Cover Page for	**Statistical Analysis Plan**
Sponsor Name	**Viking Therapeutics Inc.**
NCT Number	02578095
Sponsor Trial ID	VK5211-201
Official Title	A Phase II, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multi-Center Study to Explore the Efficacy, Safety and Tolerability of VK5211 in Subjects with Acute Hip Fracture
Document Date	February 12, 2018

INTEGRIUM, LLC
BIOMETRICS DEPARTMENT

Clinical Study Protocol: VK5211-201

A Phase II, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multi-Center Study to Explore the Efficacy, Safety and Tolerability of VK5211 in Subjects with Acute Hip Fracture

Statistical Analysis Plan (SAP)

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Sponsor: Viking Therapeutics, Inc.

Document status: Version 1.2

Dates: 12FEB2018

Number of pages: 35

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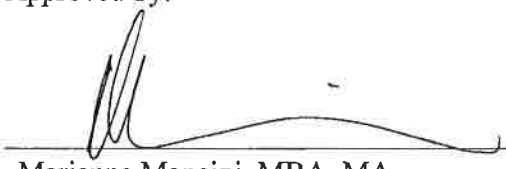
Signature Page

Statistical Analysis Plan for Clinical Study Protocol: VK5211-201

A Phase II, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multi-Center Study to Explore the Efficacy, Safety and Tolerability of VK5211 in Subjects with Acute Hip Fracture

Approved by:



13 · Feb · 2018

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Vice President Clinical Operations
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13 Feb 2018

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Document History

Version Number	Author	Date	Change
1.0	K. Homer	23AUG2017	Initial Version
1.1	K. Homer	10NOV2017	Added Multiple Imputation for missing data. Modified table output descriptions per comments on dry run output review. Modified the SF-36 Scoring System to account for the changes between version 1 and version 2. Added additional analyses for DXA, 6 Minute Walk, SPPB and SF-36.
1.2	K. Homer	12FEB2018	Added definitions for "Stringent Definition of Valid DXA" and "Liberal Definition of Valid DXA". Added tables for the "Liberal Definition of Valid DXA". Added definition of valid DXA by the central reader. Renumbered the efficacy tables accordingly to support the two different definitions.

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Glossary of Abbreviations

AE	Adverse Event
ANCOVA	Analysis of Covariance
ANOVA	Analysis of Variance
BP	Blood Pressure
CRF	Case Report Form
CSR	Clinical Study Report
ECG	Electrocardiogram
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HR	Heart Rate
ICH	International Council on Harmonisation
ITT	Intent-to-Treat
MAR	Missing at Random
MedDRA	Medical Dictionary for Regulatory Activities
MI	Multiple Imputation
MNAR	Missing Not at Random
N	Sample Size
PP	Per Protocol
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
WHO	World Health Organization
DXA	Dual Energy X-Ray Absorptiometry
TBLH	Total Body Less Head
BMD	Bone Mineral Density
PI	Principal Investigator
TEAE	Treatment Emergent Adverse Event
6MWT	Six-Minute Walk Test
SPPB	Short Physical Performance Battery

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PADL	Physical Activities of Daily Living
IADL	Instrumental Activities of Daily Living
SF-36	Short Form-36
s-CTX	Serum C-terminal crosslinking telopeptide of type 1 collagen
s-PINP	Serum procollagen type 1 propeptide

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Table of Contents

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1. Introduction

1.1. Scope

This document contains detailed information to aid the production of the Clinical Study Report (CSR) including summary tables, figures, and listings for the Viking VK5211-201 trial. The contents of this document were reviewed by the sponsor, Viking Therapeutics, Inc., and the trial biostatistician at Integrium.

1.2. Study Overview

This is a phase II, randomized, double-blind, parallel group, placebo-controlled, multi-center study to investigate the safety, tolerability, and efficacy of VK5211 after 12 weeks of treatment.

Males and females ≥ 65 years old who are ambulatory and recovering from a hip fracture will be eligible for participation 3-11 weeks post-injury.

After completing all Screening requirements, subjects will be randomized to one of four treatment arms (VK5211 0.5 mg, 1.0 mg, 2.0 mg, or placebo) in a 1:1:1:1 ratio and will receive their first dose of study treatment in the clinic.

The first bottle of study treatment will be dispensed and subjects will be instructed to take one oral dose of the assigned treatment at approximately the same time every morning, 30 minutes prior to breakfast.

Subjects will undergo safety and efficacy assessments as specified in the protocol on an approximately 4-week basis for a total treatment period of approximately 12 weeks. Following the 12-week treatment period, subjects will be followed for an additional 12-week period for assessment of safety and duration of drug effect.

During the study safety will be assessed on an ongoing basis by adverse events, identification of dose-limiting toxicities (DLTs) (if any), plasma concentrations, general physical examinations, vital signs, clinical laboratory assessments in blood, urine, as well as other specialized testing as required.

1.3. Study Objectives

1.3.1. Primary Objectives

The primary objective of this study is to determine the efficacy of VK5211 after 12 weeks of treatment by mean placebo-corrected percentage change in total body less head (TBLH) lean body mass assessed by whole body DXA scan.

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1.3.2. Secondary Objectives

The secondary objectives of this study are:

- To assess the safety and tolerability of VK5211 after 12 weeks of treatment by comparing overall adverse events, vital signs, 12-lead ECG data, physical examinations, and hematology/chemistry/urinalysis data to placebo.
- To determine the efficacy of VK5211 after 12 weeks of treatment by mean placebo-corrected change in:
    - Hip bone mineral density (BMD) assessed by DXA
    - Total lean body mass (TLBM)
    - Appendicular lean body mass (ALBM)
    - Bone turnover markers (s-CTX and s-PINP)
- To assess plasma concentration of VK5211 near T_{max} and at trough levels in relation to total lean body mass.

1.3.3. Exploratory Objectives

The exploratory objectives of this study are to determine the efficacy of VK5211 compared to placebo after 12 weeks of treatment by:

- Physical Performance Assessments
    - 6 Minute Walk Test (6MWT) and BORG Scale
    - Grip Strength
    - Short Physical Performance Battery (SPPB)
- Patient Reported Outcomes
    - Pre- and Post-fracture Physical and Instrumental Activities of Daily Living (PADLs/IADLs)
    - Short Form-36 (SF-36)

2. Detailed Statistical Methods

2.1. General Statistical Methods

Efficacy analyses will be performed with both the Intent-to-Treat and Per Protocol Population. Safety analyses will be performed with the Safety Population. Data listings will be provided for all enrolled subjects.

