverse Events	xx (xx.x%)	xx (xx.x%)
Disease Progression	xx (xx.x%)	xx (xx.x%)
No. of deaths during follow up		
Cause of death		
Adverse Events	xx (xx.x%)	xx (xx.x%)
Disease Progression	xx (xx.x%)	xx (xx.x%)
No. of deaths during survival follow up		
Cause of death		
Adverse Events	xx (xx.x%)	xx (xx.x%)
Disease Progression	xx (xx.x%)	xx (xx.x%)

~~Deaths during the treatment are those occurred within 28 days after last study drug.~~

Programming notes:

1. Analysis population: ITT
2. Program name: T_DD
3. CRF: AE and Study Completion/Early Discontinuation

10.54 Output 54 Laboratory Test Results Shift Table – Highest NCI CTCAE Grade Post-Baseline

Hemoglobin g/L (Low)		Status at Baseline						
	From	0	1	2	3	4	Total	Missing
To								
0		13(xx%)	0 (xx%)	1(xx%)	0	0	14	0
1		58(xx%)	63(xx%)	4(xx%)	0	0	125	0
2		39(xx%)	105(xx%)	28(xx%)	0	0	172	0
3		14(xx%)	23(xx%)	13(xx%)	0	0	50	0
4		3(xx%)	5(xx%)	0(xx%)	0	0	8	0
Total		127(100%)	196(100%)	46(100%)	0	0	360	0
Missing		6	6	0	0	0	12	0

NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events.
"n" denotes the number of patients with baseline and post-baseline lab data within this time interval.
For a patient with multiple post-baseline lab abnormalities, the highest (worst) grade of these abnormalities for the given lab test is reported.

Programing notes:

1. Analysis population: Safety
2. Template ID: LBT14
3. Program name: T_LB_SHIFT
4. Use **EXT_NCICTC4** for NCI-CTCAE Grades
5. Include all hematology and chemistry lab parameters split into 2 separate outputs.

10.55 Output 55 Neutrophil Count Recovery

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
ANC <1.0 × 109/L at EOT/EOI*		
Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
ANC Recovery** within 3 months of follow up		
Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
ANC Recovery** within 6 to 9 months of follow up		
Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
ANC Recovery** within 9 to 12 months of follow up		
Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx
A ANC Recovery** after 12 months of follow up Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)
n	xxx	xxx

** Neutrophil recovery is defined as ANC $\geq 1.0 \times 10^9$/L, given ANC was collected after the patient received his last dose of antibody, and ANC < 1.0×10^9/L the last previous visit before EOT/EOI. Where no ANC value occurs at the last drug intake, the next valid ANC assessment was taken.

Percentages are based on the number of patients with ANC < 1.0×10^9/L at the last previous visit before EOT/EOI.

Programing notes:

1. Analysis population: Safety
2. Program name: T_LB_ANC

10.56 Output 56 Vital Signs Change from Baseline by Visit

	Group 1 (N=nnn)	
Visit	Value at Visit	Change from Baseline
Baseline		
n	nnn	
Mean (SD)	xx.x (xx.x)	
Median	xx.x	
Min–max	xx.x –xx.x	
Cycle X		
n	nnn	nnn
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min–max	xx.x–xx.x	xx.x–xx.x

Programing notes:

1. Analysis population: Safety
2. Template ID: VST01
3. Program name: T_VS_CB
4. Analysis variables: Weight, Temperature, Respiratory rate, Pulse, SBP, DBP

10.57 Output 57 ECG Results Shift Table

Treatment x (N=xx)

	Shift FROM: Baseline			
Shift TO: ECG Result at Visit	Abnormal, clinically significant	Abnormal, not clinically significant	Normal	Total
END OF INDUCTION COMPLETION / DISCONTINUATION				
Abnormal, clinically significant	0	0	0	0
Abnormal, not clinically significant	0	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Normal	0	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
Total	0	xx (xx.xx%)	xx (xx.xx%)	xx (xx.xx%)
END OF MAINTENANCE COMPLETION / DISCONTINUATION				
Abnormal, clinically significant	0	0	0	0
Abnormal, not clinically significant	0	xx (xx.xx%)	0	xx (xx.xx%)
Normal	0	0	0	0
Total	0	xx (xx.xx%)	0	xx (xx.xx%)

Baseline assessment is the last valid assessment in the 28 day window before first administration of a study treatment component.

