STATISTICAL ANALYSIS PLAN

A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Evaluate the Safety and Efficacy of CCX168 in Subjects with Anti-Neutrophil Cytoplasmic Antibody (ANCA)-Associated Vasculitis on Background Cyclophosphamide or Rituximab Treatment

Protocol Number: CL002_168
Investigational Product: Complement 5a Receptor Antagonist CCX168

Sponsor:
ChemoCentryx, Inc.
PPD

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SIGNATURE PAGE

Protocol Title: A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Evaluate the Safety and Efficacy of CCX168 in Subjects with Anti-Neutrophil Cytoplasmic Antibody (ANCA)-Associated Vasculitis on Background Cyclophosphamide or Rituximab Treatment

Signature

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REVISION HISTORY

Version	Date	Description of Changes
1.0	July 17, 2013	Original SAP
2.0	November 3, 2015	Revisions for analysis of data for Step 3 corresponding to Protocol Amendment 4.0

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1 Introduction

This document provides a description of the statistical methods and procedures to be implemented for the analysis of data from all 3 steps of ChemoCentryx, Inc. Protocol CL002_168. An analysis was initially performed after subjects enrolled in Steps 1 and 2 of the study completed the 168-day study period. Based on the results of that analysis the protocol was amended prior to enrollment of subjects into Step 3. An overview of each of the 3 steps is provided below:

STEP 1

Twelve subjects with newly diagnosed or relapsed ANCA-associated renal vasculitis (AARV) were targeted for randomization to CCX168 or placebo in a 2:1 ratio. Randomization was stratified by disease status (newly diagnosed or relapsed). A two-thirds reduced dose of oral corticosteroids was given to subjects randomized to CCX168 and a full dose of oral corticosteroids to subjects randomized to placebo. All 12 subjects received IV cyclophosphamide treatment, which is part of standard therapy for AARV. If necessary, rescue IV methylprednisolone or oral rescue steroids after Day 1 were given to subjects with worsening disease.

STEP 2

Twelve subjects with newly diagnosed or relapsed AARV were targeted for randomization to CCX168 or placebo in a 2:1 ratio. Oral corticosteroids were not given to subjects randomized to CCX168 but a full dose of oral corticosteroids were given to subjects randomized to placebo. All subjects received IV cyclophosphamide treatment. If necessary, rescue IV or oral methylprednisolone could be given to subjects with worsening disease.

STEP 3

Approximately 36 subjects with ANCA-associated vasculitis (AAV), with or without renal disease involvement, were planned to be randomized in a 1:1:1 ratio to one of the following three groups:

> Group A: CCX168 plus cyclophosphamide/rituximab plus no oral corticosteroids;
>
> Group B: Placebo plus cyclophosphamide/rituximab plus a full starting dose of oral corticosteroids;
>
> Group C: CCX168 plus cyclophosphamide/rituximab plus a two-thirds reduced starting dose of oral corticosteroids.

Randomization was stratified based on the following three variables:

- Disease status (newly diagnosed AAV or relapsed AAV);
- ANCA positivity (MPO or PR3); and
- Standard of care treatment (cyclophosphamide or rituximab).

If necessary, rescue IV methylprednisolone or oral rescue steroids could be given to subjects with worsening disease.

For each step of the study, subjects participated in an 84-day dosing period and an 84-day follow-up period. All subjects had scheduled study visits at screening and on Days 1, 2, 8, 15, 22, 29, 43, 57, 71, 85, 99, 113, 141, and 169.

For additional details regarding the study design, please refer to the protocol.

AAV standard therapy includes cyclophosphamide and oral corticosteroids, tapered over a period of time. Severe disease warrants addition of IV corticosteroids and/or plasma exchange. Based on studies indicating the involvement of C5a and C5aR in AAV, CCX168 has the potential to be a corticosteroid sparing or corticosteroid replacement therapy for this disease. The aim of this trial is to optimize the treatment to induce remission for patients with AAV. The intent is to reduce the toxicity of induction therapy by reducing the overall exposure to or eliminating entirely the use of systemic corticosteroids during the induction period with an inhibitor of the complement C5a receptor plus cyclophosphamide or rituximab.

This analysis plan was written after finalization of protocol amendment 4. Any deviations from this analysis plan will be substantiated by sound statistical rationale and documented in the Integrated Clinical and Statistical Report.

2 Trial Objectives

As described in Amendment 4, the primary safety objective of this study is to evaluate the safety and tolerability of CCX168 in subjects with AAV on background cyclophosphamide or rituximab treatment. The primary efficacy objective is to evaluate the efficacy of CCX168 based on the Birmingham Vasculitis Activity Score (BVAS) version 3.

The secondary objectives of this study include:

1. Evaluation of the efficacy of CCX168 compared to standard of care (SOC) based on changes in renal disease activity parameters:
    - eGFR (MDRD serum creatinine equation);
    - Hematuria (central laboratory microscopic count of urinary RBCs); and
    - Albuminuria (first morning urinary albumin:creatinine ratio);
2. Assessment of changes in renal inflammatory activity based on urinary monocyte chemoattractant protein-1 (MCP-1):creatinine ratio and serum C-reactive protein (CRP) concentration with CCX168 compared to SOC;
3. Assessment of the feasibility of reducing or eliminating the use of corticosteroids in the treatment of subjects with ANCA-associated vasculitis (AAV) without the need for rescue corticosteroid measures with CCX168 compared to SOC;
4. Assessment of health-related quality-of-life changes based on Short Form-36 version 2 (SF-36v2) and EuroQOL-5D-5L (EQ-5D-5L) with CCX168 compared to SOC;
5. Assessment of changes in Vasculitis Damage Index (VDI) with CCX168 compared to SOC;
6. Assessment of changes in ANCA (anti-PR3 and anti-MPO) with CCX168 compared to SOC;

7. Assessment of changes in pharmacodynamics markers in plasma and urine with CCX168 compared to SOC; and

8. Evaluation of the pharmacokinetic profile of CCX168 in subjects with AAV.

3 Statistical Methodology

3.1 Analysis Populations

For the purposes of data analysis, the intent-to-treat (ITT) Population will include all subjects who are randomized, have received at least one dose of study drug, and have at least one post baseline on treatment BVAS assessment. The safety population will include all subjects who are randomized and have received at least one dose of study drug. A per protocol (PP) population may also be defined if there are major protocol deviations that could affect study outcome.

3.2 Analysis Overview

Data will be summarized descriptively by treatment group, step of the study, and overall. For continuous variables, summary statistics will include the sample size, mean, median, standard deviation (SD), standard error of the mean (SEM), minimum, and maximum. Continuous variables with skewed distributions will be log-transformed for analysis including urinary ACR, urinary RBC count, urinary MCP-1:creatinine ratio, and hsCRP. Frequency counts and percentages will be presented for categorical variables. All data will be displayed in data listings which will be included as part of an appendix to the Clinical Study Report.

In analysis tables and listings, the three treatment groups will be referred to as 'Placebo+Full Dose Prednisone', 'CCX168+Low Dose Prednisone', and 'CCX168+No Prednisone'. For summaries and analyses for which all subjects randomized to CCX168 treatment are pooled, the treatment group will be referred to as 'All CCX168'. Note that the 'CCX168+Low Dose Prednisone' group includes all Step 1 subjects randomized to CCX168 and all Step 3 subjects randomized to Group C. The 'CCX168+No Prednisone' group includes all Step 2 subjects randomized to CCX168 and all Step 3 subjects randomized to Group A.

3.3 Summary of Demographic and Baseline Characteristics

All subject baseline characteristics and demographic data (age, sex, race, ethnicity, weight, height, body mass index, smoking status, ECG, TB screen results, viral test results, ANCA, renal vasculitis disease duration (from time of first induction of treatment), BVAS, VDI, SF36v2, EQ-5D-5L, hsCRP, eGFR, hematuria, urine RBC casts, proteinuria (ACR), glomerular histopathology (if biopsy was taken), urinary MCP-1:creatinine ratio, physical examination abnormalities, medical history, previous (within 6 months of screening) and concomitant medications (including vasculitis medication use) at study entry will be listed by treatment group, study center, and subject number, and will also be summarized by treatment group, step of the study, and overall.

3.4 Safety Analyses

Safety assessments include adverse events, physical examination abnormalities, vital signs, clinical laboratory tests (including blood chemistry, hematology, and urinalysis), and ECGs.

Safety analyses will be performed on the Safety Population. Data will be summarized for each step and overall (including subjects from all 3 steps). For the summaries within each step, data will be presented for each randomized treatment group. For the overall summaries, data will presented for the placebo group, the CCX168 + low dose prednisone group, the CCX168 + no prednisone group, and a pooled summary that includes all CCX168 subjects. In general, separate summaries will be prepared for safety events occurring during the 84-day treatment period and the 168-day study period. No inferential analyses will be performed on safety data.

An adverse event will be considered as "pre-treatment" if the start date/time of the event is prior to the time of administration of the first dose of study medication. All other adverse events will be considered "treatment-emergent" (TEAE). Symptoms or signs of vasculitis will be considered adverse events if these increase in severity or frequency while a subject is on study.

An overview of treatment-emergent adverse events will be prepared that presents all TEAEs, serious adverse events (SAEs), TEAEs leading to discontinuation, events related to study medication, corticosteroids, cyclophosphamide, azathioprine, or rituximab, and TEAEs by maximum severity.

Adverse events will be coded using MedDRA and TEAEs will be summarized by system organ class and preferred term. Similar summaries will be prepared for TEAEs related to study medication, corticosteroids, cyclophosphamide, azathioprine, or rituximab, TEAEs by maximum severity, SAEs, and TEAEs leading to discontinuation. Adverse events will be listed by step and treatment group, including all available information of interest such as onset and resolution dates, study day of onset relative to first dosing day, severity, seriousness, causal relationship to study medication and corticosteroid use, action taken, and outcome.

Laboratory parameter results and changes from baseline will summarized by visit. Shift tables from baseline to subsequent study visits will also be generated. Notable abnormalities will be listed by step, treatment group and subject number, and will be summarized by treatment group. Laboratory values outside the reference ranges will be flagged in the listings.

Vital sign results and changes from baseline will summarized by visit. Physical examination abnormalities will be summarized by visit and body system. ECG abnormalities will be listed.

The subject incidence of effects possibly associated with glucocorticoid use including serious infections, new-onset diabetes mellitus/hyperglycemia, bone fracture, peptic ulcer disease, cataracts, new onset/worsening hypertension, weight gain more than 10 kg, and psychiatric disorders will be summarized by treatment group for the 84-day treatment period and the 168-day study period. These effects will be identified as follows:

- Serious infections: All SAEs in the System Organ Class Infections and Infestations
- New-onset diabetes mellitus/hyperglycemia: All TEAEs of hyperglycemia, diabetes, increased blood glucose, plus all patients with a fasting blood glucose level post baseline that is above the upper limit of normal on at least two consecutive study visits.
- Bone fracture: All TEAEs indicating long bone or vertebral fractures
- Peptic ulcer disease: All TEAEs indicating upper gastrointestinal ulceration, erosion, or bleeding
- Cataracts: All TEAEs of cataract

- New onset/worsening hypertension: All TEAEs of hypertension, worsening hypertension, or high blood pressure, plus all patients with a systolic blood pressure increase of at least 20 mm Hg from baseline, and >140 mm Hg (systolic), or diastolic blood pressure increase of at least 10 mm Hg from baseline, and >90 mm Hg (diastolic), that is present on at least two consecutive study visits.
- Weight gain more than 10 kg: Change from baseline in weight of > 10 kg.
- Psychiatric disorders: All TEAEs of psychosis, anxiety, amnesia, convulsions, delirium, dementia, depression, mania, emotional instability, irritability, euphoria, hallucinations, impaired cognition, increased motor activity, insomnia, memory loss, mania, mood swings, neuritis, neuropathy, paresthesia, personality changes, restlessness, schizophrenia, vertigo, or withdrawal behavior.

The subject incidence of infections, serious infections, severe infections (i.e., Grade 3), and infections leading to subject withdrawal from the study will be summarized by treatment group for the 84-day treatment period and the 168-day study period.

3.5 Efficacy Analyses

The primary efficacy endpoint is the proportion of subjects achieving disease response at Day 85 defined as BVAS percent reduction from baseline of at least 50% plus no worsening in any body system component.

Other efficacy endpoints include:

1. In patients with hematuria and albuminuria at baseline, the proportion of subjects achieving renal response at Day 85; renal response is defined as an improvement in parameters of renal vasculitis:
   a. an increase from baseline to Day 85 in eGFR (MDRD serum creatinine equation), plus
   b. a decrease from baseline to Day 85 in hematuria (central laboratory microscopic count of urinary RBCs), plus
   c. a decrease from baseline to Day 85 in albuminuria (first morning urinary albumin:creatinine ratio).
2. Proportion of subjects achieving disease remission at Day 85 defined as BVAS of 0 or 1 plus no worsening in eGFR and urinary RBC count < 10/hpf;
3. Percent change from baseline to Day 85 in BVAS;
4. Change and percent change from baseline to Day 85 in eGFR;
5. In subjects with baseline hematuria > 5 RBCs/hpf, the proportion of subjects and time to first achieving urinary RBC count ≤ 5/hpf at any time during the 84-day treatment period;
6. In subjects with baseline hematuria ≥ 30 RBCs/hpf, the proportion of subjects and time to first achieving urinary RBC count < 30/hpf at any time during the 84-day treatment period;
7. In subjects with hematuria at baseline, the percent change from baseline to Day 85 in urinary RBC count;
8. In subjects with albuminuria at baseline, the percent change from baseline to Day 85 in urinary ACR;

9. Percent change from baseline to Day 85 in urinary MCP-1:creatinine ratio;
10. Proportion of subjects requiring rescue IV or oral glucocorticoid treatment;
11. Change from baseline to Day 85 in the Vasculitis Damage Index (VDI);
12. Change from baseline to Day 85 in health-related quality-of-life as measured by the Short Form-36 version 2.0 (SF-36v2) and EuroQOL-5D-5L (EQ-5D-5L);

Other endpoints include:

1. Total cumulative study-supplied prednisone dose and duration of dosing during the 84-day treatment period;
2. Total cumulative systemic corticosteroid dose (any use) and duration of dosing during the 84-day dosing period;
3. Total cumulative cyclophosphamide or rituximab dose and duration of dosing during the 84-day dosing period;
4. Percent change from baseline in hsCRP;
5. Percent change from baseline in ANCA (anti-PR3 and anti-MPO) at Day 85;
6. Proportion of patients becoming ANCA negative at Day 85; and
7. Change and percent change from baseline in plasma and urine biomarkers.

Efficacy analyses will be presented in three groupings:

1. Steps 1 through 3 combined
2. Steps 1 and 2 combined and Step 3
3. Each step presented separately

No formal testing will be used to compare treatment groups within Step 1 and Step 2 due to the small sample size.

For all efficacy endpoints, baseline is defined as the last value prior to start of dosing with study medication (typically the Day 1 pre-dose value).

3.5.1 Primary Efficacy Analysis

The proportion of subjects achieving disease response (defined above) during the 84-day treatment period will be calculated to compare each CCX168 group against the placebo (standard of care) group. If the Day 85 result is missing, the last post-randomization result will be used, unless the subject had worsening of AAV and required rescue treatment. In the latter case the subject would be considered a non-responder.

If the lower bound of the 1-sided 95% confidence interval for the difference (CCX168 minus control group) is greater than -0.20, the respective CCX168 group will be considered not inferior to the placebo group. If the lower bound is greater than 0.0, the respective CCX168 group will be considered superior to the placebo group in achieving the disease response. For the purpose of data presentation, the 2-sided 90% confidence intervals will be displayed since the lower bound of the 1-sided 95% confidence interval is identical to the lower bound of the 2-sided 90%

confidence interval. The p-values from the hypothesis tests of non-inferiority (H_1: p_1-p_2>-0.2) and superiority (H_1: p_1-p_2>0) will also be displayed. The primary analysis will include all subjects in all 3 steps.

Similar analyses will be performed to compare the All CCX168 group to the placebo group. In addition, the analyses will be repeated for all subjects in Step 3, for subjects in Step 1 + Step 2 combined, and for Steps 1 and 2. For these analyses, confidence intervals and p-values will not be displayed for Step 1 and for Step 2 due to the small sample sizes.

These analyses of disease response will be repeated for the 168-day study period. For this analysis, if the Day 169 result is missing, the last result after Day 85 will be used, unless the subject had worsening of AAV and required rescue treatment. In the latter case the subject would be considered a non-responder.

Subgroup analyses will also be performed for the following subgroups:

1. Subjects with renal disease at baseline (defined as subjects with BVAS items scored in the renal organ system)
2. Subjects without renal disease at baseline (defined as subjects with no BVAS items scored in the renal organ system)
3. Subjects receiving cyclophosphamide background treatment
4. Subjects receiving rituximab background treatment
5. Subjects with newly diagnosed disease
6. Subjects with relapsed disease
7. Subjects with MPO+ disease
8. Subjects with PR3+ disease
9. Subjects with granulomatosis with polyangiitis (Wegener's)
10. Subjects with microscopic polyangiitis

For all subgroup analyses, confidence intervals and p-values are considered descriptive.

3.5.2 Other Efficacy Analyses

Categorical responses will be analyzed using the same approach as the primary efficacy endpoint. This includes:

- Renal response in subjects with hematuria and albuminuria at baseline at Day 85 and at Day 169;
- BVAS disease remission at Day 85 and Day 169.;

Results for subjects who became ANCA negative (PR3 and MPO) at Day 85 and Day 169 will be summarize only with no inferential statistical analyses.

Quantitative efficacy variables will be summarized at each visit as will changes and/or percent changes from baseline. Mixed models for repeated measures (MMRM) will be used to compare treatment groups during the 84-day treatment period and the 168-day study period. For analyses of Steps 1 through 3 combined, the models will include treatment group, visit, treatment-by-visit interaction, AAV disease status (new or relapsed) and ANCA positivity (MPO or PR3) as factors and the baseline value as a covariate. For analyses of data from Step 3 only, the models will include factors for treatment group, visit, treatment-by-visit interaction, AAV disease status (new or relapsed), ANCA positivity (MPO or PR3), and standard of care treatment (rituximab or cyclophosphamide), and the baseline value as a covariate. For analyses of data from Steps 1 and 2 combined, the models will include factors for treatment group, visit, treatment-by-visit interaction, disease status, ANCA positivity, and the baseline value as a covariate. The output from the MMRM analysis will include the results at each visit as well as the overall results. P-values from contrasts comparing treatment groups will be presented as will 95% confidence intervals for treatment differences.