All measured variables and derived parameters will be listed individually and, if appropriate, tabulated by descriptive statistics. For descriptive statistics, summary tables will include by treatment group summaries of sample size, arithmetic mean, standard deviation, coefficient of variation (if appropriate), median (and other percentiles, if appropriate), and minimum and maximum values. For categorical variables summary tables will include by treatment group summaries of frequency counts.

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2.2. Study Populations

Safety Population:

All subjects who have taken a single dose of the study drug and provide follow-up information will be included in the safety population.

Intent-to-Treat (ITT) Population:

All subjects who have taken a single dose of the study drug and have a valid pre-baseline and post-baseline assessment will be included in the Intent-to-Treat population. Subjects will be analyzed as randomized, rather than as treated. This is the primary analysis population for assessing efficacy.

Per Protocol (PP) Population:

All Intent-to-Treat subjects who have taken at least 80% of the expected number of doses and do not have a major protocol violation will be included in the Per Protocol population. Subjects will be analyzed as treated, rather than as randomized.

Prior to unblinding, the exclusion of any subject from the Per Protocol Population will be documented including the reason for exclusion.

2.3. Definition of Baseline

In general, the study baseline is defined as the last observation obtained prior to the administration of the first randomized study medication, unless otherwise specified.

2.4. Subject Disposition and Characteristics

An account of the subjects by disposition will be tabulated overall. The number of subjects included in each analysis population will be summarized. Subjects not completing the study will be summarized and listed with the reason for their premature discontinuation. A list of screening failures will also be provided.

2.5. Demographics and Baseline Characteristics

Demographics and baseline characteristics will be presented using summary statistics (N, mean, standard deviation, median, minimum and maximum) for continuous measurements, or frequency tables (numbers and percentages) for categorical measurements, for the Intent-to-Treat, Per Protocol, and Safety Population.

2.6. Extent of Exposure and Compliance

For the 12-week treatment period, the number of days of exposure will be calculated as the number of capsules dispensed – the number of capsules returned.

The number of days of exposure to study medication and the percent compliance (number of days of exposure*100 / 84) will be summarized by treatment group using summary statistics (N, mean, standard deviation, median, minimum and maximum).

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2.7. Prior and Concomitant Medications

Prior and concomitant medications will be coded using World Health Organization (WHO) Drug dictionary September 2015 version.

Prior medications will be defined as any medication that stops prior to the day of the first dose of study medication.

Concomitant medications taken at baseline will be defined as any medication that started on or prior to the baseline visit and stops on or after the day of the first dose of study medication.

Concomitant medications taken during treatment will be defined as any medication that stops on or after the day of the first dose of study medication, regardless of start date.

Section 2.14 describes the imputation rules for partial dates. Number and percentage of subjects receiving prior and concomitant medications will be summarized by treatment group and ATC classification (ATC level 2 and level 4) for the Safety Population. All medications will be presented in a data listing.

2.8. Medical History

Medical history terms will be coded using the Medical Dictionary for Drug Regulatory Affairs (MedDRA) version 18.1. A summary table by body system and preferred term will be presented. The complete medical history information will also be presented in a data listing.

2.9. Safety Evaluations

2.9.1. Adverse Events

Adverse events will be coded using the Medical Dictionary for Drug Regulatory Affairs (MedDRA) version 18.1 and tabulated, including categorical information of interest such as onset and resolution times, time of onset relative to dose, severity at onset, maximum severity, causal relationship to study medication, and action taken.

Treatment-emergent adverse events (TEAEs) are defined as any AE that started after the first dose of study medication or started prior to the first dose but increased in severity or frequency after dosing. The incidence of TEAEs will be presented by system organ class and preferred term. Adverse events will also be summarized by severity and relationship to the study drug.

The incidence of serious AEs, drug-related AEs, serious and drug-related AEs, and any AEs resulting in discontinuation from the study will be listed. Adverse events will be presented in decreasing order of frequency (preferred term only) to better asses the most frequent adverse events.

2.9.2. Safety Laboratory Evaluations

Individual laboratory values will be listed by visit and summarized using descriptive statistics. Individual change from baseline in laboratory values will be calculated and summarized descriptively. Shift tables from baseline to final visit will also be produced for the laboratory

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assessments based on the categories of Low, Normal, and High. Selected lab parameters will be summarized by CTC grade. A clinically significant change from baseline may be recorded as an AE if deemed appropriate by the PI or sponsor.

To better view the results of the liver function tests, the liver function tests will be presented in a separate table.

2.9.3. Vital Signs

Individual vital sign measurements (systolic/diastolic BP and heart rate) will be listed by measurement time and summarized using descriptive statistics. Individual change from baseline in vital sign measurements will be calculated and summarized descriptively. A clinically significant change from baseline may be recorded as an AE if deemed appropriate by the PI or sponsor.

2.9.4. Electrocardiogram

EGC results will be summarized for each visit at which it is performed. Any clinically significant change from baseline may be recorded as an AE if deemed appropriate by the PI or sponsor. Individual ECG values will be listed by visit and summarized using descriptive statistics. Intervals to be provided for each ECG are: RR, PR, QRS, QT, and QTcF.

2.9.5. Physical Examination

Physical examination results will be summarized for each visit at which it is performed.

2.10. Efficacy Evaluations

Efficacy assessments will be listed in data listings, and summarized in tables. Figures will be generated for selected efficacy evaluations to better understand the results.

2.10.1. Primary Efficacy Assessment

The absolute and percentage change in total body less head lean body mass at Visit 4 (Month 3) will be analyzed using an Analysis of Covariance model with baseline value as a covariate and treatment and region (country) as factors.

Observed values, percentage change and absolute change from baseline for all available visits will be summarized using mean, standard deviation, coefficient of variation (CV%), median, minimum and maximum. A 95% confidence interval on the placebo adjusted change from baseline will also be presented.

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2.10.2.Secondary Efficacy Assessments

2.10.2.1. DXA Scans

The total lean body mass, hip bone mineral density, total body mass and fat mass, appendicular lean body mass and bone turnover markers will be analyzed using an Analysis of Covariance model with baseline value as a covariate and treatment and region (country) as factors.

Observed values, percentage change, percent change from baseline and absolute change from baseline will be summarized using mean, standard deviation, coefficient of variation (CV%), median, minimum and maximum. A 95% confidence interval on the placebo adjusted change from baseline will also be presented.