Programing notes:

1. Analysis population: Safety
2. Template ID: EGT01
3. Program name: T_EG_CB
4. Analysis variables: Electrocardiogram (ECG)

10.58 OUTPUT 58 Listing of Time-to-Event Endpoints

Treatment group	CRTN/Pt No.	Overall Survival (months)	PFS (months)	EFS (months)	DFS (months)	Duration of Response (months)
	xxxx/xxxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx*	xxx*	xxx*	
		xxx	xxx	xxx	xxx	
		xxx	xxx*	xxx*	xxx*	
		xxx	xxx	xxx	xxx	
		xxx	xxx*	xxx*	xxx*	
		xxx	xxx	xxx	xxx	
…						

* Censored Observation

Programming Note:

1. Analysis population: Safety
2. Program name: L_EF_TTE
3. Time-to-Event endpoints are consist of overall survival, EFS, PFS, and duration of response.

10.59 Output 59 Listing of Tumor Response Assessment

CRTN/PT No.	Cycle	Study Day#	New Lesion	Objective evidence of clinical progression	Response not including PET scan results (IRC)	Response based upon PET-CT scans (IRC)	Response not including PET scan results (Investigator)	Response based upon PET-CT scans (Investigator)
xxxx/xxxx			Yes	Yes				

Response will be determined on the basis of PET-CT scans or CT scans alone, using the modified Lugano 2014 criteria

#: Days from first dose of study medication

Programming Note:

1. Analysis population: Safety
2. Program name: L_EF_CONCORD
3. CRF: NHL response assessment and IRC data
4. **Response based upon PET-CT scans include 2 results: using Lugano 2014 criteria and modified Lugano 2014 criteria (follow protocol).**
5. **Study BO29563: response assessment is also using Cheson 2007 criteria.**

Note: It is ok to split the table into two: one for investigator and the other for IRC.

10.60 Output 60 CR Rate at End of Induction

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Based on Modified LUGANO 2014 - PET-CT		
As Determined by the IRC		
Complete Response (CR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
As Determined by the Investigator		
Complete Response (CR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
Based on LUGANO 2014 - PET		
As Determined by the IRC		
Complete Response (CR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
As Determined by the Investigator		
Complete Response (CR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
Based on Modified CHESON 2007 - CT or MRI		
As Determined by the IRC		
Complete Response (CR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
As Determined by the Investigator		
Complete Response (CR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
Based on Modified CHESON 2007 - CT or MRI and PET		
As Determined by the IRC		
Complete Response (CR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
As Determined by the Investigator		
Complete Response (CR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)

90% CI for rates were constructed using Clopper-Pearson method.

Programming Note:

1. Analysis population: Safety
2. Template ID: RSPT01
3. Program name: T_CRR
4. EOI time window: TBD
5. Some studies may require CR tabulation based on Cheson criteria, Lugana, or modified Lugano, follow SMT instruction.

10.61 Output 61 OR Rate at End of Induction

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Based on Modified LUGANO 2014 - PET-CT		
As Determined by the IRC		
Objective Response (CR, PR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
As Determined by the Investigator		
Objective Response (CR, PR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
Based on LUGANO 2014 – PET		
As Determined by the IRC		
Objective Response (CR, PR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
As Determined by the Investigator		
Objective Response (CR, PR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
Based on Modified CHESON 2007 - CT or MRI		
As Determined by the IRC		
Objective Response (CR, PR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
As Determined by the Investigator		
Objective Response (CR, PR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
Based on Modified CHESON 2007 - CT or MRI and PET		
As Determined by the IRC		
Objective Response (CR, PR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
As Determined by the Investigator		
Objective Response (CR, PR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)

90% CI for rates were constructed using Clopper-Pearson method.

Programming Note:

1. Analysis population: Safety
2. Template ID: RSPT01

3. Program name: T_ORR
4. EOI time window: TBD

10.62 Output 62 CR Rate at 12 Months after Initiation of Induction

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Based on PET-CT as Determined by the IRC using Lugano 2014 Criteria		
Complete Response (CR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
Based on PET-CT as Determined by the Investigator using Lugano 2014 Criteria		
Complete Response (CR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
Based on PET-CT as Determined by the IRC using modified Lugano 2014 Criteria		
Complete Response (CR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
Based on PET-CT as Determined by the Investigator using modified Lugano 2014 Criteria		
Complete Response (CR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
Based on CT alone as Determined by the IRC		
Complete Response (CR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)
Based on CT alone as Determined by the Investigator		
Complete Response (CR)	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)

90% CI for rates were constructed using Clopper-Pearson method.

