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STATISTICAL ANALYSIS PLAN

Version 6

MorphoSys AG

Semmelweisstr. 7
D-82152 Planegg
GERMANY

A Phase Ib/IIa, Open-Label, Multicenter Clinical Trial to Assess Safety and Efficacy of the Human Anti-CD38 Antibody MOR202 in Anti-PLA2R Antibody Positive Membranous Nephropathy (aMN) M-PLACE

Protocol No: MOR202C103

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SIGNATURE PAGE

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1. TABLE OF CONTENTS

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2. DOCUMENT HISTORY

Document History – Changes compared to the previous finalized version

Version	Date	Changes	Rationale for Change
1.0	06-09-2019	Original	
2.0	05-06-2020	**Section 4:** Description of subjects in accordance with Clinical Trial Protocol (CTP) v.6 **Section 5:** Re-wording of study endpoints to match wording in CTP v.6 **Section 6.1:** Description of Cohort 1a and Cohort 1b in accordance with CTP v.6 **Section 6.3:** Description of Cohort 1a and Cohort 1b in accordance with CTP v.6 **Section 15.4** Modification of table shell to display results for Cohort 1a and Cohort 1b	As per CTP v.6.0 Cohort 1 is split into Cohort 1a and Cohort 1b
3.0	30-11-2020	**Section 6.1, Section 6.3:** Description of Cohort 1 and Cohort 2 in accordance with CTP v.7	As per CTP v7.0 Cohort 1a and Cohort 1b are combined to Cohort 1, and Cohort 2 definition is updated.
		Section 6.4.2: Time point of primary analysis definition extended in order to provide a clearer guidance. Addition of "*selected*" exploratory endpoints to the analysis to be performed at primary analysis.	To provide a more detailed definition of the time point of the primary completion analysis. Some exploratory endpoints are not mature enough at the time of primary completion analysis and will be analysed at the time of final analysis.
		Section 7.9 Addition of "*subjects lost to follow-up*" to the derivation of date of last contact.	To provide a more detailed definition of the use of date of last contact.
		Section 7.13.7 Listing of subjects in each analysis sets added**.**	Listing added in order to provide more details.
		Section 7.14.3	Response assessments after start of prohibited treatment or

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Version	Date	Changes	Rationale for Change
		Addition of "*prior to start of prohibited treatment or progression*" to the definition of response variables Addition of duration of response variable.	progression should not be included in the derivation of responses. Analysis of duration of response will provide more information on efficacy.
		Section 7.14.5 Addition of "*Time to BIR*" and "*Time to BPR*" to the censoring table. Addition of censoring rules for subjects receiving prohibited treatment. Censoring rule for subjects discontinuing from study without event modified to "date of *last response assessment prior to* study discontinuation"	To provide censoring rules for "Time to BIR" and "Time to BPR". Response assessments after start of prohibited treatment should not be included in the derivation of responses. Censoring rule adapted according to FDA guidance.
		Section 8.2 Percentage calculation for categorical variables changed to include percentage for missing categories.	To provide percentage of missing categories for more information.
		Section 8.4 Incidence and severity of AEs in follow-up phase added to analysis at the time of primary analysis.	To provide more information at the time of primary analysis as some patients may have entered follow-up phase at this time point already.
		Section 9.4 Removed the specification of "*important and non important protocol deviations*" for the analysis of protocol deviation and refer to the protocol deviation specification form. Frequency table for missed visits added, including missed visits in the context of COVID-19.	To not limit the deviation categories to "important and non important" but use all categories as specified in the protocol deviation specification form. To provide an analysis on the impact of missed visits in the context of COVID-19
		Section 9.5, Section 9.7.1, Section 11.6.1, Section 9.6.3 Details to the categorical variables added.	To display the categories from the categorical variables.
		Section 9.6.3 Removed several anti-PLA2R summaries and kidney ultrasounds. Removed IFTA score summaries.	As per CTP v7.0 these summaries are not needed.

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Version	Date	Changes	Rationale for Change
			IFTA score is collected as free text, thus listing of IFTA score will be provided instead.
		Section 9.7.4 Summary by infusion number replaced by cycle and day.	Display infusion by cycle and day will provide clearer information.
		Section 9.8.4 Re-categorized prior immunosuppressive medications. Removed summary on remission as entered in the eCRF during or following the last therapy.	To provide more information. Summary is already presented in section 9.6.3.
		Section 10.1 and Section 10.3 Subjects with PD and non-responder added to the summary tables of response assessments	To provide more information in the context of response assessments.
		Section 10.6 Analysis of duration of response added.	Analysis of duration of response will provide more information on efficacy.
		Section 10.8 Details on the KDQOL-36 scores added. Summary of subscales added.	To provide more information on the subscales of the total score.
		Section 10.9 Summary of change from baseline until EOS added. Mean and 95%CI for percentage change plot added. Waterfall plot per subjects added. Analyses for the PPS may be generated.	To provide more information on the kinetics of anti-PLA2R. As FAS and PPS may be similar, repeating of the analyses based on PPS is optional.
		Section 11.1 Definition of SAE and AESI removed.	Reference to the protocol is provided.
		Section 11.1.4 Summary of non-serious TEAEs regardless of study drug relationship, and summary of TEAEs related to COVID-19 added.	Newly added summaries will be needed for trial results reporting. To provide a more detailed definition.

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Version	Date	Changes	Rationale for Change
		Definition of IRR summary table extended. Removed several special AE listings.	Information of AE listing is present in the remaining listings.
		Section 11.1.4 Summary of non-serious TEAEs regardless of study drug relationship, and summary of TEAEs related to COVID-19 added. Definition of IRR summary table extended. Removed several special AE listings.	Newly added summaries will be needed for trial results reporting. To provide a more detailed definition. Information of AE listing is present in the remaining listings.
		Section 11.6.3 Summary of absolute and change from baseline of cytokines added.	To provide more information on cytokines.
		Section 13 Summary of ADA over all visits added.	To provide more on information as ADA.
		Section 14 Summary of change from EOT for biomarkers added.	Added as per clinical protocol wording.
		Throughout the document: Editorial changes	
4.0	17-11-2021	**Section 7.9 (old) and section 9.3 (old)** Removed definition of date of last contact and duration of follow-up.	Information is available in the exposure and disposition table.
		Section 7.10 and section 7.11 Added information on pre-/post dose collection for analysis visit mapping.	Information is needed for mapping algorithm
		Section 7.12.7 Removed PPS analysis for kinetics of anti-PLA2R titres.	Analyses will be performed on FAS. Due to the small sample size, SAF and FAS will not differ substantially.
		Section 9.2 Added the number of subjects ongoing in follow-up phase.	Information relevant for primary analysis
		Section 9.5.3	Information will be present in section 9.7.4, section 10.1

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Version	Date	Changes	Rationale for Change
		Removed information on prior IST treatment, baseline proteinuria value, and anti-PLA2R titres from aMN-specific medical history table. Removed kidney biopsy outputs.	Kidney biopsy information can be found in listings.
		Section 9.6.5 Removed boxplots of compliance.	Information is already available in table
		Section 9.7.2 and section 9.7.3 Merging of concomitant medication and prior and concomitant medication.	A separate category of prior and concomitant medication is not required.
		Section 10.1 Removed sensitivity analysis of excluding subjects with no post-baseline assessment.	All patients have at least one post-baseline assessment.
		Section 10.2 Replace boxplot with waterfall plot.	Waterfall plot is of higher interest.
		Section 10.4, Section 10.5 Removed plots.	For this exploratory endpoint, no figures are needed.
		Section 10.7 Added cumulative hazard plot.	Plot will provide a different view on the time to event endpoint.
		Section 10.8 Added the information on the norm used for KDQOL.	Since two versions of the questionnaires are used, the specification of the norm provides comparability of the two versions.
		Section 10.9 Removed the boxplot and plots by best response. Replaced confidence interval with standard error for the plot.	Due to small number of subjects, spaghetti plots over time can present all patients and a wide confidence interval may not be meaningful.
		Section 11.1.4 Added $\geqslant$ 5% to non-serious TEAE output. Removed AE tables of grade 5. SAE table including death cases added. Death table removed. IRR table removed. Replaced IRR by SMQ Hypersensitivity in bar chart. Removed special listings. Removed pre-treatment AE listing	Requirement added for trial result posting. Information of grade 5 is available in by grade AE tables. Table added for EudraCT posting. Information on death cases available in listings and SAE table including death cases. Information on IRR already available in AE tables. To broaden the AE event categories.

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Version	Date	Changes	Rationale for Change
			Information available in AE listing already. Information not relevant for CSR writing.
		Section 11.6.3 Removed tables for pregnancy results and categorical urinalysis variables.	Information will be present in listings.
		Section 12.4 Replaced MOR202 concentration ratio by normalized MOR202 concentration ratio**.**	Analysis of normalized concentration ratio is more meaningful.
		Section 14 Detailed specification of biomarkers.	To provide more information.
		Throughout the document: Editorial changes	
5.0	08.03.2022	**Section 7.3.16** The definition of Prohibited medication was added in the SAP	Prohibited medications make part of the analyses and should be defined in the SAP
		Section 7.10 The 'Assessment windows and analysis visits' section was substituted by 'Analysis visits' section. Assessment windows are disregarded in current version and the main difference in analysis windows approach is that: nominal (actual) visit dates will be used as per eCRF, unscheduled visits for visit-based analyses will be disregarded, except baseline assessment unscheduled visits will be considered only for patient data listings and spaghetti plots	Applying the assessment windows clarifies the approach for using unscheduled visit data.
		Section 9.6.1 Categories of exposure duration and the cumulative exposure duration were defined based on study days	This approach enables an easier interpretation of the results
		Section 10.2 Spaghetti plots for % change from baseline for each subject were added	These plots will allow detailed exploration of the results

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Version	Date	Changes	Rationale for Change
		All plots will be produced also for Urine creatinine parameter	
		Section 10.3 Analysis of Proteinuria response will be evaluated also on PPS population	UPCR is an important efficacy endpoint and the analyses done on PPS population will allow detailed interpretation of the results
		Section 10.4 Analysis of Renal Function assessed by eGFR will be evaluated also on PPS population	Renal Function is an important efficacy endpoint and the analyses done on PPS population will allow detailed interpretation of the results
		Section 10.4 The eGFR will be evaluated as % change from baseline to each visit until End of Study.	No sense from clinical point of view doing the evaluation from EOT until EOS
		Section 10.5 The serum albumin levels will be evaluated as % change from baseline to each visit until End of Study.	No sense from clinical point of view doing the evaluation from EOT until EOS
		Section 10.7 Number (%) of subjects with doubling of serum creatinine either vs. baseline or any nadir measured during the trial was removed from the analyses	Is not needed per Protocol
		Section 10.8 The kidney specific subscales will be derived using additional SAS code (Appendix 1).	The evaluation of kidney specific subscales is not included in core scoring software provided by Optum
		Section 10.9 The kinetics of anti-PLA2R titers will be evaluated as % change from baseline to each visit until End of Study.	No sense from clinical point of view doing the evaluation from EOT until EOS
		Section 10.9 Spaghetti plots for % change from baseline for each subject were added	These plots will allow detailed exploration of the results
		Section 10.10 Sensitivity analysis will be performed on FAS population excluding subjects with less than 70% of the MOR202 doses	These analyses will allow detailed interpretation of the efficacy of study treatment
		Section 11.1.4 Tables of Treatment-emergent SAEs by primary SOC and PT, regardless of study	Previously these 3 tables were defined as a single table which is not possible

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Version	Date	Changes	Rationale for Change
		treatment relationship, suspected to be related to study treatment and death cases for Final analyses were split to 3 different tables	
		Section 14 Spaghetti plots for individual pharmacodynamic biomarker level (time vs. parameter value) were removed	Boxplots for absolute pharmacodynamic biomarker levels at each visit will be used
		Section 15 Some rules were adapted to Metronomia standards	Better display of the results
		Throughout the document: Editorial changes	
6.0	19.09.2022	**Section 5** The definition of Proteinuria endpoint was updated, ie 'end of cycle 6' and 'after 12 months' were removed from its definition	It is in accordance with the Protocol section 5 and FAS includes all patients with EOT and EOS data.
		Section 7.13.3 In the Proteinuria Response section, the definition of the reference range of serum albumin was added in accordance with Q2 laboratory manual	This reference range is necessary in programming of Proteinuria Complete Response
		Section 10.10 Sensitivity Analysis was updated with new conditions: 1)excluding subjects who received at least one dose of relevant IST therapies 2)Visit windows approach was implemented to evaluate main efficacy endpoints in accordance with Protocol visit assessments.	1)From clinical point of view these subjects have negative impact on different endpoints and the sensitivity analysis should be done excluding them 2)This approach enables assigning data in accordance with calendar days when the actual visits were done by subjects. Moreover, this approach enables not losing any subject data collected.
		CCI [redacted]	
		Section 14 Bullet 'Post EOT samples only: Absolute and relative change from EOT visit to each	This analysis is covered in the analysis of change from baseline at FU and EOS visits