The analysis of the values obtained from the central reader will be the primary analysis. The values obtained from the site (as recorded on the CRF) after applying a correction factor to adjust for the different DXA machine types will also be analyzed.

The definition of valid DXA from the central reader is as follows:

> A valid DXA indicates the scan was acquired under the correct scanner setting, includes the entire region of interest and is free of artifacts that would affect quality results such as jewelry, surgical hardware, etc. Bioclinica technologists specifically trained on DXA scan analysis review the scans submitted to Bioclinica visually for those criteria as well as technical parameters such as scan mode, voltage setting, etc.

The initial concept behind the Month 3 analysis is that the subject would be on drug for at least 56 days and that the DXA measurement would be taken shortly (within 14 days) after the subject completed therapy. Thus, subjects who did not have at least 56 days of treatment or did not have their "Month 3" DXA within the allotted time was planned to be excluded from the analysis. It is important to note that the "Month 6" analysis is performed after the subject has been off therapy, so some of the data excluded from the Month 3 analysis will be included in the Month 6 analysis.

Given the variation of actual dosing and the timing of the actual DXA scan, there will be two definitions of a valid DXA for analysis purposes: "The Stringent Definition of Valid DXA" and "The Liberal Definition of Valid DXA".

The stringent definition of valid DXA is as follows:

> The subject must be on treatment for at least 56 days, have a valid baseline DXA and a DXA within 14 days after stopping treatment. (This is the definition as indicated in the protocol.)

The liberal definition of valid DXA is as follows:

> The subject must have a valid baseline DXA and a DXA after baseline and prior to 98 days after starting treatment.

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For the lean body mass measurements, the number and percent of subjects who had a 0.5kg, 1.0kg, 1.5kg and 2.0kg increase from baseline will be presented, and the number and percent of subjects who increased by 3% and number and percent of subjects who increased by 5% will also be presented.

Correlations and regression lines between total lean body mass (for both observed values and change from baseline) and the VK5211 PK concentration near Tmax and at trough levels will also be analyzed for each VK5211 treatment group and all VK5211treatment groups combined. This analysis will be performed by visit and for all post-baseline visits combined.

2.10.2.2. Plasma Concentration Analysis

Pre-dose and single post-dose plasma concentrations of VK5211 at Visits 2, 3 and 4 and the single plasma concentration at Visit 5 will be summarized using mean, geometric mean, standard deviation, coefficient of variation (CV%), median, minimum and maximum.

2.10.3.Exploratory Objectives

2.10.3.1. Physical Performance Assessments

2.10.3.1.1. 6 Minute Walk Test and BORG Scale

The 6MWT total distance walked will be analyzed using an Analysis of Covariance model with the baseline value as a covariate with treatment and region (country) as factors. Observed values and change from baseline will be summarized using mean, standard deviation, coefficient of variation (CV%), median, minimum and maximum. The number and percent of subjects that walked more than 150, 200, 250 and 300 meters and who had a change from baseline of more than 50, 100 and 150 meters will be presented.

The Borg Scale is a categorical scale with 12 possible values. There are sufficient number of categories that the Borg Scale will be analyzed as a continuous variable. The Borg Scale will be analyzed using an Analysis of Covariance model with the baseline value as a covariate with treatment and region (country) as factors. Observed values and change from baseline will be summarized using mean, standard deviation, coefficient of variation (CV%), median, minimum and maximum.

2.10.3.1.2. Grip Strength

Grip strength will be analyzed using a Repeated Measures Analysis of Covariance model with average baseline assessment as a covariate, treatment and region (country) as factors and measurement as the repeated measure (since 2 measures are being taken). Observed average, change from baseline average and placebo adjusted average change from baseline will be summarized using mean, standard deviation, coefficient of variation (CV%), median, minimum and maximum.

2.10.3.1.3. Short Physical Performance Battery

SPPB individual scores and total scores will be summarized using frequency counts and summary statistics. Observed values and change from baseline will be summarized.

Number and percent of subjects that:

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- Improved by at least 1, 2 and 3 points,
- Whose total score is greater than 7, and
- Whose 4-meter gait speed increased by more than 0.1 m/sec

will be presented.

A Cochran-Mantel-Haenszel row mean score will be used to test for differences in frequency counts between treatment groups. An Analysis of Covariance with base value as a covariate and country as factor will be used to test for differences in the mean.

2.10.3.2. Patient Reported Outcomes

2.10.3.2.1. Pre- and Post-Fracture Physical and Instrumental Activities of Daily Living

For the analysis of the PADLs/IADLs, entirely dependent means that the subject is unable to perform the activities without assistance. For Example:

- The IADL Q1 discusses how the subject got to places out of walking distance.
  - Responses that would not be entirely dependent are:
    - Response 1 (Travel alone on buses, taxis, or drive your own car)
    - Response 3 or 4 (Did not perform), if Q1a has a response of 1 (Independently)
  - Responses that would be entirely dependent are:
    - Response 2 (Have someone to help you or go with you when travelling)
    - Response 3 or 4 (Did not perform), if Q1a has a response of 2 (With Assistance) or 3 (Would not be able to at all).

A significant change from screening would be a change in the subjects entirely dependent rating. A significant positive change would the if someone was entirely dependent at screening, but independent at the post-baseline visit. A significant negative change would be if someone was independent at screening, but entirely dependent at the post-baseline visit.

The PADLs/IADLs will be analyzed as follows:

- Change in number of subjects entirely dependent in performing each activity of daily living from screening at each post-screening visit will be analyzed using the Cochran-Mantel-Haenszel Test.

- Difference in number of subjects entirely dependent in performing each activity of daily living at each visit between treatment groups will be compared using the Cochran-Mantel-Haenszel Test.

- Each activity of daily living for each visit collected will be summarized using mean, standard deviation, median, minimum and maximum.

- Significant change from screening for each activity of daily living will be analyzed using the Wilcoxon signed-rank test.

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- Differences between treatment groups for each activity of daily living will be analyzed using the Kruskal-Wallis test on the change from screening value.

2.10.3.2.2. Short Form-36

The SF-36 individual subscales (Physical Functioning (PF), Role-Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role-Emotional (RE) and Mental Health (MH)) , component measures (Physical Health Component Score and Mental Health Component Score) and total score (Physical Health Component Score + Mental Health Component Score) will be analyzed using an Analysis of Covariance model with baseline value as a covariate and treatment and region (country) as factors. Observed values, and change from baseline will be summarized using mean, standard deviation, median, minimum and maximum.