Programming Note:

1. Analysis population: Safety
2. Template ID: RSPT01
3. Program name: T_CRR12
4. **Patient subset: Patients who have positive PET scans (CR/PR) at EOI**

10.63 Output 63 Best Overall Response Rate

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Based on CT as Determined by the Investigator		
Best Overall Response (BOR)	xxx (xx.x %)	xxx (xx.x %)
CR	xxx (xx.x %)	xxx (xx.x %)
PR	xxx (xx.x %)	xxx (xx.x %)
90% CI for Response Rates	(xx.x, xx.x)	(xx.x, xx.x)

90% CI for rates were constructed using Clopper-Pearson method.

Programming Note:

1. Analysis population: Safety
2. Template ID: RSPT01
3. Program name: T_BORR

10.64 Output 64 Concordance Analysis Between the IRC Determined and the Investigator Determined CR Status

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Based on PET-CT using Lugano 2014 Criteria		
Number of patients evaluable for concordance	nn	nn
CR occurrence		
Concordance	xxx (xx.x %)	xxx (xx.x %)
CR per investigator and CR per IRC	xxx (xx.x %)	xxx (xx.x %)
No CR per investigator and no CR per IRC	xxx (xx.x %)	xxx (xx.x %)
Discordance	xxx (xx.x %)	xxx (xx.x %)
CR per investigator and no CR per IRC	xxx (xx.x %)	xxx (xx.x %)
No CR per investigator and CR per IRC	xxx (xx.x %)	xxx (xx.x %)
Based on PET-CT using modified Lugano 2014 Criteria		
Number of patients evaluable for concordance	nn	nn
CR occurrence		
Concordance	xxx (xx.x %)	xxx (xx.x %)
CR per investigator and CR per IRC	xxx (xx.x %)	xxx (xx.x %)
No CR per investigator and no CR per IRC	xxx (xx.x %)	xxx (xx.x %)
Discordance	xxx (xx.x %)	xxx (xx.x %)
CR per investigator and no CR per IRC	xxx (xx.x %)	xxx (xx.x %)
No CR per investigator and CR per IRC	xxx (xx.x %)	xxx (xx.x %)
Based on CT alone		
Number of patients evaluable for concordance	nn	nn
CR occurrence		
Concordance	xxx (xx.x %)	xxx (xx.x %)
CR per investigator and CR per IRC	xxx (xx.x %)	xxx (xx.x %)
No CR per investigator and no CR per IRC	xxx (xx.x %)	xxx (xx.x %)
Discordance	xxx (xx.x %)	xxx (xx.x %)
CR per investigator and no CR per IRC	xxx (xx.x %)	xxx (xx.x %)
No CR per investigator and CR per IRC	xxx (xx.x %)	xxx (xx.x %)

Programming Note:

1. Analysis population: Safety
2. Template ID: IRCT01
3. Program name: T_EF_CONCORD_CR

10.65 Output 65 Duration of Response

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Patients with event (%)	xxx (xx.x %)	xxx (xx.x %)
PD	xxx	xxx
Death	xxx	xxx
Patients without event (%)#	xxx (xx.x %)	xxx (xx.x %)
Time to event (month)		
Median	xxx.x	xxx.x
95% CI	(xxx, xxx)	(xxx, xxx)
25% and 75%-ile	xxx, xxx	xxx, xxx
Range##	xxx to xxx#	xxx to xxx#