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Version	Date	Changes	Rationale for Change
		subsequent visits until end of study' was removed	
		Throughout the document: Editorial changes	

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3. LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

ACEI	Angiotensin Converting Enzyme Inhibitor
ADA	Anti drug antibody
ADaM	Analysis Data Model
ADS	Analysis Dataset specification
ADR	Adverse drug reaction
AE	Adverse event, for definition see 10.8.6
AESI	Adverse Event of Special Interest
ALT	Alanine-Aminotransferase
aMN	Anti-PLA2R antibody positive membranous nephropathy
Anti-PLA2R	Anti phospholipase A2 receptor antibodies
ATC	Anatomical Therapeutic Chemical Classification
BAS	Biomarker Analysis Set
BIR	Best overall immunological response
BIRR	Best overall immunological response rate
BLOQ	Below Limit of Quantification
BPR	Best proteinuria response
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CKD-EPI	Chronic Kidney Disease Epidemiology Collaboration
CR	Complete response
CRF	Case Report Form
CRO	Contract research organization
CSR	Clinical study report
CTP	Clinical trial protocol
CxDy	Cycle x Day y (e.g. C1D1 is the 1st day of the 1st cycle)
CV	Coefficient of variation
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
eGFR	estimated glomerular filtration rate
ELISA	Enzyme-linked immunosorbent assay
EMA	European Medicines Agency
EOS	End of study visit (28 weeks after EOT)
EOT	End of therapy visit (28 days after last dose)
ESRD	End stage renal disease
EudraCT	European Union Drug Regulating Authorities Clinical Trials
FA	Final analysis
FAS	Full analysis set
FDA	Food and Drug Administration
FCBP	Female of childbearing potential
FUV	Follow up visit (14 weeks after EOT)
GCP	Good Clinical Practice
GFR	Glomerular Filtration Rate
IAS	Immunological analysis set
ICF	Informed Consent Form
ICH	International Council for Harmonisation
ICR	Immunological complete response

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IFTA score	Interstitial fibrosis and tubular atrophy score
IMP	Investigational medicinal product
IPR	immunological partial response
IRR	infusion related reaction
IST	Immunosuppressive therapy
i.v.	intravenously
CCI	[redacted]
LLOQ	Lower Limit of Quantification
MedDRA	Medical Dictionary for Regulatory Activities
mg	Milligram
mL	Milliliter
Max	maximum
Min	minimum
MM	Multiple myeloma
MN	Membranous nephropathy
NCI CTCAE 5.0	National Cancer Institute Common Terminology Criteria for Adverse Events, version 5.0
PA	Primary analysis
PD	Progressive disease
PE	Physical examination
PK	Pharmacokinetics
PKAS	Pharmacokinetic Analysis Set
PK/PD	pharmacokinetic/pharmacodynamic
PKAS	Pharmacokinetic Analysis Set
PLA2R	Phospholipase A2 receptor
PPS	Per protocol set
PR	Partial response
Prot-CR	Proteinuria Complete Response
Prot-PR	Proteinuria Partial Response
PT	Preferred term
QoL	Quality of Life
QTcB	QT interval corrected for heart rate according to Bazett
QTcF	QT interval corrected for heart rate according to Fridericia
Q1	25^{th} Percentile
Q3	75^{th} Percentile
RU	Response unit
SAE	Serious adverse event, for definition see 10.8.6
SAP	Statistical analysis plan
Scr	Serum creatinine
SDTM	Study data tabulation model
sICR	Stringent immunological complete response
SOC	Standard of Care
SOP	Standard Operating Procedure
StD	Standard deviation
TEAE	Treatment emergent adverse event
$t_{1/2}$	Terminal elimination half-life
UPCR	Urine protein to creatinine ratio
WHO	World Health Organization

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4. INTRODUCTION

This Statistical Analysis Plan (SAP) describes the planned analysis and reporting of data collected from MorphoSys protocol MOR202C103, Version 7.0, dated 07-Jul-2020. Any amendments to the protocol, which do not affect the statistical aspects of the trial will not necessitate a SAP update.

This study is a two-cohort, non-randomized, open-label, multicenter clinical trial to assess safety and efficacy of the human anti-CD38 antibody MOR202 in anti-PLA2R antibody positive membranous nephropathy (aMN) subjects eligible for immunosuppressive therapy (IST) or who have failed to respond to previous IST. The structure and content of this SAP are specified to give detailed and comprehensive description of the endpoints in the study and the corresponding analyses in accordance with the requirements identified by the Food and Drug Administration (FDA), European Medicines Agency (EMA), and International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use: Guidance on Statistical Principles in Clinical Trials. All work planned and reported from this SAP will follow internationally accepted guidelines, published by the American Statistical Association and the Royal Statistical Society, for statistical practice.

The planned analyses identified in this SAP may be included in clinical study report (CSRs) and/or in relevant summary report documents (e.g. regulatory submissions, or future manuscripts). Also, *post-hoc* exploratory analyses not necessarily identified in this SAP may be performed to further examine study data and will not require updating the final SAP. Any post-hoc, or unplanned, exploratory analysis performed will be clearly identified as such and described in the final CSR.

The SAP is based on the following documents:

- Clinical Research Protocol MOR202C103
- ICH Guidance on Statistical Principles for Clinical Trials (E9)

The reader of this SAP is encouraged to also read the clinical protocol, and other identified documents, for details on the planned conduct of this study. Operational aspects related to collection and timing of planned clinical assessments are not repeated in this SAP unless relevant to the planned analysis.

5. STUDY OBJECTIVES AND ENDPOINTS

An overview of the study objectives and endpoints is depicted in Table 5-1.

Table 5-1: Study objectives and endpoints

Study objective	**Endpoint**	**Analysis**
Primary objective:	**Primary endpoint:**	
To assess the safety and tolerability of MOR202 treatment in subjects with anti-PLA2R antibody positive membranous nephropathy (aMN)	Incidence and severity of TEAEs	Section 11.1

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Study objective	Endpoint	Analysis
Key secondary objective:	**Key secondary endpoint:**	
To assess the effect of MOR202 on serum anti-PLA2R antibodies in subjects with aMN	Best Immunological response: rate of sICR, ICR and IPR based on reduction of serum anti-PLA2R antibody titer	Section 10.1
Secondary objectives:	**Secondary endpoints:**	
1. To assess immunogenicity of MOR202 (anti-MOR202 antibody formation) in subjects with aMN	Number and antibody titers of subjects tested positive for anti-MOR202 antibodies	Section 13
2. To assess the pharmacokinetic (PK) profile of MOR202 in subjects with aMN	MOR202 serum concentrations after multiple i.v. administrations	Section 12
3. To assess the safety in subjects with aMN after MOR202 treatment and during the follow-up phase.	Incidence and severity of adverse events (AEs) in the follow-up phase.	Section 11.1
Exploratory objectives:	**Exploratory endpoints:**	
CCI [redacted]		

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Study objective	Endpoint	Analysis
CCI		

6. STUDY DESIGN

6.1. General study design

This phase Ib/IIa multicenter trial enrolls subjects with anti-PLA2R antibody positive membranous nephropathy (aMN) indicated for immunosuppressive therapy (IST) into two cohorts:

- Cohort 1 consists of approximately 20 aMN subjects newly diagnosed or relapsing subjects stable on supportive care treatment with ACEI/ARB at screening with proteinuria and medium/high serum titers of anti-PLA2R antibodies eligible for immunosuppressive therapy (IST).
- Cohort 2 consists of approximately 10 subjects with aMN refractory to IST and requiring other forms of IST.

The trial design includes a Safety Run-in, which in the initial stage of the trial intends to limit drug exposure to the first three subjects. All trial subjects, including the safety run-in subjects, will follow the clinical trial schedule in Figure 6-1. Each treatment cycle (C) consists of 28 days (D).

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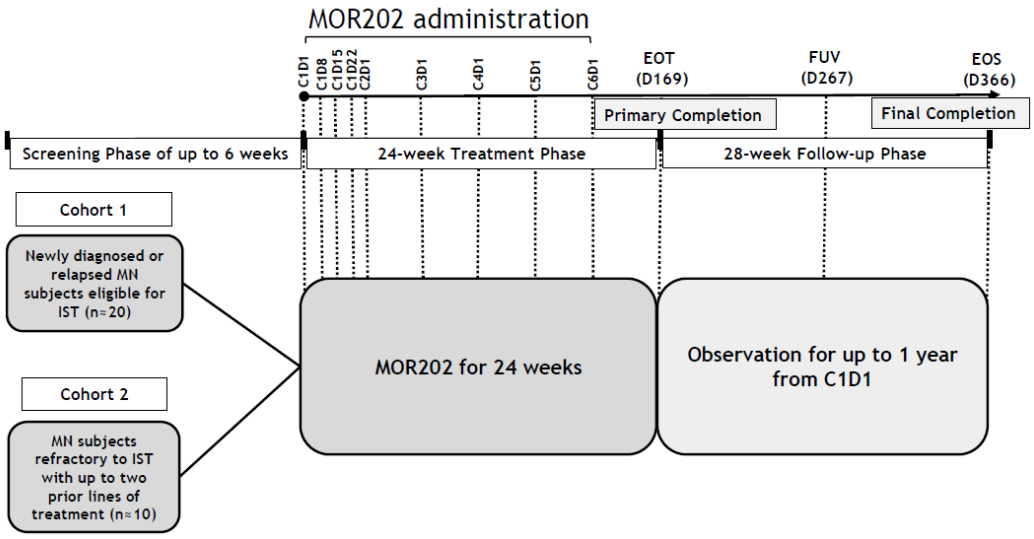

Figure 6-1 Clinical Trial Schedule

Please refer to section 6.2 of the clinical trial protocol for more details on the screening phase, treatment phase and follow-up phase.

6.2. Schedule of assessments

Please refer to section 10 of the clinical trial protocol for the full schedule of assessments.

6.3. Determination of sample size

As this is a Phase Ib/IIa trial primarily conducted to explore safety endpoints, no formal statistical hypothesis has been established for the sample size calculation of this trial.

Three evaluable subjects will be enrolled in the safety run-in phase. These subjects can belong to either Cohort 1 or Cohort 2.
Once the safety run-in is completed successfully, additional subjects will be enrolled in Cohort 1 and Cohort 2 in parallel. Approximately 20 subjects will be enrolled in Cohort 1 and approximately 10 subjects will be enrolled in Cohort 2.

With a sample size of 20 subjects in Cohort 1, there is an 88% probability to observe at least one occurrence of a particular adverse event if the natural incidence of this adverse event in Cohort 1 is 10%.

Cohort 2 includes subjects refractory to IST with up to 2 prior lines of treatment. Thus it is expected that incidence of AEs will be higher in Cohort 2 than in Cohort 1. With a sample size of 10 subjects in Cohort 2, there is a 80% probability to observe at least one occurrence of a particular adverse event if the incidence of this adverse event is 15%.

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6.4. Timing of analyses

6.4.1. Safety run-in analyses

The first three subjects dosed in this trial (regardless of cohort) will be treated and observed until Cycle 2 Day 1 or until having demonstrated a toxicity leading to discontinuation of treatment, whichever is earlier. If a grade 4/5 adverse drug reaction (ADR) occurs during the safety run-in, then a safety review will take place and start of treatment for further subjects will be contingent on safety review outcome.

The safety review will consist of an evaluation based on the number and type of all AEs occurring during the first cycle and laboratory values (biochemistry and hematology) and will be performed by representatives of the Safety Review Panel consisting of representatives of the participating investigators and the sponsor. The safety review will be held after C2D1 of the 3rd subject. For more details refer to section 6.3 of the clinical trial protocol.