Analysis of covariance (ANCOVA) will also be used to compare treatment groups in change and/or percent change from baseline at each visit, for the end of the 84-day treatment period, and the end of the 84-day study period. For analyses of Steps 1 through 3 combined, the models will include AAV disease status (new or relapsed) and ANCA positivity (MPO or PR3) as factors and the baseline value as a covariate. For analyses of data from Step 3 only, the models will include factors for AAV disease status (new or relapsed), ANCA positivity (MPO or PR3), and standard of care treatment (rituximab or cyclophosphamide) and the baseline value as a covariate. For analyses of data from Steps 1 and 2 combined, the models will include factors for disease status and ANCA positivity, and the baseline value as a covariate.

The variables to be analyzed in this manner include:

- BVAS percent change from baseline;
- eGFR (MDRD formula) change and percent change from baseline;
- Urinary RBC count ratio and percent change from baseline in subjects with hematuria at baseline;
- ACR ratio and percent change from baseline in subjects with albuminuria at baseline;
- Urinary MCP-1:creatinine ratio and percent change from baseline;
- VDI change and percent change from baseline;
- SF-36 change and percent change from baseline for subjects in Step 3 including all domains and the physical component and mental health summaries;
- EQ-5D-5L scores and VAS change and percent change from baseline for subjects in Step 3 including all domains and the physical component and mental health summaries;
- Serum hsCRP ratio and percent change from baseline;
- ANCA (anti-PR3 and anti-MPO) ratio and percent change from baseline; and
- Serum and urine biomarkers change and percent change from baseline.

The MMRM analyses will be repeated for the BVAS renal subscore and non-renal subscore for the ITT Population only.

The percentage of subjects who achieve urinary RBC<=5 RBCs/hpf during the 84-day treatment period will be summarized. The p-values from the hypothesis tests of no difference between treatments (H_1: p_1-$p_2 \neq 0$) will be displayed. For each treatment group, Kaplan-Meier estimates of the 25th percentile, median, and 75th percentile days to first occurrence will be calculated and treatment groups will be compared using the log-rank test. The analysis will be repeated for the 168-day study period as well as for each of the following subgroups:

1. Subjects with renal disease at baseline (defined as subjects with BVAS items scored in the renal organ system)
2. Subjects without renal disease at baseline (defined as subjects with no BVAS items scored in the renal organ system)
3. Subjects receiving cyclophosphamide background treatment
4. Subjects receiving rituximab background treatment
5. Subjects with newly diagnosed disease
6. Subjects with relapsed disease
7. Subjects with MPO+ disease
8. Subjects with PR3+ disease
9. Subjects with granulomatosis with polyangiitis (Wegener's)
10. Subjects with microscopic polyangiitis

Similar analyses will be presented for the endpoint RBC <30 RBC/hpf and the endpoint for the occurrence of rescue IV or oral glucocorticoid treatment. For the analysis or rescue treatment, all subjects who receive rescue before Day 92 (Day 85 + 7 day) will be considered a treatment failure.

Summaries of dose and duration of study supplied prednisone taken during the 84-day treatment period and the 168-day study period will be provided for the full study population and for each of the 10 subgroups listed above. Similar summaries will be prepared for total systemic corticosteroid treatment, cumulative cyclophosphamide treatment, and cumulative rituximab treatment (Step 3 only).

The main efficacy analysis will be in the ITT population. Sensitivity analyses may also be performed excluding subjects with major protocol deviations.

3.6 Pharmacokinetic Analyses

The results from pharmacokinetic analyses will be reported in a separate report.

4 Sample Size Justification

For the original sample size justification for this study, please refer to the protocol.

5 Interim Analysis

Efficacy and safety data from the study were summarized for review by the DMC at defined points over the course of the study. The DMC charter included details of the analyses.

As described in Section 1, when the last subject from Step 2 completed the study, all available data were summarized and evaluated to inform decisions regarding Step 3 of this study and future clinical trials.

6 General Information Regarding Data Analyses

PPD is responsible for preparing the statistical analyses used to support the final study report for Protocol CL002_168. All tables and listings will be generated in SAS® version 9.3 or higher and all programs used to generate statistical analyses will be validated according to [redacted] standard operating procedures. Generally, tables and listings will be printed using Courier New 8pt font with all margins at least one inch. This corresponds to settings in SAS of linesize=134 and pagesize=54. The format of some displays may change slightly depending on the actual length of the data displayed.

7 Table Shells

Table 14.1.1.1
Subject Disposition - Overall
All Enrolled Subjects

Total Category	Placebo + Full Dose Prednisone n (%)	CCX168 + Low Dose Prednisone n (%)	CCX168 + No Prednisone n (%)	All CCX168 n (%)	Total n (%)
Screened					
Failed screening					
Reason 1					
Reason 2					
Randomized					
Safety Population					
ITT Population					
Completed					
Early withdrawal on/before Day 85					
Early withdrawal after Day 85					
Early withdrawal (total)					
Subject withdrew consent					
Sponsor decision					
Subject lost to follow-up					
Adverse event					
Investigator decision					
Other					

- Percentage of screen failures is based on the total number of subjects screened. Percentages of Safety population (Intent-to-Treat) population, subjects completed and early withdrawals are based on the number of subjects randomized.
- The ITT Population include all subjects who were randomized and had at least one post baseline on treatment BVAS measurement.
- The Safety Population include all subjects who were randomized and received at least one dose of study drug.

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Table 14.1.1.2
Subject Disposition by Step
All Enrolled Subjects

Step Category	Placebo + Full Dose Prednisone n (%)	CCX168 + Low Dose Prednisone n (%)	CCX168 + No Prednisone n (%)	All CCX168 n (%)	Total n (%)
Step 1					
Screened					
Failed screening					
Reason 1					
Reason 2					
Randomized					
Safety Population					
ITT Population					
Completed					
Early withdrawal on/before Day 85					
Early withdrawal after Day 85					
Early withdrawal (total)					
Subject withdrew consent					
Sponsor decision					
Subject lost to follow-up					
Adverse event					
Investigator decision					
Other					

Repeat for Step 2 and Step 3

- Percentage of screen failures is based on the total number of subjects screened. Percentages of Safety population (Intent-to-Treat) population, subjects completed and early withdrawals are based on the number of subjects randomized.
- The ITT Population include all subjects who were randomized and had at least one post baseline on treatment BVAS measurement.
- The Safety Population include all subjects who were randomized and received at least one dose of study drug.

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Table 14.1.2
Listing of Subjects who Withdrew Prematurely
All Randomized Subjects

Step Treatment Subject	Age/Sex/Race	Date Randomized	First Dose Date	Withdrawal Date/Day	Last Dose Date/Day	Cumulative CCX168 Dose (mg)	Reason for withdrawal
Step 1							
XXXXXXXXXXXXX							
###-###	##/M/XXXXXXXXXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY/##	DDMMMYYYY/##	####	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Step 2							
XXXXXXXXXXXXX							
###-###	##/M/XXXXXXXXXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY/##	DDMMMYYYY/##	####	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Note: Study day is calculated based on the date of first dose.

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NOTE 1: This table will be sorted by Step, treatment group, and subject within treatment group.

NOTE 2: Cumulative dose will be reported based on the number of capsules taken, where each capsule represents 10 mg for the CCX168 treatment group and 0 mg for the placebo group.

Table 14.1.3.1
Summary of Subject Demographics - Overall
All Randomized Subjects

Demographic characteristic Statistic/Category	Placebo + Full Dose Prednisone (N=##)	CCX168 + Low Dose Prednisone (N=##)	CCX168 + No Prednisone (N=##)	All CCX168 (N=##)	Total (N=##)
Age (Years)					
n	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##
Gender, n (%)					
Male	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Female	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Ethnicity, n (%)					
Hispanic or Latino					
Not Hispanic or Latino					
Race, n (%)					
Asian					
American Indian or Alaska Native					
Black or African American					
Native Hawaiian or Other Pacific Islander					
White					
Other					

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NOTE: Only non-zero race categories will be included.

Table 14.1.3.2
Summary of Subject Demographics by Step
All Randomized Subjects

Demographic characteristic Statistic/Category	Step 1 Placebo + Full Dose Prednisone (N=##)	Step 1 CCX168 + Low Dose Prednisone (N=##)	Step 2 Placebo + Full Dose Prednisone (N=##)	Step 2 CCX168 + No Prednisone (N=##)	Step 3 Placebo + Full Dose Prednisone (N=##)	Step 3 CCX168 + Low Dose Prednisone (N=##)	Step 3 CCX168 + No Prednisone (N=##)
Age at screening							
n	##	##	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##	##	##
Gender, n (%)							
Male	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Female	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Ethnicity, n (%)							
Hispanic or Latino							
Not Hispanic or Latino							
Race, n (%)							
Asian							
American Indian or Alaska Native							
Black or African American							
Native Hawaiian or Other Pacific Islander							
White							
Other							

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NOTE: Only non-zero race categories will be included.

Table 14.1.4.1
Summary of Baseline Characteristics - Overall
All Randomized Subjects

Baseline characteristic Statistic/Category	Placebo + Full Dose Prednisone (N=##)	CCX168 + Low Dose Prednisone (N=##)	CCX168 + No Prednisone (N=##)	All CCX168 (N=##)	Total (N=##)
Body weight (kg)					
n	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##
Smoking Status, n (%)					
Current Smoker	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Past Smoker					
Never Smoked					

This table will also include summaries of baseline data for the following parameters:

Height (cm), BMI (kg/m^2), Heart rate, Systolic blood pressure, Diastolic blood pressure, Oral temperature, TB screen results, viral test results, ANCA-newly diagnosed versus relapsed, ANCA associated vasculitis disease duration [1], standard of care (rituximab or cyclophosphamide), anti-MPO+ [2], anti-PR3 + [2], anti-MPO+ and anti-PR3+ status, type of AAV (GPA, MPO, or renal limited vasculitis), BVAS, VDI, hsCRP, eGFR, hematuria, urine RBC casts, proteinuria (ACR), urinary MCP-1:creatinine ratio, SF-36 domain scores, EQ-5D-5L score and EQ-5D-5L VAS.

[1] If subject is relapsed, the recorded diagnosis date is used for this summary.
[2] For summaries of Anti-MPO+ (IU/mL) and Anti-PR3+ (IU/mL), only subjects with a non-negative baseline categorical status are included. Results reported as '>156.0' are treated as equal to 156.0 for computing summary statistics.

Table 14.1.4.2
Summary of Baseline Characteristics by Step
All Randomized Subjects

Baseline characteristic Statistic/Category	Step 1 Placebo + Full Dose Prednisone (N=##)	Step 1 CCX168 + Low Dose Prednisone (N=##)	Step 2 Placebo + Full Dose Prednisone (N=##)	Step 2 CCX168 + No Prednisone (N=##)	Step 3 Placebo + Full Dose Prednisone (N=##)	Step 3 CCX168 + Low Dose Prednisone (N=##)	Step 3 CCX168 + No Prednisone (N=##)
Body weight (kg)							
n	##	##	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##	##	##
Smoking Status, n (%)							
Current Smoker	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Past Smoker							
Never Smoked							

Height (cm), BMI (kg/m^2), Heart rate, Systolic blood pressure, Diastolic blood pressure, Oral temperature, TB screen results, viral test results, ANCA-newly diagnosed versus relapsed, ANCA associated vasculitis disease duration [1], standard of care (rituximab or cyclophosphamide), anti-MPO+ [2], anti-PR3 + [2], anti-MPO+ and anti-PR3+ status, type of AAV (GPA, MPO, or renal limited vasculitis), BVAS, VDI, hsCRP, eGFR, hematuria, urine RBC casts, proteinuria (ACR), urinary MCP-1:creatinine ratio, SF-36 domain scores, EQ-5D-5L score and EQ-5D-5L VAS.

[1] If subject is relapsed, the most recent diagnosis date is used for this summary.
[2] For summaries of Anti-MPO+ (IU/mL) and Anti-PR3+ (IU/mL), only subjects with a non-negative baseline categorical status are included. Results reported as '>156.0' were treated as equal to 156.0 for computing summary statistics.

Table 14.1.5.1
Summary of Prior Medications - Overall
All Randomized Subjects

Anatomic Therapeutic Class Preferred Term	Placebo + Full Dose Prednisone (N=##) n (%)	CCX168 + Low Dose Prednisone (N=##) n (%)	CCX168 + No Prednisone (N=##) n (%)	All CCX168 (N=##) n (%)	Total (N=##) n (%)
Any Prior Medication	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Anatomic Therapeutic Class 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Preferred Term 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)

- Prior medications are defined as any medication taken within 6 months of screening, during the screening period between the screening visit and the day of randomization.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

NOTE: Table will be sorted by descending frequency in the total column for anatomic therapeutic class and preferred term within anatomic therapeutic class.

Table 14.1.5.2
Summary of Prior Medications by Step
All Randomized Subjects

Anatomic Therapeutic Class Preferred Term	Step 1 Placebo + Full Dose Prednisone (N=##) n (%)	Step 1 CCX168 + Low Dose Prednisone (N=##) n (%)	Step 2 Placebo + Full Dose Prednisone (N=##) n (%)	Step 2 CCX168 + No Prednisone (N=##) n (%)	Step 3 Placebo + Full Dose Prednisone (N=##) n (%)	Step 3 CCX168 + Low Dose Prednisone (N=##) n (%)	Step 3 CCX168 + No Prednisone (N=##) n (%)
Any Prior Medication	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Anatomic Therapeutic Class 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Preferred Term 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)

- Prior medications are defined as any medication taken within 6 months of screening, during the screening period between the screening visit and the day of randomization.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

NOTE: Table will be sorted by descending frequency in the total column for anatomic therapeutic class and preferred term within anatomic therapeutic class.

Table 14.1.6.1
Summary of Concomitant Medications - Overall
All Randomized Subjects

Anatomic Therapeutic Class Preferred Term	Placebo + Full Dose Prednisone (N=##) n (%)	CCX168 + Low Dose Prednisone (N=##) n (%)	CCX168 + No Prednisone (N=##) n (%)	All CCX168 (N=##) n (%)	Total (N=##) n (%)
Any Concomitant Medication	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Anatomic Therapeutic Class 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Preferred Term 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)

- Concomitant medications are defined as any medication taken on or after the day of randomization.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

NOTE: Table will be sorted by descending frequency in the total column for anatomic therapeutic class and preferred term within anatomic therapeutic class.

Table 14.1.6.2
Summary of Concomitant Medications by Step
All Randomized Subjects

Anatomic Therapeutic Class Preferred Term	Step 1 Placebo + Full Dose Prednisone (N=##) n (%)	Step 1 CCX168 + Low Dose Prednisone (N=##) n (%)	Step 2 Placebo + Full Dose Prednisone (N=##) n (%)	Step 2 CCX168 + No Prednisone (N=##) n (%)	Step 3 Placebo + Full Dose Prednisone (N=##) n (%)	Step 3 CCX168 + Low Dose Prednisone (N=##) n (%)	Step 3 CCX168 + No Prednisone (N=##) n (%)
Any Concomitant Medication	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Anatomic Therapeutic Class 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Preferred Term 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)	## (###.#)

- Concomitant medications are defined as any medication taken on or after the day of randomization.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

NOTE: Table will be sorted by descending frequency in the total column for anatomic therapeutic class and preferred term within anatomic therapeutic class.

Table 14.2.1.1
Analysis of BVAS Response
Intent-to-Treat Population

Day Step	Treatment	N	n	(%)	Difference in percentages versus Placebo	Two-sided 90% CI for Difference	Non-infer. P-value	Superior. P-value
Day 85								
All	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)				
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	All CCX168 (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
3	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)				
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	All CCX168 (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
1+2	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)				
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	All CCX168 (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
2	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)				
	CCX168 + No Prednisone (N=##)	###	###	(###.#)				
1	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)				
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)				

Repeat for Day 169

- BVAS response is defined as achieving a 50% reduction from baseline in the BVAS plus no worsening in any body system component.

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The following tables will have the same layout as Table 14.2.1.1:

Table 14.2.1.2
Analysis of BVAS Response
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.1.3
Analysis of BVAS Response
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.1.4
Analysis of BVAS Response
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.1.5
Analysis of BVAS Response
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.1.6
Analysis of BVAS Response
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.1.7
Analysis of BVAS Response
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.1.8
Analysis of BVAS Response
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.1.9
Analysis of BVAS Response
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.1.10
Analysis of BVAS Response
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.1.11
Analysis of BVAS Response
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.2.1
Analysis of Renal Response for Patients with Hematuria and Albuminuria at Baseline
Intent-to-Treat Population

Day Step	Treatment	N'	n	(%)	Difference in percentages versus Placebo	Two-sided 90% CI for Difference	Non-infer. P-value	Superior. P-value
Day 85								
All	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)				
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	All CCX168 (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
3	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)				
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	All CCX168 (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
1+2	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)				
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	All CCX168 (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
2	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)				
	CCX168 + No Prednisone (N=##)	###	###	(###.#)				
1	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)				
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)				
Repeat for Day 169								

- Renal response at Day 85 is defined as improvement in the following parameters of renal vasculitis: (1) increase from baseline to Day 85 in eGFR (MDRD equation), (2) decrease from baseline to Day 85 in hematuria (microscopic count of urinary RBCs), and decrease from baseline to Day 85 in albuminuria (first morning urinary albumin: creatinine ratio).

The following tables will have the same layout as Table 14.2.2.1:

Table 14.2.2.2
Analysis of Renal Response for Patients with Hematuria and Albuminuria at Baseline
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.2.3
Analysis of Renal Response for Patients with Hematuria and Albuminuria at Baseline
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.2.4
Analysis of Renal Response for Patients with Hematuria and Albuminuria at Baseline
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.2.5
Analysis of Renal Response for Patients with Hematuria and Albuminuria at Baseline
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.2.6
Analysis of Renal Response for Patients with Hematuria and Albuminuria at Baseline
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.2.7
Analysis of Renal Response for Patients with Hematuria and Albuminuria at Baseline
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.2.8
Analysis of Renal Response for Patients with Hematuria and Albuminuria at Baseline
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.2.9
Analysis of Renal Response for Patients with Hematuria and Albuminuria at Baseline
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.3.1
Analysis of BVAS Disease Remission
Intent-to-Treat Population

Day Step	Treatment	N	n	(%)	Difference in percentages versus Placebo	Two-sided 90% CI for Difference	Non-infer. P-value	Superior. P-value
Day 85								
All	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)				
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	All CCX168 (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
3	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)				
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	All CCX168 (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
1+2	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)				
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
	All CCX168 (N=##)	###	###	(###.#)	##.##	(#.##, #.##)	#.####	#.####
2	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)				
	CCX168 + No Prednisone (N=##)	###	###	(###.#)				
1	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)				
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)				
Repeat for Day 169								

- Disease remission is defined as achieving a BVAS score of 0 or 1 plus no worsening in eGFR and urinary RBC <10/hpf.