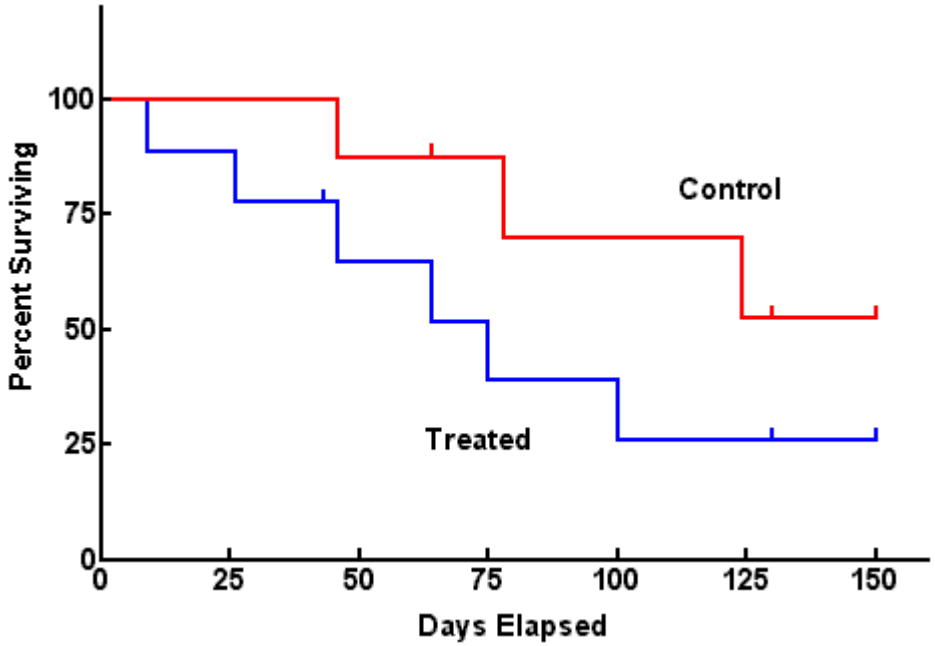
Censored value, ## Including censored observations

Summaries of <Time-to-Event Endpoint> (median, percentiles) are Kaplan-Meier estimates. 95% CI for median was computed using the method of Brookmeyer and Crowley.

Programming Note:

1. Analysis population: Safety
2. Template ID: TTET01
3. Program name: T_DOR
4. Based on CT assessment as determined by the investigators
5. Patient subset: Patients who have CR or PR

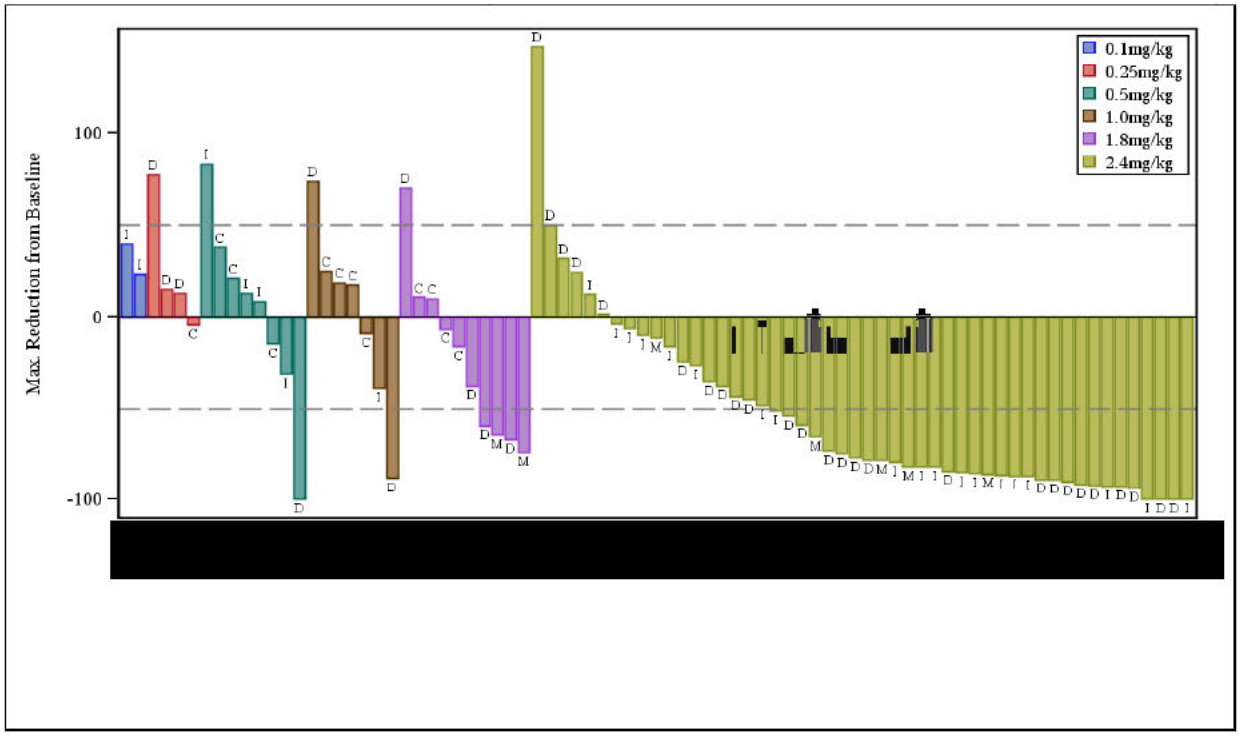
10.66 Output 66 Kaplan-Meier Curve of Duration of Response