6.4.2. Primary completion analysis

The primary completion analysis will be performed after the last subject completes Cycle 6 of treatment (after the EOT visit), or 28 days after the last subject received the last dose of MOR202 (only for early termination).

If the enrolment for one of the cohorts is significantly longer (approximately two months difference between the enrolment of the last subject in Cohort 1 and the last subject in Cohort 2), the Primary Completion Analysis may be performed by cohort. In this case, no overall summary of both cohorts will be presented in the analysis. Otherwise the analyses will be performed for both cohorts at the same time.

Primary, key secondary and selected exploratory endpoints will be analysed at the time of Primary Completion. For more details, see Table 8-1 in section 8.4.

6.4.3. Final analysis

The final analysis will be performed after all subjects completed either their EOS visit or completed the "*Early study discontinuation*" eCRF page.

7. DEFINITIONS AND GENERAL METHODOLOGY

7.1. Treatment cycle

The subjects will be administered study treatment according to cycles. Each treatment cycle (C) consists of 28 days (D).

The planned administration of MOR202 is as follows:

Cycle 1: Day 1, Day 8, Day 15, Day 22
Cycle 2 to Cycle 6: Day 1

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7.2. Study drug/treatment

Study drug and study treatment refer to the individual drug MOR202. In the rest of the SAP we will refer to it only as "study drug".

7.3. Study drug administration

7.3.1. Date of first administration of study drug

The date of first administration of study drug for a subject is the first date when a non-zero dose of study drug is administered and is referred to as "start date of study drug".

7.3.2. Date of last administration of study drug

The date of last administration of study drug for a subject is the last date when a non-zero dose of study drug is administered and is referred to as "end date of study drug".

7.4. Reference start date and study day

The reference start date will be defined as the start date of study drug for all

Safety assessments (e.g. adverse event onset, laboratory abnormality occurrence, etc.)
Efficacy assessments (e.g. response assessments, etc.)
Non-safety screening assessments, baseline disease characteristics, medical history that occurred prior to start date of study treatment

The study day describes the day of the event or assessment, relative to the reference start date. The reference start date is designated as Study Day 1. Study Day -1 is the day that precedes Study Day 1. Study Day 0 is not defined.

The study day will be calculated as:

The date of the event (visit date, assessment date, etc.) – reference start date + 1 day, if the event is on or after the reference start date
The date of the event (visit date, assessment date, etc.) – reference start date, if the event precedes the reference start date

The study day will be displayed in the data listings.

7.5. Screening failure

Screening failures are subjects who have signed informed consent and failed screening criteria. Subjects who signed informed consent and fulfilled screening criteria, but have never received treatment are not considered as screening failures. These subjects are referred to as "Not treated subjects".

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7.6. Time unit

A month-length is 30.4375 days (365.25/12). If duration is to be reported in months, duration in days is divided by 30.4375. If duration is to be reported in years, duration in days will be divided by 365.25.

7.7. Baseline

Baseline is the result of an investigation describing the "true" uninfluenced state of the subject, defined as the period from the date of signing any informed consent document to the start date of study drug.

Unless otherwise stated in the respective sections, the last non-missing assessment, including unscheduled assessments, on or before the start date of study drug prior to the first dosing of the study drug will be used as "baseline" value or "baseline" assessment. Assessments collected post-dose on the first date of treatment are not considered as baseline values.

Baseline values for proteinuria responses are defined in the respective section.

If a subject has no value as defined above, the baseline value will be considered as missing.

Data listings will include baseline flags.

Change from baseline calculation

Absolute change from baseline will be calculated as

$$[\text{visit value} - \text{baseline value}]$$

and percentage change from baseline will be calculated as

$$[\frac{\text{visit value} - \text{baseline value}}{\text{baseline value}} \times 100\ ].$$

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7.8. On treatment assessment/event

On-treatment assessment/event

An on-treatment assessment/event is defined as any assessment/event happening after the start date of study treatment, i.e. assessments/events happening in the following time interval (including the lower and upper limits):

[Start date of study drug +1 day; End date of study drug + 28 days].

Assessments collected post-dose on the start date of study drug are also considered as on-treatment assessments. Data listings will include all assessments/events, flagging those which are not on-treatment assessments/events.

Post-treatment assessment/event

A post-treatment assessment/event is defined as any assessment happening after the completion of the on-treatment phase, i.e. assessments/events happening in the following time interval (including the lower and upper limits):

[End date of study drug + 28 days + 1 day; Date of study discontinuation].

The date of study discontinuation is defined as the date of the End of Study Visit, or the date entered in the "*Early study discontinuation*" eCRF page, whichever is later.

7.9. End of treatment

End of treatment (EOT) is defined as the assessment obtained on the EOT visit date.

Change from EOT will be calculated similarly to change from baseline as described in section 7.7, replacing baseline value with the value obtained at EOT.

7.10. Analysis visits

For parameters that will be summarized by visit, the nominal visit as recorded in the eCRF (i.e. actual visit date) will be used (disregarding the allowed assessment windows). Data collected in unscheduled visits will be displayed in patient data listings and spaghetti plots only, except Baseline assessment (refer to section 7.7). The unscheduled visit results will be flagged in the listings accordingly and will be highlighted by asterisks on spaghetti plots.

In the case of multiple records for one visit, selection rules are described in section 7.11 (below).

7.11. Selection of data in the event of multiple records in a window

Depending on the statistical analysis method, single values may be required for each visit. For example, change from baseline by visit usually requires a single value per visit, whereas a time-to-event analysis would not require on value per visit but rather one value for the study.

Unless otherwise noted in the respective sections, when a single value is needed, the following rules will be used:

- If more than one assessment is assigned to the same nominal visit, select the record closest to the nominal day for that particular visit day
- If there are two assessments that are equidistant from the nominal visit day, the data of the assessment after the scheduled study day will be used

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- If more than one assessment is collected on the same day, the latest assessment on that day will be used.

7.12. Analysis populations

7.12.1. Screened population (SCR)

The screened population consists of all subjects who signed informed consent.

7.12.2. Full analysis set (FAS)

All subjects belonging to the screened population who received at least one dose of study drug. Efficacy and Safety analyses will be performed on FAS.

7.12.3. Per protocol set (PPS)

All subjects included in FAS without any protocol deviation, which could impact the efficacy outcome. Those protocol deviations leading to exclusion from FAS and creating the PPS will be listed including the subject number and specified in the Protocol Deviation specification form.

7.12.4. PK analysis set (PKAS)

All subjects included in FAS with at least one evaluable MOR202 serum concentration data.

7.12.5. Immunogenicity analysis set (IAS)

All subjects included in SCR with at least one anti-drug antibody (ADA) result available.

7.12.6. Biomarker analysis set (BAS)

All subjects included in FAS with at least one biomarker assessment available.

7.12.7. Planned analyses for the different populations

The number of subjects in each analysis set will be summarized. A listing of all analysis sets for each subject will be prepared.

Table 7-1 gives an overview of the assessments performed on the different analysis sets.

Table 7-1 Planned analyses for different populations

Analysis	SCR	FAS	PPS	PKAS	IAS	BAS
Subject disposition	X	X				
Background and demographic characteristics		X				
Medical history and aMN-specific medical history		X				

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Analysis	SCR	FAS	PPS	PKAS	IAS	BAS
Study treatment		X				
Prior and concomitant medications and aMN-specific medical history		X				
Safety analysis during and after MOR202 treatment		X				
Best immunological response		X	X			
Immunogenicity of MOR202					X	
PK profile of MOR202				X		
Summary of 24 hour urine		X				
CCI		X	X			
		X	X			
		X				
		X				
		X				
		X				
		X				
						X
Summary of vital signs, physical examination and ECG		X				
Summary of laboratory data		X				

7.12.8. Withdrawal of informed consent

The date on which a subject signs the main informed consent, additional informed consent for kidney biopsy at screening, additional informed consent for kidney biopsy at last study visit or additional informed consent for future research is recorded in the eCRF.

Any data collected in the clinical database after a subject withdraws the main informed consent from further participation in the trial, will not be included in the analysis data sets.

If a subject withdraws only any of the additional informed consents, the related data collected in the clinical database after the withdrawal, will not be included in the analysis data sets.

Exceptions are the information entered to close a page after the date of withdrawal of consent, e.g. End of Treatment or End of Study information.

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7.13. Implementation of efficacy assessments

7.13.1. Renal function

Renal function will be assessed by the estimated glomerular filtration rate (eGFR). eGFR in ml/min/1.73m^2 will be calculated as per the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation ((1), (2)):

$$eGFR = 141 \times \min\left(\frac{Scr}{\kappa}, 1\right)^{\alpha} \times \max\left(\frac{Scr}{\kappa}, 1\right)^{-1.209} \times 0.993^{Age} \times 1.018[if\ female] \times 1.159[if\ black],$$

Where:

Scr is serum creatinine in µmol/L,
κ is 61.9 for females and 79.6 for males (if Scr is measured in µmol/L),
(κ is 0.7 for females and 0.9 for males (if Scr is measured in mg/dL)),
α is -0.329 for females and -0.411 for males,
min indicates the minimum of $\frac{Scr}{\kappa}$ or 1, and
max indicates the maximum of $\frac{Scr}{\kappa}$ or 1.

Stable renal function is defined in this trial by eGFR as an eGFR of at least 80% of baseline.

7.13.2. CCI

CCI [redacted]

7.13.3. Overall response for subjects

Immunological Response

Immunological responses are reflected by the reduction of anti-PLA2R antibody titres as measured by ELISA (Euroimmun). Based on the immunological responses, the following response categories are defined for this clinical trial (the baseline value is the last measurement obtained prior to treatment start):

- Immunological Partial Response (IPR): Reduction of anti-PLA2R antibody titres by at least 50% compared to baseline
- Immunological Complete Response (ICR): Reduction of anti-PLA2R antibody titres to less than 14.0 RU/mL
- Stringent Immunological Complete Response (sICR): ICR and a negative result in anti-PLA2R immunofluorescence test

The following variables related to immunological responses are defined as follows.

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- Time to First Immunological Response (in months) prior to start of prohibited treatment (see definition in section 7.13.6) or progression, defined as
  [Date of first documented response of IPR, ICR or sICR (whichever is earlier) – Start date of study drug + 1 day]/30.4375
- Best overall immunological response (BIR) is defined when a subject is classified as having a IPR, ICR, or sIRC at any time during the trial but prior to start of prohibited treatment or progression. Responses for BIR are ordered as IPR < ICR < sICR. If a subject meets the criteria for more than one response category, the subject will be classified in the highest category.
- Time to BIR (in months), defined as
  [Date of BIR – Start date of study drug + 1 day]/30.4375
- Duration of Immunological response (in months), defined as
  [Date of death, PD or start of prohibited treatment (whichever is earlier) – Date of first documented response of IPR, ICR or sICR (whichever is earlier) + 1 day]/30.4375. Subjects with a response but no date of death, PD or start of prohibited treatment at the time of analysis cut-off will be censored at the date of last response assessment. Subjects without a response of IPR, ICR or sICR are assigned a duration time of zero.

Proteinuria Response

Proteinuria responses are reflected by the reduction of proteinuria as measured by UPCR. Based on the proteinuria responses, the following response categories are defined by this clinical trial:

- Proteinuria Complete Response (Prot-CR): Reduction of proteinuria to less than 0.5 g/g, serum albumin within the reference range (3.5 – 5.2 g/dL) and stable eGFR (at least 80% of baseline)
- Proteinuria Partial Response (Prot-PR): Reduction by at least 50% of UPCR at a given visit compared to baseline, proteinuria below 3.0 g/g and stable eGFR (at least 80% of baseline), but not meeting Prot-CR

The following variables related to proteinuria responses are defined as follows.

Overall Proteinuria Response (OPR), defined as subjects achieving either Prot-CR or Prot-PR as a response (irrespective of start of prohibited medication or progressive disease prior to the proteinuria response).
Time to First Proteinuria Response (in months) prior to start of prohibited treatment or progression, defined as
[Date of first documented response of Prot-CR or Prot-PR (whichever is earlier) – Start of study drug + 1 day]/30.4375
Best Proteinuria Response (BPR) for a subject is defined when a subject is classified as having a Prot-CR or Prot-PR at any time during the trial but prior to start of prohibited treatment or progression. Responses for BPR are ordered as Prot-PR < Prot-CR. If a subject meets the criteria for more than one response category, the subject will be classified in the highest category.
Time to BPR (in months), defined as
[Date of BPR – Start date of study drug + 1 day]/30.4375
Duration of Proteinuria Response, defined as
[Date of death, PD or start of prohibited treatment (whichever is earlier) – Date of first documented response of Prot-CR or Prot-PR (whichever is earlier) + 1 day]/30.4375. Subjects with a response but no date of death, PD or start of prohibited treatment at the time of analysis

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cut-off will be censored at the date of last response assessment. Subjects without a response of Prot-CR or Prot-PR are assigned a duration time of zero.