Derivation of the SF-36 subscales are defined in section 2.15.

2.11. Primary and Final Analyses

There are two planned analyses for the study: the primary analysis and the final analysis. The primary analysis is not an interim analysis. All subjects will have finished their treatment and the 12-week primary endpoints will be locked. Thus, the primary analysis is not subject to an alpha-spending penalty. No multiplicity adjustment is needed.

The primary analysis will be performed in a partially unblinded fashion. The generated tables will be presented using the actual treatment groups, but information pertaining to the unblinded treatment received by individual subjects will be blinded. So thus, the results will be known, but the individual subjects will still be blinded.

The primary analysis will be performed once all subjects have completed 3 months of treatment. The following variables will be included in the primary analysis:

Primary Objective

Percent Change in Total Body Less Head (TBLH) Lean Body Mass obtained from the DXA scan at 3 Months.

Secondary Objectives

Hip Bone Mineral Density (BMD) obtained from the DXA scan at 3 Months.
Total Lean Body Mass (TLBM) obtained from the DXA scan at 3 Months.
Appendicular Lean Body Mass (ALBM) obtained from the DXA scan at 3 Months.

Exploratory Objectives

6 Minute Walk Test
Short Physical Performance Battery (SPPB)
Short Form-36 (SF-36) Quality of Life Questionnaire

All analyses as indicated in the SAP will be presented for the final analysis.

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2.12. Other Analyses

There are no other analyses planned for this study.

2.13. Analysis of Subgroups

There are no subgroup analyses planned for this study, but there is a plan to perform analyses to test for significant factor effects.

At the 3 month and 6 month analyses, we will test for a significant sex effect. Sex will be added as a factor into the ANCOVA models with least squares means and 95% confidence intervals being presented by treatment and sex. P-Values will be presented for the sex effect, treatment effect and sex*treatment interaction.

2.14. Sample Size and Power Considerations

Power Considerations Prior to Study Start

Based on the observed change in total lean body mass information from previous studies (as percentage change in total lean body mass information is not available), it seems reasonable to estimate the placebo-adjusted difference in total lean body mass for the 0.5 mg group to be 0.5 kg and 1.0 kg for the 1 mg group. For the purpose of power calculations, the 2 mg group is extrapolated to show a 1.5 kg adjusted difference. The estimate of standard deviation, based on information from the previous study, is estimated to be 1.3. A sample size of 30 subjects per treatment group yields 84% power to detect a difference between the 1 mg treatment group and placebo and 99% power to detect a difference between the 2 mg treatment group and placebo.

Even though the sample size estimate is based on the observed change in total lean body mass, we believe that the resulting calculations are reasonable for the analysis of percentage change in body less head lean body mass.

120 subjects are required to have baseline and 3 months' post-treatment data to observe the power indicated above. The protocol was written to enroll 120 subjects, assuming that there would be no dropouts.

Power Considerations Once Approximately Half of the Subjects Completed Month 3

Once approximately half of the subjects had 3 month DXA data, the data was reviewed in a blinded fashion.

Modifications to the pre-study assumptions was considered appropriate.

A placebo adjusted change of 1.6, 2.4 and 4.1 for the 0.5 mg, 1.0 mg and 2.0 mg active groups respectively with a standard deviation estimate of 2.0 seemed to be more reasonable.

Under these assumptions, the power calculations are as follows:

- Placebo vs. 0.5 mg VK5211 – 26 subjects per treatment group yields 80% power
- Placebo vs. 1.0 mg VK5211 – 16 subjects per treatment group yields 90% power
- Placebo vs. 2.0 mg VK5211 – 7 subjects per treatment group yields 90% power

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Based on these numbers, it seems reasonable to randomize 104 subjects to complete approximately 92 (approximately 23 subjects per treatment group to complete). Thus, the decision was made to stop enrollment prior to randomizing all 120 subjects.

2.15. Randomization Scheme and Codes

The randomization details are documented in a separate randomization plan.

2.16. Handling Missing Data

Listings will be provided for all data. Descriptive statistics will be provided for all planned visits as provided on the Case Report Forms (CRFs).

Study days will be analyzed using the study days as reported in the Case Report Form. Likewise, unscheduled visits will not be reassigned a visit number based on the visit date.

Dates related to the adverse events and medications will be imputed using the rules below in an effort to categorize them properly into the summary tables.

Imputing partial or missing start dates:

- If the year is unknown, then the start date will not be imputed. The date will remain missing.
- If the month is unknown and the year is the same as the first dose date of the study, then impute the month and day of the date to be equal to the first dose month and day. Otherwise, impute the month as January.
- If the day is unknown and the month and year are the same as the first dose date of the study, then impute the day to be equal to the day of the first dose. Otherwise, impute the day as '01'.

Impute partial or missing stop dates:

- If the year is unknown, then the stop date will not be imputed. The date will remain missing.
- If the month is unknown, impute the month as December.
- If the day is unknown, impute the day to be the last day of the month.

If an imputed stop date is greater than the date of study completion/discontinuation date of the study, then the imputed stop date will be set equal to the date of completion/discontinuation date.

The imputed dates will be stored in the analysis datasets along with the original dates as recorded by the sites.

Efficacy and safety data collected at early termination visits will be included in the Month 3 and Month 6 analyses. Data collected on or prior to Day 112 (Day 84 + 28 Days) will be used for the Month 3 (Day 84) analyses. Data collected after Day 112 will be assigned to the Month 6 (Day 168) analyses.

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For efficacy endpoints that have multiple post-baseline visits, last observation carried forward will be presented for the Month 3 and Month 6 visits. The DXA (both central reader and CRF), Six Minute Walk, Short Physical Performance Battery and SF-36 Scales will also have a multiple imputation method performed to address missing data as discussed in section 2.17.

2.17. Multiple Imputation Method

The reason for using the Multiple Imputation Method is to minimize bias, maximize use of available information and obtain appropriate estimates of uncertainty.

A variable is said to be missing at random (MAR) if other variables (but not the variable itself) in the dataset can be used to predict missingness on a given variable, and the missing variable is not dependent upon the study conduct or the investigational product. For example, if the subject did not attend a visit (or missed the test within a visit) due to reasons other than a treatment related adverse event, lack of therapeutic effect, discontinuation of study by sponsor, ….