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The following tables will have the ame layout as Table 14.2.3.1:

Table 14.2.3.2
Analysis of BVAS Disease Remission
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.3.3
Analysis of BVAS Disease Remission
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.3.4
Analysis of BVAS Disease Remission
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.3.5
Analysis of BVAS Disease Remission
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.3.6
Analysis of BVAS Disease Remission
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.3.7
Analysis of BVAS Disease Remission
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.3.8
Analysis of BVAS Disease Remission
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.3.9
Analysis of BVAS Disease Remission
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.3.10
Analysis of BVAS Disease Remission
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.3.11
Analysis of BVAS Disease Remission
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.4.1.1
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population

Study Day / Statistic	Placebo + Full Dose Prednisone (N=##) Visit	Placebo + Full Dose Prednisone (N=##) % Change	CCX168 + Low Dose Prednisone (N=##) Visit	CCX168 + Low Dose Prednisone (N=##) % Change	CCX168 + No Prednisone (N=##) Visit	CCX168 + No Prednisone (N=##) % Change	All CCX168 (N=##) Visit	All CCX168 (N=##) % Change
Baseline								
N'	##							
Mean	##.#							
SD	##.##							
Minimum	##							
Median	##.#							
Maximum	##							
Day 29								
N'	##	##	##	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##	##	##	##
P-value*				#.####		#.####		#.####
95% CI*				(-##.#, ##.#)		(-##.#, ##.#)		(-##.#, ##.#)
Day 85								
N'	##	##	##	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##	##	##	##
P-value*				#.####		#.####		#.####
95% CI*				(-##.#, ##.#)		(-##.#, ##.#)		(-##.#, ##.#)

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
*P-values and 95% confidence intervals for differences between specified treatment groups and placebo are from a MMRM model with treatment group, visit, treatment-by visit interaction, AAV disease status (new or relapsed), and ANCA positivity (MPO or PR3) as factors and the baseline value as a covariate.

Table 14.2.4.1.1
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population

Study Day / Statistic	Placebo + Full Dose Prednisone (N=##)		CCX168 + Low Dose Prednisone (N=##)		CCX168 + No Prednisone (N=##)		All CCX168 (N=##)	
	Visit	% Change	Visit	% Change	Visit	% Change	Visit	% Change
Overall								
N'	##	##	##	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##	##	##	##
P-value*				#.####		#.####		#.####
95% CI*				(-##.#, ##.#)		(-##.#, ##.#)		(-##.#, ##.#)

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
*P-values and 95% confidence intervals for differences between specified treatment groups and placebo are from a MMRM model with treatment group, visit, treatment-by visit interaction, AAV disease status (new or relapsed), and ANCA positivity (MPO or PR3) as factors and the baseline value as a covariate.

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Note to programmer: For summary statistics in the 'Overall' category, first calculate the average value for a subject then combine subjects to obtain summary statistics.

The following tables will have the a similar layout as Table 14.2.4.1.1:

Table 14.2.4.1.2
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.4.1.3
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.4.1.4
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.4.1.5
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.4.1.6
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.4.1.7
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.4.1.8
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.4.1.9
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.4.1.10
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.4.1.11
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.4.1.12
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients

Table 14.2.4.1.13
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.4.1.14
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.4.1.15
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.4.1.16
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.4.1.17
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.4.1.18
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.4.1.19
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.4.1.20
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.4.1.21
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.4.1.22
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Note to programmer: The MMRM tables for the 168-day study period will include summaries for each post-baseline visit and the p-value and 95% confidence interval for the overall differences between each group and placebo. This comment applies to all MMRM tables for the 168-day study period for Steps 1 through 3 combined.

The tables below will have the same layout as Tables 14.2.4.1.1 and 14.2.4.1.12:

Table 14.2.4.1.23
Summary and Analysis (MMRM) of BVAS Renal Sub-score Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population

Table 14.2.4.1.24
Summary and Analysis (MMRM) of BVAS Renal Sub-score Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population

Table 14.2.4.1.25
Summary and Analysis (MMRM) of BVAS Non-renal Sub-score Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population

Table 14.2.4.1.26
Summary and Analysis (MMRM) of BVAS Non-renal Sub-score Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population

Table 14.2.4.1.27
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population

Study Day / Statistic	Placebo + Full Dose Prednisone (N=##)		CCX168 + Low Dose Prednisone (N=##)		CCX168 + No Prednisone (N=##)		All CCX168 (N=##)	
	Visit	% Change	Visit	% Change	Visit	% Change	Visit	% Change
Baseline								
N'	##							
Mean	##.#							
SD	##.##							
Minimum	##							
Median	##.#							
Maximum	##							
Day 29								
N'	##	##	##	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##	##	##	##
P-value*				#.####		#.####		#.####
95% CI*				(-##.#, ##.#)		(-##.#, ##.#)		(-##.#, ##.#)

The additional visits to be summarized include:
Day 85, End of Treatment, Day 113, Day 169, End of Follow-up

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
- The End of Treatment value is the last measurement through Day 85.
- The End of Follow-up Period is the last measurement after Day 85 through Day 169.

*P-values and 95% confidence intervals for differences between specified treatment groups and placebo are from ANCOVA models with treatment group, AAV disease status (new or relapsed) and ANCA positivity (MPO or PR3)as factors and the baseline value as a covariate.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

The following tables will have the same layout as Table 14.2.4.1.27:

Table 14.2.4.1.28
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.4.1.29
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.4.1.30
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.4.1.31
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.4.1.32
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.4.1.33
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.4.1.34
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.4.1.35
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.4.1.36
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.4.1.37
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.4.2.1
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

	Step 1 and 2 Combined						Step 3					
	Placebo + Full Dose Prednisone (N=##)		CCX168 + Low Dose Prednisone (N=##)		CCX168 + No Prednisone (N=##)		Placebo + Full Dose Prednisone (N=##)		CCX168 + Low Dose Prednisone (N=##)		CCX168 + No Prednisone (N=##)	
Study Day / Statistic	Visit	% Change	Visit	% Change	Visit	% Change	Visit	% Change	Visit	% Change	Visit	% Change
Baseline												
N'	##											
Mean	##.#											
SD	##.##											
Minimum	##											
Median	##.#											
Maximum	##											
Day 29												
N'	##	##	##	##	##	##	##	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##	##	##	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##	##	##	##	##	##	##	##
P-value*				#.####		#.####				#.####		#.####
95% CI*				(-##.#, ##.#)		(-##.#, ##.#)				(-##.#, ##.#)		(-##.#, ##.#)

Day 85 will also be summarized. In addition, the p-value and 95% confidence interval for the overall differences between each active group and placebo will be displayed.

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
*P-values and 95% confidence intervals for differences between specified treatment groups and placebo are from MMRM models with treatment group, visit, and treatment-by-visit as factors and the baseline value as a covariate. The model for analysis of Step 3 included factors for AAV disease status (new or relapsed), ANCA positivity (MPO or PR3), and standard of care treatment (rituximab or cyclophosphamide). The model for Step 1 + Step 2 included a factor for disease status and ANCA positivity.

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The following tables will have layout similar to Table 14.2.4.2.1:

Table 14.2.4.2.2
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.4.2.3
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.4.2.4
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.4.2.5
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.4.2.6
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.4.2.7
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.4.2.8
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.4.2.9
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.4.2.10
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.4.2.11
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.4.2.12
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

Table 14.2.4.2.13
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.4.2.14
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.4.2.15
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.4.2.16
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.4.2.17
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.4.2.18
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.4.2.19
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.4.2.20
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.4.2.21
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.4.2.22
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Note to programmer: The MMRM tables for the 168-day study period will include summaries for each post-baseline visit and the p-value and 95% confidence interval for the overall differences between each group and placebo. This comment applies to all MMRM tables for the 168-day study period for Steps 1 and 2 combined and Step 3.

The tables below will have the same layout as Tables 14.2.4.2.1 and 14.2.4.2.12:

Table 14.2.4.2.23
Summary and Analysis (MMRM) of BVAS Renal Sub-score Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

Table 14.2.4.2.24
Summary and Analysis (MMRM) of BVAS Renal Sub-score Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

Table 14.2.4.2.25
Summary and Analysis (MMRM) of BVAS Non-renal Sub-score Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

Table 14.2.4.2.26
Summary and Analysis (MMRM) of BVAS Non-renal Sub-score Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

Table 14.2.4.2.27
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

	Step 1 and 2 Combined						Step 3					
	Placebo + Full Dose Prednisone (N=##)		CCX168 + Low Dose Prednisone (N=##)		CCX168 + No Prednisone (N=##)		Placebo + Full Dose Prednisone (N=##)		CCX168 + Low Dose Prednisone (N=##)		CCX168 + No Prednisone (N=##)	
Study Day Statistic	Visit	% Change	Visit	% Change	Visit	% Change	Visit	% Change	Visit	% Change	Visit	% Change
Baseline												
N'	##											
Mean	##.#											
SD	##.##											
Minimum	##											
Median	##.#											
Maximum	##											
Day 29												
N'	##	##	##	##	##	##	##	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##	##	##	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##	##	##	##	##	##	##	##
P-value*				#.####		#.####				#.####		#.####
95% CI*				(-##.#, ##.#)		(-##.#, ##.#)				(-##.#, ##.#)		(-##.#, ##.#)

The additional visits to be summarized include:
Day 85, End of Treatment, Day 113, Day 169, End of Follow-up Period.

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
- The End of Treatment value is the last measurement through Day 85.
- The End of Follow-up Period is the last measurement after Day 85 through Day 169.

*P-values and 95% confidence intervals for differences between specified treatment groups and placebo are from ANCOVA models with treatment group as a factor and the baseline value as a covariate. The models for Step 3 included factors AAV disease status (new or relapsed), ANCA positivity (MPO or PR3), and standard of care treatment (rituximab or cyclophosphamide). The models for Step 1 + Step 2 included a factor for disease status and ANCA positivity.

The following tables will have a similar layout as Table 14.2.4.2.27:

Table 14.2.4.2.28
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.4.2.29
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.4.2.30
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.4.2.31
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.4.2.32
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.4.2.33
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.4.2.34
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.4.2.35
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.4.2.36
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.4.2.37
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.4.3.1
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population

Step / Study / Statistic	Placebo + Full Dose Prednisone Visit	Placebo + Full Dose Prednisone % Change	CCX168 + Low Dose Prednisone Visit	CCX168 + Low Dose Prednisone % Change	CCX168 + No Prednisone Visit	CCX168 + No Prednisone % Change	All CCX168 Visit	All CCX168 % Change
Step 3	N=##		N=##		N=##		N=##	
Baseline								
N'	##							
Mean	##.#							
SD	##.##							
Minimum	##							
Median	##.#							
Maximum	##							
Day 29								
N'	##	##	##	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##	##	##	##
P-value*				#.####		#.####		#.####
95% CI*				(-##.#, ##.#)		(-##.#, ##.#)		(-##.#, ##.#)

Day 85 will also be summarized. In addition, for Step 3, the p-value and 95% confidence interval for the overall differences between each active group and placebo will be displayed.

Repeat for Steps 2 and 1 (summary statistics only).

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
*P-values and 95% confidence intervals for differences between specified treatment groups and placebo are from MMRM models with treatment group, visit, and treatment-by-visit, AAV disease status (new or relapsed), ANCA positivity (MPO or PR3), and standard of care treatment (rituximab or cyclophosphamide) as factors and the baseline value as a covariate.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

The following tables will have a similar layout as Table 14.2.4.3.1:

Table 14.2.4.3.2
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.4.3.3
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.4.3.4
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.4.3.5
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.4.3.6
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.4.3.7
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.4.3.8
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.4.3.9
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.4.3.10
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.4.3.11
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.4.3.12
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population

Table 14.2.4.3.13
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.4.3.14
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.4.3.15
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.4.3.16
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.4.3.17
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.4.3.18
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.4.3.19
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.4.3.20
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.4.3.21
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.4.3.22
Summary and Analysis (MMRM) of BVAS Percent Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Note to programmer: The MMRM tables for the 168-day study period will include summaries for each post-baseline visit and the p-value and 95% confidence interval for the overall differences between each group and placebo for Step 3. This comment applies to all MMRM tables for the 168-day study period by Step.

The tables below will have the same layout as Tables 14.2.4.3.1 and 14.2.4.3.12:

Table 14.2.4.2.23
Summary and Analysis (MMRM) of BVAS Renal Sub-score Percent Change from Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population

Table 14.2.4.2.24
Summary and Analysis (MMRM) of BVAS Renal Sub-score Percent Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population

Table 14.2.4.2.25
Summary and Analysis (MMRM) of BVAS Non-renal Sub-score Percent Change from Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population

Table 14.2.4.2.26
Summary and Analysis (MMRM) of BVAS Non-renal Sub-score Percent Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population

Table 14.2.4.3.27
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
By Step
Intent-to-Treat Population

Step / Study / Statistic	Placebo + Full Dose Prednisone — Visit	Placebo + Full Dose Prednisone — % Change	CCX168 + Low Dose Prednisone — Visit	CCX168 + Low Dose Prednisone — % Change	CCX168 + No Prednisone — Visit	CCX168 + No Prednisone — % Change	All CCX168 — Visit	All CCX168 — % Change
Step 3	N=##		N=##		N=##		N=##	
Baseline								
N'	##							
Mean	##.#							
SD	##.##							
Minimum	##							
Median	##.#							
Maximum	##							
Day 29								
N'	##	##	##	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##	##	##	##
P-value*				#.####		#.####		#.####
95% CI*				(-##.#, ##.#)		(-##.#, ##.#)		(-##.#, ##.#)

Repeat for Steps 2 and 1. Only display p-values and confidence intervals for Step 3.

The additional visits to be summarized include:
Day 85, End of Treatment, Day 113, Day 169, End of Follow-up Period.

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
- The End of Treatment value is the last measurement through Day 85.
- The End of Follow-up Period is the last measurement after Day 85 through Day 169.

*P-values and 95% confidence intervals for differences between specified treatment groups and placebo are from ANCOVA models with treatment group and randomization strata (AAV status, ANCA positivity, and standard of care treatment) as factors and the baseline value as a covariate.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

The following tables will have the same layout as Table 14.2.4.3.27:

Table 14.2.4.3.28
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
By Step
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.4.3.29
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
By Step
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.4.3.30
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
By Step
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.4.3.31
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
By Step
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.4.32
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
By Step
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.4.3.33
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
By Step
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.4.3.34
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
By Step
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.4.3.35
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
By Step
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.4.3.36
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
By Step
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.4.3.37
Summary and Analysis (ANCOVA) of BVAS Percent Change from Baseline
By Step
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.5.1.1
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population

Study Day / Statistic	Placebo + Full Dose Prednisone (N=##)			CCX168 + Low Dose Prednisone (N=##)			CCX168 + No Prednisone (N=##)			All CCX168 (N=##)		
	Visit	Change	% Change	Visit	Change	% Change	Visit	Change	% Change	Visit	Change	% Change
Baseline												
N'	##											
Mean	##.##											
SD	##.###											
Minimum	##.#											
Median	##.##											
Maximum	##.#											
Day 2												
N'	##	##	##	##	##	##	##	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
SD	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###
Minimum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Median	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Maximum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
P-value*					#.####	#.####		#.####	#.####		#.####	#.####
95% CI for Change*					(-##.#, ##.#)			(-##.#, ##.#)			(-##.#, ##.#)	
95% CI for % Change*					(-##.#, ##.#)			(-##.#, ##.#)			(-##.#, ##.#)	

The additional visits to be summarized include:
Day 8, Day 15, Day 29, Day 43, Day 57, Day 71, Day 85, and Overall

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
*P-values and 95% confidence intervals for differences between specified treatment groups and placebo are from a MMRM model with treatment group, visit, treatment-by visit interaction, AAV disease status (new or relapsed), and ANCA positivity (MPO or PR3) as factors and the baseline value as a covariate.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

The following tables will have layout similar to Table 14.2.5.1.1:

Table 14.2.5.1.2
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.5.1.3
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.5.1.4
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.5.1.5
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.5.1.6
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.5.1.7
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.5.1.8
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.5.1.9
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.5.1.10
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.5.1.11
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.5.1.12
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population

Table 14.2.5.1.13
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.5.1.14
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.5.1.15
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.5.1.16
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.5.1.17
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.5.1.18
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.5.1.19
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.5.1.20
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.5.1.21
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.5.1.22
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.5.1.23
Summary and Analysis (ANCOVA) of eGFR (MDRD) Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population

Study Day / Statistic	Placebo + Full Dose Prednisone (N=##) Visit	Change	% Change	CCX168 + Low Dose Prednisone (N=##) Visit	Change	% Change	CCX168 + No Prednisone (N=##) Visit	Change	% Change	All CCX168 (N=##) Visit	Change	% Change
Baseline												
N'	##											
Mean	##.##											
SD	##.###											
Minimum	##.#											
Median	##.##											
Maximum	##.#											
Day 2												
N'	##	##	##	##	##	##	##	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
SD	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###
Minimum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Median	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Maximum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
P-value*					#.####	#.####		#.####	#.####		#.####	#.####
95% CI for Change*					(-##.#, ##.#)			(-##.#, ##.#)			(-##.#, ##.#)	
95% CI for % Change*					(-##.#, ##.#)			(-##.#, ##.#)			(-##.#, ##.#)	

The additional visits to be summarized include:
Day 8, Day 15, Day 29, Day 43, Day 57, Day 71, Day 85, End of Treatment, Day 99, Day 113, Day 141, Day 169, and End of Follow-up Period.

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
- The End of Treatment value is the last measurement through Day 85.
- The End of Follow-up Period is the last measurement after Day 85 through Day 169.

*P-values and 95% confidence intervals for differences between specified treatment groups and placebo are from ANCOVA models with treatment group, AAV disease status (new or relapsed) and ANCA positivity (MPO or PR3)as factors and the baseline value as a covariate.