7.13.4. Disease progression

Progressive Disease

Progressive Disease (PD) is defined as a decrease of eGFR by more than 30% of baseline eGFR, or increase in UPCR by more than 50% from baseline value and less than 10% decline of anti-PLA2R antibody titres compared to baseline.

End Stage Renal Disease

End Stage Renal Disease (ESRD) is defined as decrement in the subject's kidney function to a level at which renal replacement therapy is required to sustain life meeting one of the following criteria:

Was on dialysis therapy for more than 30 days continuously

Received a kidney transplant

A physician recommended renal replacement therapy (dialysis or transplant) and the subject refused therapy

Began dialysis and died < 30 days later

Confirmed eGFR < 10 ml/min/1.73m^2

7.13.5. Start and end date for time to event variables

Start Date

For all efficacy "time to event" variables, the start date of study drug will be used as the start date.

End Date

For all efficacy "time to event" variables, the end dates are defined as follows:

Date of first documented response IPR, ICR or sICR (for immunological response)
Date of first documented Prot-CR or Prot-PR (for proteinuria response)
Date of first documented PD

Subjects not experiencing either response or PD defined above will be censored at the time of trial discontinuation, or the date of cut-off, whichever is earlier.

Calculation of "time to event" variables:

Time to event (days) = End date – Start Date + 1 day

Censoring rules

For the analysis of time to event variables using the Kaplan-Meier method, the following censoring rules are defined.

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Situation	Time to event variable	Date of event or censoring	Outcome	Censoring Reason
Ongoing and no event until data cut-off	Time to first immunological response, Time to BIR, Time to first proteinuria response, Time to BPR, Time to PD	Date of cut-off	Censored	Ongoing
Discontinued the study with no event	Time to first immunological response, Time to BIR, Time to first proteinuria response, Time to BPR, Time to PD	Date of last response assessment prior to study discontinuation	Censored	Discontinued without event
No baseline assessment for the time to event variable	Time to first immunological response, Time to BIR, Time to first proteinuria response, time to BPR, Time to PD	Date of C1D1	Censored	No baseline assessment
Subject received prohibited treatment before event	Time to first immunological response, Time to BIR, Time to proteinuria response, Time to BPR	Date of last response assessment prior to prohibited treatment	Censored	Start of prohibited treatment
Subject with progressive disease (PD) before event	Time to first immunological response, Time to BIR, Time to first proteinuria response, Time to BPR	Date of documented PD	Censored	Start of PD
No post-baseline assessment for the event variable	Time to first immunological response, Time to BIR, Time to first proteinuria response, time to BPR, Time to PD	Date of C1D1	Censored	No post-baseline assessment

7.13.6. Prohibited medication

Prohibited medication will be identified on a case-by-case basis by a medical review of the concomitant medication. For the definition of response and time to event variables as described above the first administration of prohibited medication will be relevant. If the day of any prohibited medication is missing, it will be imputed by the first of the month. If day and month are missing, it will be imputed by 1-Jan of the corresponding year.

Subjects in need of systemic corticosteroid therapy other than for prophylaxis and treatment of IRR for more than 7 days may continue being treated with MOR202 but will be excluded from the Per Protocol Analysis Set and the Immunological Analysis Set (IAS). These subjects will be selected on the basis of concomitant medication listing as described above. The ATC level 3 ‘CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN’ will be selected for individuating patients in systemic use of corticosteroids. Out of these patients, only those who was on therapy for more than 7 days will be excluded from the PPS and IAS.

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8. STATISTICAL METHODOLOGY

8.1. General principles of statistical programming

The statistical analysis will be performed on the analysis study database with appropriate software, SAS Software version 9.4 or above (SAS Institute, Cary, N.C.).

8.2. Variable types and descriptive statistics

Descriptive statistics will be calculated using as reference the number of subjects in the relevant analysis population (any exception will be specified) according to the nature of the data as follows:

Continuous variables (e.g. age, body weight): number of non-missing observations, number of missing observations, arithmetic mean, standard deviation (StD), minimum and maximum values, quartiles (median, Q1 and Q3).

If there are less than 5 observations, only the number of non-missing observations, arithmetic mean, median, minimum and maximum will be presented.

Descriptive statistics of plasma concentrations and PK parameters will include number of observations, arithmetic mean, geometric mean, StD, median, coefficient of variation CV (%), geometric CV (%), minimum and maximum. Geometric mean and the geometric CV (%) will be derived from non-zero values. For plasma concentrations, the number of non-zero values (m) will also be reported.

Categorical variables: (e.g. gender) number of non-missing observations, the number of missing and the relevant percentage on the analysis population, number and relative frequencies.

In case of subcategories, the relative frequencies will be calculated on the basis of the subjects in the respective category, in this case a footnote will be added explaining the different denominators.

Time variables (durations): Will be summarized using arithmetic mean, StD, minimum and maximum values, median and quartiles (Q1, Q3) and will be presented in months (unless otherwise stated).

Time to event variables: (e.g. Time to Response) Unless otherwise stated, Kaplan Meier estimates of Q1, Median, and Q3 along with their 95% Confidence Intervals will be presented.

The majority of data obtained on the eCRF and entered into the database will be provided in separate data listings showing individual subject values. The planning and reporting of statistical analyses will be carried out as described in the CROs standard operating procedures (SOPs).

8.3. Convention on missing data

Unless otherwise specified, missing data will not be imputed. Details on missing data imputation are present in the respective sections.

In all listings, imputed values will be flagged.

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8.4. Data included in the analysis and cut-off date

All the analyses will be performed using data collected in the database up to the data cut-off date. A cut-off date will be defined for each of these analyses and will be specified in the outputs.

Any data collected beyond the cut-off date will not be included in the analysis. Only data with an assessment date or event start date prior to or on the cut-off date will be included in the analysis.

All events with an event start date either before or on the cut-off date and an event end date after the cut-off date will be reported as "continuing at the cut-off date". The same rule will be applied to events starting either before or on the cut-off date and not having a documented end date. This approach applies, in particular, to adverse event and concomitant medication reports. For these events, the end date will not be imputed and therefore will appear as missing in listings.

If it is required to impute an end date to be able to perform a specific analysis, the cut-off date needs to be imputed as an end date. The imputed date will be displayed and flagged in the listings.

Any data collected beyond a subject's withdrawal of consent will not be included in the analysis; except for SAEs and the date of death provided by a confirmed public registry and subject status entered after the date of withdrawal of consent on e.g. early treatment discontinuation eCRF page.

The data before cut-off for the primary analysis includes all data until the last subject completes Cycle 6 of treatment, i.e. after the EOT visit, or 28 days after the last subject received the last dose of MOR202 for early terminated subjects.

Table 8-1 below indicates the analyses performed for the primary and final analyses.

Table 8-1 Analysis included in primary and final analysis

Analysis	Primary Analysis	Final Analysis
Incidence and severity of TEAEs	X	X
Immunological response	X	X
Anti-MOR202 antibodies	X	X
MOR202 serum concentration	X	X
Incidence and severity of AEs in follow-up phase	X	X
CCI	X	X
	X	X
	X	X
	X	X
	X	X
	X	X

8.5. Specifications and analysis database

Based on dataset in SDTM format, analysis datasets adhering to CDISC ADaM standard will be generated with SAS software, version 9.4 or above, after the soft lock of data for the primary completion

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analysis or hard lock of complete study database for the final analysis and according to agreed Analysis Dataset specifications (ADS).

8.6. Pooling of investigative sites

Data will be pooled from all investigative sites for the analyses. The justification for this is based on the following:

The sites will follow protocol harmonized across the countries in the sense of study population and outcome measures (in case of country specific protocol amendments).

The sponsor will provide close monitoring of study procedures and compliance for all sites.

Each site is expected to recruit a few subjects only.

The study sites must use unified data collection procedures.

9. SUBJECT DISPOSITION, BACKGROUND AND BASELINE CHARACTERISTICS

9.1. Subject disposition - Screened subjects

The number (%) of subjects who were

Screened
Screen failure
Not treated subjects, i.e. successfully screened but never treated
In the FAS population, i.e. received at least one dose of MOR202

will be summarized and listed by cohort, country, and overall based on SCR. Percentages will be calculated based on the number of subjects screened.

The reason for screen failures (i.e. the violated inclusion or exclusion criteria) will be listed by cohort on SCR.

Subjects who were successfully screened but never started MOR202 treatment will be listed on SCR.

9.2. Subject disposition – Treatment and follow-up phase

The following summaries and listings by cohort and overall will be provided, based on the number of subjects in FAS:

- Number (%) of subjects treated with study drug
- Number (%) of subjects successfully completed treatment phase (without early treatment discontinuation)
- Number (%) of subjects, who discontinued treatment early in the treatment phase
- Reason for early treatment discontinuation
- Number (%) of subjects, who discontinued study early in the treatment phase
- Reason for early study discontinuation in the treatment phase
- Number (%) of subjects entered the follow-up phase

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- Number (%) of subjects ongoing in follow-up phase
- Number (%) of subjects completed the follow-up phase (i.e. having their scheduled last visit)
- Number (%) of subjects discontinued study early in the follow-up phase
- Reason for early study discontinuation in the follow-up phase

9.3. Protocol deviations

The number (%) of subjects in the FAS with any protocol deviation as well as the protocol deviations will be tabulated by deviation category (as specified in the Protocol deviation specification form) and will be summarized by cohort, overall and by site, and tabulated according to the categories in the Protocol deviation specification form.

Only protocol deviations directly affecting the subject will be reported. Protocol deviations pertaining to the study centers will not be considered.

In a table, for each protocol deviation, the number (%) of events (incidence) and the number (%) of subjects experiencing the protocol deviation will be displayed by cohort and overall on FAS.

A frequency table by visit will be produced for the number (%) of subjects with missed visits in the FAS with the reason for the missed visit (including missed visits in the context of COVID-19).

Protocol deviations will be listed by cohort on FAS.

9.4. Demographic characteristics

All summaries will be presented by cohort and overall for the FAS. Listings for demographic data will be produced by cohort on FAS.

The following continuous variables will be summarized by cohort and overall:

- Age at screening (Year of screening – Year of birth, in years)
- Height at screening (cm)
- Weight at screening (kg)
- Body Mass Index (BMI) ($\frac{kg}{m^2}$) at screening, calculated as BMI = $\frac{Weight\ (kg)}{Height\ (m)\text{^}2}$
- Body Surface Area (BSA) (m^2) at screening, calculated as

  BSA (m^2) = $\sqrt{\frac{Height\ (cm) \times Weight\ (kg)}{3600}}$ (3)

The following categorical variables will be summarized by cohort and overall:

Age categorized: 18 – 64 years, 65 – 84 years, ≥ 85 years
Gender
Race (White, Black or African American, Asian, American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, or Other)
Female Subjects of child bearing potential: Yes or No
Male Subject Vasectomized: Yes or No

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9.5. Medical history and current medical conditions

9.5.1. Coding

Medical history and current medical conditions will be summarised using the current Medical Dictionary for Regulatory Activities MedDRA (MedDRA Version 25.0 or higher) system organ class (SOC) and preferred term classifications. At the end of the trial, all MedDRA codes will be updated with the latest MedDRA version.

9.5.2. Medical history and current medical conditions summaries

The relevant medical history and current medical conditions, including allergies or hypersensitivities (except aMN-related) will be summarised by counts and percentages by primary SOC, PT and toxicity grade for each cohort and overall in FAS. The relevant medical history and current medical conditions will be listed for subjects in FAS.