A variable is said to be missing not at random (MNAR) if the value of the observed variable itself predicts missingness or the missing of the variable is related to study conduct or the investigational product. For example, if the subject did not attend a visit (or missed the test within a visit) due to a treatment related adverse event, lack of therapeutic effect, discontinuation of study by sponsor, ….

If a value is determined to be MAR, the value is eligible to be imputed using the multiple imputation method. If a value is determined to be MNAR, the value is not eligible to be imputed using the multiple imputation method and can be replaced with the worst-case scenario or excluded from the analysis.

There are 3 steps to the Multiple Imputation Method: 1) Imputation, 2) Analysis and 3) Pooling.

Imputation

Similar to single imputation (for example, last observation carried forward), missing values are imputed. However, the imputed values are drawn *m* times from a distribution rather than just once. At the end of this step, there should be *m* completed datasets to analyze. The distribution of the missing variable is determined by using other information contained in the study data by establishing correlations and determining other possible relationships. SAS's procedure PROC MI is used during the imputation step.

Analysis

Each of the *m* datasets is analyzed as defined in the SAP. At the end of this step there should be the results from *m* analyses.

Pooling

The *m* results are consolidated into one result by calculating the mean, variance, and confidence interval of the variable of concern. SAS's procedure PROC MIANALYZE is used during the pooling step.

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2.18. Derivation of SF-36 Scales

The scoring algorithm used to derive the SF-36 scales is obtained from RAND Health (http://www.rand.org/health/surveys_tools/mos/36-item-short-form/scoring.html). The question numbering is different than indicated on RAND Health's web site, but the questions are analogous (the questions on the web site use the English (UK) terminology whereas the questions used in this study uses the English (US) terminology), so the methodology still applies. The question numbers on the web site have been translated to match the question numbers on the survey used in the study.

Step 1: Recoding Items

Item numbers	Change original response category *	To recoded value of:
1, 2, 6, 8, 9a, 9d, 9e, 9h, 11b, 11d	1 →	100
	2 →	75
	3 →	50
	4 →	25
	5 →	0
3a, 3b, 3c, 3d, 3e, 3f, 3g, 3h, 3i, 3j	1 →	0
	2 →	50
	3 →	100
4a, 4b, 4c, 4d, 5a, 5b, 5c, 9b, 9c, 9f, 9g, 9i	1 →	0
	2 →	25
	3	50
	4	75
	5	100
7	1 →	100
	2 →	80
	3 →	60
	4 →	40
	5 →	20
	6 →	0
10, 11a, 11c	1 →	0
	2 →	25
	3 →	50
	4 →	75

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	5 →	100

Step 2: Averaging Items to Form Scales

Scale	Number of items	After recoding per Table 1, average the following items
Physical functioning (PF)	10	3a 3b 3c 3d 3e 3f 3g 3h 3i 3j
Role limitations due to physical health (RP)	4	4a 4b 4c 4d
Role limitations due to emotional problems (RE)	3	5a 5b 5c
Vitality (VT)	4	9a 9e 9g 9i
Mental Health (MH)	5	9b 9c 9d 9f 9h
Social functioning (SF)	2	6 10
Bodily Pain (BP)	2	7 8
General health (GH)	5	1 11a 11b 11c 11d
Physical Health		Average PF RP BP GH Scales
Mental Heath		Average VT SF RE MH Scales

2.19. Protocol Deviations

Protocol deviations will be displayed in a data listing as provided by the clinical team.

2.20. Computer Systems and Packages Used for Statistical Analyses

SAS® version 9.4 on the Microsoft Windows 7 64 bit platform will be used for all analyses. All computations will be performed using SAS®. The exact form of the various algorithms will be the SAS® defaults. The output from any SAS® procedure will be used in the tables using SAS® macros.

3. Data Listing Shells

3.1. Data Listings Table of Contents

The following post-text listings will be generated.

Listing Number	Listing Title
16.1.7	Randomization Schedule
16.2.1.1	Screen Failure Status / Reason for Screen Failure
16.2.1.2	Subject Completion / Discontinuation
16.2.2	Protocol Deviations
16.2.3	Population Status
16.2.4.1	Demographics and Baseline Characteristics
16.2.4.2	Subject Eligibility and Informed Consent

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16.2.4.3	Medical History / Surgical History / Procedures
16.2.4.4.1	Substance Use - Alcohol History
16.2.4.4.2	Substance Use - Caffeine History
16.2.4.4.3	Substance Use - Nicotine History
16.2.4.5.1	Prior and Concomitant Medications
16.2.4.5.2	Bisphosphonate Therapy
16.2.4.6	Concomitant Non-Drug Treatment
16.2.4.7	Mini-Mental State Exam
16.2.4.8	4-Meter Walk
16.2.4.9	Meal Log
16.2.5.1	Drug Accountability
16.2.5.2	Drug Exposure
16.2.6.01.1	Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Central Reader
16.2.6.01.2	Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – As Reported on the Case Report Form
16.2.6.02	Plasma PK Concentrations
16.2.6.03	Six-Minute Walk Test (6MWT)
16.2.6.04	Borg Scale
16.2.6.05	Grip Strength
16.2.6.06	Short Physical Performance Battery (SPPB)
16.2.6.07	Physical Activities of Daily Living (PADLs)
16.2.6.08	Instrumental Activities of Daily Living (IADLs)
16.2.6.09	Short Form SF-36 - Responses
16.2.6.10	Short Form SF-36 - Scale Scores
16.2.6.11	Bone Turnover Markers
16.2.7.1	Adverse Events
16.2.7.2	Adverse Events Leading to Discontinuation of Study
16.2.7.3	Serious Adverse Events
16.2.8.1.1	Safety Laboratory Results - Hematology
16.2.8.1.2	Safety Laboratory Results – Chemistry
16.2.8.1.3	Safety Laboratory Results – Urinalysis
16.2.8.1.4	Other Laboratory Results
16.2.9.1	Vital Signs
16.2.9.2	Electrocardiogram Results
16.2.9.3	Physical Examination

3.2. Data Listings

All subjects and all data will be presented in the listings. The listings will be sorted by treatment and subject number.

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4. Summary Table and Figure Shells

4.1. Post-text Table of Contents

The following post-text tables will be generated.

