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Institute of Epidemiology and Medical Biometry

Statistical Analysis Plan

Pembrolizumab in Marginalzone Lymphoma (POLE-1)

A MULTICENTER OPEN LABEL SINGLE-ARM PHASE II STUDY

EUDRACT Number: 2018-000187-28
ClinicalTrials.gov Identifier: NCT-No: NCT04268277

Version: 01

Final date:

24.07.2025
date

Content

Signature Page

I have read this statistical analysis plan and I agree with performing the statistical analysis according to the procedures described below.

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Abbreviations/Definitions

Abbreviation	Definition
AE	Adverse Event
AESI	Adverse Event of Special Interest
ALAT (SGPT)	ALanine Transaminase (Serum Glutamic Pyruvic Transaminase)
ANC	Absolute Neutrophil Count
ASAT (SGOT)	ASpartate Transaminase (Serum Glutamic Oxaloacetic Transaminase)
BSA	Body Surface Area
CBC	Complete blood count
CNS	central nervous system
CR	Complete Remission/Response
CRP	C reactive protein
CRR	CR Rate
CSS	Cause specific survival
CT	Computed Tomography
CTCAE	Common Toxicity Criteria for Adverse Events
CTP	Clinical Trial Protocol
DFS	Disease-free survival time
DR	Duration of Remission/Response
ECOG	Eastern Cooperative Oncology Group
ECG	Electrocardiogram
eCRF	electronic Case Report Form
EOT	End of Treatment
EWB	Emotional Well-being
FACT-G	Functional Assessment of Cancer Therapy – general
FACT-Lym	Functional Assessment of Cancer Therapy – lymphoma
FWB	Functional Well-being
Hb	Hemoglobin
HBV	Hepatitis-B-Virus
HCV	Hepatitis-C-Virus
HIV	Human immunodeficiency virus
ICF	Informed consent form
ICH	International Conference on Harmonisation
Ig	Immunoglobulin
ITT	Intention-To-Treat
LDH	Lactic DeHydrogenase
LLN	Lower limits of normal
LYMS	Lymphoma Subscale
MedDRA	Medical Dictionary for Regulatory Activieties
MZL	Marginal Zone Lymphom
MRD	Minimal Residual Disease
NCI	National Cancer Institute
OS	Overall Survival
ORR	Overall response rate
PD	Progressive Disease
PFS	Progression Free Survival
Plt	Platelets
PWB	Physical Well-being
PR	Partial Remission
R	R Programming Language
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System

SC	Subcutaneous
SD	Stable Disease
SOC	System Organ Class
SWB	Social/Family Well-being
TOI	Trial Outcome Index
TTF	Time to treatment failure
ULN	Upper Limit of Normal
WBC	White blood cells

1 Version History

Version 01, there are no other legacy versions.

2 Trial

2.1 Trial Summary and Trial Design

POLE-1 is a multicenter, single-arm, open-label, phase II trial of 18 cycles of Pembrolizumab and Rituximab in patients aged ≥ 18 years with previously untreated or relapsed MZL in need of treatment. The study comprises a treatment phase and the follow-Up phase. The study flow is as follows:

- Previously untreated or relapsed patients were screened for eligibility for the trial. If the patient was eligible for the study, the patient was registered before the first cycle of treatment.
- Patients who progressed at any time point during treatment were considered as treatment failure. They were followed up for overall survival until end of follow up period or death.
- Patients, who achieved at least a stable disease (SD) after treatment were followed up for response until progression/relapse and for overall survival until death.

The objective of this trial is to test the efficacy and toxicity of the treatment with Pembrolizumab/Rituximab in patients with MZL in need of treatment, who have failed or are not eligible for local therapy or relapsed after local or systemic therapy. For efficacy, the rate of complete remissions (according to the GELA criteria for gastric MALT or to the Cheson 2007 criteria for non-gastric extranodal, nodal and splenic MZL) after therapy will be primarily analysed. For toxicity assessment treatment associated adverse events, quality of life and cumulative incidence of secondary malignancies are documented.

Primary endpoint is the complete response (CR rate (CRR)) determined after end of treatment (18 cycles).

Secondary endpoints are the response rate (CR, PR, CR or PR), best response, time to best response, time to first response, progression free survival (PFS), time to treatment failure (TTF), duration of response (DR), cause specific survival (CSS), overall survival (OS), and quality of life during therapy.

Safety variables include AEs, SAEs, AESIs, laboratory parameters, and ECG. The severity of AEs will be graded using the NCI-CTCAE version 5.0 dictionary. An AE is defined as any event arising or worsening from the time a signed and dated informed consent form (ICF) is obtained until 110 days after the last study drug intake. Safety variables will be summarized by means of descriptive statistics and/or frequency tables as appropriate. All AEs, drug related AEs, serious AEs will be summarized by MedDRA classification (SOC and preferred term) and worst CTCAE grade.

The estimated duration of 12-18 months for patient recruitment on which the study design was based during initial planning has been exceeded substantially. The trial was stopped after inclusion of 22 (MALT lymphoma: n=8, splenic MZL: n=7, nodal MZL: n=7) of 56 planned patients since the initiation of the first site in Aug 2021. Additionally, eight patients not fulfilling the inclusion criteria had signed the ICF. The end of treatment visit of the last patient enrolled was 06 Dec 2024. Patients were included in Germany in 9 of 12 activated trial sites.

Further information about the trial is in the study protocol (V-3.0, 12 Apr 2021). Figure 1 shows the study design (see also CTP, page 33).