9.5.3. aMN-specific medical history and diagnosis

The medical history related to membranous nephropathy will be summarized by cohort and overall including the following summaries

Disease status at screening (newly diagnosed, relapsed or refractory)
Time since initial aMN diagnosis (months) defined as: [Date of screening – Date of initial diagnosis of aMN + 1 day]/30.4375

- If the date of initial diagnosis of aMN is completely missing, the date will not be imputed and the subject will have a missing time since initial aMN diagnosis
- If only the day is missing, then it will be replaced by the first day of the month
- If both the day and month are missing, then it will be replaced by the first day of the year

Proteinuria remission
Number (%) of subjects with a Proteinuria remission during or following previous therapy before starting MOR202 treatment (overall and split by complete vs. partial remission)
Duration of remission during or following previous therapy (months) (overall and split by complete remission vs. partial remission)
Number (%) of subjects with a remission for ≥ 6 months vs. < 6 months during or following previous therapy according to the clinical judgement (months) as entered in the eCRF (overall and split by complete vs. partial remission)
Immunofluorescence test results for anti-PLA2R
Number (%) of subjects with positive/negative immunofluorescence test during remission (overall and by remission categories for complete vs. partial remission)
Anti-PLA2R titre
Number (%) of subjects with anti-PLA2R titre of less than 20.0 RU/ml during remission (overall and split by complete vs. partial remission)

The following calculations will be defined:

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- Duration of remission to previous therapy (months): [End date of last remission – start date of remission + 1 day]/30.4375
    - If start or end date is completely missing, then duration of response will not be imputed and is missing.
    - If both day and month are missing, the date will not be imputed
    - If only day is missing for the start date, it will be replaced by the first day of the month
    - If only day is missing for end date, it will be replaced by the last day of the month
- If after imputation, the end date of last remission is after the date of screening, the end date of last remission will be replaced by the date of screening
- If after imputation, the duration of remission is < 6 months, and the result of "*Duration of remission during or following previous therapy according to the clinical judgement*" in the eCRF is ≥ 6 months, the start date will be replaced by [End date – 6 months - 1 day]
- If after imputation, the duration of remission is ≥ 6 months, and the result of "*Duration of remission during or following previous therapy according to the clinical judgement*" in the eCRF is < 6 months, the start date will be replaced by [End date – 6 months + 1 day]

9.6. Study treatment

9.6.1. Exposure

Duration of exposure to study drug

Exposure to study treatment will be summarized for the FAS population. The duration of exposure will be calculated as follows:

Duration of exposure (days) = [end date of study drug – start date of study drug + 1 day]

Cumulative Dose

The MOR202 dose for each infusion can be calculated following the drug handling manual as follows:

$$\textbf{MOR202 infusion dose (mg)} = \frac{Actual\ total\ infusion\ volume\ administered\ (ml)}{Total\ volume\ in\ the\ prepared\ infusion\ bag\ (ml)} \times Volume\ of\ reconstituted\ drug\ solution\ added\ into\ the\ infusion\ bag\ (ml) \times 65\ (\frac{mg}{ml})$$

The cumulative dose is defined as the sum of total doses that the subject received from the first study treatment administration until the last study treatment administration.

A summary table with the following information will be presented by cohort and overall on FAS:

- Duration of exposure (months)
- Duration of exposure categorized as follows:

Days of exposure
>0 to <7 days

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>=7 to <14 days
>=14 to <21 days
>=21 to <30 days
>=30 to <60 days
>=60 to <90 days
>=90 to <120 days
>=120 to <183 days
>=183 days

In addition, the cumulative exposure duration will be displayed as described above.

- Number (%) of subjects completing each cycle (Cycle 1, 2, 3, 4, 5, and 6)
- Total number of MOR202 infusions per subject (categorized: 1-2 infusions, 3-4 infusions, etc.)
- Cumulative Dose (mg) per subject

Individual study drug administration data will be listed by subject and cohort on FAS, including the information on start and end times of administration, including the study day, infusion volume, and reason(s) for dose interruptions, if applicable.

Listings of the vial numbers for each subjects per administration will be provided.

9.6.2. Dose reduction

Not applicable.

9.6.3. Dose interruption

The number (%) of subjects with at least one temporary interruption (during infusion and interruptions due to toxicity) and the associated reasons will be summarized by cohort, cycle and day on FAS.

9.6.4. Permanent treatment discontinuations

The number (%) of subjects who discontinued MOR202 permanently and the associated reasons will be summarized and listed by cohort, cycle and day on FAS.

9.6.5. Compliance

Compliance for a MOR202 infusion (based on infusion volumes) will be calculated by dividing the actual MOR202 infusion dose with the planned MOR202 infusion dose and multiplied by 100 (refer to the drug handling manual for the calculation of the planned MOR202 infusion dose).

Overall compliance for MOR202 per subject (based on cumulative infusion volumes) will be calculated by dividing the sum of actual MOR202 infusion doses with the sum of planned MOR202 infusion doses and multiplied by 100.

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A subject is non-compliant for each infusion if the MOR202 dose administered is ≤ 70% or > 130% of the planned MOR202 dose. Such non-compliance is recorded in the eCRF. Subjects with overall compliance ⩽ 70% are excluded from the FAS in the Sensitivity Analysis, refer to section 10.10.

Any MOR202 dose missed without medical reason is considered as non-compliance.

The following information will be displayed by cohort and on FAS:

- Number (%) of subjects in the following compliance categories per single infusion:
  - ≤ 70%
  - > 70% - ≤ 130%
  - > 130%
- Summary statistics of compliance per infusion visit
- Number (%) of subjects in the following compliance categories for the overall compliance:
  - ≤ 70%
  - > 70% - ≤ 130%
  - > 130%
- Summary statistics of the overall compliance

9.7. Prior and concomitant medications and non-drug treatments/procedures

9.7.1. Coding

Concomitant medications will be recorded and coded using the WHO Drug Dictionary Enhanced and grouped by Anatomical Therapeutic Chemical (ATC) classes; non-drug treatments/procedures will be coded using the MedDRA (MedDRA Version 25.0 or higher). Tabulations with counts and percentages will show the number of medications and non-drug treatments /percentage used in each class / preferred term by cohorts and overall.

9.7.2. Definitions

Pre-medication: Medication given prior to MOR202 infusion to mitigate potential infusion-related reactions. Pre-medication encompasses antihistamine, antipyretic and glucocorticoids.

Prior medication/non-drug treatment: If the treatment start and stop dates are both before the start of study drug, the medication/non-drug treatment will be classified as prior medication/non-drug treatment. Subjects will only be counted once for multiple drug use by preferred drug name.

Concomitant medication/non-drug treatment: If the medication start date is on or after start of study drug, the medication will be considered as concomitant medication. If the medication start date If before start date of study treatment but ongoing or with stop date after the start of study treatment, the medication will be considered as concomitant medication. Subjects will only be counted once for multiple drug use by preferred drug name. If the medication start and stop date are incomplete, the following algorithm will apply to exclude the medication from the category concomitant medication. If the start date is missing and

- If stop day is missing but month is complete, medication will only be excluded from concomitant medication if stop month is before month of treatment start.
- If stop day and month are missing but year is complete, medication will only be excluded from concomitant medication if stop year is before year of treatment start.

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- If stop date is completely missing, medication will not be excluded.

9.7.3. Data presentation

Summary tables (excluding aMN-specific prior therapies) will be presented by cohort and overall for:

Prior medications
Concomitant medications
Prior non-drug treatments/procedures
Concomitant non-drug treatments/procedures
Pre-medications

All summaries will be conducted on FAS. Listings will be shown for pre-medication, prior medication/non-drug treatments or procedures and concomitant medication/non-drug treatments or procedures (excluding aMN-specific prior therapies).

9.7.4. aMN-specific prior therapies

A summary table will be presented by cohort and overall on FAS for the following aMN-specific therapies:

Prior medications/non-drug procedures given for aMN (= medication with indication given as "Primary disease (aMN)" and end date prior or equal to date of screening)

Number of subjects (%) with at least one prior medication
Number of subjects (%) with at least one non-drug procedure
Time since last prior anti-aMN medication/non-drug procedure (months) (see calculation below)

Prior immunosuppressive medications (= medication recorded on prior IST eCRF page with latest end date prior or equal to screening)

- Number of subjects (%) treated with no, one, two and more than two immunosuppressive medication categorized and continuous. Different recordings of the same preferred term according to the WHO Drug Dictionary are not counted as separate immunosuppressive medications.

- Duration of last prior IST (months) (see calculation below)

Separate listings will be presented on prior aMN medications/non-drug procedures and immunosuppressive medications. Listings on IST therapy will include information on:

- Medication name
- Number of the particular IST therapy line
- Therapy start date
- Therapy end date
- Route and dosing regimen
- Date and type of the remission during or following the last IST therapy before start of MOR202 treatment

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The following calculations are defined:

- Time since last prior anti-aMN medication/non-drug procedure: [Date of screening – End date of last prior anti-aMN medication/non-drug procedure + 1 day]/30.4375
  If the end date of last prior aMN medication/non-drug procedure is completely missing, the date will not be imputed
  If only the day of the end date is missing, then it will be replaced by the day 15 of the month
  If both the day and month, or year are missing, the date will not be imputed
  If after imputation, the end date of last prior anti-aMN medication/non-drug procedure is after the date of screening, the end date will be replaced by the date of screening
  Duration of last prior IST: [End date of last prior IST – Start date of last prior IST + 1 day]/30.4375
  If the end date or the start date is completely missing, the date will not be imputed
  If both the day and month, or year of the start or end date is missing, the date will not be imputed
  If the day of the start date is missing, it will be replaced by the first day of the month
  If the day of the end date is missing, it will be replaced by the last day of the month, or the date of screening, whichever is first

10. EFFICACY ANALYSIS

For the primary completion analysis, the analyses will be performed based on the visits during the safety run-in phase and treatment phase.

For the final analysis, the analyses will be performed based on all the visits during the trial.

10.1. Analysis of best immunological response rate

The key secondary objective in this trial is to assess the effect of MOR202 on serum anti-PLA2R antibodies in subjects with aMN in terms of best overall immunological response rate (BIRR).

The best overall immunological response (BIR) is defined as achieving any response of IPR, ICR or sICR at any time during the trial but prior to start of prohibited medication or progression based on the definitions in section 7.13.3.

The best overall immunological response rate (BIRR) is defined as the proportion of subjects with a best overall immunological response. The denominator will be the total number of subjects included in the analysis population.

Main Analysis

The main analysis will be conducted on FAS. The following information will be presented by cohort and overall:

Number (%) of subjects achieving a BIR of IPR at any time during the trial
Number (%) of subjects achieving a BIR of ICR at any time during the trial
Number (%) of subjects achieving a BIR of sICR at any time during the trial
BIRR along with the 95% confidence interval (CI, using the Clopper-Pearson exact method)
Number (%) of subjects with a BIR of PD at any time during the trial
Number (%) of subjects classified as Non-responder

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For each visit available, the number and percentages of subjects in each of the response categories will be tabulated, including missing response evaluations and subjects with a progressive disease. Subjects, who are not classified in either response category or progressive disease will be tabulated as "*Non-Responders*". Subjects with no post-baseline assessment of response will be included as "*Non-Responders*".

If a subject achieves several responses, the subject will be tabulated in the highest achieved response category.

No formal hypothesis testing will be conducted.

Sensitivity Analysis

The main analysis as described above will be conducted using the PPS population.

Listings of individual responses per visit will be generated on FAS.

10.2. Analysis of 24 hour urine

24 hour urine will be collected to assess the following parameters:

- Urine protein
- Urine creatinine
- Urine sodium
- CCI [redacted]

The following information will be summarized for each 24 hour urine parameter above by cohort and overall on FAS:

Absolute levels by visit
Absolute and percentage change from baseline to each visit until end of study

Listings with individual urine parameter levels will be generated by visit on FAS.

- The following plots will be generated by cohort on FAS for UPCR and Urine creatinine:
  Spaghetti plots (time vs. parameter value for each subject)
  Spaghetti plots (time starting from baseline vs. % change from baseline for each subject) – please add dotted reference lines for upper (50%) and lower (-50%) thresholds.
  Waterfall plot for relative change from baseline at EOT, FUV and EOS – please add study days under the corresponding subject IDs

10.3. CCI [redacted]

CCI [redacted]

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CCI

[redacted]

10.4. CCI

CCI [redacted]

10.5. CCI [redacted]

CCI [redacted]

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CCI [redacted]

10.6. CCI [redacted]

CCI [redacted]

10.7. CCI [redacted]

CCI [redacted]

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CCI

10.8. CCI

CCI

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10.9. CCI

CCI [redacted]

10.10. Sensitivity analysis

The sensitivity analysis will be performed on the FAS excluding subjects who received ≤ 70% of the MOR202 doses overall (please see section 9.6.5 for the details) or who received at least one dose of relevant IST therapies at any timepoint of the study in accordance with the visit windows defined in Table 3. The relevant IST therapies will be identified on a case-by-case basis by a medical review of the concomitant medication listing (please refer to section 7.13.6 for the details) and documented in the data review meeting minutes.