Table Number	Table Title
14.1.1.1	Summary of Screening Status – All Subjects
14.1.1.2	Summary of Subject Disposition – Safety Population
14.1.1.3	Summary of Subject Disposition – Intent-to-Treat Population
14.1.1.4	Summary of Subject Disposition – Per Protocol Population
14.1.2.1	Summary of Demographics and Baseline Characteristics – All Subjects
14.1.2.2	Summary of Demographics and Baseline Characteristics – Safety Population
14.1.2.3	Summary of Demographics and Baseline Characteristics – Intent-to-Treat Population
14.1.2.4	Summary of Demographics and Baseline Characteristics – Per Protocol Population
14.1.3.1	Summary of Medical History – Safety Population
14.1.4.1	Summary of Prior Medications – Safety Population
14.1.4.2.1	Summary of Concomitant Medications at Baseline Visit – Safety Population
14.1.4.2.2	Summary of Concomitant Medications Taken During the Treatment Period – Safety Population
14.1.5.1	Summary of Study Drug Administration – Safety Population
14.1.5.2	Summary of Study Drug Administration – Intent-to-Treat Population
14.1.5.3	Summary of Study Drug Administration – Per Protocol Population
14.2.01.1.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Central Reader – Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.01.1.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Central Reader – Multiple Imputation Method - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.01.1.3	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Central Reader – Sex Effect - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.01.1.4	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Central Reader – Liberal Definition of Valid DXA - Intent-to-Treat Population

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Table Number	Table Title
14.2.01.1.5	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Central Reader – Multiple Imputation Method - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.01.1.6	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Central Reader – Sex Effect - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.01.2.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Central Reader - Stringent Definition of Valid DXA - Per Protocol Population
14.2.01.2.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Central Reader – Multiple Imputation Method - Stringent Definition of Valid DXA - Per Protocol Population
14.2.01.2.3	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Central Reader – Sex Effect - Stringent Definition of Valid DXA - Per Protocol Population
14.2.01.2.4	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Central Reader - Liberal Definition of Valid DXA - Per Protocol Population
14.2.01.2.5	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Central Reader – Multiple Imputation Method - Liberal Definition of Valid DXA - Per Protocol Population
14.2.01.2.6	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Central Reader – Sex Effect - Liberal Definition of Valid DXA - Per Protocol Population
14.2.02.1.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density – Central Reader - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.02.1.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density – Central Reader – Multiple Imputation Method - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.02.1.3	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density – Central Reader – Sex Effect - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.02.1.4	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density – Central Reader - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.02.1.5	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density – Central Reader –

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Table Number	Table Title
	Multiple Imputation Method - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.02.1.6	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density – Central Reader – Sex Effect - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.02.2.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density– Central Reader - Stringent Definition of Valid DXA - Per Protocol Population
14.2.02.2.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density– Central Reader – Multiple Imputation Method - Stringent Definition of Valid DXA - Per Protocol Population
14.2.02.2.3	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density– Central Reader – Sex Effect - Stringent Definition of Valid DXA - Per Protocol Population
14.2.02.2.4	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density– Central Reader - Liberal Definition of Valid DXA - Per Protocol Population
14.2.02.2.5	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density– Central Reader – Multiple Imputation Method - Liberal Definition of Valid DXA - Per Protocol Population
14.2.02.2.6	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density– Central Reader – Sex Effect - Liberal Definition of Valid DXA - Per Protocol Population
14.2.03.1.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Central Reader - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.03.1.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Central Reader – Multiple Imputation Method - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.03.1.3	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Central Reader – Sex Effect - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.03.1.4	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Central Reader - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.03.1.5	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Central Reader – Multiple Imputation Method - Liberal Definition of Valid DXA - Intent-to-Treat Population

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Table Number	Table Title
14.2.03.1.6	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Central Reader – Sex Effect - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.03.2.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Central Reader - Stringent Definition of Valid DXA - Per Protocol Population
14.2.03.2.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Central Reader – Multiple Imputation Method - Stringent Definition of Valid DXA - Per Protocol Population
14.2.03.2.3	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Central Reader – Sex Effect - Stringent Definition of Valid DXA - Per Protocol Population
14.2.03.2.4	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Central Reader - Liberal Definition of Valid DXA - Per Protocol Population
14.2.03.2.5	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Central Reader – Multiple Imputation Method - Liberal Definition of Valid DXA - Per Protocol Population
14.2.03.2.6	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Central Reader – Sex Effect - Liberal Definition of Valid DXA - Per Protocol Population
14.2.04.1.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Central Reader - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.04.1.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Central Reader – Multiple Imputation Method - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.04.1.3	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Central Reader – Sex Effect - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.04.1.4	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Central Reader - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.04.1.5	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Central Reader – Multiple Imputation Method - Liberal Definition of Valid DXA - Intent-to-Treat Population

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Table Number	Table Title
14.2.04.1.6	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Central Reader – Sex Effect - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.04.2.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Central Reader - Stringent Definition of Valid DXA - Per Protocol Population
14.2.04.2.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Central Reader – Multiple Imputation Method - Stringent Definition of Valid DXA - Per Protocol Population
14.2.04.2.3	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Central Reader –Sex Effect - Stringent Definition of Valid DXA - Per Protocol Population
14.2.04.2.4	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Central Reader - Liberal Definition of Valid DXA - Per Protocol Population
14.2.04.2.5	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Central Reader – Multiple Imputation Method - Liberal Definition of Valid DXA - Per Protocol Population
14.2.04.2.6	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Central Reader –Sex Effect - Liberal Definition of Valid DXA - Per Protocol Population
14.2.05.1	Correlations and Regression Analyses of Plasma Concentrations of VK5211 near Tmax and at trough levels in relation to total lean body mass – Intent-to-Treat Population
14.2.05.2	Correlations and Regression Analyses Plasma Concentrations of VK5211 near Tmax and at trough levels in relation to total lean body mass – Per Protocol Population
14.2.06.1	Summary of 6-Minute Walk Test – Intent-to-Treat Population
14.2.06.1.1	Summary of 6-Minute Walk Test – Multiple Imputation Method - Intent-to-Treat Population
14.2.06.1.2	Summary of 6-Minute Walk Test – Sex Effect - Intent-to-Treat Population
14.2.06.2	Summary of 6-Minute Walk Test – Per Protocol Population
14.2.06.2.1	Summary of 6-Minute Walk Test – Multiple Imputation Method - Per Protocol Population
14.2.06.2.2	Summary of 6-Minute Walk Test – Sex Effect - Per Protocol Population
14.2.07.1	Summary of Borg Scale – Intent-to-Treat Population
14.2.07.2	Summary of Borg Scale – Per Protocol Population