Programming Note:

1. Analysis population: Safety
2. Template ID: KMG01
3. Program name: G_KM_DOR
4. Based on CT assessment as determined by the investigators

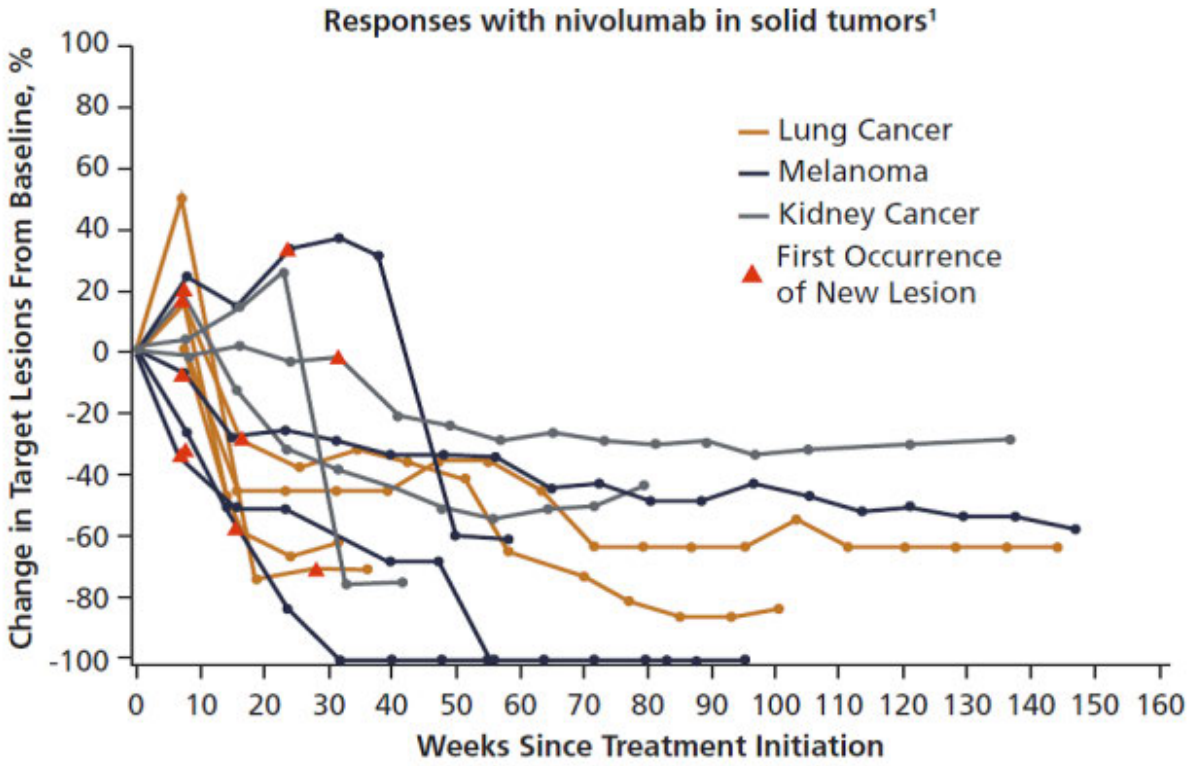
10.67 Output 67 Waterfall Plot of Best Change from Baseline (%) in Indicator Lesion Size



Programming Note:

1. Analysis population: Safety
2. Program name: G_EF_WTF
3. Based on CT assessment as determined by the investigators

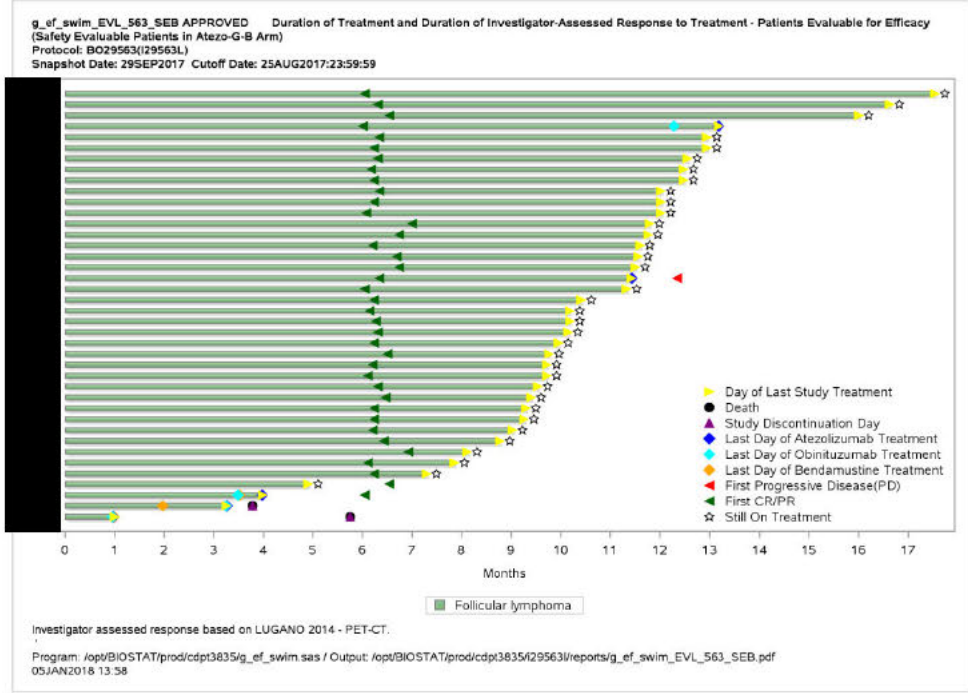
10.68 Output 68 Spider Plot of Change from Baseline (%) in Indicator Lesion Size over Time



Programming Note:

1. Analysis population: Safety
2. Program name: G_EF_SPIDER
3. Based on CT assessment as determined by the investigators

10.69 Output 69 Swimmer Plot of Time to Response and Duration of Response



Programming Note:

1. Analysis population: Safety
2. Program name: G_EF_SWIM
3. Based on Lugano 2014 PET-CT assessment as determined by the investigators
4. Details: TBD

10.70 Output 70 Progression-Free Survival

	Treatment Group 1 (N=nn)	Treatment Group 2 (N=nn)
Patients with event (%)	xxx (xx.x %)	xxx (xx.x %)
PD	xxx	xxx
Death	xxx	xxx
Patients without event (%)#	xxx (xx.x %)	xxx (xx.x %)
Time to event (month)		
Median	xxx.x	xxx.x
95% CI	(xxx, xxx)	(xxx, xxx)
25% and 75%-ile	xxx, xxx	xxx, xxx
Range##	xxx to xxx#	xxx to xxx#
Time Point Analysis		
6 months duration		
Patients remaining at risk	xx	xx
Event free rate (%)	xx.x	xx.x
95% CI	(xx.x, xx.x)	(xx.x, xx.x)

Censored value, ## Including censored observations

Summaries of <Time-to-Event Endpoint> (median, percentiles) are Kaplan-Meier estimates. 95% CI for median was computed using the method of Brookmeyer and Crowley. 95% CI for landmark estimate was computed using Greenwood method.

Programming Note:

1. Analysis population: Safety
2. Program name: T_EF_TTE_PFS
3. Based on CT assessment as determined by the investigators
4. Landmark estimates of the proportion of patients who are event free at 6 months, 9 months, 1 year, and 2 years will be provided, along with 95% asymptotic Cis using Greenwood's formula for standard errors.

10.71 Output 71 Kaplan-Meier Curve of Progression-free Survival

Programming Note:

1. Analysis population: Safety
2. Program name: G_EF_KM_PFS
3. Based on CT assessment as determined by the investigators

10.72 Output 72 Event-Free Survival

Programming Note:

1. Analysis population: Safety
2. Program name: T_EF_TTE _EFS
3. Based on CT assessment as determined by the investigators
4. Landmark estimates of the proportion of patients who are event free at 6 months, 9 months, 1 year, and 2 years will be provided, along with 95% asymptotic Cls using Greenwood's formula for standard errors.

