Statistical Analysis Plan

Viromed Co., Ltd

US 06-1-001

A Phase I, Dose-Escalation, Single Center Study to Assess the Safety and Tolerability of VM202 in Subjects with Critical Limb Ischemia

Protocol Version 5.0- November 29, 2007

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Version: 2

Date of Creation: September 14, 2007

Last Updated: January 10, 2008

TABLE OF CONTENTS

LIST OF ABBREVIATIONS **4**

DEFINITIONS **6**

1. INTRODUCTION **7**

2. OBJECTIVES **7**

2.1 PRIMARY OBJECTIVE 7
2.2 SECONDARY OBJECTIVES 7

3. STUDY OVERVIEW **7**

4. GENERAL ANALYSIS CONSIDERATIONS **8**

5. ANALYSIS POPULATIONS **9**

6. SUBJECT DISPOSITION **9**

7. DEMOGRAPHIC AND BASELINE CHARACTERISTICS **9**

8. EFFICACY ANALYSES **9**

8.1 EFFICACY VARIABLES 9
8.2 BASELINE VALUES 10
8.3 HANDLING MISSING DATA 10
8.4 INTERIM ANALYSES 10
8.5 MULTIPLICITY ADJUSTMENTS 10
8.6 BY CENTER ANALYSES 10

9. METHODS OF EFFICACY ANALYSIS **10**

9.1 AREA OF ISCHEMIC ULCER 10
9.2 HEMODYNAMIC ASSESSMENTS 11
9.3 VISUAL ANALOGUE SCALE FOR PAIN 11
9.4 TRANSCUTANEOUS OXYGEN PRESSURE ASSESSMENT 11
9.5 SUBJECT ANALGESIC USE 11
9.6 HIGH RESOLUTION MRA 12

10. SAFETY ANALYSES **12**

10.1 STUDY DRUG EXPOSURE 12
10.2 ADVERSE EVENTS 12
10.3 CLINICAL LABORATORY EVALUATION 13
10.4 PHYSICAL EXAMINATIONS 13
10.5 VITAL SIGNS 13
10.6 RETINAL FUNDOSCOPY 14
10.7 INFECTION TESTS 14
10.8 TUMOR MARKER 14
10.9 INJECTION SITE REACTION 14
10.10 PRIOR AND CONCOMITANT MEDICATIONS 14

11. PHARMACOKINETICS 15

12. PHARMACODYNAMICS 15

APPENDIX A: LIST OF TABLES AND LISTINGS 16

APPENDIX B: TABLE LAYOUTS 20

LIST OF ABBREVIATIONS

ABI	ankle-brachial index
AE	adverse event
ALT	alanine transaminase (SGPT)
AST	aspartate transaminase (SGOT)
AUC	area under the plasma concentration time curve
BUN	blood urea nitrogen
°C	degrees Celsius
CBC	complete blood count
cDNA	complementary deoxyribonucleic acid
CHF	congestive heart failure
CFR	Code of Federal Regulation
CLI	critical limb ischemia
Cm	centimeter(s)
C_{max}	maximum concentration of drug
CRF	case report form
CRO	clinical research organization
CVD	cardiovascular disease
D	day(s)
dL	deciliter(s)
DSMC	Data Safety Monitoring Committee
ECG	electrocardiogram
ET	endothelin
°F	degrees Fahrenheit
FDA	Food and Drug Administration
G	gram(s)
GCP	Good Clinical Practices
HGF	hepatocyte growth factor
IBC	Institutional Biosafety Committee
ICH	International Conference on Harmonisation
IDUR	investigational drug utilization record
IND	Investigational New Drug
INR	international normalized ratio
IRB	Institutional Review Board
IV	intravenous
IVRS	Interactive Voice Response System
Kg	kilogram(s)
LOCF	last observation carried forward

LIST OF ABBREVIATIONS (CONTINUED)

LV	left ventricular
Mg	milligram(s)
Min	minute(s)
mmHg	millimeters mercury
MRA	magnetic resonance angiography
MTD	maximum tolerated dose
N	number
Ng	nanogram(s)
NIH	National Institutes of Health
NYHA	New York Heart Association
O_2	oxygen
OBA	Office of Biotechnology Activities
PAD	peripheral artery disease
pH	hydrogen ion concentration
PHI	protected health information
PPG	photoplethysmograph
PTA	percutaneous transluminal angioplasty
QD	once daily
RBC	red blood count
SAE	serious adverse event
SAP	Statistical Analysis Plan
sDBP	sitting diastolic blood pressure
SE	standard error
SGPT	serum glutamic pyruvic transaminase (same as ALT)
SOC	System Organ Class
SVR	systemic vascular resistance
$t_{½}$	elimination half-life
t_{max}	time of occurrence for maximum (peak) drug concentration
TBI	toe-brachial index
$TcPO_2$	Transcutaneous Oxygen Pressure Assessment
VAS	visual analog scale
VEGF	vascular endothelial growth factor
vs.	versus
WBC	white blood count
WHO	World Health Organization

DEFINITIONS

Adverse Event	An adverse event (AE) is the development of an undesirable medical condition following or during exposure to a pharmaceutical product, whether or not considered causally related to the product.
Baseline	The last non-missing value prior to first dose of study drug.
Serious AE	An AE occurring at any dose that: results in death; is a life-threatening experience; requires hospitalization or prolongation of an existing hospitalization; results in a persistent or significant disability/incapacity; or is a congenital anomaly/birth defect in the offspring of a subject who received study drug.
Treatment-emergent AE	AEs with an onset time after the initial dose of study drug.

1. INTRODUCTION

This document outlines the statistical methods to be implemented during the analyses of data collected within the scope of ViroMed Co., Ltd. Protocol US 06-1-001 [A Phase I, Dose-Escalation, Single Center Study to Assess the Safety and Tolerability of VM202 in Subjects with Critical Limb Ischemia]. The purpose of this plan is to provide specific guidelines from which the analysis will proceed. Any deviations from these guidelines will be documented in the clinical study report (CSR).

2. OBJECTIVES

2.1 Primary Objective

The primary objective of this study is to evaluate the safety and tolerability of intramuscular VM202 as a vehicle for therapeutic angiogenesis in subjects with critical limb ischemia.