Fig.1: Study Design

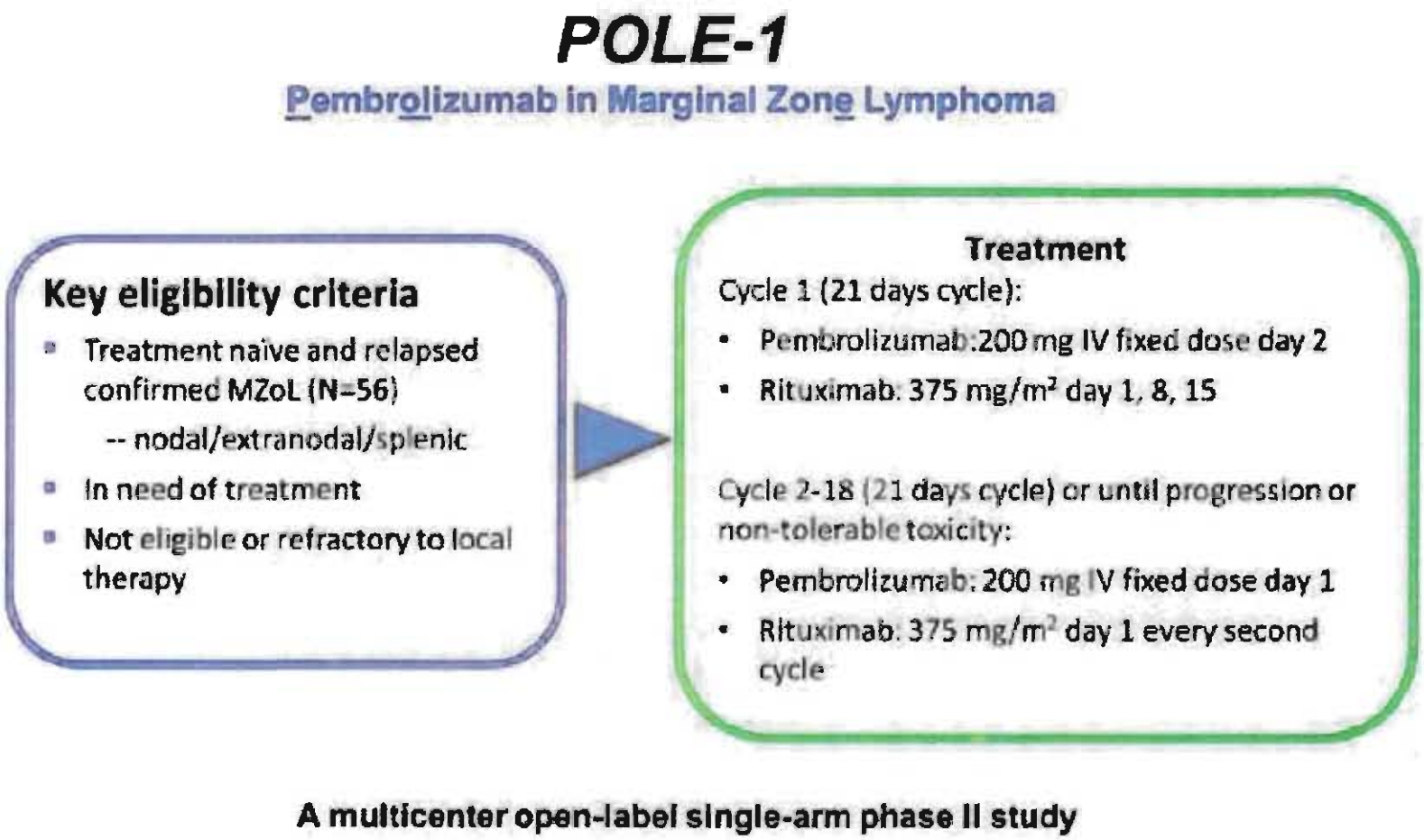

Figure 1: POLE-1 study design. The Follow-Up phase follows after the treatment phase.

2.2 Biometrical Report

Results of statistical analysis (e.g. tables, figures, and summary statistics) will be provided to the Comprehensive Cancer Center / Department of Internal Medicine III / Institute of Experimental Cancer Research for preparation of the Synopsis according to the ICH E3 guideline (CPMP/ICH/137/95, July 1996). All outputs will be provided in English language (e.g. title of tables, listings or figures, names of variables in listings and tables). A separate biometrical report will not be provided.

3 Changes in the Conduct of the Study or Planned Analyses

The trial was stopped after recruiting of 22 of 56 planned patients because of delayed recruitment. Due to the small sample sizes, the exploratory use of univariate logistic regression analysis to investigate the influence of putative risk factors associated with CRR will not be done due to expected problems in model fitting. Likewise, the planned subgroup analyses for the MZL subtype strata MALT lymphoma, splenic MZL, nodal MZL will not be performed because summary statistics (e.g. mean, standard deviation, percentages) would be not meaningful. Instead, a simple description of the patients in the three subgroups will be provided (e.g. number of patients, time course, primary and secondary endpoints). No other deviations from the study protocol are known at time of finalizing this plan.

4 Analysis Sets

Core Analysis Population: As this study is a trial with only one treatment arm, all analyses will be performed only for one analysis population, the Core Analysis Population. This analysis population consists of all eligible patients included in the study who received at least one cycle of treatment. Patients without staging at regular end of treatment will be defined as non-responder (i.e. CR='NO'). Only patients who withdraw will be excluded from this analysis population (about 15% were expected). The results on efficacy in the Core Analysis Population were considered to be the main efficacy results (confirmatory results).

Safety Population: The safety population and the Core Analysis Population are identical in this trial.

5 Definitions

The following notation will be used in this SAP:

- the ***bold and italic marked word*** specify the data table in the SAS data base
- the *italic marked word* signs a variable or a value of a variable in the SAS data base

Primary endpoint:

Primary endpoint is the complete response (CR rate (CRR)) determined after end of treatment (18 cycles). Patients who progress before EOT will be treated as CR='NO' and will be included in the calculation of the primary endpoint. No primary endpoint will be determined for patients who withdraw. These patients will be excluded from the confirmatory data analysis but will be analysed in a separate exploratory sensitivity analysis of the primary endpoint.

Secondary Endpoints:

The following parameters are the secondary endpoints:

- Response rate
- Best response

- Time to best response
- Time to first response
- Progression free survival (PFS)
- Time to treatment failure (TTF)
- Duration of Response (DR)
- Cause specific survival (CSS)
- Overall survival (OS)
- Quality of life during trial (therapy)

For details of definition of each secondary endpoint, see part 7.5.

Safety variables:

Safety variables include AEs, SAEs, AESIs, laboratory parameters, and ECG. The severity of AEs will be graded using the NCI-CTCAE version 5.0 dictionary. An AE is defined as any event arising or worsening after start of study drug administration until 110 days (based on five times the terminal elimination half-life of Rituximab and Pembrolizumab) after the last study drug intake. Safety variables will be summarized by means of descriptive statistics and/or frequency tables as appropriate. All AEs, drug related AEs, serious AEs will be summarized by MedDRA classification (SOC and preferred term) and worst CTCAE grade.

Further variables:

Strata:

Data analysis according to the MZL subtype (strata MALT lymphoma, splenic MZL, and nodal MZL; variable *LYMTYPE* in table **TOL**) is limited due to the small patient numbers. A simple description will be performed instead.

6 Treatment of Data

Primary endpoint (complete response (CR rate (CRR) determined after end of treatment (18 cycles)): Patients who progress before EOT will be treated as CR='NO' and will be included in the calculation of the primary endpoint. Patients without staging at regular end of treatment will be defined as non-responder (i.e. CR='NO'). No primary endpoint will be determined for patients who withdraw. These patients will be excluded from the confirmatory data analysis but will be analysed in a separate exploratory sensitivity analysis of the primary endpoint.