The following tables will have the same layout as Table 14.2.5.1.23:

Table 14.2.5.1.24
Summary and Analysis (ANCOVA) of eGFR (MDRD) Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.5.1.25
Summary and Analysis (ANCOVA) of eGFR (MDRD) Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.5.1.26
Summary and Analysis (ANCOVA) of eGFR (MDRD) Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.5.1.27
Summary and Analysis (ANCOVA) of eGFR (MDRD) Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.5.1.28
Summary and Analysis (ANCOVA) of eGFR (MDRD) Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.5.1.29
Summary and Analysis (ANCOVA) of eGFR (MDRD) Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.5.1.30
Summary and Analysis (ANCOVA) of eGFR (MDRD) Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.5.1.31
Summary and Analysis (ANCOVA) of eGFR (MDRD) Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.5.1.32
Summary and Analysis (ANCOVA) of eGFR (MDRD) Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.5.1.33
Summary and Analysis (ANCOVA) of eGFR (MDRD) Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.5.2.1.1
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

	Step 1 and 2 Combined						Step 3					
	Placebo + Full Dose Prednisone (N=##)		CCX168 + Low Dose Prednisone (N=##)		CCX168 + No Prednisone (N=##)		Placebo + Full Dose Prednisone (N=##)		CCX168 + Low Dose Prednisone (N=##)		CCX168 + No Prednisone (N=##)	
Study Day Statistic	Visit	% Change	Visit	% Change	Visit	% Change	Visit	% Change	Visit	% Change	Visit	% Change
Baseline												
N'	##											
Mean	##.#											
SD	##.##											
Minimum	##											
Median	##.#											
Maximum	##											
Day 2												
N'	##	##	##	##	##	##	##	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##	##	##	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##	##	##	##	##	##	##	##
P-value*				#.####		#.####				#.####		#.####
95% CI*				(-##.#, ##.#)		(-##.#, ##.#)				(-##.#, ##.#)		(-##.#, ##.#)

The additional visits to be summarized include:
Day 8, Day 15, Day 29, Day 43, Day 57, Day 71, Day 85

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
*P-values and 95% confidence intervals for differences between specified treatment groups and placebo are from MMRM models with treatment group, visit, and treatment-by-visit as factors and the baseline value as a covariate. The model for analysis of Step 3 included factors for AAV disease status (new or relapsed), ANCA positivity (MPO or PR3), and standard of care treatment (rituximab or cyclophosphamide). The model for Step 1 + Step 2 included a factor for disease status.

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The following tables will have layouts similar to Table 14.2.5.2.1.1:

Table 14.2.5.2.1.2
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.5.2.1.3
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.5.2.1.4
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.5.2.1.5
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.5.2.1.6
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.5.2.1.7
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.5.2.1.8
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.5.2.1.9
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.5.2.1.10
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.5.2.1.11
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.5.2.1.12
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

Table 14.2.5.2.1.13
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.5.2.1.14
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.5.2.1.15
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.5.2.1.16
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.5.2.1.17
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.5.2.1.18
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.5.2.1.19
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.5.2.1.20
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.5.2.1.21
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.5.2.1.22
Summary and Analysis (MMRM) of eGFR (MDRD) Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Microscopic Polyangiitis

Table 14.2.5.2.2.1
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

Table 14.2.5.2.2.2
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.5.2.2.3
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.5.2.2.4
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.5.2.2.5
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.5.2.2.6
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.5.2.2.7
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.5.2.2.8
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.5.2.2.9
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.5.2.2.10
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.5.2.2.11
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.5.2.2.12
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

Table 14.2.5.2.2.13
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.5.2.2.14
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.5.2.2.15
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.5.2.2.16
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.5.2.2.17
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.5.2.2.18
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.5.2.2.19
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.5.2.2.20
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.5.2.2.21
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.5.2.2.22
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Microscopic Polyangiitis

Table 14.2.5.3.1
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during 84-day Treatment Period
By Step
Intent-to-Treat Population

Step / Study / Statistic	Placebo + Full Dose Prednisone: Visit	Placebo + Full Dose Prednisone: Change	Placebo + Full Dose Prednisone: % Change	CCX168 + Low Dose Prednisone: Visit	CCX168 + Low Dose Prednisone: Change	CCX168 + Low Dose Prednisone: % Change	CCX168 + No Prednisone: Visit	CCX168 + No Prednisone: Change	CCX168 + No Prednisone: % Change	All CCX168: Visit	All CCX168: Change	All CCX168: % Change
Step 3		N=##			N=##			N=##			N=##	
Baseline												
N'	##											
Mean	##.##											
SD	##.###											
Minimum	##.#											
Median	##.##											
Maximum	##.#											
Day 2												
N'	##	##	##	##	##	##	##	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
SD	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###
Minimum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Median	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Maximum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
P-value*					#.####	#.####		#.####	#.####		#.####	#.####
95% CI for Change*					(-##.#, ##.#)			(-##.#, ##.#)			(-##.#, ##.#)	
95% CI for % Change*					(-##.#, ##.#)			(-##.#, ##.#)			(-##.#, ##.#)	

Repeat for Steps 2 and 1. Only display p-values and confidence intervals for Step 3.

The additional visits to be summarized include:
Day 8, Day 15, Day 29, Day 43, Day 57, Day 71, Day 85, End of Treatment, Day 99, Day 113, Day 141, Day 169, and End of Follow-up Period.

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
- The End of Treatment value is the last measurement through Day 85.
- The End of Follow-up Period is the last measurement after Day 85 through Day 169.

*P-values and 95% confidence intervals for differences between specified treatment groups and placebo are from a MMRM model with treatment group and randomization strata (AAV status, ANCA positivity, and standard of care treatment) as factors and the baseline value as a covariate.

The following tables will have a layout similar to Table 14.2.5.3.1:

Table 14.2.5.3.2
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.5.3.3
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.5.3.4
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.5.3.5
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.5.3.6
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.5.3.7
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.5.3.8
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.5.3.9
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.5.3.10
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.5.3.11
Summary and Analysis (MMRM) of eGFR (MDRD) Change and Percent Change from Baseline during 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.5.3.12
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population

Table 14.2.5.3.13
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.5.3.14
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.5.3.15
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.5.3.16
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.5.3.17
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.5.3.18
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.5.3.19
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.5.3.20
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.5.3.21
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.5.3.22
Summary and Analysis (MMRM) of eGFR (MDRD) Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Note to programmer: The MMRM tables for the 168-day study period will include summaries for each post-baseline visit. In addition, for Step 3 the p-value and 95% confidence interval for the overall differences between each group and placebo will be displayed.

Table 14.2.6.1
Incidence and Time to the First Occurrence of Urinary-RBC <=5 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population

Period Step	Treatment	N'	n	(%)	P-value	Days to First Occurrence of Urinary RBC <=5/HPF 25th percentile	Median	75th percentile	P-value [1]
84-day dosing period									
All	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)		##	##.#	##	
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
	All CCX168 (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
3	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)		##	##.#	##	
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
	All CCX168 (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
1+2	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)		##	##.#	##	
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
	All CCX168 (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
2	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)		##	##.#	##	
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
1	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)		##	##.#	##	
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
Repeat for 168-Day Study Period									

- N' = number of subjects with baseline urinary-RBC of greater than 5 RBC/hpf and at least one post-baseline urinary-RBC assessment during the specified period
- n = number of subjects with urinary-RBC of <=5 RBC/hpf during the specified period
[1] Estimates are Kaplan-Meier estimates and p-values are from the log-rank test to compare the specified treatment group to placebo.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

The following tables will have the same layout as Table 14.2.6.1:

Table 14.2.6.2
Incidence and Time to the First Occurrence of Urinary-RBC <=5 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.6.3
Incidence and Time to the First Occurrence of Urinary-RBC <=5 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.6.4
Incidence and Time to the First Occurrence of Urinary-RBC <=5 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.6.5
Incidence and Time to the First Occurrence of Urinary-RBC <=5 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.6.6
Incidence and Time to the First Occurrence of Urinary-RBC <=5 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.6.7
Incidence and Time to the First Occurrence of Urinary-RBC <=5 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.6.8
Incidence and Time to the First Occurrence of Urinary-RBC <=5 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.6.9
Incidence and Time to the First Occurrence of Urinary-RBC <=5 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population - All Patients with Microscopic Polyangiitis

Table 14.2.7.1
Incidence and Time to the First Occurrence of Urinary-RBC <30 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population

Period Step	Treatment	N'	n	(%)	P-value	Days to First Occurrence of Urinary RBC <30/HPF: 25th percentile	Median	75th percentile	P-value [1]
84-day dosing period									
All	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)		##	##.#	##	
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
	All CCX168 (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
3	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)		##	##.#	##	
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
	All CCX168 (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
1+2	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)		##	##.#	##	
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
	All CCX168 (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
2	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)		##	##.#	##	
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
1	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)		##	##.#	##	
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	#.####	##	##.#	##	#.####
Repeat for 168-day study period									

- N' = number of subjects with baseline urinary-RBC of >=30 RBC/hpf and at least one post-baseline urinary-RBC assessment during the specified period
- n = number of subjects with urinary-RBC of <30 RBC/hpf during the specified period
[1] Estimates are Kaplan-Meier estimates and p-values are from the log-rank test to compare the specified treatment group to placebo.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

The following tables will have the same layout as Table 14.2.7.1:

Table 14.2.7.2
Incidence and Time to the First Occurrence of Urinary-RBC <30 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.7.3
Incidence and Time to the First Occurrence of Urinary-RBC <30 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.7.4
Incidence and Time to the First Occurrence of Urinary-RBC <30 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.7.5
Incidence and Time to the First Occurrence of Urinary-RBC <30 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.7.6
Incidence and Time to the First Occurrence of Urinary-RBC <30 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.7.7
Incidence and Time to the First Occurrence of Urinary-RBC <30 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.7.8
Incidence and Time to the First Occurrence of Urinary-RBC <30 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.7.9
Incidence and Time to the First Occurrence of Urinary-RBC <30 RBCs/hpf in the Urine
Urinary-RBC Assessed by Central Laboratory
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.8.1.1
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline

Study Day / Statistic	Placebo + Full Dose Prednisone (N=##) Visit	Ratio	% Change	CCX168 + Low Dose Prednisone (N=##) Visit	Ratio	% Change	CCX168 + No Prednisone (N=##) Visit	Ratio	% Change	All CCX168 (N=##) Visit	Ratio	% Change
Baseline												
N'	##											
Mean	##.##											
Geo. Mean (GM)	##.##											
Minimum	##.#											
Median	##.##											
Maximum	##.#											
Day 2												
N'	##	##	##	##	##	##	##	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Geo. Mean (GM)	##.###	##.###		##.###	##.###		##.###	##.###		##.###	##.###	
Minimum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Median	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Maximum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
P-value^					#.####			#.####			#.####	
95% CI^ for Ratio					(-#.##, #.##)			(-#.##, #.##)			(-#.##, #.##)	

Additional visits to be summarized include:
Day 8, Day 15, Day 29, Day 43, Day 57, Day 71, Day 85, and Overall

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
- Ratio is defined for each subject as the visit value divided by the baseline value.

* Since urinary-RBC values are reported as ranges, quantitative values are defined as: 75 for result of '>75', 50 for '50-75', 30 for '30-49', 16 for '16-29', 10 for '10-15', 6 for '6-9', 3 for '3-5', 1 for '1-2', 0.5 for 'Occ', and 0.1 for 'None'.

^P-values and 95% confidence intervals for differences between specified treatment groups and placebo are from a MMRM model with treatment group, visit, treatment-by visit interaction, AAV disease status (new or relapsed), and ANCA positivity (MPO or PR3) as factors and the baseline value as a covariate. Logarithmic transformations were applied to the data before fitting the ANCOVA model. The 95% confidence interval was transformed back to the original scale.

The following tables will a layout similar Table 14.2.8.1.1:

Table 14.2.8.1.2
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline and Receiving Cyclophosphamide Background Treatment

Table 14.2.8.1.3
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline and Receiving Rituximab Background Treatment

Table 14.2.8.1.4
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline and Newly Diagnosed Disease

Table 14.2.8.1.5
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline and Relapsed Disease

Table 14.2.8.1.6
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline and MPO+ Disease

Table 14.2.8.1.7
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline and PR3+ Disease

Table 14.2.8.1.8
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline and Granulomatosis Polyangiitis (Wegener's)

Table 14.2.8.1.9
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline and Microscopic Polyangiitis

Table 14.2.8.1.10
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Hematuria at Baseline

Table 14.2.8.1.11
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Hematuria at Baseline and Receiving Cyclophosphamide Background Treatment

Table 14.2.8.1.12
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Hematuria at Baseline and Receiving Rituximab Background Treatment

Table 14.2.8.1.13
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Hematuria at Baseline and Newly Diagnosed Disease

Table 14.2.8.1.14
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Hematuria at Baseline and Relapsed Disease

Table 14.2.8.1.15
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Hematuria at Baseline and MPO+ Disease

Table 14.2.8.1.16
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Hematuria at Baseline and PR3+ Disease

Table 14.2.8.1.17
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Hematuria at Baseline and Polyangiitis (Wegener's)

Table 14.2.8.1.18
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Hematuria at Baseline and Microscopic Polyangiitis

Table 14.2.8.1.19
Summary and Analysis (ANCOVA) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline

Study Day / Statistic	Placebo + Full Dose Prednisone (N=##) Visit	Ratio	% Change	CCX168 + Low Dose Prednisone (N=##) Visit	Ratio	% Change	CCX168 + No Prednisone (N=##) Visit	Ratio	% Change	All CCX168 (N=##) Visit	Ratio	% Change
Baseline												
N'	##											
Mean	##.##											
Geo. Mean (GM)	##.##											
Minimum	##.#											
Median	##.##											
Maximum	##.#											
Day 2												
N'	##	##	##	##	##	##	##	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Geo. Mean (GM)	##.###	##.###		##.###	##.###		##.###	##.###		##.###	##.###	
Minimum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Median	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Maximum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
P-value^					#.####			#.####			#.####	
95% CI^ for Ratio					(-#.##, #.##)			(-#.##, #.##)			(-#.##, #.##)	

Additional visits to be summarized include:
Day 8, Day 15, Day 29, Day 43, Day 57, Day 71, Day 85, End of Treatment, Day 99, Day 113, Day 141, Day 169, and End of Follow-up Period.

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
- The End of Treatment value is the last measurement through Day 85.
- The End of Follow-up Period is the last measurement after Day 85 through Day 169.
- Ratio is defined for each subject as the visit value divided by the baseline value.

* Since urinary-RBC values are reported as ranges, quantitative values are defined as: 75 for result of '>75', 50 for '50-75', 30 for '30-49', 16 for '16-29', 10 for '10-15', 6 for '6-9', 3 for '3-5', 1 for '1-2', 0.5 for 'Occ', and 0.1 for 'None'.

^P-values and 95% confidence intervals for differences between specified treatment groups and placebo are from ANCOVA models with treatment group, AAV disease status (new or relapsed), and ANCA positivity (MPO or PR3)as factors and the baseline value as a covariate. Logarithmic transformations were applied to the data before fitting the ANCOVA model. The 95% confidence interval was transformed back to the original scale.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

The following tables will have the same layout as Table 14.2.8.1.19:

Table 14.2.8.1.20
Summary and Analysis (ANCOVA) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline and Receiving Cyclophosphamide Background Treatment

Table 14.2.8.1.21
Summary and Analysis (ANCOVA) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline and Receiving Rituximab Background Treatment

Table 14.2.8.1.22
Summary and Analysis (ANCOVA) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline and Newly Diagnosed Disease

Table 14.2.8.1.23
Summary and Analysis (ANCOVA) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline and Relapsed Disease

Table 14.2.8.1.24
Summary and Analysis (ANCOVA) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline and and MPO+ Disease

Table 14.2.8.1.25
Summary and Analysis (ANCOVA) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline and PR3+ Disease

Table 14.2.8.1.26
Summary and Analysis (ANCOVA) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline and Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.8.1.27
Summary and Analysis (ANCOVA) of Urinary RBC* Count: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Hematuria at Baseline and Microscopic Polyangiitis

Table 14.2.8.2.1
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline

	Step 1 and 2 Combined						Step 3					
	Placebo + Full Dose Prednisone (N=##)		CCX168 + Low Dose Prednisone (N=##)		CCX168 + No Prednisone (N=##)		Placebo + Full Dose Prednisone (N=##)		CCX168 + Low Dose Prednisone (N=##)		CCX168 + No Prednisone (N=##)	
Study Day Statistic	Visit	Ratio	Visit	Ratio	Visit	Ratio	Visit	Ratio	Visit	Ratio	Visit	Ratio
Baseline												
N'	##											
Mean	##.##											
Geo. Mean (GM)	##.##											
Minimum	##.#											
Median	##.##											
Maximum	##.#											
Day 2												
N'	##	##	##	##	##	##	##	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Geo. Mean (GM)	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##	##	##	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##	##	##	##	##	##	##	##
P-value^				#.####		#.####				#.####		#.####
95% CI^ for Ratio				(-#.##, #.##)		(-#.##, #.##)				(-#.##, #.##)		(-#.##, #.##)

The additional visits to be summarized include:
Day 8, Day 15, Day 29, Day 43, Day 57, Day 71, Day 85

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
* Since urinary-RBC values are reported as ranges, quantitative values are defined as: 75 for result of '>75', 50 for '50-75', 30 for '30-49', 16 for '16-29', 10 for '10-15', 6 for '6-9', 3 for '3-5', 1 for '1-2', 0.5 for 'Occ', and 0.1 for 'None'.
^P-values and 95% confidence intervals for differences between specified treatment groups and placebo are from MMRM models with treatment group, visit, and treatment-by-visit as factors and the baseline value as a covariate. The model for analysis of Step 3 included factors for AAV disease status (new or relapsed), ANCA positivity (MPO or PR3), and standard of care treatment (rituximab or cyclophosphamide. The model for Step 1 + Step 2 included a factor for disease status.as factors and the baseline value as a covariate. Logarithmic transformations were applied to the data before fitting the ANCOVA model. The 95% confidence interval was transformed back to the original scale.

The following tables will have a layout similar to Table 14.2.8.2.1:

Table 14.2.8.2.2
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline and Receiving Cyclophosphamide Background Treatment

Table 14.2.8.2.3
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline and Receiving Rituximab Background Treatment

Table 14.2.8.2.4
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline and Newly Diagnosed Disease

Table 14.2.8.2.5
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline and Relapsed Disease

Table 14.2.8.2.6
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline and MPO+ Disease

Table 14.2.8.2.7
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline and PR3+ Disease

Table 14.2.8.2.8
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline and Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.8.2.9
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline and Microscopic Polyangiitis

Table 14.2.8.2.10
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline

Table 14.2.8.2.11
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline and Receiving Cyclophosphamide Background Treatment

Table 14.2.8.2.12
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline and Receiving Rituximab Background Treatment

Table 14.2.8.2.13
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline and Newly Diagnosed Disease

Table 14.2.8.2.14
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline and Relapsed Disease

Table 14.2.8.2.15
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline and MPO+ Disease

Table 14.2.8.2.16
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline and PR3+ Disease

Table 14.2.8.2.17
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline and Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.8.2.18
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Hematuria at Baseline and Microscopic Polyangiitis

Table 14.2.8.3.1
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – Patients with Hematuria at Baseline

Step	Placebo +			CCX168 +			CCX168 +					
Study	-- Full Dose Prednisone --			-- Low Dose Prednisone --			----- No Prednisone -----			------- All CCX168 ------		
Statistic	Visit	Ratio	% Change	Visit	Ratio	% Change	Visit	Ratio	% Change	Visit	Ratio	% Change
Step 3		N=##			N=##			N=##			N=##	
Baseline												
N'	##											
Mean	##.##											
Geo. Mean (GM)	##.##											
Minimum	##.#											
Median	##.##											
Maximum	##.#											
Day 2												
N'	##	##	##	##	##	##	##	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Geo. Mean (GM)	##.###	##.###		##.###	##.###		##.###	##.###		##.###	##.###	
Minimum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Median	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Maximum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
P-value^					#.####			#.####			#.####	
95% CI^ for Ratio					(-#.##, #.##)			(-#.##, #.##)			(-#.##, #.##)	

Repeat for Steps 2 and 1. Only display p-values and confidence intervals for Step 3.