2.2 Secondary Objectives

The secondary objectives of the study will include the following exploratory evaluations:

- To investigate the effects of the intramuscular VM202 to improve pain at rest and/or to heal ischemic ulcers of the affected limb. The VAS assessment tool will be used for this evaluation;
- To evaluate the anatomic and physiological extent of collateral vessel development in subjects with critical limb ischemia as measured by MRA;
- To evaluate the change in serum HGF levels from Day 1 to Day 59;
- To evaluate the change in VM202 DNA levels from Day 1 to Day 59;
- To evaluate the immune response to HGF in subjects with CLI as measured by the change in anti-HGF antibodies from Day 1;
- To evaluate the ability of VM202 to stimulate endothelial progenitor cells as measured by the change in endothelial cell progenitor assay levels from screening to Day 59.

3. STUDY OVERVIEW

This is a prospective, dose-escalation single center study to evaluate the safety and tolerability of intramuscular VM202 in subjects with critical limb ischemia.

Subjects selected for this study will have critical limb ischemia that has not responded to standard therapy with symptoms including pain at rest or ischemic ulcers.

The study will consist of four (4) cohorts with a total of 3 subjects enrolled in each cohort to VM202. The cohorts will be based on the planned different amounts of VM202 to be given. Planned levels of VM202 to be administered (defining the 4 cohorts) are the following: 2 mg, 4 mg, 8 mg and 16 mg. For each dose cohort, VM202 will be administered as a local intramuscular injection in 2 divided doses with a 2-week interval between the injections. Preliminary efficacy (hemodynamic assessments), safety and tolerability will be evaluated at Baseline (screening) and at designated time points throughout the study.

After all subjects in the first dose cohort have completed the 30-day (± 2 days) follow-up visit following the 1st dose of study drug, an interim safety evaluation will be performed with the submission of safety data to the Data Safety Monitoring Committee (DSMC). If the DSMC recommends continuing the study, the second dose cohort will be treated. This process will be repeated between the second and third dose cohort and between the third and fourth dose cohort. All 4 dose cohorts will be followed for up to five years from the time of the first dose of study drug administration. If a dose limiting toxicity (DLT) is observed in one subject in any dose group, three additional subjects will be added to the dose cohort in which the toxicity was observed. If no additional DLTs are observed in the 6 subjects in this dose level, it will be considered the maximum tolerated dose (MTD). If a DLT occurs in 2/6 subjects, then the preceding dose level will be considered the MTD.

4. GENERAL ANALYSIS CONSIDERATIONS

The statistical analyses will be reported using summary tables, figures, and data listings. Continuous variables will be summarized with means, standard deviations, medians, minimums, and maximums. Categorical variables will be summarized by counts and by percentage of subjects in corresponding categories.

Individual subject data obtained from the case report forms (CRFs), pharmacokinetic/ pharmacodynamic data, and any derived data will be presented by subject in data listings.

All analyses and tabulations will be performed using SAS® Version 8.2 or higher on a PC platform. Tables and listings will be presented in RTF format. Upon completion, all SAS® programs will be validated by an independent programmer. In addition, all program output will undergo a senior level statistical review. The validation process will be used to confirm that statistically valid methods have been implemented and that all data manipulations and calculations are accurate. Checks will be made to ensure accuracy, consistency with this plan, consistency within tables, and consistency between tables and

corresponding data listings. Upon completion of validation and quality review procedures, all documentation will be collected and filed by the project statistician or designee.

5. ANALYSIS POPULATIONS

The following subject populations will be used for analysis:

The Safety population will include all subjects who received at least one dose of study drug medication. Safety analysis will be performed on the Safety population.

The Intent-to-Treat (ITT) population will include all subjects who received at least one dose of study drug medication and had at least one post dose assessment. Efficacy, pharmacokinetic (PK) and pharmacodynamic (PD) analysis will be performed on the ITT population.

6. SUBJECT DISPOSITION

Subject disposition information will be summarized for all subjects by dose cohort. Summaries will include: the number of enrolled subjects, the number of subjects in each analysis population, the number of subjects who received both planned doses of VM202, the last scheduled visit completed, the number of subjects completing the study and the primary reason for discontinuation.

7. DEMOGRAPHIC AND BASELINE CHARACTERISTICS

Demographic variables include: age, sex, ethnicity, race. Medical history and peripheral vascular disease intervention history at baseline will also be considered. Demographic and baseline characteristics will be summarized for the Safety and ITT analysis populations.

8. EFFICACY ANALYSES

Efficacy analysis will be based on the ITT analysis population. The efficacy analysis generated for this study is intended to be used for preliminary and exploratory considerations and is not meant to be confirmatory in nature.

8.1 Efficacy Variables

The following efficacy endpoints of equal interest will be collected and analyzed:

- Area of Ischemic Ulcer (largest contiguous area of ulceration)
- Hemodynamic Assessments to include:
    1. Ankle-Brachial Index (ABI)

2. Toe-Brachial Index (TBI)
3. Wave Form Analysis (PVR);

- Pain Visual Analogue Scale (VAS) Score;
- Transcutaneous Oxygen Pressure Assessment ($TcPO_2$);
- Subject Analgesic Use;
- High resolution MRA.

8.2 Baseline Values

The baseline value for each variable is the value recorded at the last visit on or before start of dosing. In most cases, baseline values are expected to be based on the assessment collected at the Day 1 (Pre-Dose) visit.

8.3 Handling Missing Data

Only data collected will be used for analysis. Missing values will not be imputed for this study.

8.4 Interim Analyses

No interim analysis of efficacy data is planned.

8.5 Multiplicity Adjustments

No alpha adjustments for multiple comparisons will be made since this is an open-label study with no formal cohort comparisons.

8.6 By Center Analyses

As this is a single center study, no by-center analysis is planned.

9. METHODS OF EFFICACY ANALYSIS

9.1 Area of Ischemic Ulcer

For each subject, the ulcer with the largest contiguous area will be measured both before and after the first dose of study medication. Planned post dose measurements of the ulcer include measurements at Day 15 (Pre-Dose), Day 28, Day 59, Day 91, Day 180 and Day 365. Ulcer measurements will be summarized using descriptive statistics at baseline and at each post baseline time point. Changes from baseline will also be summarized.

9.2 Hemodynamic Assessments

Hemodynamic assessments will be taken before the first dose of medication and at Day 15 (Pre-Dose), Day 28, Day 59, Day 91, Day 180 and Day 365. Hemodynamic assessments will be summarized using descriptive statistics at baseline and at each post baseline time point. Changes from baseline will also be summarized. Hemodynamic assessments, all in units of mmHg, include the following:

- Ankle Brachial-Index – measurements taken on both legs. Counts and percentages of the index limb (right/left) will be also be presented;
- Toe Brachial-Index – measurements taken on toe of right and left foot.

Confirmation that wave form analysis (PVR) was collected will be presented in listings.