Conversion of laboratory results: There is no standardized unit for the laboratory results (haematology, quantitative immunoglobulins, serum chemistry, thyroid hormones) in the data base (see annotated CRF at pages 105-113, 162f, 170-182, 186f). Therefore, the Comprehensive Cancer Center / Department of Internal Medicine III / Institute for Experimental Tumour Research will provide a table for the conversion of the laboratory results in units which will be used in the statistical analysis. These units are mentioned in the appendix (part 12.1). All conversion factors for units known at the time of finalization of this document are listed in the appendix (see part 12.1).

Harmonization of response categories for tumor assessment: For the statistical analysis of the primary endpoint and some secondary endpoints in the whole study population, a harmonization of the response categories for tumor assessment will be performed. This is due to the different response categories in the three subgroups (see annotated CRF at page 188ff, CTP at page 116ff). The response categories after the harmonization are complete remission (CR), partial remission (PR), stable disease (SD), progressive disease (PD) and not evaluated (NE). The appendix (part 12.2) shows the allocation of the single response categories.

Format of date variables: All date variables given in the database are strings in the format yyyy-mm-dd. In the statistical analysis, all date variables will be presented in the format dd/mm/yyyy.

General remarks: All data are stored in a data base provided by X-act Cologne Clinical Research GmbH. The data will be provided as SAS data (sas7bdat). No checks of plausibility and consistency will be carried out by the Institute of Epidemiology and Medical Biometry. All variables containing information for organisation, data entry, and data management are not mentioned in this document and will not be analysed. No English translation will be done in case of German data base entries.

7 Listing of Variables

The descriptive methods will be applied for whole study population. Additionally, a simple description will be performed for the MZL subtype strata MALT lymphoma, splenic MZL, nodal MZL instead subgroup analyses.

7.1 Background and Demographic Characteristics, Variables measured during treatment

Inclusion/Exclusion criteria/Eligibility criteria: Frequencies of "Does the patient meet all inclusion and none of the exclusion criteria according to the protocol?" (yes/no). Frequencies of (yes/no) for each inclusion and exclusion criteria.

Type of Lymphoma/MYD88 mutation: Frequencies for Type of lymphoma (MALT lymphoma/ splenic MZL/nodal MZL), extranodal MZL expression (extragastric/gastric), PD-L1 expression in lymphoma cells (negative/positive/not done) and MYD88 mutation (negative/positive/not done). The variables *LYMTYPE*, *TOLEX_EXGA*, *MYDMUT*, and *TOLP_DEX* in table ***TOL*** will be used.

Demographic characteristics: Demographic characteristics are age, sex, childbearing potential, and ethnic origin. For the analysis, the variables *AGE*, *SEX*, *RPORRES*, *CETHNIC*, and *ETHNICOTH* in table ***DM*** will be used.

Medical / Surgical History and Concomitant Diseases: Previous and concomitant diseases will be listed (name of disease, grade, start date, ongoing at the end of study, stop date).

Anamnesis and Status of Tumor: Frequencies of patients with previous rituximab/chemotherapy / rituximab single agent therapy / radiotherapy, Number and median of previous treatments in total and number of previous rituximab/chemotherapies / rituximab single agent therapies / radiotherapies will be calculated (variables *MHTHERAP*, *MHTHERAPN* in table ***MH2***). The kind of therapy incl. start date, stop date, best response and duration of best response will be listed. The respective variables are *MHTHERKN*, *MHTSRT*, *MHTSTP*, *MHTHRESP*, *MHRESPDUR* and *MHTHERKN_x*, *MHTSRT_x*, *MHTSTP_x*, *MHTHRESP_x*, *MHRESPDUR_x*, *x=2, 3, 4, 5* in table ***MH2***. Frequencies for LDH value above the upper limit and Ann Arbor staging (I, II, III, IV) will be calculated. The respective variables are *MHLDHV* and *MHSTAGE* in table ***MH2***. The MALT-IPI score will be evaluated as continuous variable (variable *MHMSCORE* in table ***MH2***); only in patients with MALT lymphoma. An additional variable *MZLIPI* will be calculated as follows: if *MHMSCORE=0* then *MZLIPI='Low (LRG)'*, if *MHMSCORE in (1 2)* then *MZLIPI='Intermediate (IRG)'*, if *MHMSCORE>=3* then *MZLIPI='High (HRG)'*.

B Symptoms: The frequency for B-symptoms (yes/no) and the frequencies (yes/no) for Fever, Night sweats, Unintentional weight loss, and other relevant symptoms will be calculated. In case of other relevant symptoms, the symptoms will be listed. The respective variables are *FAYN*, *FEV_FAORRES*, *NS_FAORRES*, *WL_FAORRES*, *FAOTHYN*, and *FAOTHSPY* in table ***FA***.

Hematology: The frequency of "Examination performed?" (yes/no) will be calculated. Parameters of hematology are hemoglobin, hematocrit, platelets, erythrocytes, leukocytes, neutrophils, and lymphocytes. The respective variables are *HGB_LBORRES*, *HCT_LBORRES*, *PLAT_LBORRES*, *RBC_LBORRES*, *WBC_LBORRES*, *NEUT_LBORRES*, and *LYM_LBORRES* in table ***LBHM***.

Furthermore, for each of the parameter the frequency for 'clinically significant' (yes/no) will be calculated. Other cells examined will be listed.

Serum chemistry: The frequency of "Examination performed?" (yes/no) will be calculated. Parameters of serum chemistry are potassium, LDH, ALT, AST, GGT, alkaline phosphatase, uric acid, and CRP. The respective variables are *K_LBORRES*, *LDH_LBORRES*, *ALT_LBORRES*, *AST_LBORRES*, *GGT_LBORRES*, *ALPH_LBORRES*, *URIC_LBORRES*, and *CRP_LBORRES* in table ***LBCC***. Furthermore, for each of the parameter the frequency for 'clinically significant' (yes/no) will be calculated.

Serum protein electrophoresis (SPEP) / immunofixation in serum (IF): For serum protein electrophoresis the frequency of "Examination performed?" (yes/no) will be calculated. The quantity will be analyzed for albumin, alpha1, alpha2, beta, and gamma (variables *SPEP_ALBU_ORRES*, *SPEP_ALPI_ORRES*, *SPEP_ALPII_ORRES*, *SPEP_BETA_ORRES*, and *SPEP_GAMMA_ORRES* in table ***LBSIS***). Furthermore, the test result (M-protein in SPEP) and the absolute and relative quantity will be analyzed (variables *SPEP_LBORRES*, *SPEPQ_LBORRES*, and *SPEPQ_LBORRES2* in table ***LBSIS***). For immunofixation in serum the frequency of "Examination performed?" (yes/no) will be calculated. The result of M-protein in IF and the specifications will be analyzed (variables *IF_LBPERF*, *IF_LBORRES*, *IF_LBTEST*, and *IFS_LBORRES* in table ***LBSIS***).