Additional visits include Day 2 8, 15, 29, 43, 57, 71, and 85.

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
- Ratio is defined for each subject as the visit value divided by the baseline value.

* Since urinary-RBC values are reported as ranges, quantitative values are defined as: 75 for result of '>75', 50 for '50-75', 30 for '30-49', 16 for '16-29', 10 for '10-15', 6 for '6-9', 3 for '3-5', 1 for '1-2', 0.5 for 'Occ', and 0.1 for 'None'.

^P-values and 95% confidence intervals for differences between specified treatment groups and placebo are from a MMRM models with treatment group and randomization strata (AAV status, ANCA positivity, and standard of care treatment) as factors and the baseline value as a covariate. Logarithmic transformations were applied to the data before fitting the ANCOVA model. The 95% confidence interval was transformed back to the original scale.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

The following tables will have layouts similar to Table 14.2.8.3.1:

Table 14.2.8.3.2
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – Patients with Hematuria at Baseline and Receiving Cyclophosphamide Background Treatment

Table 14.2.8.3.3
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – Patients with Hematuria at Baseline and Receiving Rituximab Background Treatment

Table 14.2.8.3.4
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population Patients with Hematuria at Baseline and Newly Diagnosed Disease

Table 14.2.8.3.5
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – Patients with Hematuria at Baseline and Relapsed Disease

Table 14.2.8.3.6
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – Patients with Hematuria at Baseline and MPO+ Disease

Table 14.2.8.3.7
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – Patients with Hematuria at Baseline and PR3+ Disease

Table 14.2.8.3.8
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – Patients with Hematuria at Baseline and Polyangiitis (Wegener's)

Table 14.2.8.3.9
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – Patients with Hematuria at Baseline and Microscopic Polyangiitis

Table 14.2.8.3.10
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population – Patients with Hematuria at Baseline

Table 14.2.8.3.11
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population – Patients with Hematuria at Baseline and Receiving Cyclophosphamide Background Treatment

Table 14.2.8.3.12
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population – Patients with Hematuria at Baseline and Receiving Rituximab Background Treatment

Table 14.2.8.3.13
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population Patients with Hematuria at Baseline and Newly Diagnosed Disease

Table 14.2.8.3.14
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population – Patients with Hematuria at Baseline and Relapsed Disease

Table 14.2.8.3.15
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population – Patients with Hematuria at Baseline and MPO+ Disease

Table 14.2.8.3.16
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population – Patients with Hematuria at Baseline and PR3+ Disease

Table 14.2.8.3.17
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population – Patients with Hematuria at Baseline and Polyangiitis (Wegener's)

Table 14.2.8.3.18
Summary and Analysis (MMRM) of Urinary RBC* Count: Ratio Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population – Patients with Hematuria at Baseline and Microscopic Polyangiitis

The following tables will have layouts similar to to Tables 14.2.8.x

Table 14.2.9.1.1
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline

Table 14.2.9.1.2
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Receiving Cyclophosphamide Background Treatment

Table 14.2.9.1.3
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Receiving Rituximab Background Treatment

Table 14.2.9.1.4
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Newly Diagnosed Disease

Table 14.2.9.1.5
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Relapsed Disease

Table 14.2.9.1.6
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline and MPO+ Disease

Table 14.2.9.1.7
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline and PR3+ Disease

Table 14.2.9.1.8
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Granulomatosis Polyangiitis (Wegener's)

Table 14.2.9.1.9
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Microscopic Polyangiitis

Table 14.2.9.1.10
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline

Table 14.2.9.1.11
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Receiving Cyclophosphamide Background Treatment

Table 14.2.9.1.12
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Receiving Rituximab Background Treatment

Table 14.2.9.1.13
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Newly Diagnosed Disease

Table 14.2.9.1.14
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Relapsed Disease

Table 14.2.9.1.15
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline and MPO+ Disease

Table 14.2.9.1.16
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline and PR3+ Disease

Table 14.2.9.1.17
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Polyangiitis (Wegener's)

Table 14.2.9.1.18
Summary and Analysis (MMRM) of ACR: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Microscopic Polyangiitis

Table 14.2.9.1.19
Summary and Analysis (ANCOVA) of ACR: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Albuminuria at Baseline

Table 14.2.9.1.20
Summary and Analysis (ANCOVA) of ACR: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Albuminuria at Baseline and Receiving Cyclophosphamide Background Treatment

Table 14.2.9.1.21
Summary and Analysis (ANCOVA) of ACR: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Albuminuria at Baseline and Receiving Rituximab Background Treatment

Table 14.2.9.1.22
Summary and Analysis (ANCOVA) of ACR: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Albuminuria at Baseline and Newly Diagnosed Disease

Table 14.2.9.1.23
Summary and Analysis (ANCOVA) of ACR: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Albuminuria at Baseline and Relapsed Disease

Table 14.2.9.1.24
Summary and Analysis (ANCOVA) of ACR: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Albuminuria at Baseline and MPO+ Disease

Table 14.2.9.1.25
Summary and Analysis (ANCOVA) of ACR: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Albuminuria at Baseline and PR3+ Disease

Table 14.2.9.1.26
Summary and Analysis (ANCOVA) of ACR: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Albuminuria at Baseline and with Granulomatosis Polyangiitis (Wegener's)

Table 14.2.9.1.27
Summary and Analysis (ANCOVA) of ACR: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – Patients with Albuminuria at Baseline and Microscopic Polyangiitis

Table 14.2.9.2.1
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Albuminuria at Baseline

Table 14.2.9.2.2
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Albuminuria at Baseline and Receiving Cyclophosphamide Background Treatment

Table 14.2.9.2.3
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Albuminuria at Baseline and Receiving Rituximab Background Treatment

Table 14.2.9.2.4
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Albuminuria at Baseline and Newly Diagnosed Disease

Table 14.2.9.2.5
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Albuminuria at Baseline and Relapsed Disease

Table 14.2.9.2.6
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Albuminuria at Baseline and MPO+ Disease

Table 14.2.9.2.7
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Albuminuria at Baseline and PR3+ Disease

Table 14.2.9.2.8
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Albuminuria at Baseline and Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.9.2.9
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – Patients with Albuminuria at Baseline and Microscopic Polyangiitis

Table 14.2.9.2.10
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - Patients with Albuminuria at Baseline

Table 14.2.9.2.11
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Receiving Cyclophosphamide Background Treatment

Table 14.2.9.2.12
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Receiving Rituximab Background Treatment

Table 14.2.9.2.13
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Newly Diagnosed Disease

Table 14.2.9.2.14
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Relapsed Disease

Table 14.2.9.2.15
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - Patients with Albuminuria at Baseline and MPO+ Disease

Table 14.2.9.2.16
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - Patients with Albuminuria at Baseline and PR3+ Disease

Table 14.2.9.2.17
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.9.2.18
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Microscopic Polyangiitis

Table 14.2.9.3.1
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – Patients with Albuminuria at Baseline

Table 14.2.9.3.2
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
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Table 14.2.9.3.3
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
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Intent-to-Treat Population – Patients with Albuminuria at Baseline and Receiving Rituximab Background Treatment

Table 14.2.9.3.4
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population Patients with Albuminuria at Baseline and Newly Diagnosed Disease

Table 14.2.9.3.5
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – Patients with Albuminuria at Baseline and Relapsed Disease

Table 14.2.9.3.6
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – Patients with Albuminuria at Baseline and MPO+ Disease

Table 14.2.9.3.7
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – Patients with Albuminuria at Baseline and PR3+ Disease

Table 14.2.9.3.8
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
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Table 14.2.9.3.9
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – Patients with Albuminuria at Baseline and Microscopic Polyangiitis

Table 14.2.9.3.10
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - Patients with Albuminuria at Baseline

Table 14.2.9.3.11
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Receiving Cyclophosphamide Background Treatment

Table 14.2.9.3.12
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Receiving Rituximab Background Treatment

Table 14.2.9.3.13
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
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Table 14.2.9.3.14
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
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Intent-to-Treat Population - Patients with Albuminuria at Baseline and Relapsed Disease

Table 14.2.9.3.15
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
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Intent-to-Treat Population - Patients with Albuminuria at Baseline and MPO+ Disease

Table 14.2.9.3.16
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - Patients with Albuminuria at Baseline and PR3+ Disease

Table 14.2.9.3.17
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Polyangiitis (Wegener's)

Table 14.2.9.3.18
Summary and Analysis (MMRM) of ACR: Ratio Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - Patients with Albuminuria at Baseline and Microscopic Polyangiitis

The following tables will have layouts similar to to Tables 14.2.8.x

Table 14.2.10.1.1
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population

Table 14.2.10.1.2
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
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Table 14.2.10.1.3
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
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Table 14.2.10.1.4
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
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Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.10.1.5
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
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Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.10.1.6
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
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Table 14.2.10.1.7
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
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Table 14.2.10.1.8
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
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Table 14.2.10.1.9
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
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Table 14.2.10.1.10
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
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Table 14.2.10.1.11
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
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Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.10.1.12
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
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Table 14.2.10.1.13
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
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Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.10.1.14
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
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Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.10.1.15
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
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Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.10.1.16
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.10.1.17
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
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Table 14.2.10.1.18
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.10.1.19
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.10.1.20
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.10.1.21
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Granulomatosis Polyangiitis (Wegener's)

Table 14.2.10.1.22
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.10.1.23
Summary and Analysis (ANCOVA) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population

Table 14.2.10.1.24
Summary and Analysis (ANCOVA) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.10.1.25
Summary and Analysis (ANCOVA) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.10.1.26
Summary and Analysis (ANCOVA) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline
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Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.10.1.27
Summary and Analysis (ANCOVA) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline
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Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.10.1.28
Summary and Analysis (ANCOVA) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.10.1.29
Summary and Analysis (ANCOVA) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
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Table 14.2.10.1.30
Summary and Analysis (ANCOVA) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
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Table 14.2.10.1.31
Summary and Analysis (ANCOVA) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.10.1.32
Summary and Analysis (ANCOVA) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Granulomatosis Polyangiitis (Wegener's)

Table 14.2.10.1.33
Summary and Analysis (ANCOVA) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.10.2.1
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

Table 14.2.10.2.2
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.10.2.3
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.10.2.4
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.10.2.5
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.10.2.6
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
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Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.10.2.7
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
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Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.10.2.8
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
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Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.10.2.9
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.10.2.10
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Granulomatosis Polyangiitis (Wegener's)

Table 14.2.10.2.11
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.10.2.12
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

Table 14.2.10.2.13
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.10.2.14
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.10.2.15
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.10.2.16
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.10.2.17
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
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Table 14.2.10.2.18
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
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Table 14.2.10.2.19
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
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Table 14.2.10.2.20
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
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Table 14.2.10.2.21
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Granulomatosis Polyangiitis (Wegener's)

Table 14.2.10.2.22
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.10.3.1
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population

Table 14.2.10.3.2
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.10.3.3
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.10.3.4
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.10.3.5
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.10.3.6
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.10.3.7
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.10.3.8
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.10.3.9
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.10.3.10
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Granulomatosis Polyangiitis (Wegener's)

Table 14.2.10.3.11
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.10.3.12
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population

Table 14.2.10.3.13
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.10.3.14
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.10.3.15
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.10.3.16
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.10.3.17
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.10.3.18
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.10.3.19
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.10.3.20
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.10.3.21
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population – All Patients with Granulomatosis Polyangiitis (Wegener's)

Table 14.2.10.3.22
Summary and Analysis (MMRM) of Urinary MCP-1:Creatinine Ratio: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.11
Listing of Rescue IV or Oral Glucocorticoid Treatment
Intent-to-Treat Population

Step Treatment Subject	Date of First Dose of Study Med.	RT: Reported Term ATC: Anatomic Therapeutic Class PT: Preferred Term	Start Date (Day)/ End Date (Day)	Duration (Days)	Dose/Unit	Route
Step 1 XXXXXXXXXXXXXXXXXXXXXXXXXXXX						
###-###	DDMMMYYYY	RT:XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX ATC:XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX PT:XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY (###)/ DDMMMYYYY (###)	##	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX

The following tables will have similar layouts to Tables 14.2.5.x:

Table 14.2.12.1.1
Summary and Analysis (MMRM) of VDI Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population

Table 14.2.12.1.2
Summary and Analysis (MMRM) of VDI Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.12.1.3
Summary and Analysis (MMRM) of VDI Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.12.1.4
Summary and Analysis (MMRM) of VDI Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.12.1.5
Summary and Analysis (MMRM) of VDI Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.12.1.6
Summary and Analysis (MMRM) of VDI Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.12.1.7
Summary and Analysis (MMRM) of VDI Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.12.1.8
Summary and Analysis (MMRM) of VDI Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.12.1.9
Summary and Analysis (MMRM) of VDI Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.12.1.10
Summary and Analysis (MMRM) of VDI Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.12.1.11
Summary and Analysis (MMRM) of VDI Change and Percent Change from Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.12.2.1.12
Summary and Analysis (MMRM) of VDI Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

Table 14.2.12.2.1.13
Summary and Analysis (MMRM) of VDI Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.12.2.1.14
Summary and Analysis (MMRM) of VDI Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.12.2.1.15
Summary and Analysis (MMRM) of VDI Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.12.2.1.16
Summary and Analysis (MMRM) of VDI Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.12.2.1.17
Summary and Analysis (MMRM) of VDI Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.12.2.1.18
Summary and Analysis (MMRM) of VDI Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.12.2.1.19
Summary and Analysis (MMRM) of VDI Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.12.2.1.20
Summary and Analysis (MMRM) of VDI Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.12.2.1.21
Summary and Analysis (MMRM) of VDI Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.12.2.1.22
Summary and Analysis (MMRM) of VDI Percent Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.12.1.23
Summary and Analysis (ANCOVA) of VDI Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population

Table 14.2.12.1.24
Summary and Analysis (ANCOVA) of VDI Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.12.1.25
Summary and Analysis (ANCOVA) of VDI Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.12.1.26
Summary and Analysis (ANCOVA) of VDI Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.12.1.27
Summary and Analysis (ANCOVA) of VDI Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.12.1.28
Summary and Analysis (ANCOVA) of VDI Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.12.1.29
Summary and Analysis (ANCOVA) of VDI Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.12.1.30
Summary and Analysis (ANCOVA) of VDI Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.12.1.31
Summary and Analysis (ANCOVA) of VDI Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.12.1.32
Summary and Analysis (ANCOVA) of VDI Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.12.1.33
Summary and Analysis (ANCOVA) of VDI Change and Percent Change from Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.12.2.2.1
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

Table 14.2.12.2.2.3
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.12.2.2.4
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.12.2.2.4
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.12.2.2.5
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.12.2.2.6
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.12.2.2.7
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.12.2.2.8
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.12.2.2.9
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.12.2.2.10
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.12.2.2.11
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.12.3.1
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population

Table 14.2.12.3.2
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.12.3.3
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.12.3.4
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.12.3.5
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.12.3.6
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.12.3.7
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.12.3.8
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.12.3.9
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.12.3.10
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.12.3.11
Summary and Analysis (MMRM) of VDI Change from Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.13.1
Summary of SF-36 v2.0: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population

Domain / Study Day / Statistic	Placebo + Full Dose Prednisone (N=##)			CCX168 + Low Dose Prednisone (N=##)			CCX168 + No Prednisone (N=##)			All CCX168 (N=##)		
	Visit	Change	% Change	Visit	Change	% Change	Visit	Change	% Change	Visit	Change	% Change
Physical Functioning												
Baseline												
N'	##											
Mean	##.##											
SD	##.###											
Minimum	##.#											
Median	##.##											
Maximum	##.#											
Day 29												
N'	##	##	##	##	##	##	##	##	##	##	##	##
Mean	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
SD	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###	##.###
Minimum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Median	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Maximum	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
P-value*					#.####	#.####		#.####	#.####		#.####	#.####
95% CI for Change*					(-##.#, ##.#)			(-##.#, ##.#)			(-##.#, ##.#)	
95% CI for %Change*					(-##.#, ##.#)			(-##.#, ##.#)			(-##.#, ##.#)	

The domains to be summarized include:
Role-Physical, Role-Emotional, Social Functioning, Bodily Pain, Mental Health, Vitality, General Health Perceptions, Change in Health, Physical Component Summary, Mental Health Summary.

The additional visits to be summarized include:
Day 29, Day 85, End of Treatment, Day 169, and End of Follow-up Period.

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
- The End of Treatment value is the last measurement through Day 85.
- The End of Follow-up Period is the last measurement after Day 85 through Day 169.

*P-values and 95% confidence intervals for differences between specified treatment groups and placebo are from a MMRM model with treatment group as a factor and randomization strata (AAV status, ANCA positivity, and standard of care treatment) as covariates.

NOTE: The SF-36 was only collected for patients participating in Step 3.