9.3 Visual Analogue Scale for Pain

Throughout the study, subjects will be asked to assess the level of pain they feel by placing a perpendicular line on a scale of 0 (No Pain) to 100 (Pain as bad as it can be). The subject's Visual Analogue Scale (VAS) score will be determined by where the subject places the perpendicular line. Measurements of VAS will be collected prior to first study drug administration and at Day 15 (Pre-Dose), Day 28, Day 59, Day 91, Day 180 and Day 365 of the study. VAS measurements will be summarized using descriptive statistics at baseline and at each post baseline time point. Changes from baseline will also be summarized.

9.4 Transcutaneous Oxygen Pressure Assessment

Before the first dose of medication and at Day 15 (Pre-Dose), Day 28, Day 59, Day 91, Day 180 and Day 365 of the study, assessments of the transcutaneous oxygen pressure ($TcPO_2$) in various regions of the body will be taken. Those regions include assessments of the anterior calf, posterior calf, dorsum foot and chest. $TcPO_2$ measurements for each body region will be summarized using descriptive statistics at baseline and at each post baseline time point. Changes from baseline will also be summarized.

9.5 Subject Analgesic Use

Concomitant medication use will be collected throughout the study on an ongoing basis. A review of concomitant medications used by subjects will be carried out to determine which concomitant medications were administered for analgesic use. Based on the review of concomitant medications, subjects will be classified as either having used an analgesic or not. Counts and percentages showing the number of subjects having used or not having used analgesics will be presented.

9.6 High Resolution MRA

Occluded arteries will be identified as one of the following categories on CRFs: Super femoral artery (SFA), popliteal, peroneal, anterior tibeal, post tibial, infrapopliteal. Information regarding occluded arteries will be presented in listings. The quantitative blood flow of the target occluded artery and the volumetric analysis of newly developed artery will be not be recorded on the CRF. That information will be in a separate report compiled by the site and another vendor.

10. SAFETY ANALYSES

All subjects who received study drug will be included in the safety analyses, analyzed according to the study treatment actually received.

10.1 Study Drug Exposure

Study drug exposure will be summarized by dose cohort for Day 1 (planned first dose of VM202) and Day 15 (planned second dose of VM202). Categorical variables to be summarized using counts and percentages include "Was dose administered?" (Yes, No), the zone of the dose administration (I, II, III, IV, V, VI) and "Was the total volume of dose administered per protocol?" (Yes, No). In addition, the volume of study drug administered (continuous variable) will be summarized in minutes using summary statistics.

10.2 Adverse Events

All adverse event summaries will be restricted to Treatment Emergent Adverse Events (TEAE), which are defined as those AEs that occurred after dosing and those existing AEs that worsened during the study. Verbatim terms on case report forms will be mapped to preferred terms and system organ classes using the MedDRA dictionary (version 9.1).

Each adverse event summary will be displayed by dose cohort. Summaries that are displayed by system organ class and preferred terms will be ordered by descending order of incidence of system organ class and preferred term within each system organ class. Summaries of the following types will be presented:

- Subject incidence of TEAEs and total number of unique TEAEs by MedDRA system organ class and preferred term;
- Subject incidence of TEAEs by MedDRA system organ class, preferred term, and highest severity. At each level of subject summarization a subject is classified according to the highest severity if the subject reported one or more events. AEs with missing severity will be considered severe for this summary;

- Subject incidence of TEAEs by MedDRA system organ class, preferred term, and closest relationship to study drug (Related/Not Related). At each level of subject summarization a subject is classified according to the closest relationship if the subject reported one or more events. AEs with a missing relationship will be considered related for this summary;
- Subject incidence of serious TEAEs and total number of unique serious TEAEs by MedDRA system organ class and preferred term.

10.3 Clinical Laboratory Evaluation

Before the first dose of medication and at Day 15 (Pre-Dose), Day 16, Day 28, Day 59, Day 91, Day 180 and Day 365 of the study, clinical laboratory evaluations (Hematology, Chemistry, Urinalysis) will be taken. Laboratory parameters will be summarized using descriptive statistics at baseline and at each post baseline time point. Changes from baseline will also be summarized. Baseline is defined as the last non-missing value prior to first dose of study drug.

In addition, shift tables (i.e., low-normal-high at baseline versus low-normal-high at follow-up in a 3-by-3 contingency table) will be provided to assess changes in laboratory values from baseline to most abnormal follow-up result.

10.4 Physical Examinations

At Screening, a physical examination will be carried out on the following body systems: HEENT, Skin/Dermatologic, Lymph Nodes, Chest/Lungs, Heart/Cardiovascular, Abdomen, Extremities, Neurologic, Stool for Occult Blood, Other. Assessments for each of the body systems will be one of the following: Normal, Abnormal-Not Clinically Significant, Abnormal-Clinically Significant, Not Done. At Day 15 (Pre-Dose), Day 28, Day 59, Day 91, Day 180 and Day 365, changes in any of the body systems will be recorded.

Shift tables will be provided to assess changes in body systems from baseline to each follow up visit.

10.5 Vital Signs

At each visit, vital signs will be collected. Additional vital signs will be collected on the days of dosing (Day 1 and Day 15) at 15, 30 and 60 minutes post dose. Vital signs will be summarized using descriptive statistics at baseline and at each post baseline time point.

Changes from baseline will also be summarized. Baseline is defined as the last non-missing value prior to first dose of study drug.

10.6 Retinal Fundoscopy

A retinal fundoscopy of each eye will be performed at Screening and at Day 365. Each eye will be given one of the following assignments: Normal, Abnormal-Not Clinically Significant, Abnormal-Clinically Significant. Shift tables will be provided to assess changes in retinal fundoscopy.

10.7 Infection Tests

Tests will be carried out to determine the presence of selected infections at Screening and on Day 59, Day 180 and Day 365. Infections to be tested will include Hepatitis BSAg, HCV, HTLV, CMV and VDRL. The counts and percentages of number of subjects reporting a positive infection test will be presented by visit and infection type.

10.8 Tumor Marker

Measurements of selected tumor markers will be made at Screening, Day 59, Day 180 and Day 365. Tumor markers to be considered are the following: Alpha Fetoprotein (AFP), Carcino Embryonic Antigen (CEA), Prostate Specific Antigen (PSA), Cancer Antigen 19-9 (CA19-9), CA 125. Tumor marker results will be summarized using descriptive statistics at baseline and at each post baseline time point. Changes from baseline will also be summarized.

10.9 Injection Site Reaction

Assessments of the existence of an injection site reaction are planned for Day 1 (Post-Dose), Day 8, Day 15 (Post-Dose), Day 16, Day 21, Day 28 and Day 59. The number and percentage of subjects with an injection site reaction will be summarized.