Table 3. Allowed assessment windows.

Visit	Target day	Analysis Window
1 week	Day 7	Day 2 to Day 10
2 weeks	Day 14	Day 11 to Day 17
3 weeks	Day 21	Day 18 to Day 26
1 month	Day 30	Day 27 to Day 45
2 months	Day 61	Day 46 to Day 75
3 months	Day 92	Day 76 to Day 107
4 months	Day 122	Day 108 to Day 138

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6 months	Day 183	Day 139 to Day 229
9 months	Day 274	Day 230 to Day 320
12 months	Day 366	≥ Day 321

The closest value to the target day should be taken into analysis. If there are two values equidistant from the target date, then the latest value will be taken in the analysis. Unscheduled visits are considered in sensitivity analysis.

The sensitivity analyses will be applied to the following endpoints:

Best immunological response rate, section 10.1
CCI [redacted]
Renal Function assessed by eGFR, section 10.4
Serum Albumin Levels, section 10.5
Kinetics of anti-PLA2R titres, section 10.9

11. SAFETY ANALYSES

The analysis of safety assessments in this trial will include the evaluation of:

- Adverse Events
- Vital signs
- Physical Examination
- Electrocardiogram
- Laboratory evaluations

11.1. Adverse events

Adverse Event (AE)

An AE is defined as any untoward medical occurrence in a subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.

An AE can therefore be any unfavourable and unintended sign (including a clinically relevant abnormal laboratory finding), symptom, or disease temporally associated with the use of an IMP, whether or not considered related to that product. For more details, refer to study protocol section 10.8.5.

All AEs will be recorded with information regarding onset, start and end date/time, relationship to study drug, intensity, toxicity grade, action taken with study drug, treatment of event and outcome.

Treatment Emergent Adverse Event (TEAE)

TEAEs are defined as any adverse event reported within the following time interval (including the lower and upper limits), which is referred to as the treatment-emergent period:

[Start date of study drug, End date of study drug + 28 days].

The analysis of TEAEs will serve as primary endpoint of this trial.

If the start date and time of an AE are partially or completely missing, the AE will be assumed to be a TEAE if it cannot be definitely shown that the AE did not occur during the treatment emergent period

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(worst case approach). Missing dates and times will not be replaced. The following approach will be followed:

- If the start time of an AE is missing but the start date is complete, an AE will only be excluded from TEAE if the start day is before the day of first study drug administration or the start date is after the end date of the treatment-emergent period
- If the start time and day are missing but the start month is complete, an AE will only excluded from TEAE if the start month is before the month of first study drug administration or the start month is after the end month of the treatment-emergent period or if the stop date and time is before the start of first study drug administration
- If the start day and months are missing but the start year is complete, an AE will only be excluded from TEAE if the start year is before the year of first study drug administration or if the start year is after the end year of the treatment-emergent period or if the stop date and time is before the start of first study drug administration
- If the start date is completely missing, an AE will not be excluded from TEAE unless the stop date and time is before the start of first study drug administration

AEs starting during the study but before the first date of study drug administration will be classified as pre-treatment adverse events and will be presented in a separate adverse events listing.

An AE present prior to first study drug administration but increased in severity after treatment start, will also be included as TEAE.

Post-Treatment Adverse Event

Post-treatment AEs are defined as any adverse event reported within the following time interval (including the lower and upper limits), which is referred to as the post-treatment period:

[End date of study drug + 28 days + 1 day; Date of study discontinuation].

The analysis of post-treatment AEs will serve as one of the secondary endpoints.

Serious Adverse Events (SAE)

SAEs are defined in the protocol section 10.8.6.

Adverse Events of Special Interest (AESI)

AESIs in this clinical trial are defined in the protocol section 10.8.7.

11.1.1. Dictionary coding of adverse events

AEs will be coded according to the current Medical Dictionary for Regulatory Activities (MedDRA) version and will be reported by primary system organ class (SOC) and preferred term (PT). At the end of the trial all MedDRA codes will be updated to the newest version.

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11.1.2. Grading of adverse events

The toxicity grade of AEs will be graded according to the NCI-CTCAE version 5.0 of November 27, 2017 using the following definitions:

- Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
- Grade 2: Moderate; minimal, local or non-invasive intervention indicated; limiting age-appropriate instrumental activities of daily living (refers to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.)
- Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living
- Grade 4: Life-threatening consequences; urgent intervention indicated
- Grade 5: Death related to AE

11.1.3. General Rules for AE reporting

AE tables

- All safety analyses will be done using the FAS by cohort and overall.
- AEs will be summarised by SOC and PT. The SOCs and PTs will be used for tabulation
- AE frequency tables will display the number of events (incidence), the number of subjects experiencing an event and the percentage of subjects with the event by SOC and PT
- If a subject reported more than one AE with the same PT, the AE with greatest severity and the closest association with the study drug will be presented
- If a subject reported more than one AE with the same PT, the AE with the maximum toxicity grade will be presented
- If a subject reported more than one AE within the same SOC, the subject will be counted only once with the maximum toxicity grade at the SOC level, where applicable

AE listings

- All AEs will be listed by subject and cohort, along with information regarding onset, start and end date, relationship to study drug, intensity, toxicity grade, action taken with study drug, treatment of event, and outcomes based on FAS.
- In the AE listings, AEs that started prior to the administration of study drug will be flagged as pre-treatment AEs. AEs that start 28 days after the last date of study drug administration will be flagged as post-treatment AEs

11.1.4. Adverse Event summaries and listings

Overall Summary of AEs

An AE summary table will be presented showing the number of events, number of subjects and the percentage of subjects in each cohort and overall having:

- TEAEs
- Post-treatment AEs
- TEAEs by maximum intensity

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- Post-treatment AEs by maximum intensity
- TEAEs by maximum grade
- Post-treatment AEs by maximum grade
- Treatment-emergent SAEs
- Post-treatment SAEs
- On-treatment deaths
- Post-treatment deaths
- TEAEs suspected to be related to study drug
- TEAEs suspected to be related to study drug in each intensity/toxicity grading
- Post-treatment AEs suspected to be related to study drug
- Post-treatment AEs suspected to be related to study drug in each intensity/toxicity grading
- All AEs suspected to be related to study drug
- All AEs suspected to be related to study drug in each intensity/toxicity grading
- TEAEs leading to discontinuation of study drug
- IRRs by grade
- Treatment-emergent AESIs by grade
- Post-treatment AESIs by grade

TEAEs (serious and non-serious)

The following summary tables will be provided:

TEAEs regardless of study drug relationship by primary SOC, PT and grade
Non-serious TEAEs in ≥ 5% of subjects regardless of study drug relationship by primary SOC and PT
TEAEs regardless of study drug relationship by primary SOC, PT and intensity
TEAEs regardless of study treatment relationship of ≥ grade 3 by primary SOC, PT and grade.
TEAEs suspected to be related to study drug by primary SOC, PT and grade
TEAEs suspected to be related to study drug by primary SOC, PT and intensity
TEAEs suspected to be related to study drug of ≥ grade 3 by primary SOC, PT and grade.
TEAEs leading to any action on study drug by primary SOC, PT and grade (any action includes: Drug withdrawn, drug interrupted)
TEAEs related to COVID-19 by primary SOC, PT and grade

Post-treatment AEs (serious and non-serious)

The following summary tables will be provided:

Post-treatment AEs regardless of study drug relationship by primary SOC, PT and grade
Post-treatment AEs regardless of study drug relationship by primary SOC, PT and intensity
Post-treatment AEs regardless of study treatment relationship of ≥ grade 3 by primary SOC, PT and grade
Post-treatment AEs suspected to be related to study drug by primary SOC, PT and grade
Post-treatment AEs suspected to be related to study drug by primary SOC, PT and intensity
Post-treatment AEs suspected to be related to study drug of ≥ grade 3 by primary SOC, PT and grade

Treatment-emergent and post-treatment SAE

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The following summary tables will be provided:

Treatment-emergent SAEs regardless of study drug relationship by primary SOC, PT and grade
Treatment-emergent SAEs regardless of study drug relationship ≥ grade 3 by primary SOC, PT and grade
Treatment-emergent SAEs suspected to be related to study drug by primary SOC, PT and grade
Treatment-emergent SAEs suspected to be related to study drug ≥ grade 3 by primary SOC, PT and grade

Post-treatment SAEs regardless of study drug relationship by primary SOC, PT and grade
Post-treatment SAEs regardless of study drug relationship ≥ grade 3 by primary SOC, PT and grade
Post-treatment SAEs suspected to be related to study drug by primary SOC, PT and grade
Post-treatment SAEs suspected to be related to study drug ≥ grade 3 by primary SOC, PT and grade

For the final analysis, the following tables of treatment-emergent SAEs by primary SOC and PT will be produced in addition:

regardless of study treatment relationship;
suspected to be related to study treatment;
death cases.

Treatment-emergent and post-treatment AESIs

The following summary tables will be provided:

- Treatment-emergent AESIs regardless of study drug relationship by primary SOC, PT and grade
- Treatment-emergent AESIs suspected to be related to study drug by primary SOC, PT and grade
- Post-treatment AESIs regardless of study drug relationship by primary SOC, PT and grade
- Post-treatment AESIs suspected to be related to study drug by primary SOC, PT and grade

All AEs suspected to be related to study drug (TEAEs and post-treatment AEs)

The following summary tables will be provided:

All AEs suspected to be related to study drug by primary SOC, PT and grade
All AEs suspected to be related to study drug by primary SOC, PT and intensity
All AEs suspected to be related to study drug of ≥ grade 3 by primary SOC, PT and grade
All SAEs suspected to be related to study drug by primary SOC, PT and grade
All SAEs suspected to be related to study drug ≥ grade 3 by primary SOC, PT and grade
All AESIs suspected to be related to study drug by primary SOC, PT and grade

All TEAEs (irrespective of causality) and post-treatment AEs suspected to be related to study drug

The following summary tables will be provided:

All TEAEs (irrespective of causality) and post-treatment AEs suspected to be related to study drug by primary SOC, PT and grade
All TEAEs (irrespective of causality) and post-treatment AEs suspected to be related to study drug by primary SOC, PT and intensity

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All TEAEs (irrespective of causality) and post-treatment AEs suspected to be related to study drug of ≥ grade 3 by primary SOC, PT and grade

Deaths

Information on death is captured on "Adverse Events" and "Early study discontinuation" page in the eCRF.

All deaths including those that occurred on-treatment and post-treatment, will be listed along with the primary cause of death. Post-treatment deaths will be flagged in listings.

Infusion related reactions (IRRs)

A bar chart will be generated, showing the number of infusions (e.g. 1st infusion, 2nd infusion, etc.) (x-axis) vs. the number of subjects with at least one event of SMQ "Hypersensitivity" (narrow version) (y-axis) during or in the context of this infusion. The number of subjects receiving the respective infusion will be displayed in the bar chart as well. This analysis would be useful to identify the trend of IRR over consecutive infusions.

Special AE listings

Special AE listings for TEAEs and post-treatment AEs by cohort on FAS, displaying details of the event(s) captured on the eCRF, will be provided for:

- Serious adverse events
- AEs leading to discontinuation of study drug
- AEs of special interest
- AEs leading to death
- AEs related to Covid-19 as assessed by the investigator in the eCRF

AEs that start 28 days after the last date of study drug administration will be flagged as post-treatment AEs.

11.1.5. Specific safety evaluation

Not applicable for this trial.

11.1.6. General rules for specific safety evaluation

Not applicable for this trial.

11.1.7. Time to onset and duration of selected AE

For TEAEs in the following categories:

AESIs
Hematological AEs (AEs pertaining to the SOC "Blood and lymphatic system disorders" and AEs pertaining to the HLGT "Haematology investigations")
SAEs

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a plot for each category will be generated by subject (y-axis) vs. time on study (months, x-axis) showing the start and end time of an AE. Ongoing AEs and grading information will be marked for each subject.