Serology: Frequencies for the result (negative/positive) for HIV, HBsAg, HBcAb, HBV-DNA, HBsAb, HCV, and HCV-RNA will be calculated. The respective variables are *HIV_LBORRES*, *HBSAG_LBORRES*, *HBCAB_LBORRES*, *HBVD_LBORRES*, *HBSAB_LBORRES*, *HCV_LBORRES*, and *HCVRND_LBORRES* in table ***LBSER***.

Peripheral blood -/ Leukocyte Immunophenotyping (FACS) – Antigen expression of the lymphoma: Frequencies for "FACS analysis performed?" (yes/no) and "Positive for malignant lymphoma cells?" (yes/no) will be calculated (variables *LBPBPERF* and *LBPBCAT* in table ***LBPB***). Furthermore, and the kappa-result, lambda-result, and kappa / lambda ratio – result will be analysed. The respective variables are *KAPPALC_LBORRES*, *LMBDLC_LBORRES*, and *KLCLLC_LBORRES* in table ***LBPB***).

Quantitative Immunoglobulins: Frequencies for "Examination performed?" (yes/no) will be calculated (variable *QIM_LBPERF* in table ***LBIMG***). The results for IgA, IgG, and IgM will be analysed (variables *IGA_LBORRES*, *IGG_LBORRES*, and *IGM_LBORRES* in table ***LBIMG***).

7.2 Variables measured during Follow-Up

Variables measured during Follow-Up cover the following: ECOG Performance Status, B symptoms, hematology, serum chemistry, urine analysis, HBV DNA PCR, new anti-lymphoma treatment, survival follow-up, CT/MRI scan and tumor assessment (if initially positive), leukocyte immunophenotyping (FACS), quantitative immunoglobulins (IgA, IgG, IgM), serum protein immunofixation (if positive before), bone marrow aspirate and biopsy, and QoL questionnaire (FACT-Lym). Details are mentioned in part 7.1, see above. Patients with disease progression will be followed for new anti-lymphoma treatment and survival twice per year until the end of the study. Patients, who have not progressed so far, will be observed according to the follow up schedule in the CTP.

7.3 End of treatment

For evaluation of the end of treatment, the frequencies (yes/no) for the question "Was study medication in treatment period applied?" will be calculated. The date of last application and the reason (variables *EXENDAT_ET* and *EXREASND_ET* in table ***DSET***) will be listed. Additionally, the frequencies for the primary reasons for termination will be calculated and listed (variable *DSDECOD_ET* in table ***DSET***). The specifications for termination and the date of progression and

the date will be listed (variables *DSAESPY_ET* and *RSDAT_ET* in table ***DSET***). Additionally, the date of last contact and the specification will be listed (variables *DSLSTDAT_ET* and *DSTERM_ET* in table ***DSET***). Furthermore, the frequency of specification (Refusal of further study treatment/Withdrawal of consent) and status of patient (Patient continues with follow-up/Patient discontinues study) will be calculated (variables *DSDECOD_ET2* and *DSCONT_ET* in table ***DSET***).

7.4 End of Study

For evaluation of the end of study, the primary reasons for termination will be calculated and listed and the specifications will be listed (variables *DSDECOD_EST*, *DSSF_EST*, and *DSAESPY_EST* in table ***DSEOS***). The date and specification of last contact will be listed (variables *DSLSTDAT_EST* and *DSTERM_EST* in table ***DSEOS***). The frequencies (yes/no) for the question "Is the patient still alive?" will be calculated. The date and cause of death and will be listed. The frequencies for the cause of death (tumor-related/adverse event/other) will be calculated. The variables are *SURVSTAT*, *DTHDAT*, *PRCDTH_DDORRES*, and *DSAESP_EST* in table ***DSEOS***.

7.5 Variables for Analysis of Primary and Secondary Endpoints

Tumor assessment was done according to defined response criteria for the following three types of lymphomas: Nodal MZL and extragastric MALT lymphoma, Extranodal Gastric MZL, splenic MZL. The respective assessment categories will be collapsed in the following for calculation of the primary endpoint and parts of the secondary endpoints.

The **primary endpoint** is the complete response (CR) rate (CRR) determined after end of treatment (18 cycles), point in time EOT/ET visit C18/D1. For statistical analysis, a new variable CR_yes_no will be calculated as follows:

- Patients with tumor assessment at the end of treatment (variable *RSPERF = 1* in table ***RS*** for *ACTIVITY_ID = 'EOT_ASS'*): The complete response will be determined using the result of tumor assessment at this point in time. The SAS code is as follows:
  - In case of nodal MZL and extragastric MALT lymphoma: if ACTIVITY_ID = ‚EOT_ASS' and LYMTYPE = 2 and RSPERF = 1 and RSPERF_NMZEG = 1 and then CR_yes_no = 1 and RSORRES_NMZEG = 1 then CR_yes_no = 1;
    if ACTIVITY_ID = ‚EOT_ASS' and LYMTYPE = 2 and RSPERF = 1 and RSPERF_NMZEG = 1 and RSORRES_NMZEG > 1 then CR_yes_no = 0;
  - In case of extranodal gastric MALT lymphoma: if ACTIVITY_ID = ‚EOT_ASS' and LYMTYPE = 3 and RSPERF = 1 and RSPERF_EGM = 1 and RSORRES_EGM = 1 then CR_yes_no = 1;
    if ACTIVITY_ID = ‚EOT_ASS' and LYMTYPE = 3 and RSPERF = 1 and RSPERF_EGM = 1 and RSORRES_EGM > 1 then CR_yes_no = 0;
  - In case of splenic MZL: if ACTIVITY_ID = ‚EOT_ASS' and LYMTYPE = 1 and RSPERF = 1 and RSPERF_SMZ = 1 and RSORRES_SMZ = 1 then CR_yes_no = 1;
    if ACTIVITY_ID = ‚EOT_ASS' and LYMTYPE = 1 and RSPERF = 1 and RSPERF_SMZ = 1 and RSORRES_SMZ > 1 then CR_yes_no = 0;
  - In case of missing tumor assessment at end of treatment (variable *RSPERF* = 0): No primary endpoint will be determined for patients who withdraw. The collected data will be used until the time of withdrawal. If the date of withdrawal is before the date of end of treatment, the complete response can be determined only in case of progress (i.e. a progression is documented at any point in time before end of therapy). In all other cases the complete response cannot be evaluated (i.e. CR_yes_no will be missing).