10.10 Prior and Concomitant Medications

Verbatim terms on case report forms will be mapped to Anatomical/Therapeutic/Chemical (ATC) Level 4 categories and Drug Reference Names using the World Heath Organization (WHO) dictionary (version 5.3).

Prior medications are those medications taken within 30 days prior to the initial dose of study drug. Concomitant medications are those medications taken after the initial dose of study drug. Prior and concomitant medications will be summarized for each treatment by

WHO ATC class and medication name. These summaries will present the number and percentage of subjects using each medication. Subjects may have more than one medication per ATC category and medication. At each level of subject summarization, a subject is counted once if he/she reported one or more medications at that level. Each summary will be ordered by descending order of incidence of ATC class and medication within each ATC class.

11. PHARMACOKINETICS

VM202 DNA levels will be determined before dose on Day 1. In addition, VM202 DNA levels will be collected on Day 21 and Day 59 (if DNA is detected on Day 21). VM202 DNA level results will be summarized using descriptive statistics at baseline and at each post baseline time point. Changes from baseline will also be summarized.

12. PHARMACODYNAMICS

An endothelial progenitor cell assay test will be performed at Screening, Day 1 (Post Dose), Day 15 (Post Dose), Day 28, Day 59, Day 180 and Day 365. Endothelial progenitor cell assay test results will be summarized using descriptive statistics at baseline and at each post baseline time point. Changes from baseline will also be summarized.

Serum HGF levels will be collected at Day 1 (Pre-Dose), Day 8, Day 15 (Pre-Dose), Day 21 and Day 59. Results and changes from baseline will be presented by time point.

Anti-HGF antibodies data will be collected on Day 1 (Pre-Dose), Day 15 (Pre-Dose), Day 59 and possibly Day 180. Results will be presented in listings.

APPENDIX A: LIST OF TABLES AND LISTINGS

List of Tables

Table Number	Table Description
1	Subject Disposition
2	Demographic Characteristics (ITT/Safety Population)
3	Abnormal Medical History at Baseline (Safety Population)
4	Peripheral Vascular Disease Intervention History (Safety Population)
5	Ulcer Measurement (ITT Population)
6	Ankle Brachial-Index (ITT Population)
7	Toe Brachial-Index (ITT Population)
8	Visual Analogue Scale for Pain (ITT Population)
9	Transcutaneous Oxygen Pressure Assessment- $TcPO_2$ (ITT Population)
10	Subject Analgesic Use (ITT Population)
11	Study Drug Exposure(Safety Population)
12	Treatment Emergent Adverse Events by Cohort (Safety Population)
13	Treatment Emergent Adverse Events by System Organ Class and Severity (Safety Population)
14	Treatment Emergent Adverse Events by System Organ Class and Relationship to Study (Safety Population)
15	Treatment Emergent Serious Adverse Events by Cohort (Safety Population)
16.1	Hematology (Safety Population)
16.2	Chemistry (Safety Population)
16.3	Urinalysis (Safety Population)
17.1	Hematology – Shift from Baseline (Safety Population)
17.2	Chemistry – Shift from Baseline (Safety Population)
17.3	Urinalysis – Shift from Baseline (Safety Population)
18	Physical Examinations- Shift from Baseline (Safety Population)
19	Vital Signs (Safety Population)
20	Retinal Fundoscopy- Shift from Baseline (Safety Population)
21	Infection Tests (Safety Population)
22	Tumor Markers (Safety Population)
23	Injection Site Reaction (Safety Population)
24	Concomitant Medications (Safety Population)

List of Tables (cont)

Table Number	Table Description
25	VM202 DNA Levels (ITT Population)
26	Endothelial Progenitor Cell Assay (ITT Population)
27	Serum HGF Levels (ITT Population)

List of Data Listings

Listing Number	Listing Description	CRF Plate(s)
1	Subject Disposition (including Informed Consent Date/Investigator Signature)	Derived,1, 100
2	Inclusion/ Exclusion Criteria	1-3
3	Demographics/ 12-Lead ECG Results	4,9
4	Medical History	5
5	Peripheral Vascular Disease Intervention History	6
6	Serum/Urine Pregnancy Test/ Mammogram/ Pap Smear Results/ Pregnancy Outcome	4,15,19,24
7	Ulcer Measurements	16
8	High Resolution MRA/ Injection Site Reaction	16
9	Assessment of CLI	17
10	Hemodynamic Assessments	18
11	Visual Analogue Scale for Pain	19
12	Transcutaneous Oxygen Pressure Assessment- $TcPO_2$	19
13	Concomitant Medications Identified as being Analgesic in Nature	98
14	Study Drug Administration	20
15	Adverse Events	97
16	Serious Adverse Events	97
17	Hematology	11
18	Chemistry	12
19	Urinalysis	13
20	Physical Examinations	7,8
21	Vital Signs	9
22	Retinal Fundoscopy/ Chest X-Ray/ CT Scan	10
23	Infection Tests	14
24	Tumor Markers	15
25	Concomitant Medications	98
26	VM202 DNA Levels (include Collection Date/Time from CRF)	16, Lab
27	Endothelial Progenitor Cell Assay	14
28	Serum HGF/ Anti HGF Antibodies (include Collection Date/Time from CRF)	14, Lab
29	Telephone Follow-Up Contact	22
30	Waiver	23

List of Data Listings (cont)

Listing Number	Listing Description	CRF Plate(s)
31	Death	101

APPENDIX B: TABLE LAYOUTS

Table 1
Subject Disposition
All Subjects

	VM202- 2 mg	VM202- 4 mg	VM202- 8 mg	VM202- 16 mg
Subjects Enrolled	n	n	n	n
Safety Population [1]	n	n	n	n
ITT Population [2]	n	n	n	n
Received 2 Doses of VM202?				
Yes	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)
Last Visit Completed				
Any Visit Prior to Visit- Day 21	n (%)	n (%)	n (%)	n (%)
Visit- Day 21	n (%)	n (%)	n (%)	n (%)
Visit- Day 28	n (%)	n (%)	n (%)	n (%)
Visit- Day 59	n (%)	n (%)	n (%)	n (%)
Visit- Day 91	n (%)	n (%)	n (%)	n (%)
Visit- Day 180	n (%)	n (%)	n (%)	n (%)
Visit- Day 365	n (%)	n (%)	n (%)	n (%)
Completed Study?				
Yes	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)
Primary Reason for Discontinuation				
Screen failure	n (%)	n (%)	n (%)	n (%)
Lost to Follow-up	n (%)	n (%)	n (%)	n (%)
Adverse Event	n (%)	n (%)	n (%)	n (%)
Non-compliance	n (%)	n (%)	n (%)	n (%)
Subject withdrew consent	n (%)	n (%)	n (%)	n (%)
Principal Investigator decision	n (%)	n (%)	n (%)	n (%)
Subject requires intervention for treatment of acute limb ischemia	n (%)	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)	n (%)

* Percentages based on number of subjects Enrolled.
[1] All subjects who received at least one dose of study drug.
[2] All subjects who received at least one dose of study drug and had at least one post dose assessment.