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Table Number	Table Title
14.2.08.1	Summary of Grip Strength – Intent-to-Treat Population
14.2.08.2	Summary of Grip Strength – Per Protocol Population
14.2.09.1	Summary of Short Physical Performance Battery (SPPB) – Intent-to-Treat Population
14.2.09.1.1	Summary of Short Physical Performance Battery (SPPB) – Multiple Imputation Method - Intent-to-Treat Population
14.2.09.1.2	Summary of Short Physical Performance Battery (SPPB) – Sex Effect - Intent-to-Treat Population
14.2.09.2	Summary of Short Physical Performance Battery (SPPB) – Per Protocol Population
14.2.09.2.1	Summary of Short Physical Performance Battery (SPPB) – Multiple Imputation Method - Per Protocol Population
14.2.09.2.2	Summary of Short Physical Performance Battery (SPPB) – Sex Effect - Per Protocol Population
14.2.10.1	Summary of Physical Activities of Daily Living (PADL) – Intent-to-Treat Population
14.2.10.2	Summary of Physical Activities of Daily Living (PADL) – Per Protocol Population
14.2.11.1	Summary of Instrumental Activities of Daily Living (IADL) – Intent-to-Treat Population
14.2.11.2	Summary of Instrumental Activities of Daily Living (IADL) – Per Protocol Population
14.2.12.1	Summary of Short Form-36 (SF-36) Responses – Intent-to-Treat Population
14.2.12.2	Summary of Short Form-36 (SF-36) Responses – Per Protocol Population
14.2.13.1	Summary of Short Form-36 (SF-36) Scales – Intent-to-Treat Population
14.2.13.1.1	Summary of Short Form-36 (SF-36) Scales – Multiple Imputation Method - Intent-to-Treat Population
14.2.13.1.2	Summary of Short Form-36 (SF-36) Scales – Sex Effect - Intent-to-Treat Population
14.2.13.2	Summary of Short Form-36 (SF-36) Scales – Per Protocol Population
14.2.13.2.1	Summary of Short Form-36 (SF-36) Scales – Multiple Imputation Method - Per Protocol Population
14.2.13.2.2	Summary of Short Form-36 (SF-36) Scales – Sex Effect - Per Protocol Population
14.2.14.1	Summary of Bone Turnover Markers – Intent-to-Treat Population
14.2.14.2	Summary of Bone Turnover Markers – Per Protocol Population
14.2.15.1.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Site Results with DXA

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Table Number	Table Title
	Type Correction Factor - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.15.1.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Site Results with DXA Type Correction Factor – Multiple Imputation Method - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.15.1.3	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Site Results with DXA Type Correction Factor – Sex Effect - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.15.1.4	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Site Results with DXA Type Correction Factor - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.15.1.5	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Site Results with DXA Type Correction Factor – Multiple Imputation Method - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.15.1.6	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Site Results with DXA Type Correction Factor – Sex Effect - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.15.2.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Site Results with DXA Type Correction Factor - Stringent Definition of Valid DXA - Per Protocol Population
14.2.15.2.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Site Results with DXA Type Correction Factor – Multiple Imputation Method - Stringent Definition of Valid DXA - Per Protocol Population
14.2.15.2.3	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Site Results with DXA Type Correction Factor – Sex Effect - Stringent Definition of Valid DXA - Per Protocol Population
14.2.15.2.4	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Site Results with DXA Type Correction Factor - Liberal Definition of Valid DXA - Per Protocol Population
14.2.15.2.5	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Site Results with DXA Type Correction Factor – Multiple Imputation Method - Liberal Definition of Valid DXA - Per Protocol Population
14.2.15.2.6	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head – Site Results with DXA Type Correction Factor – Sex Effect – Liberal Definition of Valid DXA - Per Protocol Population

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Table Number	Table Title
14.2.16.1.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density – Site Results with DXA Type Correction Factor - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.16.1.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density – Site Results with DXA Type Correction Factor – Multiple Imputation Method - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.16.1.3	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density – Site Results with DXA Type Correction Factor –Sex Effect - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.16.1.4	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density – Site Results with DXA Type Correction Factor - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.16.1.5	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density – Site Results with DXA Type Correction Factor – Multiple Imputation Method - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.16.1.6	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density – Site Results with DXA Type Correction Factor –Sex Effect - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.16.2.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density– Site Results with DXA Type Correction Factor - Stringent Definition of Valid DXA - Per Protocol Population
14.2.16.2.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density– Site Results with DXA Type Correction Factor – Stringent Definition of Valid DXA - Multiple Imputation Method - Per Protocol Population
14.2.16.2.3	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density– Site Results with DXA Type Correction Factor – Sex Effect - Stringent Definition of Valid DXA - Per Protocol Population
14.2.16.2.4	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density– Site Results with DXA Type Correction Factor - Liberal Definition of Valid DXA - Per Protocol Population
14.2.16.2.5	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density– Site Results with DXA Type Correction Factor – Liberal Definition of Valid DXA - Multiple Imputation Method - Per Protocol Population
14.2.16.2.6	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density– Site Results with

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Table Number	Table Title
	DXA Type Correction Factor – Sex Effect - Liberal Definition of Valid DXA - Per Protocol Population
14.2.17.1.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Site Results with DXA Type Correction Factor - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.17.1.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Site Results with DXA Type Correction Factor – Multiple Imputation Method - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.17.1.3	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Site Results with DXA Type Correction Factor – Sex Effect - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.17.1.4	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Site Results with DXA Type Correction Factor - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.17.1.5	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Site Results with DXA Type Correction Factor – Multiple Imputation Method - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.17.1.6	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Site Results with DXA Type Correction Factor – Sex Effect - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.17.2.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Site Results with DXA Type Correction Factor - Stringent Definition of Valid DXA - Per Protocol Population
14.2.17.2.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Site Results with DXA Type Correction Factor – Multiple Imputation Method - Stringent Definition of Valid DXA - Per Protocol Population
14.2.17.2.3	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Site Results with DXA Type Correction Factor – Sex Effect - Stringent Definition of Valid DXA - Per Protocol Population
14.2.17.2.4	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Site Results with DXA Type Correction Factor - Liberal Definition of Valid DXA - Per Protocol Population
14.2.17.2.5	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Site Results with DXA Type Correction Factor – Multiple Imputation Method - Liberal Definition of Valid DXA - Per Protocol Population