The **secondary endpoints** are

a) Response rate (CR, PR, OR (CR or PR))
b) Best response
c) Time to best response
d) Time to first response
e) Progression free survival (PFS)
f) Time to treatment failure (TTF)
g) Duration of Response (DR)
h) Cause specific survival (CSS)
i) Overall survival (OS)
j) Quality of life during trial (therapy)

Details for a): The response rates (complete response (CR), partial response (PR) and overall response rate (OR (CR or PR))) are evaluated 4 weeks after the end of treatment at point in time EOT/ET visit C18/D1. The complete response CR is therefore identical with the primary endpoint (see above). For the analysis of the response rates and the overall response rate, the variables *RSORRES_NMZEG* (nodal MZL and extragastric MALT lymphoma), *RSORRES_EGM* (extranodal gastric MALT lymphoma) and *RSORRES_SMZ* (splenic MZL) in table ***RS*** for the variable *ACTIVITY_ID* = *'EOT_ASS'* will be used. The single categories for the response rates are CR, PR, SD, PD, and NE and will be defined using the categories in the database/CRF as follows:

- CR: nodal MZL and extragastric MALT lymphoma: CR; extranodal gastric MALT lymphoma: CR/pMRD; splenic MZL: CR
- PR: nodal MZL and extragastric MALT lymphoma: PR; extranodal gastric MALT lymphoma: PR/rRD; splenic MZL: PR
- SD: nodal MZL and extragastric MALT lymphoma: SD; extranodal gastric MALT lymphoma: SD / NC; splenic MZL: SD / No Response
- PD: nodal MZL and extragastric MALT lymphoma: PD; extranodal gastric MALT lymphoma: PD; splenic MZL: PD
- NE: nodal MZL and extragastric MALT lymphoma: NE; extranodal gastric MALT lymphoma: NE; splenic MZL: NE

For analysis, a new variable *ASS_RESULT* will be calculated as follows:

- nodal MZL and extragastric MALT lymphoma:
  IF RSORRES_NMZEG = 1 THEN ASS_RESULT = 1;*CR;
  IF RSORRES_NMZEG = 2 THEN ASS_RESULT = 2;*PR;
  IF RSORRES_NMZEG = 3 THEN ASS_RESULT = 3;*SD;
  IF RSORRES_NMZEG = 4 THEN ASS_RESULT = 4;*PD;
  IF RSORRES_NMZEG = 5 THEN ASS_RESULT = 5;*missing;
- extranodal gastric MALT lymphoma
  IF RSORRES_EGM = 1 THEN ASS_RESULT = 1;*CR;
  IF RSORRES_EGM = 2 THEN ASS_RESULT = 2;*PR;
  IF RSORRES_EGM = 3 THEN ASS_RESULT = 3;*SD;
  IF RSORRES_EGM in (4 5) THEN ASS_RESULT = 4;*PD;
  IF RSORRES_EGM = 6 THEN ASS_RESULT = 5;*missing value;
- splenic MZL:
  IF RSORRES_SMZ = 1 THEN ASS_RESULT = 1;*CR;
  IF RSORRES_SMZ = 2 THEN ASS_RESULT = 2;*PR;
  IF RSORRES_SMZ = 3 THEN ASS_RESULT = 3;*SD;
  IF RSORRES_SMZ = 4 THEN ASS_RESULT = 4;*PD;
  IF RSORRES_SMZ = 5 THEN ASS_RESULT = 5;*missing value;

For the analysis of the overall response rate (CR or PR), a new variable *ORR* (yes/no) will be calculated from the variable *ASS_RESULT* as follows: IF ASS_RESULT in (1 2) THEN ORR = 1; ELSE ORR = 0;
Absolute and relative frequencies will be calculated for the statistical analysis of the variables *ASS_RESULT* and *ORR*.
Details for b): Best response (CR, PR, SD, PD) is determined in the time interval from the start of therapy to end of follow-up. At first, the single categories for the analysis of the response rates (CR, PR, SD, PD, NE) will be defined and calculated as described in section 'Details for a)' (see above) for each point in time in which a tumor assessment was performed and a new variable *THERAPY_RESULT* will be created. The best response for a patient is the minimum (i.e. the best outcome) of the variable *THERAPY_RESULT*, measured across all points in time with tumor assessment (over the entire observation time). The result is stored in a new variable *BEST_RESPONSE*.
Details for c): Time to best response is defined as the time from the start of therapy to best response the patient achieves (CR, PR). For calculation, the difference between the date of the first day of treatment in cycle 1 (C1/D1; see CTP pages 106-110) (variable *EXSTDAT* for *ACTIVITYID* = *'C1D1_SV'* in table ***EX1***) and the date of best response (i.e. first date at which CR is reached; in case of no CR is reached, the first date at which PR is reached) will be used. For the determination, the variable *THERAPY_RESULT* (see section 'Details for b)' above) will be used, together with the date of assessment which is calculated as variable *ASS_DATE* from the variables *RSDAT_NMZEG*, *RSDAT_EGM* and *RSDAT_SMZ* in table ***RS***. Patients who reach CR or PR: The earliest date at which CR or PR is documented will be determined for each patient across all points in time with tumor assessment and will be used as end date for time to best response (not censored). Patients who do not achieve the response category CR or PR, will be censored at the latest tumor assessment date.
Details for d): Time to first response is defined as the time from the start of therapy to first response (CR, PR). For calculation, the difference between the date of the first day of treatment in cycle 1 (C1/D1; see CTP pages 106-110) (variable *EXSTDAT* for *ACTIVITYID* = *'C1D1_SV'* in table ***EX1***) and the date of first response (first date at which CR or PR is reached) will be used. For the determination, the variable *THERAPY_RESULT* (see section 'Details for b)' above) will be used, together with the date of assessment which is calculated as variable *ASS_DATE* from the variables *RSDAT_NMZEG*, *RSDAT_EGM* and *RSDAT_SMZ* in table ***RS***. Patients who reach CR or PR: The earliest date at which CR or PR is documented will be determined for each patient across all points in time with tumor assessment and will be used as end date for time to first response (not censored). Patients who do not achieve the response category CR or PR, will be censored at the latest tumor assessment date.
Details for e): Progression free survival is defined as the time of registration to the first occurrence of progression or relapse as assessed by the investigator, or death from any cause. PFS for patients without disease progression, relapse, or death will be censored at the time of the last tumor assessment. Progression free survival will be calculated as difference between time of registration (date of patient signed written informed consent; variable *RFICDAT* in table ***DM***) and the earliest date of the event (progression or relapse or death) or the date of last tumor assessment (in case of no event). For the earliest date in case of progression or relapse the dates in table ***RS*** will be used as follows: nodal MZL and extragastric MALT lymphoma: variable *RSDAT_NMZEG* for *RSORRES*_NMZEG = *4*, extranodal gastric MALT lymphoma: variable *RSDAT_EGM* for *RSORRES_EGM in (4 5)*, splenic MZL: variable *RSDAT_SMZ* for *RSORRES_SMZ = 4*. Additionally for the date of progression, the variable *RSDAT_ET* (table ***DSET*** IF *DSDECOD_ET* = *3*) will be used for identifying patients with PD. For patients who died, the date of death will be determined using the variable *DTHDAT* in table ***DSEOS***.