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Table 2
Demographic Characteristics
ITT Population

	VM202- 2 mg (N=)	VM202- 4 mg (N=)	VM202- 8 mg (N=)	VM202- 16 mg (N=)
Age (years) [1]				
N	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Sex				
Male	n (%)	n (%)	n (%)	n (%)
Female	n (%)	n (%)	n (%)	n (%)
Ethnicity				
Hispanic or Latino	n (%)	n (%)	n (%)	n (%)
Not Hispanic or Latino	n (%)	n (%)	n (%)	n (%)
Race				
American Indian or Alaska Native	n (%)	n (%)	n (%)	n (%)
Asian	n (%)	n (%)	n (%)	n (%)
Black or African American	n (%)	n (%)	n (%)	n (%)
Native Hawaiian or Other Pacific Islander	n (%)	n (%)	n (%)	n (%)
White	n (%)	n (%)	n (%)	n (%)
Multiple Races Checked	n (%)	n (%)	n (%)	n (%)

[1] Age calculated by determining the number of years between the date of informed consent and the date of birth.
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Programmer note Table 2.2 will be identical to Table 2.1 for the Safety Population.

Table 3
Abnormal Medical History at Baseline
Safety Population

Body System	VM202- 2 mg (N=)	VM202- 4 mg (N=)	VM202- 8 mg (N=)	VM202- 16 mg (N=)
Respiratory	n (%)	n (%)	n (%)	n (%)
Cardiovascular	n (%)	n (%)	n (%)	n (%)
Gastrointestinal	n (%)	n (%)	n (%)	n (%)
Hepatic	n (%)	n (%)	n (%)	n (%)
Endocrine/Metabolic	n (%)	n (%)	n (%)	n (%)
Central Nervous System	n (%)	n (%)	n (%)	n (%)
Hematopoietic/Lymphatic	n (%)	n (%)	n (%)	n (%)
Dermatological	n (%)	n (%)	n (%)	n (%)
Musculoskeletal	n (%)	n (%)	n (%)	n (%)
Genitourinary/Reproductive	n (%)	n (%)	n (%)	n (%)
Psychiatric	n (%)	n (%)	n (%)	n (%)
Alcohol/Drug Abuse	n (%)	n (%)	n (%)	n (%)
Drug Allergy	n (%)	n (%)	n (%)	n (%)
Non-Drug Allergy	n (%)	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)	n (%)

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Table 4
Peripheral Vascular Disease Intervention
Safety Population

Intervention	VM202- 2 mg (N=)	VM202- 4 mg (N=)	VM202- 8 mg (N=)	VM202- 16 mg (N=)
PTA	n (%)	n (%)	n (%)	n (%)
Peripheral bypass	n (%)	n (%)	n (%)	n (%)
Amputation above the knee	n (%)	n (%)	n (%)	n (%)
Amputation below the knee	n (%)	n (%)	n (%)	n (%)
Atherectomy	n (%)	n (%)	n (%)	n (%)
Surgical bypass	n (%)	n (%)	n (%)	n (%)
Endarterectomy	n (%)	n (%)	n (%)	n (%)
Thrombectomy	n (%)	n (%)	n (%)	n (%)
Stent placement	n (%)	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)	n (%)

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Table 5
Ulcer Measurement (cm^2) [1]
ITT Population

	VM202- 2 mg (N=)		VM202- 4 mg (N=)		VM202- 8 mg (N=)		VM202- 16 mg (N=)	
	Result	Change [3]	Result	Change [3]	Result	Change [3]	Result	Change [3]
Baseline [2]								
N	n		n		n		n	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
Day 15 (Pre-Dose)								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 28								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 59								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

...

[1] Measurement taken was the largest contiguous area of ulceration.
[2] Baseline defined as measurement taken most closely prior to first study drug administration.
[3] Change= Change from Baseline

path\t_program.sas date time

Programmer Note Repeat for all available time points.

Table 6
Ankle Brachial-Index (mmHg)
ITT Population

	VM202- 2 mg (N=)		VM202- 4 mg (N=)		VM202- 8 mg (N=)		VM202- 16 mg (N=)	
	Result	Change [2]	Result	Change [2]	Result	Change [2]	Result	Change [2]
Index Limb								
Right	n (%)		n (%)		n (%)		n (%)	
Left	n (%)		n (%)		n (%)		n (%)	
ABI Index Leg								
Baseline [1]								
N	n		n		n		n	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
Day 15 (Pre-Dose)								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
…	…	…	…	…	…	…	…	…
ABI Non-Index Leg								
Baseline [1]								
N	n		n		n		n	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
…	…		…		…		…	

[1] Baseline defined as measurement taken most closely prior to first study drug administration.
[2] Change= Change from Baseline

path\t_program.sas date time
Programmer Note For each measurement, repeat for all available time points.

Table 7
Toe Brachial-Index (mmHg)
ITT Population

	VM202- 2 mg (N=)		VM202- 4 mg (N=)		VM202- 8 mg (N=)		VM202- 16 mg (N=)	
	Result	Change [2]	Result	Change [2]	Result	Change [2]	Result	Change [2]
TBI Index Toe								
Baseline [1]								
N	n		n		n		n	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
Day 15 (Pre-Dose)								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
…	…	…	…	…	…	…	…	…
TBI Non-Index Toe								
Baseline [1]								
N	n		n		n		n	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
…	…		…		…		…	

[1] Baseline defined as measurement taken most closely prior to first study drug administration.
[2] Change= Change from Baseline

path\t_program.sas date time
Programmer Note For each measurement, repeat for all available time points.

Table 8
Visual Analogue Scale for Pain (mm)
ITT Population

	VM202- 2 mg (N=)		VM202- 4 mg (N=)		VM202- 8 mg (N=)		VM202- 16 mg (N=)	
	Result	Change [2]	Result	Change [2]	Result	Change [2]	Result	Change [2]
Baseline [1]								
N	n		n		n		n	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
Day 15 (Pre-Dose)								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 28								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 59								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

...

[1] Baseline defined as measurement taken most closely prior to first study drug administration.
[2] Change= Change from Baseline

path\t_program.sas date time

Programmer Note Repeat for all available time points.