10.73 Output 73 Kaplan-Meier Curve of Event-Fee Survival

Programming Note:

1. Analysis population: Safety
2. Program name: G_EF_KM_EFS
3. Based on CT assessment as determined by the investigators

10.74 Output 74 Disease-Free Survival

Programming Note:

1. Analysis population: Safety
2. Program name: T_EF_TTE _DFS
3. Based on CT assessment as determined by the investigators
4. Landmark estimates of the proportion of patients who are event free at 6 months, 9 months, 1 year, and 2 years will be provided, along with 95% asymptotic Cis using Greenwood's formula for standard errors.

10.75 Output 75 Kaplan-Meier Curve of Disease-Fee Survival

Programming Note:

1. Analysis population: Safety
2. Program name: G_EF_KM_DFS
3. Based on CT assessment as determined by the investigators

10.76 Output 76 Overall Survival

Programming Note:

1. Analysis population: Safety
2. Program name: T_EF_TTE _OS
3. Landmark estimates of the proportion of patients who are event free at 6 months, 9 months, 1 year, and 2 years will be provided, along with 95% asymptotic CIs using Greenwood's formula for standard errors.

10.77 Output 77 Kaplan-Meier Curve of Overall Survival

Programming Note:

1. Analysis population: Safety
2. Program name: G_EF_KM_OS

Appendix 1 Region Categories

We only display regions and countries here where actually patients were enrolled.

Input needed from Study SPA/BioStats: Add any other countries to this table if your study has a site there with patients enroled

Region	Member Countries
Western Europe	Belgium, Finland, France, Germany, Italy, Spain, Sweden, United Kingdom
Eastern Europe	Czech Republic, Hungary, Russia
North America	Canada, United States
Asia	China, Japan, Taiwan, South Korea
Other	Australia, Israel, New Zealand

DAP M 2 Update Log

Date	Section	Description	Author
24MAY2017	Output 57	Changed Change from Baseline to Shift Table	[redacted]
16MAY2017	Output36	Added "Total number of patients with at least one AE" category instead of displaying sub-category under "Total number of patients with at least one" category	
07JUN2017	Output53	Added "Other" as sub-category under "Causes of Death" category	
14JUN2017	Output5	Updated "Induction Phase" categorie as "Induction started", similarly "Maintenance/Consolidation Phase" to "Maintenance / Consolidation Phase started" . Also added "Discontinued Induction" & "Discontinued Maintenance/Consolidation" categories.	
17JUL2017	Table Selected AE	Removed tick for bo29561 for Late onset/prolonged neutropenia. Updated definition of Neutropenia for BO29561-3	
21JUL2017	Table Selected AE/AESI Titles of summaries	Second Malignancy and TLS moved to AESI In Summaries titles 'Summary of' removed	
26JUL2017	Safety Summary (Ouput 36)	Removed last row as this is not part of original STREAM template and is not appropriate to use: No connection between related AE and AE given as reason for study discontinuation (based on study completion page)	
08AUG2017	Output 24	Add programming note: Use visit instead of cycle for BO29561 and BO29563	
14AUG2017	Table 6.2.2, Title of AESI outputs	AESI categories updated in Table. AESI renamed to 'potential AESI' in output titles.	
11AUG2017	6.2.1, output 34, output 41	In BO29561/2/3 additional AESI tables based on eCRF tickbox.	
14Aug2017	Output 78	Use categories Low/Intermediate/High for FLIPI. Low/High for IPI.	
22AUG2017	Table 6.2.2	AESI category Hypersensitivity updated	

17OCT2017	6.4.5	Hy's law: use BL instead of ULN for AST/ALT	[redacted]
29JAN2017	output 36	Added 2 rows into template	
06SEP2018	Output53	Removed "Deaths during the treatment are those occurred within 28 days after last study drug." footnote.	
10OCT2018	Table 6.2.2	Added AESI category 'Auto-immune hemolytic anaemia', updated AESI categories for Diabetes mellitus and Rash as requested by [redacted] in email on 09OCT2018	
17OCT2018	Table 6.2.2	Updated AESI categories IRR and myocarditis as requested by [redacted] in email on 17OCT2018	
10DEC2018	6.4.9	Added HACA in this section	
29JAN2019	6.2.1/6.2.2	Added conditions for Atezo specific AESI (onset >= cycle 2, causality to Atezo suspected)	