The following table will have similar layouts to Tables 14.2.13.1:

Table 14.2.13.2
Summary of SF-36 v2.0: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.13.3
Summary of SF-36 v2.0: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.13.4
Summary of SF-36 v2.0: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.13.5
Summary of SF-36 v2.0: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.13.6
Summary of SF-36 v2.0: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.13.7
Summary of SF-36 v2.0: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.13.8
Summary of SF-36 v2.0: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.13.9
Summary of SF-36 v2.0: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.13.10
Summary of SF-36 v2.0: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.13.11
Summary of SF-36 v2.0: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population - All Patients with Microscopic Polyangiitis

The following table will have similar layouts to Tables 14.2.13.1:

Table 14.2.14.1
Summary of EQ-5D-5L Health Scale Score and VAS: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population

Table 14.2.14.2
Summary of EQ-5D-5L Health Scale Score and VAS: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.14.3
Summary of EQ-5D-5L Health Scale Score and VAS: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.14.4
Summary of EQ-5D-5L Health Scale Score and VAS: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.14.5
Summary of EQ-5D-5L Health Scale Score and VAS: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.14.6
Summary of EQ-5D-5L Health Scale Score and VAS: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.14.7
Summary of EQ-5D-5L Health Scale Score and VAS: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.14.8
Summary of EQ-5D-5L Health Scale Score and VAS: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.14.9
Summary of EQ-5D-5L Health Scale Score and VAS: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.14.10
Summary of EQ-5D-5L Health Scale Score and VAS: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.14.11
Summary of EQ-5D-5L Health Scale Score and VAS: Actual, Change and Percent Change from Baseline by Visit
Step 3
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.15
Summary of Dose and Duration of Study Supplied Prednisone
By Step
Intent-to-Treat Population

Step Period Variable	CCX168 + Full Dose Prednisone	CCX168 + Low Dose Prednisone	CCX168 + No Prednisone	All CCX168
All Steps	N=##	N=##	N=##	N=##
84-day dosing period, N' (%)				
Total study-supplied prednisone/placebo dose (mg)				
N'				
Mean				
SD				
Minimum				
Median				
Maximum				
Total duration of study-supplied prednisone/placebo use (days)				
N'				
Mean				
SD				
Minimum				
Median				
Maximum				
Repeat for 168-day study period				

- N' = number of subjects who took study supplied prednisone during the designated study period.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY

NOTE: Repeat for Step 3, Steps 1 and 2 Combined, Step 2, and Step 1.

Table 14.2.16
Summary of Dose and Duration of Total Systemic Corticosteroid Treatment*
By Step
Intent-to-Treat Population

Step Period Variable	CCX168 + Full Dose Prednisone	CCX168 + Low Dose Prednisone	CCX168 + No Prednisone	All CCX168
All Steps	N=##	N=##	N=##	N=##
84-day dosing period, N' (%)				
Total systemic corticosteroid dose (mg)				
N'				
Mean				
SD				
Minimum				
Median				
Maximum				
Total duration of systemic corticosteroid use (days)				
N'				
Mean				
SD				
Minimum				
Median				
Maximum				
Repeat for 168-day study period				

- N' = number of subjects who took corticosteroid during the designated study period.
*Total systemic (IV and oral) corticosteroid treatment includes (1) study-supplied prednisone use, (2) new corticosteroid use, and (3) maintenance corticosteroid use over the course of the trial.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY

NOTE: Repeat for Step 3, Steps 1 and 2 Combined, Step 2, and Step 1.

Table 14.2.17.1
Summary of Total Cumulative Cyclophosphamide Dose
By Step
Intent-to-Treat Population

Step Period Variable	CCX168 + Full Dose Prednisone	CCX168 + Low Dose Prednisone	CCX168 + No Prednisone	All CCX168
All Steps	N=##	N=##	N=##	N=##
84-day dosing period, n (%)				
Total cumulative dose (mg)				
N'				
Mean				
SD				
Minimum				
Median				
Maximum				
Total duration of dosing (days)				
N'				
Mean				
SD				
Minimum				
Median				
Maximum				
Repeat for 168-day study period				

- N' = number of subjects who took at least one dose of cyclophosphamide during the designated study period.
- Cyclophosphamide dose was calculated as recorded amount(mg/kg)*weight at that visit. If weight was missing, the last weight for that subject would be used.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY

NOTE: Repeat for Step 3, Steps 1 and 2 Combined, Step 2, and Step 1.

Table 14.2.17.2
Summary of Total Cumulative Rituximab Dose
Step 3
Intent-to-Treat Population

Step Period Variable	CCX168 + Full Dose Prednisone	CCX168 + Low Dose Prednisone	CCX168 + No Prednisone	All CCX168
All Steps	N=##	N=##	N=##	N=##
84-day dosing period, n (%)				
Total cumulative dose (mg)				
N'				
Mean				
SD				
Minimum				
Median				
Maximum				
Total duration of dosing (days)				
N'				
Mean				
SD				
Minimum				
Median				
Maximum				
Repeat for 168-day study period				

- N' = number of subjects who took at least one dose of cyclophosphamide during the designated study period.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY

The following tables will have similar layouts to Tables 14.2.8.x:

(For these tables, the last footnote will be '- Results of '< 0.2' were imputed to have a value of 0.2 for analysis.')

Table 14.2.18.1.1
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population

Table 14.2.18.1.2
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.18.1.3
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.18.1.4
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.18.1.5
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.18.1.6
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.18.1.7
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.18.1.8
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.18.1.9
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.18.1.10
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.18.1.11
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.18.1.12
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population

Table 14.2.18.1.13
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.18.1.14
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.18.1.15
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.18.1.16
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.18.1.17
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.18.1.18
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.18.1.19
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.18.1.20
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.18.1.21
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.18.1.22
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.18.1.23
Summary and Analysis (ANCOVA) of Serum hsCRP: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population

Table 14.2.18.1.24
Summary and Analysis (ANCOVA) of Serum hsCRP: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.18.1.25
Summary and Analysis (ANCOVA) of Serum hsCRP: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.18.1.26
Summary and Analysis (ANCOVA) of Serum hsCRP: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.18.1.27
Summary and Analysis (ANCOVA) of Serum hsCRP: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.18.1.28
Summary and Analysis (ANCOVA) of Serum hsCRP: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.18.1.29
Summary and Analysis (ANCOVA) of Serum hsCRP: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.18.1.30
Summary and Analysis (ANCOVA) of Serum hsCRP: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.18.1.31
Summary and Analysis (ANCOVA) of Serum hsCRP: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.18.1.32
Summary and Analysis (ANCOVA) of Serum hsCRP: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.18.1.33
Summary and Analysis (ANCOVA) of Serum hsCRP: Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Microscopic Polyangiitis

Table 14.2.18.2.1
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

Table 14.2.18.2.2
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.18.2.3
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.18.2.4
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.18.2.5
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.18.2.6
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.18.2.7
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.18.2.8
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.18.2.9
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.18.2.10
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.18.2.11
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.18.2.12
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

Table 14.2.18.2.13
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.18.2.14
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.18.2.15
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.18.2.16
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.18.2.17
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.18.2.18
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.18.2.19
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.18.2.20
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.18.2.21
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.18.2.22
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Microscopic Polyangiitis

Table 14.2.18.3.1
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population

Table 14.2.18.3.2
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.18.3.3
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.18.3.4
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.18.3.5
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.18.3.6
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.18.3.7
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.18.3.8
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.18.3.9
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.18.3.10
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.18.3.11
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.18.3.12
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population

Table 14.2.18.3.13
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.18.3.14
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.18.3.15
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.18.3.16
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.18.3.17
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.18.3.18
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.18.3.19
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.18.3.20
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.18.3.21
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.18.3.22
Summary and Analysis (MMRM) of Serum hsCRP: Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Microscopic Polyangiitis

The following tables will have similar layouts to Tables 14.2.8.x:

Table 14.2.19.1.1
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population

Table 14.2.19.1.2
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.19.1.3
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.19.1.4
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.19.1.5
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.19.1.6
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.19.1.7
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.19.1.8
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.19.1.9
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.19.1.10
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.19.1.11
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Microscopic Polyangiitis

Table 14.2.19.1.12
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population

Table 14.2.19.1.13
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.19.1.14
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.19.1.15
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.19.1.16
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.19.1.17
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.19.1.18
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.19.1.19
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.19.1.20
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.19.1.21
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.19.1.22
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Microscopic Polyangiitis

Table 14.2.19.1.23
Summary and Analysis (ANCOVA) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population

Table 14.2.19.1.24
Summary and Analysis (ANCOVA) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.19.1.25
Summary and Analysis (ANCOVA) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.19.1.26
Summary and Analysis (ANCOVA) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.19.1.27
Summary and Analysis (ANCOVA) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.19.1.28
Summary and Analysis (ANCOVA) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.19.1.29
Summary and Analysis (ANCOVA) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.19.1.30
Summary and Analysis (ANCOVA) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.19.1.31
Summary and Analysis (ANCOVA) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.19.1.32
Summary and Analysis (ANCOVA) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.19.1.33
Summary and Analysis (ANCOVA) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline
Steps 1 through 3 Combined
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.19.2.1
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

Table 14.2.19.2.2
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.19.2.3
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.19.2.4
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.19.2.5
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.19.2.6
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.19.2.7
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.19.2.8
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with MPO+ Disease

Table 14.2.19.2.9
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with PR3+ Disease

Table 14.2.19.2.10
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.19.2.11
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.2.19.2.12
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population

Table 14.2.19.2.13
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.19.2.14
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.19.2.15
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.19.2.16
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.19.2.17
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.19.2.18
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.19.2.19
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.19.2.20
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.19.2.21
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.19.2.22
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
Steps 1 and 2 Combined and Step 3
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.19.3.1
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population

Table 14.2.19.3.2
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.19.3.3
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.19.3.4
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.19.3.5
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.19.3.6
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.19.3.7
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.19.3.8
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.19.3.9
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.19.3.10
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.19.3.11
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 84-day Treatment Period
By Step
Intent-to-Treat Population - All Patients with Microscopic Polyangiitis

Table 14.2.19.3.12
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population

Table 14.2.19.3.13
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Renal Disease at Baseline

Table 14.2.19.3.14
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Non-Renal Disease at Baseline

Table 14.2.19.3.15
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.19.3.16
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients Receiving Rituximab Background Treatment

Table 14.2.19.3.17
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Newly Diagnosed Disease

Table 14.2.19.3.18
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Relapsed Disease

Table 14.2.19.3.19
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with MPO+ Disease

Table 14.2.19.3.20
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with PR3+ Disease

Table 14.2.19.3.21
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.19.3.22
Summary and Analysis (MMRM) of ANCA (anti-PR3 and anti-MPO): Ratio and Percent Change Compared to Baseline during the 168-day Study Period
By Step
Intent-to-Treat Population - All Patients with Microscopic Polyangiitis

Table 14.2.20.1
Analysis of Subjects who Became ANCA Negative
Intent-to-Treat Population

Parameter / Day / Step	Treatment	N'	n	(%)	Difference in percentages versus Placebo
PR3 (cANCA) antibody by ELISA					
Day 85					
All	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)	
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	###.#
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	###.#
	All CCX168 (N=##)	###	###	(###.#)	###.#
3	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)	
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	###.#
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	###.#
	All CCX168 (N=##)	###	###	(###.#)	###.#
1+2	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)	
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	###.#
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	###.#
	All CCX168 (N=##)	###	###	(###.#)	###.#
2	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)	
	CCX168 + No Prednisone (N=##)	###	###	(###.#)	###.#
1	Placebo + Full Dose Prednisone (N=##)	###	###	(###.#)	
	CCX168 + Low Dose Prednisone (N=##)	###	###	(###.#)	###.#
Repeat for Day 169					
Repeat for parameter: MPO (pANCA) antibody by ELISA (IU/mL)					

- N'=number of subjects who were PR3 positive (for PR3 analysis) and MPO positive (for MPO analysis) at baseline with post-baseline ANCA data during the specified dosing period.

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The following tables will have the ame layout as Table 14.2.20.1:

Table 14.2.20.2
Analysis of Subjects who Became ANCA Negative
Intent-to-Treat Population – All Patients with Renal Disease at Baseline

Table 14.2.20.3
Analysis of Subjects who Became ANCA Negative
Intent-to-Treat Population – All Patients with Non-Renal Disease at Baseline

Table 14.2.20.4
Analysis of Subjects who Became ANCA Negative
Intent-to-Treat Population – All Patients Receiving Cyclophosphamide Background Treatment

Table 14.2.20.5
Analysis of Subjects who Became ANCA Negative
Intent-to-Treat Population – All Patients Receiving Rituximab Background Treatment

Table 14.2.20.6
Analysis of Subjects who Became ANCA Negative
Intent-to-Treat Population – All Patients with Newly Diagnosed Disease

Table 14.2.20.7
Analysis of Subjects who Became ANCA Negative
Intent-to-Treat Population – All Patients with Relapsed Disease

Table 14.2.20.8
Analysis of Subjects who Became ANCA Negative
Intent-to-Treat Population – All Patients with Granulomatosis with Polyangiitis (Wegener's)

Table 14.2.20.9
Analysis of Subjects who Became ANCA Negative
Intent-to-Treat Population – All Patients with Microscopic Polyangiitis

Table 14.3.1.1
Overview of Treatment-emergent Adverse Events during the 84-day Treatment Period
Safety Population

Step Category	Placebo + Full Dose Prednisone n (%)	CCX168 + Low Dose Prednisone n (%)	CCX168 + No Prednisone n (%)	All CCX168 n (%)
Overall	N=##	N=##	N=##	N=##
Treatment-emergent adverse event (TEAE)	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Possibly Study Medication Related TEAE				
Possibly Corticosteroid Use Related TEAE				
Possibly Cyclophosphamide Related TEAE				
Possibly Azathioprine Related TEAE				
Possibly Rituximab Related TEAE				
Maximum severity of TEAE				
Mild				
Moderate				
Severe				
Life-threatening				
Death				
Serious TEAE				
Possibly-Study Medication Related Serious TEAE				
Possibly-Corticosteroid Use Related Serious TEAE				
Possibly-Cyclophosphamide Related Serious TEAE				
Possibly Azathioprine Related Serious TEAE				
Possibly Rituximab Related Serious TEAE				
Discontinued study medication due to TEAE				
Due to Possibly-Study Medication Related Serious TEAE				
Due to Possibly-Corticosteroid Use Related TEAE				
Due to Possibly-Corticosteroid Use Related Serious TEAE				
Due to Possibly-Cyclophosphamide Related TEAE				
Due to Possibly-Cyclophosphamide Related Serious TEAE				
Due to Possibly-Rituximab Related TEAE				
Due to Possibly- Rituximab Related Serious TEAE				

- An adverse event is considered treatment-emergent if the start date of the event is on or after administration of the first dose of study medication.

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NOTE: Repeat for Step 3, 2, and 1.

The following tables will have the same layout as Table 14.3.1.1:

Table 14.3.1.2
Overview of Treatment-emergent Adverse Events during the 168-day Study Period
Safety Population

Table 14.3.1.3
Summary of Treatment-emergent Adverse Events During the 84-Day Treatment Period
by System Organ Class and Preferred Term
Safety Population

Step System Organ Class Preferred Term	Placebo + Full Dose Prednisone n (%)	CCX168 + Low Dose Prednisone n (%)	CCX168 + No Prednisone n (%)	All CCX168 n (%)
Overall	N=##	N=##	N=##	N=##
Any Treatment-emergent Adverse Event	## (###.#)	## (###.#)	## (###.#)	## (###.#)
System Organ Class 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Preferred Term 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)

- An adverse event is considered treatment-emergent if the start date of the event is on or after administration of the first dose of study medication.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

NOTE: Table will be sorted by Step of the study, descending frequency in the total column for system organ class and preferred term within system organ class.

NOTE: Repeat for Step 3, 2, and 1.

The following tables will have the same layout as Table 14.3.1.3:

Table 14.3.1.4
Summary of Treatment-emergent Adverse Events during the 168-day Study Period
by System Organ Class and Preferred Term
Safety Population

Table 14.3.1.5
Summary of Treatment-emergent Adverse Events during the 168-day Treament Period
by System Organ Class, Preferred Term and Relationship to Study Drug
Safety Population

Step System Organ Class Preferred Term Relationship to Study Drug	Placebo + Full Dose Prednisone n (%)	CCX168 + Low Dose Prednisone n (%)	CCX168 + No Prednisone n (%)	All CCX168 n (%)
Overall	N=##	N=##	N=##	N=##
Any Treatment-emergent Adverse Event	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Possibly related to study drug	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Probably not related to study drug	## (###.#)	## (###.#)	## (###.#)	## (###.#)
System Organ Class 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Possibly related to study drug	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Probably not related to study drug	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Preferred Term 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Possibly related to study drug	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Probably not related to study drug	## (###.#)	## (###.#)	## (###.#)	## (###.#)

- An adverse event is considered treatment-emergent if the start date of the event is on or after administration of the first dose of study medication.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

NOTE: Table will be sorted by step of the study, descending frequency in the total column for system organ class and preferred term within system organ class.

NOTE: Repeat for Step 3, 2, and 1.

Table 14.3.1.6
Summary of Treatment-emergent Adverse Events during the 84-day Treatment Period
by System Organ Class, Preferred Term and Relationship to Corticosteroid Use
Safety Population

Step System Organ Class Preferred Term Relationship to Corticosteroid Use	Placebo + Full Dose Prednisone n (%)	CCX168 + Low Dose Prednisone n (%)	CCX168 + No Prednisone n (%)	All CCX168 n (%)
Overall	N=##	N=##	N=##	N=##
Any Treatment-emergent Adverse Event	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Possibly related to corticosteroid use	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Probably not related to corticosteroid use	## (###.#)	## (###.#)	## (###.#)	## (###.#)
System Organ Class 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Possibly related to corticosteroid use	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Probably not related to corticosteroid use	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Preferred Term 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Possibly related to corticosteroid use	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Probably not related to corticosteroid use	## (###.#)	## (###.#)	## (###.#)	## (###.#)

- An adverse event is considered treatment-emergent if the start date of the event is on or after administration of the first dose of study medication.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

NOTE: Table will be sorted by step of the study, descending frequency in the total column for system organ class and preferred term within system organ class.

NOTE: Repeat for Step 3, 2, and 1.

The following table will have the same layout as Table 14.3.1.6:

Table 14.3.1.7
Summary of Treatment-emergent Adverse Events during the 168-day Study Period
by System Organ Class, Preferred Term and Relationship to Corticosteroid Use
Safety Population

Table 14.3.1.8
Summary of Treatment-emergent Adverse Events during the 84-day Treatment Period
by System Organ Class, Preferred Term and Relationship to Cyclophosphamide Use
Safety Population

Step System Organ Class Preferred Term Relationship to Cyclophosphamide Use	Placebo + Full Dose Prednisone n (%)	CCX168 + Low Dose Prednisone n (%)	CCX168 + No Prednisone n (%)	All CCX168 n (%)
Overall	N=##	N=##	N=##	N=##
Any Treatment-emergent Adverse Event	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Possibly related to cyclophosphamide use	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Probably not related to cyclophosphamide use	## (###.#)	## (###.#)	## (###.#)	## (###.#)
System Organ Class 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Possibly related to cyclophosphamide use	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Probably not related to cyclophosphamide use	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Preferred Term 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Possibly related to cyclophosphamide use	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Probably not related to cyclophosphamide use	## (###.#)	## (###.#)	## (###.#)	## (###.#)

- An adverse event is considered treatment-emergent if the start date of the event is on or after administration of the first dose of study medication.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

NOTE: Table will be sorted by step of the study, descending frequency in the total column for system organ class and preferred term within system organ class.

NOTE: Repeat for Step 3, 2, and 1.