Table 9
Transcutaneous Oxygen Pressure Assessment- $TcPO_2$ (mmHg)
ITT Population

	VM202- 2 mg (N=)		VM202- 4 mg (N=)		VM202- 8 mg (N=)		VM202- 16 mg (N=)	
	Result	Change [2]	Result	Change [2]	Result	Change [2]	Result	Change [2]
Anterior Calf								
Baseline [1]								
N	n		n		n		n	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
Day 15 (Pre-Dose)								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
…	…	…	…	…	…	…	…	…
Posterior Calf								
Baseline [1]								
N	n		n		n		n	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
…	…		…		…		…	

[1] Baseline defined as measurement taken most closely prior to first study drug administration.
[2] Change= Change from Baseline

path\t_program.sas date time
Programmer Note For each measurement, repeat for all available time points. Results for other measurements to be shown include Dosrum Foot and Chest..

Table 10
Subject Analgesic Use [1]
ITT Population

	VM202- 2 mg (N=)	VM202- 4 mg (N=)	VM202- 8 mg (N=)	VM202- 16 mg (N=)
Subject reported using analgesic during study?				
Yes	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)

[1] Subject identified as having used analgesic based on whether subject reported using any concomitant medications considered to be an analgesic.

path\t_program.sas date time

Programmer Note:

Table 11
Study Drug Exposure
Safety Population

	VM202- 2 mg (N=)	VM202- 4 mg (N=)	VM202- 8 mg (N=)	VM202- 16 mg (N=)
Day 1				
Dose Administered?				
Yes	n (%)	n (%)	n (%)	n (%)
No, DLT from previous injection	n (%)	n (%)	n (%)	n (%)
No, Other	n (%)	n (%)	n (%)	n (%)
Zone of Injections				
I	n (%)	n (%)	n (%)	n (%)
II	n (%)	n (%)	n (%)	n (%)
III	n (%)	n (%)	n (%)	n (%)
IV	n (%)	n (%)	n (%)	n (%)
V	n (%)	n (%)	n (%)	n (%)
VI	n (%)	n (%)	n (%)	n (%)
Total Volume Administered per Protocol?				
Yes	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)
Time Dose Administration (mg)				
N	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Day 15				
Dose Administered?				
Yes	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)
...	...	...	...	...

path\t_program.sas date time

Table 12
Treatment Emergent Adverse Events by Cohort [1]
Safety Population

	VM202- 2 mg (N=)		VM202- 4 mg (N=)		VM202- 8 mg (N=)		VM202- 16 mg (N=)	
System Organ Class / Preferred Term	Number of Subjects [1]	Number of Events	Number of Subjects [1]	Number of Events	Number of Subjects [1]	Number of Events	Number of Subjects [1]	Number of Events
Subjects Reporting at Least One Adverse Event	n (%)	n	n (%)	n	n (%)	n	n (%)	n
System Organ Class 1	n (%)	n	n (%)	n	n (%)	n	n (%)	n
Preferred Term 1	n (%)	n	n (%)	n	n (%)	n	n (%)	n
Preferred Term 2	n (%)	n	n (%)	n	n (%)	n	n (%)	n
.								
.								
System Organ Class 2	n (%)	n	n (%)	n	n (%)	n	n (%)	n
Preferred Term 1	n (%)	n	n (%)	n	n (%)	n	n (%)	n
Preferred Term 2	n (%)	n	n (%)	n	n (%)	n	n (%)	n

[1] At each level of summation (overall, system organ class, preferred term), subjects reporting more than one adverse event are counted only once.

path\t_program.sas date time

Table 13
Treatment Emergent Adverse Events by System Organ Class and Severity [1]
Safety Population
Part 1 of 2

	VM202- 2 mg (N=)					VM202- 4 mg (N=)				
System Organ Class / Preferred Term	Mild	Moderate	Severe	Life Threat.	Death	Mild	Moderate	Severe	Life Threat.	Death
Subjects Reporting at Least One Adverse Event	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
System Organ Class 1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
.										
.										
System Organ Class 2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

[1] At each level of summation (overall, system organ class, preferred term), subjects reporting more than one adverse event are counted only once using the highest severity.

path\t_program.sas date time

Table 13
Treatment Emergent Adverse Events by System Organ Class and Severity [1]
Safety Population
Part 2 of 2

	VM202- 8 mg (N=)					VM202- 16 mg (N=)				
System Organ Class / Preferred Term	Mild	Moderate	Severe	Life Threat.	Death	Mild	Moderate	Severe	Life Threat.	Death
Subjects Reporting at Least One Adverse Event	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
System Organ Class 1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
.										
.										
System Organ Class 2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

[1] At each level of summation (overall, system organ class, preferred term), subjects reporting more than one adverse event are counted only once using the highest severity.

path\t_program.sas date time

Table 14
Treatment Emergent Adverse Events by System Organ Class and Relationship to Study Drug [1]
Safety Population

	VM202- 2 mg (N=)		VM202- 4 mg (N=)		VM202- 8 mg (N=)		VM202- 16 mg (N=)	
System Organ Class / Preferred Term	Related [2]	Not Related [3]	Related [2]	Not Related [3]	Related [2]	Not Related [3]	Related [2]	Not Related [3]
Subjects Reporting at Least One Adverse Event	n (%)	n	n (%)	n	n (%)	n	n (%)	n
System Organ Class 1	n (%)	n	n (%)	n	n (%)	n	n (%)	n
Preferred Term 1	n (%)	n	n (%)	n	n (%)	n	n (%)	n
Preferred Term 2	n (%)	n	n (%)	n	n (%)	n	n (%)	n
.								
.								
System Organ Class 2	n (%)	n	n (%)	n	n (%)	n	n (%)	n
Preferred Term 1	n (%)	n	n (%)	n	n (%)	n	n (%)	n
Preferred Term 2	n (%)	n	n (%)	n	n (%)	n	n (%)	n

[1] At each level of summation (overall, system organ class, preferred term), subjects reporting more than one adverse event are counted only once using the closest relationship to study drug.
[2] Includes all events reported as "Possibly," "Probably," or of "Definitely" relationship to study drug.
[3] Includes all events reported as "Unlikely" or "Unrelated" relationship to study drug.

path\t_program.sas date time

Table 15
Treatment Emergent Serious Adverse Events by Cohort [1]
Safety Population