Details for f): Time to treatment failure is defined as the time of registration to discontinuation of therapy for any reason including death from any cause, progression, toxicity or add-on of new anti-cancer therapy. Time to treatment failure will be calculated as difference between time of registration (date of patient signed written informed consent; variable *RFICDAT* in table ***DM***) and the earliest date of the event (discontinuation of therapy for any reason). The following information will be used for the determination of the last mentioned date:

- discontinuation of therapy for any reason: variable *EXENDATE_ET* in table ***DSET*** for *DSDECOD_ET not in (1 3)*.
- death from any cause: the date of death will be determined using the variable *DTHDAT* in table ***DSEOS***
- progression: the dates in table ***RS*** will be used as follows: nodal MZL and extragastric MALT lymphoma: variable *RSDAT_NMZEG* for *RSORRES_NMZEG = 4*, extranodal gastric MALT lymphoma: variable *RSDAT_EGM* for *RSORRES_EGM in (4 5)*, splenic MZL: variable *RSDAT_SMZ* for *RSORRES_SMZ = 4*. Additionally for the date of progression, the variable *RSDAT_ET* (table ***DSET*** for *DSDECOD_ET = 3*) will be used for identifying patients with PD.
- end of treatment: variable *RSDAT_ET* for *DSDECOD_ET = 3* in table ***DSET***
- death: variable *DTHDAT* for *DSDECOD_EST = 4* in table ***DSEOS***
- add-on of new anti-cancer therapy: variable *PRSTDAT* in table ***PR2*** for the first event in a patient

Patients alive without treatment failure are censored at the latest tumor assessment date.

Details for g): Duration of Response will be calculated in patients with response to therapy (CR, PR) from diagnosis of response to the date of progression, relapse or death from any cause. It will be calculated as difference between date of diagnosis of response and the earliest event date (progression, relapse or death from any cause). The date of diagnosis of response will be determined as variable *ASS_DAT* from the variables *RSDAT_NMZEG* (nodal MZL and extragastric MALT lymphoma), *RSDAT_EGM* (extranodal gastric MALT lymphoma) and *RSDAT_SMZ* (splenic MZL) in table ***RS*** for the variable *ACTIVITY_ID = 'EOT_ASS'* and *ASS_RESULT in (1 2)* (see section 'Details for a)' above).

For the determination of the earliest event date, the following information will be used:

- progression and relapse: For the date in case of progression or relapse the data in the tables ***RS***, ***DSET***, and ***DSEOS*** will be used as described in section 'Details for e)', see above
- death from any cause: For patients who died, the date of death will be determined using the variable *DTHDAT* in table ***DSEOS***

In case of an event is the event date for remission duration the earliest date among these dates. Patients alive without progression and relapse will be censored at the latest tumor assessment date or the stopping date.

Details for h): Cause specific survival is defined as the period from the study registration to death from lymphoma or lymphoma related cause; death unrelated to MZL is considered as a competing event. CSS will be calculated as difference between time of registration (date of patient signed written informed consent; variable *RFICDAT* in table ***DM***) and the date of an event (variable *DTHDAT* for *SURVSTAT = 0* and *PRCDTH_DDORRES = 1* in table ***DSEOS***). Patients who have not died or died from another reason than lymphoma or lymphoma related cause until the time of the analysis will be censored at their last contact date.

Details for i): Overall survival is defined as the period from the registration to death from any cause. Overall survival will be calculated as difference between time of registration (date of patient signed written informed consent; variable *RFICDAT* in table ***DM***) and the date of death (variable *DTHDAT*

for *SURVSTAT = 0* in table ***DSEOS***). Patients who have not died until the time of the analysis will be censored at their last contact date.

Details for j): Quality of life was measured by the FACT Lym before start of treatment and during trial participation. For statistical analysis, the FACT-Lymphoma Trial Outcome Index (TOI), the FACT-G total score, the FACT-Lymphoma total score and the sum score for each of the five subscales (physical well-being (PWB), social/family well-being (SWB), emotional well-being (EWB), functional well-being (FWB), lymphoma subscale (LYMS)), will be calculated. Details about the calculations are provided in two separate documents doc01_Administration Guidelines_Manual_082505.pdf and doc19_ScoringFACT-Lym v4-REVISED.pdf.

7.6 Variables for Safety Analysis

Safety evaluations include AEs/SAEs/AESIs, clinical laboratory parameters (hematology, serum chemistry, serum immunoglobulin (IgG, IgM, IgA), CRP), and ECG. Laboratory parameters cover parameters of serum chemistry, hematology, quantitative immunoglobulins (IgA, IgG, IgM), and CRP. More details are in the parts 7.1 and 7.2, see above. For ECG, the frequencies of 'Normal or not clinically significant' or 'Clinically significant' will be calculated.

The severity of AEs will be graded using the NCI-CTCAE version 5.0 dictionary. An AE is defined as any event arising or worsening after start of study drug administration until 110 days (based on five times the half-life of Rituximab and Pembrolizumab) after the last study drug intake. All AEs, drug related AEs, serious AEs will be summarized by MedDRA classification (SOC and preferred term) and worst CTCAE grade. Additionally, adverse events of special interest (AESIs) will be analysed as a separate category.

Adverse events (AE), serious adverse events (SAE) adverse events of special interest (AESI): Following variables will be used in the analysis of AEs, SAEs and AESI: *SUBJECTID*, *AESPID*, *AETERM*, *AETOXGR*, *AERELPEM*, *AERELRIT*, *AEACNPEM*, *AEACNRIT*, *AESER*, *AESI*, *AESS*, *AESSCAS*, *AESTDAT*, *AEOUT*, and *AEENDAT* in table ***AE***. For the analysis of AEs, the final outcome will be analysed only. AEs, SAEs (variable *AESER* in table ***AE***) and AESIs (variable *AESI* in table ***AE***) will be analysed separately. Additionally, AEs / SAEs / AESIs of grade ≥ 3 (variable *AETOXGR* in table ***AE***) will be analysed separately.

Concomitant medication: Concomitant medication is documented during treatment period. Variables for analysis are *SUBJECTID*, *CMSPID*, *CMTRT*, *CMINDC*, *CMDSTXT*, *CMFREQ*, *CMROUTE*, *CMROUTEOTH*, *CMSTDAT*, *CMONGO*, and *CMENDAT* in table ***CM***.

7.7 Further Variables

For the analysis of treatment duration, the difference between the last day of treatment (variable *EXENDAT_ET* in table ***DSET***) and first day of treatment (variable *EXSTDAT* for *ACTIVITYID = 'C1D1_SV'* in table ***EX1***) will be analysed. For the analysis of study duration, the difference between time of registration (date of patient signed written informed consent; variable *RFICDAT* in table ***DM***) and date of EOS (variable *DSEOSENDAT* in table ***DSEOS***; in case of loss of contact: variable *DSLSTDAT_EST* in table ***DSEOS***) will be analysed.