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Table Number	Table Title
14.2.17.2.6	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Site Results with DXA Type Correction Factor – Sex Effect - Liberal Definition of Valid DXA - Per Protocol Population
14.2.18.1.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Site Results with DXA Type Correction Factor - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.18.1.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Site Results with DXA Type Correction Factor – Multiple Imputation Method - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.18.1.3	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Site Results with DXA Type Correction Factor – Sex Effect - Stringent Definition of Valid DXA - Intent-to-Treat Population
14.2.18.1.4	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Site Results with DXA Type Correction Factor - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.18.1.5	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Site Results with DXA Type Correction Factor – Multiple Imputation Method - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.18.1.6	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Site Results with DXA Type Correction Factor – Sex Effect - Liberal Definition of Valid DXA - Intent-to-Treat Population
14.2.18.2.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Site Results with DXA Type Correction Factor - Stringent Definition of Valid DXA - Per Protocol Population
14.2.18.2.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Site Results with DXA Type Correction Factor – Multiple Imputation Method - Stringent Definition of Valid DXA - Per Protocol Population
14.2.18.2.3	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Site Results with DXA Type Correction Factor – Sex Effect - Stringent Definition of Valid DXA - Per Protocol Population
14.2.18.2.4	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Site Results with DXA Type Correction Factor - Liberal Definition of Valid DXA - Per Protocol Population

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Table Number	Table Title
14.2.18.2.5	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Site Results with DXA Type Correction Factor – Multiple Imputation Method - Liberal Definition of Valid DXA - Per Protocol Population
14.2.18.2.6	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Site Results with DXA Type Correction Factor – Sex Effect - Liberal Definition of Valid DXA - Per Protocol Population
14.3.1.1.1	Summary of Adverse Events – Safety Population
14.3.1.1.2	Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term – Safety Population
14.3.1.1.3	Summary of Treatment Emergent Adverse Events in Decreasing Order of Frequency by Preferred Term – Safety Population
14.3.1.1.4	Summary of Treatment Emergent Adverse Events by Severity – Safety Population
14.3.2.1	Summary of Treatment Emergent Adverse Events Leading to Discontinuation by System Organ Class and Preferred Term – Safety Population
14.3.2.2.1	Summary of Serious Adverse Events by System Organ Class and Preferred Term – Safety Population
14.3.2.2.2	Summary of Serious Adverse Events in Decreasing Order of Frequency by Preferred Term – Safety Population
14.3.3.1	Summary of Liver Function Tests – Safety Population
14.3.3.2	Summary of Safety Lab Parameters – Hematology – Safety Population
14.3.3.3	Summary of Safety Lab Parameters – Chemistry – Safety Population
14.3.3.4	Summary of Safety Lab Parameters – Urinalysis – Safety Population
14.3.4.1	Shifts in Liver Function Tests – Safety Population
14.3.4.2	Shifts in Selected Lab Parameters by CTC Grade – Safety Population
14.3.4.3	Shifts in Safety Lab Parameters – Hematology – Safety Population
14.3.4.4	Shifts in Safety Lab Parameters – Chemistry – Safety Population
14.3.5	Summary of Vital Signs – Safety Population
14.3.6	Summary of Electrocardiogram Results – Safety Population
14.3.7	Summary of Physical Exam Findings – Safety Population

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4.2. Post-text Figures Tables of Contents

The following post-text figures will be generated.

Figure Number	Figure Title
14.2.01.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head Lean Body Mass – Central Reader - Intent-to-Treat
14.2.01.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Body Less Head Lean Body Mass – Central Reader- Per Protocol Population
14.2.02.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density – Central Reader - Intent-to-Treat
14.2.02.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Hip Bone Mineral Density – Central Reader- Per Protocol Population
14.2.03.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Central Reader - Intent-to-Treat
14.2.03.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Total Lean Body Mass – Central Reader- Per Protocol Population
14.2.04.1	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Central Reader - Intent-to-Treat
14.2.04.2	Summary of Whole Body Dual Energy X-Ray Absorptiometry (DXA) scan – Appendicular Lean Body Mass – Central Reader- Per Protocol Population
14.2.05.1	Correlations and Regression Analyses of Plasma Concentrations of VK5211 near Tmax and at Trough Levels in Relation to Lean Body Mass – Intent-to-Treat Population
14.2.05.2	Correlation and Regression Analyses of Plasma Concentrations of VK5211 near Tmax and at Trough Levels in Relation to Lean Body Mass – Per Protocol Population
14.2.06.1	Summary of Bone Turnover Markers – Intent-to-Treat Population
14.2.06.2	Summary of Bone Turnover Markers – Per Protocol Population
14.2.07.1	Summary of 6-Minute Walk Test – Intent-to-Treat Population
14.2.07.2	Summary of 6-Minute Walk Test – Per Protocol Population
14.2.08.1	Summary of Borg Scale – Intent-to-Treat Population
14.2.08.2	Summary of Borg Scale – Per Protocol Population
14.2.09.1	Summary of Grip Strength – Intent-to-Treat Population
14.2.09.2	Summary of Grip Strength – Per Protocol Population

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14.2.10.1	Summary of Short Physical Performance Battery (SPPB) – Intent-to-Treat Population
14.2.10.2	Summary of Short Physical Performance Battery (SPPB) – Per Protocol Population
14.2.11.1	Summary of Physical Activitis of Daily Living (PADL) – Intent-to-Treat Population
14.2.11.2	Summary of Physical Activitis of Daily Living (PADL) – Per Protocol Population
14.2.12.1	Summary of Instrumental Activities of Daily Living (IADL) – Intent-to-Treat Population
14.2.12.2	Summary of Instrumental Activities of Daily Living (IADL) – Per Protocol Population
14.2.13.1	Summary of Short Form-36 (SF-36) Responses – Intent-to-Treat Population
14.2.13.2	Summary of Short Form-36 (SF-36) Responses – Per Protocol Population
14.2.14.1	Summary of Short Form-36 (SF-36) Scales – Intent-to-Treat Population
14.2.14.2	Summary of Short Form-36 (SF-36) Scales – Per Protocol Population

4.3. Table Shells

The table shells can be found in a separate file. The following number of decimal places will be used when presenting summary statistics:

- N to 0 decimal places
- Minimum and maximum to the same number of decimal places as recorded in the raw data.
- Means and medians, and confidence intervals to 1 more decimal place than is recorded in the raw data. Standard deviations to 2 more decimal places than is recorded in the raw data.
- Percentages to 1 decimal place.

The precision may be changed for individual endpoints as needed.

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