	VM202- 2 mg (N=)		VM202- 4 mg (N=)		VM202- 8 mg (N=)		VM202- 16 mg (N=)	
System Organ Class / Preferred Term	Number of Subjects [1]	Number of Events	Number of Subjects [1]	Number of Events	Number of Subjects [1]	Number of Events	Number of Subjects [1]	Number of Events
Subjects Reporting at Least One Serious Adverse Event	n (%)	n	n (%)	n	n (%)	n	n (%)	n
System Organ Class 1	n (%)	n	n (%)	n	n (%)	n	n (%)	n
Preferred Term 1	n (%)	n	n (%)	n	n (%)	n	n (%)	n
Preferred Term 2	n (%)	n	n (%)	n	n (%)	n	n (%)	n
.								
.								
System Organ Class 2	n (%)	n	n (%)	n	n (%)	n	n (%)	n
Preferred Term 1	n (%)	n	n (%)	n	n (%)	n	n (%)	n
Preferred Term 2	n (%)	n	n (%)	n	n (%)	n	n (%)	n

[1] At each level of summation (overall, system organ class, preferred term), subjects reporting more than one adverse event are counted only once.

path\t_program.sas date time

Table 16.1
Hematology
Safety Population

	VM202- 2 mg (N=)		VM202- 4 mg (N=)		VM202- 8 mg (N=)		VM202- 16 mg (N=)	
Analyte	Result	Change [2]	Result	Change [2]	Result	Change [2]	Result	Change [2]
Analyte #1 (unit)								
Baseline [1]								
N	n		n		n		n	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
Day 15 (Pre-Dose)								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 16								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 28								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

...

[1] Baseline defined as measurement taken most closely prior to first study drug administration.
[2] Change= Change from Baseline

path\t_program.sas date time

Programmer Note Repeat for all available time points and analytes. Analytes to be shown include Hematocrit, Hemoglobin, RBC, WBC, Platelets, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, MCV, MCHC, MCH.

Table 16.2
Chemistry
Safety Population

	VM202- 2 mg (N=)		VM202- 4 mg (N=)		VM202- 8 mg (N=)		VM202- 16 mg (N=)	
Analyte	Result	Change [2]	Result	Change [2]	Result	Change [2]	Result	Change [2]
Analyte #1 (unit)								
Baseline [1]								
N	n		n		n		n	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
Day 15 (Pre-Dose)								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 16								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 28								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

...

[1] Baseline defined as measurement taken most closely prior to first study drug administration.
[2] Change= Change from Baseline

path\t_program.sas date time

Programmer Note Repeat for all available time points and analytes. Analytes to be shown include Albumin, Alkaline Phosphate, ALT, AST, Bicarbonate, BUN, Calcium, Chloride, Creatinine, GGT Glucose, LDH, Phosphorus, Sodium, Total Bilirubin, Total Protein, Uric Acid.

Table 16.3
Urinalysis
Safety Population

	VM202- 2 mg (N=)		VM202- 4 mg (N=)		VM202- 8 mg (N=)		VM202- 16 mg (N=)	
Analyte	Result	Change [2]	Result	Change [2]	Result	Change [2]	Result	Change [2]
Analyte #1 (unit)								
Baseline [1]								
N	n		n		n		n	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
Day 15 (Pre-Dose)								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 16								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 28								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

...

[1] Baseline defined as measurement taken most closely prior to first study drug administration.
[2] Change= Change from Baseline

path\t_program.sas date time

Programmer Note Repeat for all available time points and analytes. Analytes to be shown include Specific Gravity, pH.

Table 17.1
Hematology- Shift from Baseline
Safety Population

	Baseline [1]											
	VM202- 2 mg (N=)			VM202- 4 mg (N=)			VM202- 8 mg (N=)			VM202- 16 mg (N=)		
Follow Up [2]	High	Normal	Low	High	Normal	Low	High	Normal	Low	High	Normal	Low
Analyte #1 (unit)												
High	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Low	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Analyte #2 (unit)												
High	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Low	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

...

[1] Baseline defined as measurement taken most closely prior to first study drug administration.
[2] Follow Up defined as most abnormal post dose result.
path\t_program.sas date time

Programmer Note If a subject has both a High and Low post dose result, the subject will be assigned a High result for the Most Abnormal Post Dose Result,. Analytes to be shown include Hematocrit, Hemoglobin, RBC, WBC, Platelets, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, MCV, MCHC, MCH.

Table 17.2
Chemistry- Shift from Baseline
Safety Population

	Baseline [1]											
	VM202- 2 mg (N=)			VM202- 4 mg (N=)			VM202- 8 mg (N=)			VM202- 16 mg (N=)		
Follow Up [2]	High	Normal	Low	High	Normal	Low	High	Normal	Low	High	Normal	Low
Analyte #1 (unit)												
High	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Low	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Analyte #2 (unit)												
High	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Low	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

...

[1] Baseline defined as measurement taken most closely prior to first study drug administration.
[2] Follow Up defined as most abnormal post dose result.
path\t_program.sas date time

Programmer Note If a subject has both a High and Low post dose result, the subject will be assigned a High result for the Most Abnormal Post Dose Result. Analytes to be shown include Albumin, Alkaline Phosphate, ALT, AST, Bicarbonate, BUN, Calcium, Chloride, Creatinine, GGT Glucose, LDH, Phosphorus, Sodium, Total Bilirubin, Total Protein, Uric Acid.

Table 17.3
Urinalysis- Shift from Baseline
Safety Population

	Baseline [1]											
	VM202- 2 mg (N=)			VM202- 4 mg (N=)			VM202- 8 mg (N=)			VM202- 16 mg (N=)		
Follow Up [2]	High	Normal	Low	High	Normal	Low	High	Normal	Low	High	Normal	Low
Analyte #1 (unit)												
High	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Low	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Analyte #2 (unit)												
High	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Low	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Baseline defined as measurement taken most closely prior to first study drug administration.
[2] Follow Up defined as most abnormal post dose result.
path\t_program.sas date time

Programmer Note If a subject has both a High and Low post dose result, the subject will be assigned a High result for the Most Abnormal Post Dose Result. Analytes to be shown include Specific Gravity, pH.

Table 18
Physical Examinations- Shift from Baseline
Safety Population

	Screening Visit											
	VM202- 2 mg (N=)			VM202- 4 mg (N=)			VM202- 8 mg (N=)			VM202- 16 mg (N=)		
Body System	Normal	Abn, Not CS[1]	Abn, CS [2]	Normal	Abn, Not CS[1]	Abn, CS [2]	Normal	Abn, Not CS[1]	Abn, CS [2]	Normal	Abn, Not CS[1]	Abn, CS [2]
Body System #1												
Day 15	n			n			n			n		
Normal	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 28	n			n			n			n		
Normal	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 59	n			n			n			n		
Normal	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

...