The following table will have the same layout as Table 14.3.1.8:

Table 14.3.1.9
Summary of Treatment-emergent Adverse Events during the 168-day Study Period
by System Organ Class, Preferred Term and Relationship to Cyclophosphamide Use
Safety Population

Table 14.3.1.10
Summary of Treatment-emergent Adverse Events during the 84-day Treatment Period
by System Organ Class, Preferred Term and Relationship to Rituximab Use
Safety Population

Step System Organ Class Preferred Term Relationship to Rituximab Use	Placebo + Full Dose Prednisone n (%)	CCX168 + Low Dose Prednisone n (%)	CCX168 + No Prednisone n (%)	All CCX168 n (%)
Step 3	N=##	N=##	N=##	N=##
Any Treatment-emergent Adverse Event	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Possibly related to rituximab use	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Probably not related to rituximab use	## (###.#)	## (###.#)	## (###.#)	## (###.#)
System Organ Class 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Possibly related to rituximab use	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Probably not related to rituximab use	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Preferred Term 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Possibly related to rituximab use	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Probably not related to rituximab use	## (###.#)	## (###.#)	## (###.#)	## (###.#)

- An adverse event is considered treatment-emergent if the start date of the event is on or after administration of the first dose of study medication.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

NOTE: Table will be sorted by step of the study, descending frequency in the total column for system organ class and preferred term within system organ class. Also note that rituximab was only allowed in Step 3.

The following table will have the same layout as Table 14.3.1.10:

Table 14.3.1.11
Summary of Treatment-emergent Adverse Events during the 168-day Study Period
by System Organ Class, Preferred Term and Relationship to Rituximab Use
Safety Population

Table 14.3.1.12
Summary of Treatment-emergent Adverse Events during the 84-day Treatment Period
by System Organ Class, Preferred Term and Maximum Severity
Safety Population

Step System Organ Class Preferred Term Maximum Severity	Placebo + Full Dose Prednisone n (%)	CCX168 + Low Dose Prednisone n (%)	CCX168 + No Prednisone n (%)	All CCX168 n (%)
Overall	N=##	N=##	N=##	
Any Treatment-emergent Adverse Event	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Mild	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Moderate	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Severe	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Life-threatening	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Death	## (###.#)	## (###.#)	## (###.#)	## (###.#)
System Organ Class 1	## (###.#)	## (###.#)	## (###.#)	
Mild	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Moderate	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Severe	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Life-threatening	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Death	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Preferred Term 1	## (###.#)	## (###.#)	## (###.#)	
Mild	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Moderate	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Severe	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Life-threatening	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Death	## (###.#)	## (###.#)	## (###.#)	## (###.#)

- An adverse event is considered treatment-emergent if the start date of the event is on or after administration of the first dose of study medication.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

NOTE: Table will be sorted by Step of the study, descending frequency in the total column for system organ class and preferred term within system organ class.

NOTE: Repeat for Step 3, 2, and 1.

NOTE: If there are no events in a category, e.g. Death, the row will not appear in the summary table.

The following table will have the same layout as Table 14.3.1.12:

Table 14.3.1.13
Summary of Treatment-emergent Adverse Events during the 168-day Study Period
by System Organ Class, Preferred Term and Maximum Severity
Safety Population

Table 14.3.1.14
Summary of Treatment-emergent Adverse Effects Possibly Associated with Glucocorticoid Use during the 84-day Treatment Period
by System Organ Class and Preferred Term
Safety Population

Step System Organ Class Preferred Term	Placebo + Full Dose Prednisone n (%)	CCX168 + Low Dose Prednisone n (%)	CCX168 + No Prednisone n (%)	All CCX168 n (%)
Overall	N=##	N=##	N=##	N=##
Any Treatment-emergent Adverse Effect	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Serious Infections	## (###.#)	## (###.#)	## (###.#)	## (###.#)
New onset diabetes/hyperglycemia	## (###.#)	## (###.#)	## (###.#)	## (###.#)

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Note to Programmer: These adverse effects will be identified as follows:

- Serious infections: All SAEs in the System Organ Class Infections and Infestations
- New-onset diabetes mellitus/hyperglycemia: All TEAEs of hyperglycemia, diabetes, increased blood glucose, plus all patients with a fasting blood glucose level post baseline that is above the upper limit of normal on at least two consecutive study visits.
- Bone fracture: All TEAEs indicating long bone or vertebral fractures
- Peptic ulcer disease: All TEAEs indicating upper gastrointestinal ulceration, erosion, or bleeding
- Cataracts: All TEAEs of cataract
- New onset/worsening hypertension: All TEAEs of hypertension, worsening hypertension, or high blood pressure, plus all patients with a systolic blood pressure increase of at least 20 mm Hg from baseline, and >140 mm Hg (systolic), or diastolic blood pressure increase of at least 10 mm Hg from baseline, and >90 mm Hg (diastolic), that is present on at least two consecutive study visits.
- Weight gain more than 10 kg: Change from baseline in weight of > 10 kg.
- Psychiatric disorders: All TEAEs of psychosis, anxiety, amnesia, convulsions, delirium, dementia, depression, mania, emotional instability, irritability, euphoria, hallucinations, impaired cognition, increased motor activity, insomnia, memory loss, mania, mood swings, neuritis, neuropathy, paresthesia, personality changes, restlessness, schizophrenia, vertigo, or withdrawal behavior.

The following table will have the same layout as Table 14.3.1.14:

Table 14.3.1.15
Summary of Treatment-emergent Adverse Effects Possibly Associated with Glucocorticoid Use during the 168-day Study Period
by System Organ Class and Preferred Term
Safety Population

Table 14.3.1.16
Summary of Treatment-emergent Infections* during the 84-day Treatment Period
by System Organ Class and Preferred Term
Safety Population

Step System Organ Class Preferred Term	Placebo + Full Dose Prednisone n (%)	CCX168 + Low Dose Prednisone n (%)	CCX168 + No Prednisone n (%)	All CCX168 n (%)
Overall	N=##	N=##	N=##	N=##
Any Treatment-emergent Infection	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Any Serious Treatment-emergent Infection	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Any Severe Treatment-emergent Infection	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Any Treatment-emergent Infection Leading to Withdrawal	## (###.#)	## (###.#)	## (###.#)	## (###.#)
System Organ Class 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)
Preferred Term 1	## (###.#)	## (###.#)	## (###.#)	## (###.#)

- An adverse event is considered treatment-emergent if the start date of the event is on or after administration of the first dose of study medication.
*Summary table includes treatment-emergent infections including serious infections, severe infections (i.e., Grade 3), and infections Leading to withdrawal from the study.

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The following table will have the same layout as Table 14.3.1.16:

Table 14.3.1.17
Summary of Treatment-emergent Infections* during the 168-day Study Period
by System Organ Class and Preferred Term
Safety Population

The following tables will have the same layouts as Tables in Section 14.3.1:

Table 14.3.1.18
Summary of Serious Treatment-emergent Adverse Events during the 84-Day Treatment Period
by System Organ Class and Preferred Term
Safety Population

Table 14.3.1.19
Summary of Serious Treatment-emergent Adverse Events during the 168-day Study Period
by System Organ Class and Preferred Term
Safety Population

Table 14.3.1.20
Summary of Treatment-emergent Adverse Events Leading to Discontinuation of Study Medication
Safety Population

Table 14.3.2.1
Listing of Serious Adverse Events
Safety Population

Step / Treatment / Subject	TEAE?	RT: Reported Term / OC: Primary System Organ Class / PT: Preferred Term	Start Date (Day)/ End Date (Day)	Severity	Related-ness[1]	Action Taken[2]	Out-come[3,4]	SAE: Improve/ Disappear[5]	SAE: Reappear/ Worsen[6]
Step 3									
XXXXXXXXXXXXXXXXXXXXXXXXXXXX									
###-###	XXX	RT:XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY (###)/	XXXXXXXX	#/#/#	#	#/#	XX	XX
		OC:XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY (###)						
		PT:XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX							
Last Dose Date (Day): DDMMMYYYY (###) Cumulative Dose (mg) [7]:###									

- An adverse event is considered treatment-emergent if the start date of the event is on or after administration of the first dose of study medication. 'Day' is the number of days from the date of randomization.
[1] Relatedness:(Study Medication/Corticosteroid/Cyclophosphamide) 0=Probably Not Related, 1=Possibly Related
[2] Actions Taken: 1=None, 2=Study medication discontinued, 3=Study medication interrupted
[3] Outcome: 1=Resolved, 2=Resolved with sequelae, 3=Ongoing, 4=Death, 5=Unknown
[4] Serious Outcome: 1=Results in death, 2=Life threatening, 3=Inpatient hospitalization or prolongation of existing hospitalization, 4=Persistent or significant disability/incapacity, 5=Congenital abnormality or birth defect, 6=Important medical event
[5] Did the event improve or disappear after stopping study medication (dechallenge)?
[6] Did the event reappear or worsen after restarting study medication (rechallenge)?
[7] Represents the cumulative dose (mg) of CCX168 taken prior to onset of event.

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NOTE: This table will be sorted by Step of the study, treatment group and subject within treatment group.

NOTE: Repeat for Steps 2 and 1.

NOTE: Cumulative dose for placebo subjects will be 0 mg.

The following table will have the same layout as Table 14.3.2.1:

Table 14.3.2.2
Listing of Adverse Events Leading to Discontinuation of Study Medication
Safety Population

Table 14.3.2.3
Listing of Treatment-emergent Infections
Safety Population

Table 14.3.4.1
Summary of Changes in Hematology Laboratory Parameters by Visit
Safety Population

Step Parameter Study Day Statistic	Placebo + -- Full Dose Prednisone -- Visit	 Change	CCX168 + -- Low Dose Prednisone -- Visit	 Change	CCX168 + ----- No Prednisone ----- Visit	 Change	 ------- All CCX168 ------ Visit	 Change
Overall	N=##		N=##		N=##		N=##	
Parameter 1 (Unit)								
Baseline								
N'	##		##		##		##	
Mean	##.#		##.#		##.#		##.#	
SD	##.##		##.##		##.##		##.##	
SEM	##.##		##.##		##.##		##.##	
Minimum	##		##		##		##	
Median	##.#		##.#		##.#		##.#	
Maximum	##		##		##		##	
Day 2								
N'	##	##	##	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
SEM	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##	##	##	##

The laboratory parameters to be summarized include:
Hematology: Hemoglobin, Hematocrit, RBC Count, WBC Count (with both absolute and % differential), Platelet count, MCH, MCHC and MCV.

The visits to be summarized include:
Day 2, Day 8, Day 15, Day 29, Day 43, Day 71, Day 85, End of Treatment, Day 99, Day 141, Day 169, End of Follow-up Period.

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
- The End of Treatment value is the last measurement through Day 85.
- The End of Follow-up Period is the last measurement after Day 85 through Day 169.

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NOTE: Repeat for Steps 3, 2 and 1.

Table 14.3.4.2
Summary of Changes in Chemistry Laboratory Parameters by Visit
Safety Population

Step Parameter Study Day Statistic	Placebo + -- Full Dose Prednisone -- Visit	 Change	CCX168 + -- Low Dose Prednisone -- Visit	 Change	CCX168 + ----- No Prednisone ----- Visit	 Change	 ------- All CCX168 ------ Visit	 Change
Overall	N=##		N=##		N=##		N=##	
Parameter 1 (Unit)								
Baseline								
N'	##		##		##		##	
Mean	##.#		##.#		##.#		##.#	
SD	##.##		##.##		##.##		##.##	
SEM	##.##		##.##		##.##		##.##	
Minimum	##		##		##		##	
Median	##.#		##.#		##.#		##.#	
Maximum	##		##		##		##	
Day 2								
N'	##	##	##	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
SEM	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##	##	##	##

The laboratory parameters to be summarized include:
Total Bilirubin, LDH, SGOT/AST, SGPT/ALT, BUN, Creatinine, CPK, Albumin, Sodium, Potassium, Bicarbonate, Chloride, Calcium, Inorganic phosphorus, Glucose, Total protein, Alkaline phosphatase, Cholesterol and Uric acid.

The visits to be summarized include:
Day 2, Day 8, Day 15, Day 29, Day 43, Day 71, Day 85, End of Treatment, Day 99, Day 141, Day 169, End of Follow-up Period.

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
- The End of Treatment value is the last measurement through Day 85.
- The End of Follow-up Period is the last measurement after Day 85 through Day 169.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

NOTE: Repeat for Steps 3, 2 and 1.

Table 14.3.4.3
Summary of Changes in Urinalysis Laboratory Parameters by Visit
Safety Population

Step Parameter Study Day Statistic	Placebo + -- Full Dose Prednisone -- Visit	Placebo + -- Full Dose Prednisone -- Change	CCX168 + -- Low Dose Prednisone -- Visit	CCX168 + -- Low Dose Prednisone -- Change	CCX168 + ----- No Prednisone ----- Visit	CCX168 + ----- No Prednisone ----- Change	------- All CCX168 ------ Visit	------- All CCX168 ------ Change
Overall	N=##		N=##		N=##		N=##	
Parameter 1 (Unit)								
Baseline								
N'	##		##		##		##	
Mean	##.#		##.#		##.#		##.#	
SD	##.##		##.##		##.##		##.##	
SEM	##.##		##.##		##.##		##.##	
Minimum	##		##		##		##	
Median	##.#		##.#		##.#		##.#	
Maximum	##		##		##		##	
Day 2								
N'	##	##	##	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
SEM	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##	##	##	##

The laboratory parameters to be summarized include:
pH and specific gravity.

The visits to be summarized include:
Day 2, Day 8, Day 15, Day 29, Day 43, Day 71, Day 85, End of Treatment, Day 99, Day 141, Day 169, End of Follow-up Period.

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
- The End of Treatment value is the last measurement through Day 85.
- The End of Follow-up Period is the last measurement after Day 85 through Day 169.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

NOTE: Repeat for Steps 3, 2 and 1.

Table 14.3.4.4
Shift Table for Categorical Changes in Hematology Parameters by Visit
Safety Population

Step/ Parameter(Normal Range)	Visit	Treatment	Baseline Category	Category at Specified Visit <LLN	Normal	>ULN
Overall						
Parameter 1 (###-###)	Day 2	Placebo+Full Dose Prednisone (N'=##)	< LLN	## (###.#)	## (###.#)	## (###.#)
			Normal	## (###.#)	## (###.#)	## (###.#)
			> ULN	## (###.#)	## (###.#)	## (###.#)
		CCX168+Low Dose Prednisone (N'=##)				
		CCX168+No Prednisone (N'=##)				
		All CCX168 (N'=##)				

The laboratory parameters to be summarized will include:
Hemoglobin, Hematocrit, Red blood cell count, White blood cell count (with differential), Platelet count, MCH, MCHC and MCV.

Chemistry: Total Bilirubin, LDH, SGOT/AST, SGPT/ALT, BUN, Creatinine, CPK, Albumin, Sodium, Potassium, Bicarbonate, Chloride, Calcium, Inorganic phosphorous, Glucose, Total protein, Alkaline phosphatase, Cholesterol, and Uric acid.

Urinalysis: pH and specific gravity.

The visits to be summarized include:
Day 2, Day 8, Day 15, Day 29, Day 43, Day 71, Day 85, End of Treatment, Day 99, Day 141, Day 169, End of Follow-up Period.

- N'= number of subjects in group with assessment of parameter at baseline and specified visit
- n = number of subjects in group with post-baseline measurement outside specified limit
- % = 100*n/N'
- The End of Treatment value is the last measurement through Day 85.
- The End of Follow-up Period is the last measurement after Day 85 through Day 169.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

NOTE: Repeat for Steps 3, 2, and 1.

The following table will have the same layout as Table 14.3.4.4:

Table 14.3.4.5
Shift Table for Categorical Changes in Chemistry Parameters by Visit
Safety Population

The parameters to be summarized in Table 14.3.4.5 include: Total Bilirubin, LDH, SGOT/AST, SGPT/ALT, BUN, Creatinine, CPK, Albumin, Sodium, Potassium, Bicarbonate, Chloride, Calcium, Inorganic phosphorous, Glucose, Total protein, Alkaline phosphatase, Cholesterol, and Uric acid.

Table 14.3.4.7
Shift Table for Categorical Urinalysis Parameters by Visit
Safety Population

Step Parameter Visit	Baseline Value	Post-Baseline Value	Placebo + Full Dose Prednisone n (%)	CCX168+ Low Dose Prednisone n (%)	CCX168+ No Prednisone n (%)	All CCX168 n (%)
Overall			N=##	N=##	N=##	N=##
Parameter 1			N'=##	N'=##	N'=##	N'=##
Day 2	Category 1	Category 1				
		Category 2				
		Category n				

The urinalysis parameters include:
Glucose, Nitrite, Ketones, Bilirubin, Blood Urobilinogen, RBC, and WBC

The visits to be summarized include:
Day 2, Day 8, Day 15, Day 22, Day 29, Day 43, Day 57, Day 71, Day 85, End of Treatment, Day 99, Day 113, Day 141, Day 169, End of Follow-up Period.

- N'= number of subjects in group with baseline and post-baseline measurements of specified parameter
- n = number of subjects in group with post-baseline measurement outside specified limit
- % = 100*n/N'
- The End of Treatment value is the last measurement through Day 85.
- The End of Follow-up Period is the last measurement after Day 85 through Day 169.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

NOTE: Repeat for Steps 3, 2 and 1.

Table 14.3.4.8
Listing of Laboratory Data for Subjects with Notable Laboratory Abnormalities
Safety Population

Step Treatment Subject	Parameter (Unit)	Normal Range	Visit (Study Day)	Value	Clinical Significance
Step 1 XXXXXXXXXXXXXXXXXXXX ####-####	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXX-XXXX	XXXXXXXXXXXXXX (##)	############	NOTABLE HIGH

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY

NOTE: The table will include all records for each parameter that has at least one occurrence of a NOTABLE or CRITICAL abnormality as identified by the central laboratory. This table will be sorted by Step, treatment group and subject within treatment group.

Table 14.3.5.1
Summary of Changes in Vital Signs, Weight, and BMI by Visit
Safety Population

Step / Parameter / Study Day / Statistic	Placebo + Full Dose Prednisone: Visit	Placebo + Full Dose Prednisone: Change	CCX168 + Low Dose Prednisone: Visit	CCX168 + Low Dose Prednisone: Change	CCX168 + No Prednisone: Visit	CCX168 + No Prednisone: Change	All CCX168: Visit	All CCX168: Change
Overall	N=##		N=##		N=##		N=##	
Parameter 1 (Unit)								
Baseline								
N'	##		##		##		##	
Mean	##.#		##.#		##.#		##.#	
SD	##.##		##.##		##.##		##.##	
Minimum	##		##		##		##	
Median	##.#		##.#		##.#		##.#	
Maximum	##		##		##		##	
Day 2								
N'	##	##	##	##	##	##	##	##
Mean	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
SD	##.##	##.##	##.##	##.##	##.##	##.##	##.##	##.##
Minimum	##	##	##	##	##	##	##	##
Median	##.#	##.#	##.#	##.#	##.#	##.#	##.#	##.#
Maximum	##	##	##	##	##	##	##	##

The vital sign parameters to be summarized include:
Systolic blood pressure, Diastolic blood pressure, Heart rate, Oral temperature, Weight, BMI.