11.2. Definition of new abnormalities

For the evaluation of clinical laboratory results, vital sign results and ECG results the following terms are defined:

- A new abnormality will be any abnormal post baseline result for a subject whose baseline was within normal limits
- A significant worsening will be any numeric measurement that represents a change from baseline by ≥ 25% of the baseline value, in the direction away from normal (i.e., in the direction that is clinically significant)
- An outlying result for any numeric measurement will be any post administration change from baseline that meets either of the following criteria:
  - < 25th percentile (Q1) – 1.5 * interquartile range
  - > 75th percentile (Q3) + 1.5 * interquartile range
- An extreme value for any numeric measurement will be any post administration change from baseline that meets either of the following criteria:
  - < 25th percentile (Q1) – 3 * interquartile range
  - > 75th percentile (Q3) + 3* interquartile range

Q1, Q3 and the interquartile range will be calculated for each visit in summary statistics.

11.3. Vital signs

11.3.1. Vital signs variables

The Vital Signs captured in the eCRF for each subject at each visit are the following:

Weight (Screening Visit, C1D1 and C2D1 onwards)
Height (only Screening Visit)
Systolic Blood Pressure (all visits)
Diastolic Blood Pressure (all visits)
Heart Rate (all visits)
Body Temperature (all visits)

11.3.2. Vital signs analysis

The following information will be summarized by cohort on FAS:

- Absolute values and percentage changes from baseline for all time points available
- Number (%) of subjects with at least one post-baseline abnormal value below or above the normal limit by vital signs variables
- Number (%) of subjects with at least one post-baseline significant worsening by vital sign variables
- Number (%) of subjects with at least one post-baseline outlying value by vital sign variables
- Number (%) of subjects with at least one post-baseline extreme value by vital sign variables

Normal limits are defined as follows:

Systolic blood pressure: 90-120 mmHg
Diastolic blood pressure: 60-80 mmHg

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Heart rate: 60-100 beats per minute
Body temperature:
35.9-37.1 °C axillary temperature
35.9-37.5 °C oral, ear, forehead, rectal temperature

All collected data on vital signs will be listed by visit. Each abnormal value will be flagged to show whether it is a value below or above the normal limit and whether the value is a significant worsening, an outlying value or an extreme value as defined in section 11.2.

11.4. Physical examination

At Screening, End of Treatment and End of Study full physical examinations will be performed. Limited physical examinations will include at least vital signs and general appearance. If clinically indicated, a full PE must be performed. New and worsening clinically relevant abnormal physical examination findings during the study will be entered as AEs and analysed within the AE tables.
Physical examination summaries and listings will be presented for each cohort on FAS.

The number (%) of subjects at screening, EOT visit, EOS visit and any visit with a full physical examination assessment by body system of the following categories:

Normal
Abnormal, clinically relevant
Abnormal, not clinically relevant

For all other visits, the number (%) of subjects with abnormal findings (clinically relevant or not clinically relevant) by body system and cohort will be displayed.

Listings on individual full and limited physical examination will be presented by visit and cohort, including the assessments and description of the abnormalities.

11.5. Electrocardiogram (ECG)

ECG recordings will be obtained by a standard 12-lead ECG.

11.5.1. ECG variables

The Electrocardiogram variables captured in the eCRF for each subject at each visit are the following:

- QRS Interval
- RR Interval
- PR Interval
- QT Interval
- Heart Rate

In addition to the QT interval, QTc corrections will be calculated as follows

Bazett's Correction (QTcB) (5): $QTcB = \frac{QT_{msec}}{\sqrt{RR}}$

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Friderica's Correction (QTcF) (6): $QTcF = \frac{QT_{msec}}{\sqrt[3]{RR}}$

Where relative rate (RR) = 60/heart rate.

11.5.2. ECG analysis

The following information will be summarized by cohort on FAS:

- Absolute values and percentage changes from baseline for all time points
- Number (%) of subjects with at least one post-baseline abnormal value below or above the normal limit by ECG variables
- Number (%) of subjects with at least one post-baseline significant worsening by ECG variables, as defined in section 11.2
- Number (%) of subjects with at least one post-baseline outlying value by ECG variables, as defined in section 11.2
- Number (%) of subjects with at least one post-baseline extreme value by ECG variables, as defined in section 11.2
- Number (%) of subjects at each time point with an ECG assessment of the following categories
  - Normal
  - Abnormal, clinically relevant
  - Abnormal, not clinically relevant
- Number (%) of subjects at each time point experienced a QTcF change from baseline of
  - < 30 ms
  - ≥ 30 ms and < 60 ms
  - ≥ 60 ms
- Number (%) of subjects at each time point experienced a QTcF prolongation of
  - QTcF: <= 450 ms
  - QTcF: > 450 ms and ≤ 480 ms
  - QTcF: > 480 ms and ≤ 500 ms
  - QTcF: > 500 ms

Normal limits are defined as follows:

PR interval: 120-200 ms
QRS interval: 80-100 ms
RR interval: 600-1200 ms
QT interval: 400-440 ms

All individual ECG data will be listed by visit and cohort, including the assessments and description of abnormalities. Each abnormal value will be flagged to show whether it is a value below or above the normal limit and whether the value is a significant worsening, an outlying value or an extreme value as defined in section 11.2.

11.6. Laboratory data

Local and central laboratory assessments will be collected in the eCRF.

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11.6.1. Laboratory variables

Laboratory parameters measured in the central laboratory can be classified into

- Blood parameters from
  - Haematology
  - Serum biochemistry
  - Coagulation parameters
  - Serology parameters for HBV (HBsAg, HBsAb and HBcAb), HCV (anti-HCV Ab) and HIV (anti HIV 1/2 Ab)
  - Cytokines (samples collected due to IRR)
- Urine parameters from
  - 24 hour urine
  - Spot urine
- Pregnancy tests (from serum and urine sample): B-hCG (only for female of childbearing potential)

Local laboratory parameters include

- Blood parameters from haematology
- Urine parameters from urinalysis, urine microscopy

11.6.2. Grading of laboratory results

Laboratory data grades of severity will be derived according to the Common Terminology Criteria for Adverse Events (CTCAE), version 5.0. A severity grade of 0 will be assigned when the value is within normal limits. Grade 5 will not be used.

Laboratory values having hyper or hypo shifts will be classified as a particular CTCAE grade irrespective of the shift direction (no differentiation between CTCAE grades due to increased, or decreased lab values).

Laboratory test results will also be flagged in listings by the low/normal/high classifications based on laboratory normal ranges.

For duplicate laboratory measurements with grades taken at the last assessment date on or before the start date of study treatment, the value of lower CTCAE grade will be considered as the baseline value.

For non-gradable laboratory values with duplicate measurements taken at the last assessment date on or before the start date of study treatment, the following rules apply:

- If both within normal range, use the average value
- If one within normal range and the other outside, use the one within normal range
- If both outside normal range, use the one closest to the normal range

Laboratory values with missing units or normal range may not be included in laboratory tables.

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11.6.3. Laboratory analysis

Laboratory data that are continuous in nature but are less than the lower limit of quantitation or above the upper limit of quantitation will be imputed. The limit of quantitation will be used for calculation of descriptive statistics if the data is reported in the form of "≤ x" or "< x" or "≥ x" or ">x" (x is considered as the limit of quantitation).

The following analysis on laboratory parameters by cohort and overall on FAS will be performed:

Laboratory Tables

- Central haematology, coagulation and serum biochemistry parameters
  - Descriptive summaries of absolute values and absolute change from baseline values will be presented for continuous parameters for FAS by visit
  - Number (%) of subjects at each time point having clinical relevant findings of laboratory parameters will be tabulated by visit for each clinical laboratory parameter
  - For each laboratory parameter shifts in assessments from baseline (low, normal or high) to worst-post baseline will be presented based on classifications relative to the laboratory reference ranges (low/normal/high) for laboratory parameters where NCI-CTCAE grades are not defined. If a subject experiences both "*low*" and "*high*" assessments in the course of the trial, the worst post-baseline will be defined as "*Low and High*"
  - If NCI-CTCAE grades are available for a clinical laboratory parameter, frequency and shift tables based on grades will be created as follows:
    - Number (%) of subjects with worst post-baseline grade. Each subject will be counted only for the worst grade observed on-treatment.
    - Shift tables to compare baseline to the worst post-baseline value using CTCAE grades for laboratory parameters where grades are defined
- Central serology parameters
  - Descriptive summaries of absolute values and change from baseline values will be presented for FAS by visit
- Cytokine (due to IRR ≥ grade 3)
  - Descriptive summaries of absolute values will be presented for FAS on visits where the IRR was observed (split by samples taken at time of IRR and 24 hours after IRR)
  - Absolute and relative change from baseline, if the baseline values are available
- 24 hour urine
  - Analysis of parameters from 24h urine is described in section 10.2
- Spot Urine
  - Descriptive summaries of absolute values and change from baseline values for UPCR from spot urine will be presented for FAS by visit

The tables will include only assessment on-treatment.

Laboratory Listings

- Listings of subjects with laboratory values outside the reference ranges will be produced, including the information of the laboratory result with the corresponding CTCAE grade and the classifications relative to the laboratory reference ranges, including the indication whether
  - the value is below or above the reference range
  - the investigator assessed the abnormal value as clinically relevant

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- the value is a significant worsening, an outlying value or an extreme value as defined in section 11.2

- Listings on individual laboratory results will be presented by visit on FAS

12. PHARMACOKINETIC (PK) ANALYSES

12.1. Available Data

MOR202 concentrations in serum (free drug levels).

12.2. PK Parameters

The following PK parameter will be determined by non-compartmental analysis using individual concentration-time profiles:

- $t_{1/2}$: terminal elimination half-life (h)

The analyses will be performed on the PKAS population for the final analysis.

12.3. PK Parameter Derivation Rules

Time deviation:
The actual sampling time will be used for PK parameter calculation and graphical presentation of individual data.

Handling of Below Lower Limit of Quantification (BLOQ) values:
Concentration BLOQ will be imputed by 0 for the calculation of descriptive statistics, PK analyses and graphical presentation except for the geometric mean and the geometric CV, where it will be imputed as Lower Limit of Quantification (LLOQ)/2
If the concentrations before the first quantifiable concentration time point is BLOQ, the concentration will be set to 0.
If the concentrations after the last quantifiable concentration time point is BLOQ, the concentration will be set to missing.
If there are embedded BLOQ values between quantifiable concentrations, these BLOQ values will be set to missing.
If there is a quantifiable concentration after 2 consecutive BLOQ values at the end of the profile, this quantifiable concentration and any further quantifiable concentration will be set to missing.

PK parameters:
Terminal elimination half-life estimate:
At least three time points (post-last study drug administration) should be used for determination of the elimination rate constant (λ_z);
The adjusted correlation coefficient of the linear regression should be ≥ 0.90.
If these two criteria are not met the terminal elimination half-life will not be reported.

Handling of other potential anomalies in the serum PK profiles will be discussed with the sponsor before PK parameter derivation.

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12.4. Summary Statistics

Summary statistics include n, arithmetic mean, standard deviation (StD), geometric mean, coefficient of variation (CV), median, minimum and maximum. The CV will be expressed as a percentage and calculated as follows:

CV of the arithmetic mean (%): $\frac{\text{StD}}{\text{mean}} \times 100$

CV of the geometric mean (%): $\sqrt{\exp(\text{variance for log transformed data}) - 1} \times 100$

A table with summaries by cohort and overall, and by study visit will be presented with the following information:

- MOR202 serum concentrations

A table with summaries by cohort and overall will be presented with the following information:

- Terminal elimination half-life (days)

Individual plots of MOR202 serum concentrations over actual sample time with all subjects on the same plot will be generated using linear and semi-logarithmic scales (i.e. log y-axis) by cohort and sampling time (pre-and post-dose).

Figures of mean (± standard error) serum concentrations of MOR202 versus nominal days by cohort will be generated using both linear and semi-logarithmic scales (i.e. log y-axis) and split by pre-dose and 30 minutes post-dose.

MOR202 serum levels may be further analysed performing population PK analyses, which will be reported separately.

Listings of individual serum concentrations and sampling time of MOR202 and individual terminal elimination half-life values will be presented by cohort on PKAS.