[1] Abn, Not CS= Abnormal, Not Clinically Significant
[2] Abn, CS= Abnormal, Clinically Significant

path\t_program.sas date time

Programmer Note Repeat for all available time points and body systems. Body Systems to be shown include HEENT, Skin/Dermatologic, Lymph Nodes, Chest/Lungs, Heart/Cardiovascular, Abdomen, Extremities, Neurologic, Stool for Occult Blood, Other.

Table 19
Vital Signs
Safety Population

	VM202- 2 mg (N=)		VM202- 4 mg (N=)		VM202- 8 mg (N=)		VM202- 16 mg (N=)	
Vital Sign	Result	Change [2]	Result	Change [2]	Result	Change [2]	Result	Change [2]
Heart Rate (bpm)								
Baseline [1]								
N	n		n		n		n	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
Day 1 (15 Minutes Post Dose)								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 1 (30 Minutes Post Dose)								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 1 (60 Minutes Post Dose)								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

...

[1] Baseline defined as measurement taken most closely prior to first study drug administration.
[2] Change= Change from Baseline

path\t_program.sas date time

Programmer Note Repeat for all available time points and vital signs.

Table 20
Retinal Fundoscopy- Shift from Baseline
Safety Population

	Screening/Baseline											
	VM202- 2 mg (N=)			VM202- 4 mg (N=)			VM202- 8 mg (N=)			VM202- 16 mg (N=)		
	Normal	Abn, Not CS[1]	Abn, CS [2]	Normal	Abn, Not CS[1]	Abn, CS [2]	Normal	Abn, Not CS[1]	Abn, CS [2]	Normal	Abn, Not CS[1]	Abn, CS [2]
Day 365/ Early Termination												
Right												
Normal	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Left												
Normal	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Abn, Not CS= Abnormal, Not Clinically Significant
[2] Abn, CS= Abnormal, Clinically Significant

path\t_program.sas date time

Table 21
Infection Tests
Safety Population

	VM202- 2 mg (N=)			VM202- 4 mg (N=)			VM202- 8 mg (N=)			VM202- 16 mg (N=)		
	Pos	Neg	Not Done	Pos	Neg	Not Done	Pos	Neg	Not Done	Pos	Neg	Not Done
Screening	n			n			n			n		
Hepatitis BSAg	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
HCV	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
HTLV	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
CMV	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
VDRL	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 59	n			n			n			n		
Hepatitis BSAg	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
HCV	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
HTLV	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
CMV	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
VDRL	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 180	n			n			n			n		
Hepatitis BSAg	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
HCV	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
HTLV	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
CMV	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
VDRL	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 365	n			n			n			n		
Hepatitis BSAg	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
HCV	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
HTLV	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
CMV	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
VDRL	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

path\t_program.sas date time

Table 22
Tumor Markers
Safety Population

	VM202- 2 mg (N=)		VM202- 4 mg (N=)		VM202- 8 mg (N=)		VM202- 16 mg (N=)	
Tumor Marker	Result	Change [2]	Result	Change [2]	Result	Change [2]	Result	Change [2]
AFP (Alpha Fetoprotein) (ng/mL)								
Baseline [1]								
N	n		n		n		n	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
Day 15 (Pre-Dose)								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 59								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 180								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

...

[1] Baseline defined as measurement taken most closely prior to first study drug administration.
[2] Change= Change from Baseline

path\t_program.sas date time

Programmer Note Repeat for all available time points and tumor markers. Tumor Markers to be shown include CEA (Carcino Embryonic Antigen), PSA (Prostate Specific Antigen), CA 19-9 (Cancer Antigen 19-9), CA 125..

Table 23
Injection Site Reaction
Safety Population

	VM202- 2 mg (N=)	VM202- 4 mg (N=)	VM202- 8 mg (N=)	VM202- 16 mg (N=)
Subject reported an Injection Site Reaction?				
Yes	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)

path\t_program.sas date time

Programmer Note:

Table 24
Concomitant Medications [1]
Safety Population

ATC Drug Class / Medication Term	VM202- 2 mg (N=)	VM202- 4 mg (N=)	VM202- 8 mg (N=)	VM202- 16 mg (N=)
Subjects Receiving any Concomitant Medications	n (%)	n (%)	n (%)	n (%)
Drug Class 1	n (%)	n (%)	n (%)	n (%)
Medication Term 1	n (%)	n (%)	n (%)	n (%)
Medication Term 2	n (%)	n (%)	n (%)	n (%)
.				
.				
Drug Class 2	n (%)	n (%)	n (%)	n (%)
Medication Term 1	n (%)	n (%)	n (%)	n (%)
Medication Term 2	n (%)	n (%)	n (%)	n (%)
.				
.				

[1] At each level of summation (overall, ATC drug class, medication term), subjects reporting more than medication are counted only once.

path\t_program.sas date time

Table 25
VM202 DNA Levels (unit)
ITT Population

	VM202- 2 mg (N=)		VM202- 4 mg (N=)		VM202- 8 mg (N=)		VM202- 16 mg (N=)	
	Result	Change [2]	Result	Change [2]	Result	Change [2]	Result	Change [2]
Baseline [1]								
N	n		n		n		n	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
Day 21								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 59								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

[1] Baseline defined as measurement taken most closely prior to first study drug administration.
[2] Change= Change from Baseline

path\t_program.sas date time

Programmer Note Repeat for all available time points.

Table 26
Endothelial Progenitor Cell Assay (%)
ITT Population

	VM202- 2 mg (N=)		VM202- 4 mg (N=)		VM202- 8 mg (N=)		VM202- 16 mg (N=)	
	Result	Change [2]	Result	Change [2]	Result	Change [2]	Result	Change [2]
Baseline [1]								
N	n		n		n		n	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
Day 1 (Post Dose)								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 15 (Post Dose)								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 28								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

...

[1] Baseline defined as measurement taken most closely prior to first study drug administration.
[2] Change= Change from Baseline

path\t_program.sas date time

Programmer Note Repeat for all available time points.

Table 27
Serum HGF Levels (unit)
ITT Population

	VM202- 2 mg (N=)		VM202- 4 mg (N=)		VM202- 8 mg (N=)		VM202- 16 mg (N=)	
	Result	Change [2]	Result	Change [2]	Result	Change [2]	Result	Change [2]
Baseline [1]								
N	n		n		n		n	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx		xx, xx	
Day 8								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 15 (Pre-Dose)								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 21								
N	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

…

[1] Baseline defined as measurement taken most closely prior to first study drug administration.
[2] Change= Change from Baseline

path\t_program.sas date time

Programmer Note Repeat for all available time points.