For the analysis of extranodal involvement, the frequencies (yes/no/not assessable) of bone marrow infiltration and splenomegaly will be analysed using the variables *PRSNT_IBM* and *PRSNT_SPLMG* in table ***ENI***.

For analysis of the lymph node status the total number of affected lymph nodes (all regions) will be calculated as sum of the variables *PRSNT_CEL*, *PRSNT_CER*, *PRSNT_CLL*, *PRSNT_CLR*, *PRSNT_AXL*, *PRSNT_AXR*, *PRSNT_MED*, *PRSNT_HIL*, *PRSNT_HIR*, *PRSNT_PER*, *PRSNT_TC*, *PRSNT_PAR*, *PRSNT_SPH*, *PRSNT_HOL*, *PRSNT_MES*, *PRSNT_ILL*, *PRSNT_ILR*, *PRSNT_IGL*, *PRSNT_IGR*, and *LNSOTHNUM* in table ***LNS***.

For analysis of toxicity, all patients with a delay of treatment due to toxicity (variable *EXTDEL_TOX = 1* in table ***EX2***) will be listed. Additionally, the frequency of these patients will be calculated separate for Pembrolizumab and Rituximab (variables *EXTDELSPY1* and *EXTDELSPY2* in table ***EX2***).
For analysis of study drug administration, the percentage (from scheduled dose) of study drug administered will be calculated (variables *EXPEMORRES* and *EXRITORRES* in table ***EX1***). Additionally, all patients with deviations in study drug administration will be listed (variable *EXIAYN = 1* in table ***EX1***).

8 Statistical Methods

8.1 Methods for Descriptive Statistics

Continuous variables:
Continuous variables will be summarised using the following standard descriptive summary statistics (if appropriate): number of observations, number of missing observations arithmetic mean, standard deviation, minimum, lower quartile, median, upper quartile, maximum. Furthermore, graphical methods will be used, e.g. Boxplots, plots of time course of mean +/- standard deviation resp. median +/- ½·inter quartile range, Kaplan-Meier plots for variables of the secondary endpoint as appropriate. In case of too few measurements, the single measured values will be displayed.
Categorical variables:
Categorical data will be described using absolute and relative frequencies. In case of too few measurements, the single measured values will be displayed. Missing data will be treated as separate category in statistical analysis.

8.2 Details of Statistical Analysis

8.2.1 Efficacy Analysis of the Primary Endpoint

The primary endpoint (CRR) will be evaluated after end of treatment (18 cycles) after the last recruited patient has started her/his treatment. The primary parameter CRR will be evaluated in a modified intention to treat way, which means that all patients for whom the primary endpoint CRR is measured after end of treatment will be included in the analysis of the primary endpoint (Core Analysis Population, see CTP subsection 12.6.1). Patients without staging at regular end of treatment will be defined as non-responder. Only patients who withdraw will be excluded. The results on efficacy in the Core Analysis Population were considered to be the main efficacy results (confirmatory results). The one sample exact binomial test will be used for the analysis of the primary endpoint to test the CRR against the fixed value 56% at the 2.5% significance level (one-sided). Thus, the decision about the new concept will be based on a statistical test of the form: H_A: {CRR > 56%} vs. H_0: {CRR ≤ 56%}.
Patients who withdraw will be included in a separate explorative analysis. Additionally, a one-sided 97.5% confidence interval for CRR will be calculated as an effect estimator.
A separate exploratory sensitivity analysis of the primary endpoint will be done to investigate the influence of withdrawals.

8.2.2 Sample Size Calculation

Full details of the sample size calculation are in the CTP at pages 13 and 92.

8.2.3 Efficacy Analysis of Secondary Endpoints

All secondary endpoints (Response rate, Best response, Time to best response, Time to first response, PFS, TTF, DR, CSS, OS and Quality of life during trial (therapy)) will be analysed exploratory by respective descriptive analysis, statistical tests and two-sided 95%-confidence intervals. Missing values will not be replaced.

Response rate and best response: The rates incl. the two-sided 95% confidence intervals (Clopper-Pearson) will be provided. The confidence limits can be used for a comparison with a fixed value.

Time to best response, time to first response, PFS, TTF, RD, CSS, OS: Kaplan-Meier plots will be provided. Because time to best response and time to first response describe a favourable event, the ordinate of the Kaplan-Meier plot will be "1 minus survival probability" instead "survival probability".

Quality of life during trial: The FACT-Lymphoma Trial Outcome Index (TOI), the FACT-G total score, the FACT-Lymphoma total score and the sum score for each of the five subscales (PWB, SWB, EWB, FWB, LYMS), will be analysed as continuous variable.

With exception of the efficacy analysis of the primary endpoint, each statistical test will be performed two-sided at a significance level of 5%. All results from these analyses will be regarded as hypothesis generating only and not as proof of efficacy.

8.2.4 Further Analyses

Because of the small sample size and the comparatively high number of trial sites, no further analyses of effects of trial sites will be provided.

8.2.5 Sensitivity Analyses

Sensitivity analyses are planned for the stability investigation of the result of the confirmatory analysis of the primary endpoint. Patients who withdraw will be excluded from the confirmatory data analysis but will be analysed in a separate exploratory sensitivity analysis. Two distinct scenarios will be regarded to investigate the influence of withdrawals. In a first scenario is the primary endpoint in all withdrawals set to CR='no'. In the second scenario is the primary endpoint in all withdrawals set to CR='yes'.

Another sensitivity analysis is planned for patients with discrepancy between using the modified 2007 Cheson criteria and the data base entries regarding the evaluation of the primary endpoint. If there are such patients, two further scenarios for the primary endpoint will be investigated: In the first scenario the modified 2007 Cheson criteria will be applied, in the second scenario the data base entries as entered by the sites will be used.

8.2.6 Safety Analysis

Generally, safety evaluations include: adverse events and clinical laboratory parameters (hematology, serum chemistry, serum immunoglobulin (IgG, IgM, IgA), CRP). The severity of adverse events will be assessed using National Cancer Institute Common Terminology Criteria for Adverse Events, Version 5.0.

Analysis of adverse events (AE), serious adverse events (SAE) and adverse events of special interest (AESI): AEs, SAEs and AESIs will be listed in tabular form. Listings will be provided for all AEs, SAEs, AESIs, and for AEs of grade ≥ 3, SAEs of grade ≥ 3, AESIs of grade ≥ 3. Furthermore, the proportion (incl. 95% confidence interval) of patients with at least one AE / SAE / AESI will be calculated.