The visits to be summarized include:
Day 2, Day 8, Day 15, Day 22, Day 29, Day 43, Day 57, Day 71, Day 85, End of Treatment, Day 99, Day 113, Day 141, Day 169, End of Follow-up Period for systolic blood pressure, diastolic blood pressure, heart rate, and oral temperature, and Day 15, Day 29, Day 57, Day 85, End of Treatment, Day 113, Day 169, and End of Follow-up Period for Weight and BMI.

- Baseline is defined as the last pre-dose value.
- N'=number of subjects with data at baseline and the specified visit.
- The End of Treatment value is the last measurement through Day 85.
- The End of Follow-up Period is the last measurement after Day 85 through Day 169.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

NOTE: Repeat for Steps 3, 2, and 1.

Table 14.3.5.2
Summary of Physical Examination and Body System Reviews by Visit
Safety Population

Step / Day / Body System	Result	Placebo+ Full Dose Prednisone N'	n	(%)	CCX168+ Low Dose Prednisone N'	n	(%)	CCX168+ No Prednisone N'	n	(%)	All CCX168 N'	n	(%)
Overall		N=##			N=##			N=##			N=##		
Day 1													
General Appearance	Normal/same as previous PE	##	##	(###.#)	##	##	(###.#)	##	##	(###.#)	##	##	(###.#)
	Abnormal, new since previous PE	##	##	(###.#)	##	##	(###.#)	##	##	(###.#)	##	##	(###.#)
HEENT	Normal/same as previous PE	##	##	(###.#)	##	##	(###.#)	##	##	(###.#)	##	##	(###.#)
	Abnormal, new since previous PE	##	##	(###.#)	##	##	(###.#)	##	##	(###.#)	##	##	(###.#)

The body systems to be summarized include:
General Appearance/Mental Status, HEENT, Dermatologic, Cardiovascular, Respiratory, Gastrointestinal, Musculoskelatal, and Dermatologic.

The visits to be summarized include:
Day 1, Day 2, Day 8, Day 15, Day 22, Day 29, Day 43, Day 57, Day 71, Day 85, Day 99, Day 113, Day 141, and Day 169.

- N'=number of subjects with body system reviewed at the specified visit.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

NOTE: Repeat for Steps 3, 2, and 1.

Table 14.3.5.3
Listing of ECG Abnormalities
Safety Population

Step Treatment Subject	Age/Sex/Race	Date/Day	Abnormality	Clinically Significant?
XXXXXXXXXXXXXXXXXXXXX ####-####	##/M/XXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY/XX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	Yes

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY

NOTE: This table will be sorted by Step, treatment group and subject within treatment group.

8 Listing Shells

Listing D1
Subject Treatment Information, Demographics, and Baseline Characteristics
All Randomized Subjects

SUBJECT: ###-###

TREATMENT INFORMATION

Treatment: CCX168
Date of First Dose: DDMMMYYYY
Date of Last Dose (Day): Ongoing
Date of Completion/Early Termination (Day): Ongoing
Did the Subject Complete the Study?: No
Primary Reason for Withdrawal: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

BASELINE INFORMATION

Age/Sex/Ethnicity/Race: ##/FEMALE/Not Hispanic or Latino/XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Protocol version: Amendment #
Body weight (kg): ##.#
BMI (kg/m^2): ##.#
Smoking status: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
AAV Status: (Specify as newly diagnosed or relapsed.)
Date of AAV Diagnosis: DDMMMYYYY
Duration of AAV disease: ##.#
Type of AAV: (Specify as Granulomatosis with polyangiitis (Wegener's), Microscopic polyangiitis, or Renal limited vasculitis)
IIF Test for P-ANCA: (Specify as positive or negative.)
IIF Test for C-ANCA: (Specify as positive or negative.)
ELISA Test for Anti-proteinase-3: (Specify as positive or negative.)
ELISA Test for Anti-myeloperoxidase: (Specify as positive or negative.)
Baseline Birmingham Vasculitis Activity Score (BVAS): ##
Baseline Vasculitis Damage Index Score (VDI): ##
Was renal biopsy done to confirm diagnosis of renal vasculitis? XXX [If yes, describe abnormalities.]
Baseline Estimated Glomerular Filtration Rate (MDRD) Results (mL/min/1.73 m^2): ##.#
Baseline ACR (mg/g): ##.#
Baseline Urine Red Blood Cell Count (/hpf): ##
Baseline MCP-1:Creatinine Ratio(pg/mg Creatinine): ##

Listing D2
Study Medication Information
All Randomized Subjects

Step Treatment Subject	Visit	Date	CCX168/Placebo Capsules Dispensed	CCX168/Placebo Capsules Returned	Prednisone/Placebo Capsules Dispensed	Prednisone/Placebo Capsules Returned
Step 1						
XXXXXXXXXXXXXXXXXXXXXXXXXXXX						
###-###	Day 1	DDMMMYYYY	##	##	##	##
	Day 8	DDMMMYYYY	##	##	##	##
	Day 15	DDMMMYYYY	##	##	##	##
	Duration of Dosing (days):		###		###	
	Overall Percent Compliance:		###.#		###.#	
	Total CCX168 or Prednisone Dose:		###		###	
Step 2						
XXXXXXXXXXXXXXXXXXXXXXXXXXXX						
###-###	Day 1	DDMMMYYYY	##	##	##	##
	Day 8	DDMMMYYYY	##	##	##	##
	Day 15	DDMMMYYYY	##	##	##	##
	Duration of Dosing (days):		###		###	
	Overall Percent Compliance:		###.#		###.#	
	Total CCX168 or Prednisone Dose:		###		###	

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

Note to programmer: For the calculation of prednisone dose, most subjects used bottles containing 20 mg prednisone for the first week and then bottles containing 5 mg prednisone after week 1 (refer to protocol section 11.6 for details).

Listing D3.1
Cyclophosphamide IV Dosing
All Randomized Subjects

Step Treatment Subject	Visit	Date	Was Cyclophosphamide Administered At This Visit?	Dose Aministered (mg/kg)	Total Dose Aministered (mg)
Step 1					
XXXXXXXXXXXXXXXXXXXXXXXXXXXXX					
###-###	Day 1	DDMMMYYYY	XXX	###	
	Day 15	DDMMMYYYY	XXX	###	###
	Day 29	DDMMMYYYY	XXX	###	###
	Day 57	DDMMMYYYY	XXX	###	###
	Day 85	DDMMMYYYY	XXX	###	###
	Total Days of Dosing During 84-Day Treatment Period:				###
	Cumulative Dose 84 Day Treatment Period:				###
	Day 113	DDMMMYYYY	XXX	###	###
	Day 141	DDMMMYYYY	XXX	###	###
	Day 169	DDMMMYYYY	XXX	###	###
	Total Days of Dosing During 168-Day Treatment Period:				###
	Cumulative Dose 168 Day Treatment Period:				###

Listing D3.2
Rituximab Dosing (Step 3)
All Randomized Subjects

Treatment Subject	Visit	Date	Was Rituximab Administered At This Visit?	Start Date/Time	Stop Date/Time	Total Dose Aministered (mg)	Reason Not Done
XXXXXXXXXXXXXXXXXXXXXXXXXXXX							
###-###	Day 1	DDMMMYYYY	XXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	###	XXXXXXXXXXXXXXXXXXX
	Day 15	DDMMMYYYY	XXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	###	XXXXXXXXXXXXXXXXXXX
	Day 22	DDMMMYYYY	XXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	###	XXXXXXXXXXXXXXXXXXX
	UNS	DDMMMYYYY	XXX	DDMMMYYYY/HH:MM	DDMMMYYYY/HH:MM	###	XXXXXXXXXXXXXXXXXXX

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

Listing D4
Concomitant Medications
All Randomized Subjects

Step Treatment Subject	RT: Reported Term ATC: Anatomic Therapeutic Class PT: Preferred Term	Start Date (Day)/ End Date (Day)	Dose/Unit	Route	Frequency
Step 1 XXXXXXXXXXXXXXXXXXXXXXXXXXXX					
###-###	RT:XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX OC:XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX PT:XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY (###)/ DDMMMYYYY (###)	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXXXXXXXXX

Listing D5
Adverse Events
All Randomized Subjects

Step Treatment Subject	TEAE?	RT: Reported Term OC: Primary System Organ Class PT: Preferred Term	Start Date (Day)/ End Date (Day)	Severity	Related-ness[1]	Action Taken[2]	Out-come[3,4]	SAE Improve/ Disappear[5]	SAE Reappear/ Worsen[6]
Step 1 XXXXXXXXXXXXXXXXXXXXXXXXXXX									
###-###	XXX	RT:XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX OC:XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX PT:XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	DDMMMYYYY (###)/ DDMMMYYYY (###)	XXXXXXXX	#/#/#	#	#/#	XX	XX

- An adverse event is considered treatment-emergent if the start date of the event is on or after administration of the first dose of study medication. 'Day' is the number of days from the date of randomization.
[1] Relatedness:(Study Medication/Corticosteroid/Cyclophosphamide) 0=Probably Not Related, 1=Possibly Related
[2] Actions Taken: 1=None, 2=Study medication discontinued, 3=Study medication interrupted
[3] Outcome: 1=Resolved, 2=Resolved with sequelae, 3=Ongoing, 4=Death, 5=Unknown
[4] Serious Outcome: 1=Results in death, 2=Life threatening, 3=Inpatient hospitalization or prolongation of existing hospitalization, 4=Persistent or significant disability/incapacity, 5=Congenital abnormality or birth defect, 6=Important medical event
[5] Did the event improve or disappear after stopping study medication (dechallenge)?
[6] Did the event reappear or worsen after restarting study medication (rechallenge)?

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

Listing D6
Central Laboratory Data - Chemistry
All Randomized Subjects

Step Treatment Subject	Parameter (Unit)	Normal Range	Visit	Value	Abnormal Flag
Step 1 XXXXXXXXXXXXXXXXXXXX ####-####	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXX-XXXX	XXXXXXXXXXXXXX	############	NOTABLE HIGH

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY

The following listings will have the same layout as Listing D6:

Listing D7
Central Laboratory Data – Hematology
All Randomized Subjects

Listing D8
Central Laboratory Data – Urinalysis
All Randomized Subjects

Listing D9
Central Laboratory Data – Urine Chemistry
All Randomized Subjects

Listing D10.1
Local Laboratory Data – Serum Chemistry, Hematology, and Coagulation
All Randomized Subjects

Listing D10.2
Local Laboratory Data – Virology, Immunology, and Chest X-ray Results
All Randomized Subjects

Note to programmer: Verify the contents of this table with data management.

Listing D11
Local Laboratory Data - Urinalysis
All Randomized Subjects

Step Subject	Treatment	Sample Collected?	RBC Count (/hpf)	RBC Casts	Any Clots Present?	Was Transfusion Required/ Any Urinary Tract Obstruction?
Step 1						
####-####	XXXXXXXXXXXXXXXXXXXXX	XXX	###	XXXXXXXX	XXX	XXX

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY

Listing D12
Birmingham Vasculitis Activity Score (BVAS)
All Randomized Subjects

Step Subject	Treatment	Visit	Date	Was BVAS Assessed?	Category	Baseline Score	Visit Score	Change from Baseline	% Change from Baseline
Step 1									
###-###	XXXXXXXXX	Screening	DDMMMYYYY	Yes	General	##	##	##	##.#
					Cutaneous				
					Mucous membrane/eyes				
					Ear, nose, throat				
					Chest				
					Cardiovascular				
					Abdominal				
					Renal				
					Nervous system				
					Other				
					BVAS Total				

Listing D13
Vasculitis Damage Index
All Randomized Subjects

Step Subject	Treatment	Visit	Date	Was VDI Assessed?	Category	Baseline Score	Visit Score	Change from Baseline	% Change from Baseline
Step 1									
###-###	XXXXXXXXX	Screening	DDMMMYYYY	Yes	Musculoskelatal	##	##	##	##.#
					Skin/Mucous membranes				
					Ocular				
					ENT				
					Pulmonary				
					Cardiovascular				
					PVD				
					Gastrointestinal				
					Renal				
					Neuropsychiatric				
					Other				
					Overall VDI Score				

Listing D14
ANCA Results
All Randomized Subjects

Step Subject	Treatment	Visit	Date	Parameter	Baseline Result	Visit Result	Change from Baseline	% Change from Baseline
Step 1								
###-###	XXXXXXXXX	Screening	DDMMMYYYY	Anti-PR3 (IU/mL)	##	##	##	##.#
				Anti-MPO (IU/mL)				

- Baseline is defined as the last pre-dose value.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

Listing D15
Serum hsCRP Results (mg/L)
All Randomized Subjects

Step Subject	Treatment	Visit	Date	Baseline Result	Visit Result	Change from Baseline	% Change from Baseline
Step 1							
###-###	XXXXXXXXX	Screening	DDMMMYYYY	##	##	##	##.#

- Baseline is defined as the last pre-dose value.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

Listing D16
Serum Urinary MCP-1:Creatinine Ratio Results (pg/mg Creatinine)
All Randomized Subjects

Step Subject	Treatment	Visit	Date	Baseline Result	Visit Result	Change from Baseline	% Change from Baseline
Step 1							
###-###	XXXXXXXXX	Screening	DDMMMYYYY	##	##	##	##.#

- Baseline is defined as the last pre-dose value.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

Listing D17
Estimated Glomerular Filtration Rate (MDRD) Results (mL/min/1.73 m^2)
All Randomized Subjects

Step Subject	Treatment	Visit	Date	Baseline Result	Visit Result	Change from Baseline	% Change from Baseline
Step 1							
###-###	XXXXXXXXX	Screening	DDMMMYYYY	##	##	##	##.#

- Baseline is defined as the last pre-dose value.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

Listing D18
ACR Results (mg/g)
All Randomized Subjects

Step Subject	Treatment	Visit	Date	Baseline Result	Visit Result	Change from Baseline	% Change from Baseline
Step 1							
###-###	XXXXXXXXX	Screening	DDMMMYYYY	##	##	##	##.#

- Baseline is defined as the last pre-dose value.

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

Listing D19
Vital Signs, Weight, and BMI
All Randomized Subjects

Step Subject	Treatment	Visit	Date	Parameter	Baseline Result	Visit Result	Change from Baseline
Step 1							
###-###	XXXXXXXXX	Screening	DDMMMYYYY	Systolic Blood Pressure (mmHg)	##	##	##
				Diastolic Blood Pressure (mmHg)			
				Heart Rate (bpm)			
				Oral Temperature (F)			
				Height (cm)			
				Weight (kg)			
				Body Mass Index (kg/m^2)			

Listing D20
Physical Exam and Body System Reviews
All Randomized Subjects

Step Subject	Treatment	Visit	Date	Body System	Result	Abnormal Finding(s)
Step 1						
###-###	XXXXXXXXX	Screening	DDMMMYYYY	General Apperance/Mental Status	Not done	
				HEENT	Normal	
				Dermatologic	Normal	
				Cardiovascular	Normal	
				Respiratory	Normal	
				Gastrointestinal	Normal	
				Musculoskeletal	Normal	
				Neurologic	Abnormal	xxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Listing D21
SF-36v2 Health Survey
All Randomized Subjects in Step 3

SUBJECT: ###-### STEP: X TREATMENT: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

VISIT: Day 1 DATE: MMDDYYYY

In genereral, would you say your health is:	XXXXXXXXXXXXXXXXXXXX
Compared to one year ago, how would you rate your health in general now:	XXXXXXXXXXXXXXXXXXXX
How much does your health now limit you in the following activities:	
Vigorous activities:	XXXXXXXXXXXXXXXXXXXXX
Moderate activites:	
Lifting of carrying grocieries:	
Climbing several flights of stairs:	
Climbing one flight of stairs:	
Bending, kneeling, or stooping:	
Walking more than a mile:	
Walking several hundred yards:	
Walking one hundred yards:	
Bathing or dressing yourself:	
During the past 4 weeks, how much of the time have you had problems with the following as a result of your physcial health:	
Cut down on the amount of time you spent on work or other activities:	
Accomplished less than you would like:	
Were limited in the kind of work or other activities:	
Had difficulty performing the work or other activities:	
During the past 4 weeks, how much of the time have you had problems with the following as a result of your emotional health:	
Cut down on the amount of time you spent on work or other activities:	
Accomplished less than you would like:	
Did work or other activities less carefully than usual:	
During the past 4 weeks, to what extent has physical or emotional health interfered with social activites:	
How much bodily pain have you had in the last 4 weeks:	
During the past 4 weeks, how much did pain interfere with your normal work:	

Listing D21
SF-36v2 Health Survey
All Randomized Subjects in Step 3

SUBJECT: ###-### STEP: X TREATMENT: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

VISIT: Day 1 DATE: MMDDYYYY

During the past 4 weeks:
Did you feel full of life:
Have you been very nervous:
Have you felt so down in the dumps that nothing could cheer you up:
Have you felt calm and peaceful:
Did you have a lot of energy:
Have you felt downhearted and low:
Did you feel worn out:
Have you been happy:
Did you feel tired:

During the past 4 weeks, how much of the time has your physical or emotional problems interfered with your social activities:
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

How TRUE or FALSE is each of the following statements for you:
I seem to get ill more easily than other people
I am as healthy as anybody I know:
I expect my health to get worse:
My health is excellent:

Summary Scores:
Role-Physical:
Role-Emotional:
Social Functioning:
Bodily Pain:
Mental Health:
General Health Perceptions:
Change in Health:
Physcial Component Summary:
Mental Health Summary:

Program Name: XXXXXXXX.sas Run Date: DDMMMYYYY HH:MM Database last modified: DDMMYYYY HH:MM

Listing D22
EQ-5D-5L Questionnaire and VAS
All Randomized Subjects in Step 3

Step Subject	Treatment	Visit	Date	Question	Result
Step 1					
###-###	XXXXXXXXXXXX	Day 1	DDMMMYYYY	Mobility	XXXXXXXXXXXXXXX
				Self-care	
				Usual activities	
				Pain/Discomfort	
				Anxiety Depression	
				Health Scale Score	
				VAS	