The following information will be summarized by arm and overall on PKAS:

Absolute normalized urine levels (i.e. MOR202 urine level/CREA frozen level, both values derived from the same frozen urine sample) by visit

Listings with individual frozen Creatinine values, MOR202 PK samples, and CREA frozen normalized urine levels will be generated by visit on FAS.

13. IMMUNOGENICITY ANALYSES

ADA status (positive/negative), the ADA titre when ADA positive and potential drug interference in the assay when ADA negative (yes/no) will be summarized descriptively, by treatment group and time point. The analyses will be performed using the IAS population.

The following results will be tabulated for each cohort and by visit and overall (across all visits):

Number (%) of subjects with ADA status positive/negative
For ADA status positive subjects: summary (n, mean, median, SD, min, max) of ADA titre

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For ADA status negative subjects: number (%) of subjects with potential drug interference in the assay (yes/no)

Listings of individual ADA results incl. titre values when ADA positive and potential drug interference in the assay when ADA negative (yes/no) will be presented by cohort and on IAS.

14. BIOMARKERS ANALYSES

Additional pharmacodynamic biomarkers may include the following:

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15. GENERAL GUIDANCE ON REPORTING

15.1. Document headers and footers

The following header will be used for all tables, listings and figures outlined in this document:

MorphoSys AG	**Tables, *Version* for *Reporting Event***
MOR202C103	Database status: Draft, DD-Mmm-YYYY (Cut-off date: DD-Mmm-YYYY)
MOR202	Page x of X

The following labels of *reporting event* will be used for all outputs:

- Primary Analysis
- Final Analysis

Version could be Dry-Run, Draft v0x, Final v01.

The following display will be used for outputs:

- footnote 1

- footnote 2

- footnote 3

Created on date by program.

For example:

Created on 11-Jan-2022 / 12:18 by program T14_1.sas

In the applicable outputs, the MedDRA version and WHO-DDE version used for reporting the study will be specified as a footnote.

- MedDRA Version <xx.x> has been used for the reporting

- WHO-DDE Version <xx.x> has been used for the reporting

The latest available version of dictionaries at the time of reporting will be used.

15.2. Presentation of output numbering and titles within this document

In practice, the numbering and title for all tables, figures and listings defined in this document will be formatted as follows, respectively:

Table XX.X Title Title Title Title Title Title - Population

Listing XX.X Title Title Title Title Title Title - Population

15.3. Presentation of analysis sets

The outputs to be produced based on this document will use ‘SCR’, ‘FAS’, “PPS’, ‘PKAS’, ‘IAS”, “BAS” in the table/figure/listing titles.

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15.4. General rules for presenting frequencies and percentages

If a summary table displays only categorical variables then the convention illustrated in the following example will be used:

Preferred Term	Cohort 1 (newly diagnosed subjects) N=xx n (%)	Cohort 1 (relapsed subjects) N=xx n (%)	Cohort 2 (refractory subjects) N=xx n (%)
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)
Fatigue	xx (xx.x)	xx (xx.x)	xx (xx.x)
Nausea	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anemia	xx (xx.x)	xx (xx.x)	xx (xx.x)

However, if a summary table displays both continuous and categorical variables, then the convention illustrated in the following example will be used:

	Cohort 1(newly diagnosed subjects) N=xx	Cohort 1 (relapsed subjects) N=xx	Cohort 2 (refractory subjects) N=xx	All Subjects N=xx
Sex, n (%)				
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Age (Years)				
n	xx	xx	xx	xx
Mean (StD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx

15.5. General rule for tables/listings

All data as documented in the eCRF will be listed and/or tabulated using descriptive statistics or counts/percentages depending on the nature of data. All the data derived in the trial will be presented in subject data listings.

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15.6. Format of tables/listings and displays with no data

Where a listing or table has been planned, but no data meet the criteria, then a single line stating 'No data meeting the criteria are present' will be provided in the output. The default tables, listings and figures (TLF) layout will be as follows.

Orientation	Landscape
Paper Size	A4
Margins	Top: 2 cm Bottom: 1.5 cm Left: 1.5 cm Right: 1.5 cm
Font	Arial 9pt
Headers	see section 15.1
Footers	see section 15.1

The font size may be reduced as necessary to allow additional columns to be presented, but not at the expense of clarity. Also the orientation may be changed to portrait if appropriate.

15.7. Precision rules

For continuous variables, minimum and maximum will be presented to the same precision as the raw data. Mean, median, 25th and 75th percentiles will be presented to one more decimal place and standard deviation to two more decimal places than the raw data. An exception will be made for biomarker representing cell counts where mean and median will be presented without a decimal place. Geometric mean will be presented to one more decimal place than the raw data. CV of mean and CV of geometric mean will be shown to one decimal place.

For concentrations and PK parameters 3 significant digits apply for mean, geometric mean, median, StD, min and max.

For categorical variables, the number (n) and percentage (%) of subjects per category will be presented. If the count is zero in a cell, then only '0' count will be presented and not '0.0 (0.0)'. The number of missing values will be presented as a "Missing" category. Percentage values are to be rounded and presented to one decimal place. If percentages are equal to 100, then no decimal places will be presented 'xx (100)'.

The confidence intervals of a percentage will be presented to the same precision as the percentage. Hazard ratios and respective confidence intervals will be presented to two decimal places.

15.8. General rules for presenting listings

The following general rules for presenting listings should be applied by default for all listings.

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For listings, the default sorting order is by subject number and event/assessment date unless otherwise stated.

The first column of the listing will always be "Subject identifier" field.

Where a listing or table has been planned, but no data meet the criteria, then a single line stating 'No data meeting the criteria are present' will be provided in the output.

The study day will always be displayed in the listings if applicable. It will be printed under the label 'Study Day' in all listings. The definition of study day is:

The reference start date ***for all safety assessments*** (e.g. adverse event onset, laboratory abnormality occurrence, vital sign measurement, dose interruption, etc.) and ***for all efficacy assessments*** (e.g. death, disease progression, response) will be the start date of study treatment. The following footnote will be added in all safety listings: "Study Day is relative to the first date of study treatment (Day 1)".

For data collected at the visit level: 'Visit' column will be displayed in the listings. Unscheduled visits will appear as "U0X" (or similar) in all the listings, if any.

For all laboratory parameters, SI units are used as default.

When a variable collected in the eCRF is linked to another variable, one or both variables will be presented in the same column of the listing or in adjacent columns if space permits this.

For example:

- 'Setting'='OTHER' and 'Other, specify'='Lung'
  "OTHER: Lung" will be displayed in the column as 'Setting'.
- 'Dose'='120' and Dose unit ='mg'
  '120 mg' will be displayed in the column as 'dose (unit)'.

  Date = "12-05-2012" and Study day ="5".
  "12MAY2012 (5)" will be displayed in the column as 'Date (Study Day)'.

  End date = "22-05-2012" and Study day ="15"
  "22MAY2012 (15)" will be displayed in the column as 'End date (Study Day)'

  End date = " " and ongoing is ticked
  "Ongoing" will be displayed in the column as 'End date / Study Day'

15.9. Presentation of dates

Calendar dates and times (optional) in all the listings will be displayed in the format:

YYYY-MM-DD hh:mm e.g. 2012-01-15 00:20.

Note: If time is not collected, calendar dates will be displayed as: YYYY-MM-DD.

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16. CCI [redacted].

CCI [redacted]

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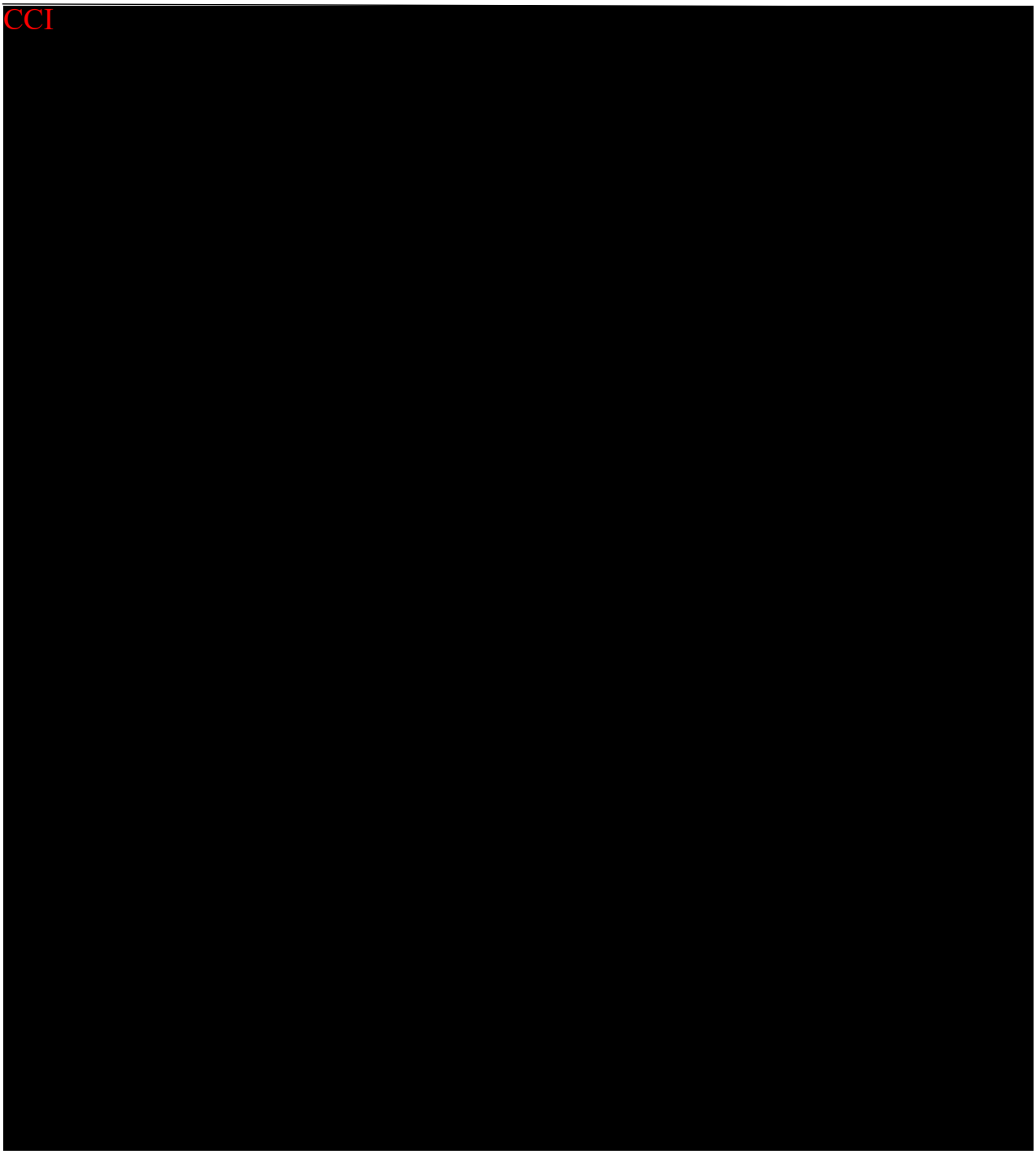

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17. REFERENCES

1. *Expressing the Modification of Diet in Renal Disease Study equation for estimating glomerular filtration rate with standardized serum creatinine values.* **Levey AS, Coresh J, Greene T, Marsh J, Stevens LA, Kusek JW et al.** 2007, Clin Chem, pp. 53 (4): 766-72.

2. *A new equation to estimate glomerular filtration rate.* **Levey AS, Stevens LA, Schmid CH, Zhang YL, Castro AF, Feldmann HI et al.** 2009, Ann Intern Med, pp. 150(9): 604-12.

3. *Simplified calculation of body-surface area.* **Mosteller, RD.** s.l. : New English Journal of Medicine, 1987, Vol. 317:1098.

4. *Optum Smart Measurement System ("SMS") Scoring Solution.* **Sciences, OptumInsight Life.** 2019.

5. *An analysis of the time relationships or time-relations of electrocardiograms.* **Bazett HC.** 1920, Heart, pp. 7:353-80.

6. *Die Systolendauer im Elektrokardiogramm bei normalen Menschen und bei Herzkranken. [The duration of systole in the elctrocardiogram of normal subjects and of patients with heart disease.].* **Fridericia LS.** 1920, Acta Medica Scandinavica, pp. 53: 469-86.