Analysis of concomitant medication: The time course of concomitant medication will be provided for each patient as listing of main variables (*SUBJECTID*, *CMSPID*, *CMTRT*, *CMINDC*,

CMDSTXT, *CMFREQ*, *CMROUTE*, *CMROUTEOTH*, *CMSTDAT*, *CMONGO*, and *CMENDAT* in table ***CM***) of each medication ordered by number of medication (variable *CMSPID* in table ***CM***).
Analysis of clinical laboratory parameter (hematology, serum chemistry, serum immunoglobulin (IgG, IgM, IgA), and CRP)): For each of the parameters of hematology (hemoglobin, hematocrit, platelets, erythrocytes, leukocytes, neutrophils, lymphocytes), serum chemistry (potassium, LDH, ALT, AST, GGT, alkaline phosphatase, uric acid, and CRP), and immunoglobulin (IgA, IgG, IgM) the time course will be analysed descriptively in a separate table with results from descriptive statistics. There will be a separate row for each point in time (see CTP pages 106-110). Furthermore, for each parameter of haematology and serum chemistry the frequency of clinical significant ratings and not clinically significant ratings will be provided.
Analysis of ECG findings: The frequencies for 'Examination performed?' (yes/no) and result (negative/positive) will be calculated for each point in time. In case of a clinically significant result, the time course of the results in the respective patient will be listed (variable *EGORRES* in table ***EG***). Additionally, the respective database record in table ***MH1*** will be listed in this case.

8.2.7 Medical history and concomitant diseases

The analysis of previous diseases and concomitant diseases is based on number of occurrences together with corresponding counts of patients. In all tables, counts and frequencies of occurrences together with corresponding counts of patients will be listed.

9 Listings, Tables, Figures

All results from statistical analyses will be provided by means of listings, tables and figures as Word file (*.docx) or RTF file (*.rtf).

10 Software

All statistical analyses will be performed using SAS, version 9.4 (SAS Inc. Cary/NC, USA) under Windows 10 or 11. SAS- macros developed at the Institute of Epidemiology and Medical Biometry will be used for analyses, if applicable. Some Figures will be created using R, version 4.5.0, as appropriate.

11 Use of Results of Statistical Analysis

Parts of the statistical analysis (e.g. tables, figures, and summary statistics) will be provided to the Comprehensive Cancer Center / Department of Internal Medicine III / Institute for Experimental Tumour Research for preparation of the Synopsis according to the ICH E3 guideline. The shorted clinical trial summary report and other scientific contributions (e.g. article, oral presentation, poster) will be prepared by the Comprehensive Cancer Center / Department of Internal Medicine III / Institute for Experimental Tumour Research. (At least) one employee from the Institute of Epidemiology and Medical Biometry will be mentioned as co-author in each scientific contribution. The employee will be informed about the content of each scientific contribution.

12 Appendices

12.1 Conversion Factors for Laboratory Units

The following tables show the units which will be used in the statistical analysis.

Hematology				
Value	**unit for statistical analysis**		**value**	**unit for statistical analysis**
Hemoglobin	g/dL		Leukocytes	/nL
Hematocrit	%		Neutrophils	/nL
Platelets	10^9/L		Lymphocytes	/nL
Erythrocytes	/pL			

Quantitative Immunoglobulins	
value	**unit for statistical analysis**
IgA	mg/dL
IgG	mg/dL
IgM	mg/dL

Serum chemistry				
Value	**unit for statistical analysis**		**value**	**unit for statistical analysis**
Potassium	mmol/L		GGT	U/L
LDH	U/L		Alkaline Phosphatase	U/L
ALT	U/L		Uric acid	µmol/L
AST	U/L		CRP	mg/L

Peripheral blood -/ Leukocyte Immunophenotyping (FACS) – Antigen expression of the lymphoma	
value	**unit for statistical analysis**
Kappa	mg/dL
Lambda	mg/dL
Kappa / Lambda ratio	-

Thyroid hormones	
value	**unit for statistical analysis**
Triiodthyronin (T3)	nmol/L
Thyroxin (T4)	nmol/L
Thyreotropin (TSH)	mU/L

The following table shows the conversion factors which will be used for the conversion of the laboratory results in units that will be used in the statistical analysis.

Parameter Group	Parameter	Unit for statistical analysis	Actual unit	Conversion factor
Hematology	Hemoglobin	g/dL	mmol/L	1.61
Hematology	Hematocrit	%	L/L	100
Hematology	Platelets	10^9/L	x10^3/uL	1.000
Hematology	Platelets	10^9/L	10^9/L	1.000
Hematology	Platelets	10^9/L	/uL	0.001
Hematology	Platelets	10^9/L	/nL	1.000
Hematology	Erythrocytes	/pL	T/L	1.000
Hematology	Erythrocytes	/pL	/pL	1.000
Hematology	Leukocytes	/nL	x10^3/uL	1.000
Hematology	Leukocytes	/nL	/uL	0.001
Hematology	Leukocytes	/nL	/nL	1.000
Hematology	Leukocytes	/nL	10^9/L	1.000
Hematology	Leukocytes	/nL	Giga/L	1.000
Hematology	Neutrophils	/nL	%	Leukocytes
Hematology	Neutrophils	/nL	/uL	1.000
Hematology	Neutrophils	/nL	/nL	1.000
Hematology	Neutrophils	/nL	10^9/L	1.000
Hematology	Neutrophils	/nL	Giga/L	1.000
Hematology	Lymphocytes	/nL	%	Leukocytes
Hematology	Lymphocytes	/nL	10^9/L	1.000
Hematology	Lymphocytes	/nL	Giga/L	1.000
Serum chemistry	Potassium	mmol/L	mg/dL	0.256
Serum chemistry	LDH	U/L	ukat/L	60
Serum chemistry	ALT	U/L	ukat/L	60
Serum chemistry	AST	U/L	ukat/L	60
Serum chemistry	GGT	U/L	ukat/L	60
Serum chemistry	Alkaline phosphatase	U/L	ukat/L	60
Serum chemistry	Uric acid	µmol/L	umol/L	1.000
Serum chemistry	Uric acid	µmol/L	mg/dL	59.485
Serum chemistry	CRP	mg/L	mg/dL	10
Thyroid hormones	Triiodthyronin (T3)	nmol/L	ng/dL	0.0154
Thyroid hormones	Thyroxin (T4)	nmol/L	ug/dL	12.8722
Thyroid hormones	Thyreotropin (TSH)	mU/L	uU/mL	1.000

12.2 Allocation of response categories

The following table shows the allocation for the responses categories in the tumor assessment for the statistical analysis of secondary endpoints in the whole study group.

Subtype	Response category (subtype)	Harmonized response category
Extranodal gastric MALT lymphoma	CR / pMRD	CR
	PR / rRD	PR
	SD / NC	SD
	PD	PD
	Relapse	PD
	NE	NE
Splenic MZL		
	CR	CR
	PR	PR
	SD / No response	SD
	PD	PD
	NE	NE
Nodal MZL/extragastric MALT lymphoma		
	CR	CR
	PR	PR
	SD	SD
	PD	PD
	NE	NE