A Phase 2 Randomized, Double-Blinded, Placebo-Controlled Study to Evaluate the Effects of Multiple Subcutaneous Injections of Elamipretide on Left Ventricular Function in Subjects with Stable Heart Failure with Reduced Ejection Fraction

NCT02788747

04 DECEMBER 2017

STATISTICAL ANALYSIS PLAN

Trial Sponsor: Stealth BioTherapeutics, Inc.

Protocol Number: SPIHF-201 **IND Number:** N/A **EUDRACT Number:** 2014-005724-10 **Investigational Drug:** Elamipretide (MTP-131)

Indication: Heart Failure with reduced Ejection Fraction (HFrEF)

Dosage Form/Strength: Elamipretide (MTP-131) 40 mg/1 mL of sterile solution for subcutaneous injection with doses of 4 mg or 40 mg administered once daily

Protocol Title: A Phase 2 Randomized, Double-Blinded, Placebo-Controlled Study to Evaluate the Effects of Multiple Subcutaneous Injections of Elamipretide on Left Ventricular Function in Subjects with Stable Heart Failure with Reduced Ejection Fraction

FINAL SIGN-OFF APPROVAL

Author Biostatistician: Meleana Dunn
Principal Biostatistician
Everest Clinical Research

Meleana Dunn — **Signature** — 05 Dec 2017 — **Date**

Peer Review Biostatistician: Dean Rutty
Executive Director, Biometrics
Everest Clinical Research

Signature — 05 DEC 2017 — **Date**

Approved by: Douglas Weaver
Chief Medical Officer
Stealth BioTherapeutics

Signature — 5 Dec 2017 — **Date**

Approved by: James Carr
Chief Clinical Development Officer
Stealth BioTherapeutics

Signature — 5 Dec 2017 — **Date**

Approved by: Jeffrey Finman
Statistical Consultant
Stealth BioTherapeutics

Signature — 05-Dec-2017 — **Date**

CHANGE LOG FOR CHANGES MADE AFTER THE INITIAL APPROVAL

Revision Date*	Section(s) Modified	Brief Description of Revision(s) or Reason(s) for Revision	Modifications Reviewed and Approved by**
			Sponsor, Everest

* Update the Last Revision Dates on the cover page and the document header.

** Provide person's initial and last name.

TABLE OF CONTENTS

	6-minute walk test
AE	Adverse event
ATP	Adenosine triphosphate
ATP_{max}	Maximal ATP synthetic mitochondrial energy coupling
AUC	Area under the plasma concentration versus time curve
BMI	Body mass index
BP	Blood pressure
BSA	Body surface area
BUN	Blood urea nitrogen
CK	Creatine kinase
ECG	Electrocardiogram
eCRF	electronic Case Report Form
EF	Ejection fraction
DBP	Diastolic blood pressure
HFrEF	Heart failure with reduced ejection fraction
Hgb	Hemoglobin
IMP	Investigational medicinal product
ITT	Intent-to-treat
IV	Intravenous
IWRS	Interactive web-based response system
KCCQ	Kansas City Cardiomyopathy Questionnaire
LA	Left atria
LV	Left ventricle
LV EDV	Left ventricular end diastolic volume
LVEF	Left ventricular ejection fraction

LV ESV	Left ventricular end systolic volume
Mb	Myoglobin

Abbreviation	**Term**
6MWT	

GLOSSARY OF ABBREVIATIONS

MedDRA	Medical Dictionary for Regulatory Activities
MRI	Magnetic resonance imaging
MRS	Magnetic resonance spectroscopy
MTP-131	Elamipretide
NAD	Nicotine adenine dinucleotide
NT-pro-BNP	N-terminal pro-brain natriuretic peptide
PCr	Phosphocreatine
^{31}P	Phosphorus-31
P/O	Mitochondrial coupling
PT	Preferred term
RBC	Erythrocyte count
RV	Right ventricle
RVSP	Right ventricular systolic pressure
SAE	Serious adverse event
SAP	Statistical analysis plan
SBP	Systolic blood pressure
SC	Subcutaneous
SOC	System organ class
TEAE	Treatment-emergent adverse event
US	United States
WBC	Leukocytes
WHO-DD	World Health Organization Drug Dictionary

1. INTRODUCTION

This Statistical Analysis Plan (SAP) outlines the planned statistical methods for the display, summary and analysis of data collected within the scope of Stealth BioTherapeutics, Inc. protocol SPIHF-201 version 8.0 dated 21 March 2017. The analysis of the data should allow

changes in the plan to the extent that deviations from the original plan would provide a more reliable and valid analysis of the data. As such, deviations from this SAP must be substantiated by a sound statistical rationale and described in the clinical study report (CSR).

The SAP should be read in conjunction with the study protocol and the electronic Case Report Forms (eCRFs). This version of the SAP has been developed using the final version of the protocol mentioned above and the final version of the annotated eCRFs dated 16 June 2016.

The SAP details the analysis of the data collected in the study and the presentation of the results of the analyses. The table, listing, and figure (TLF) shells are displayed in a companion document which provides information on the layout of the data displays. Analysis dataset specifications will be developed to detail the programming specifications and mapping rules needed to create the analysis datasets and the TLFs.

All statistical analyses will be performed using SAS® version 9.3, or higher. Adverse events will be coded using the latest version of the Medical Dictionary for Regulatory Activities (MedDRA 19.1 or newer).

This study is a Phase 2, randomized, double-blind, placebo-controlled, multiple dose study, conducted in up to 20 centers in Europe, enrolling 66 subjects with previous evidence of stable heart failure with reduced ejection fraction (HFrEF) to evaluate the effects of multiple subcutaneous (SC) doses of elamipretide on left ventricular end systolic volume (LV ESV).

2. STUDY OBJECTIVES

2.1 Primary Objective

To evaluate the effects of multiple SC doses of elamipretide on LV ESV assessed by cardiac Magnetic Resonance Imaging (MRI).

2.2 Secondary Objectives

- To evaluate the safety and tolerability of multiple SC doses of elamipretide.
- To evaluate the effects of multiple SC doses of elamipretide on left ventricular (LV) systolic and diastolic function to include: LV volumes, LV global longitudinal strain, left atrial (LA) volume, LV mass, extent of mitral and tricuspid regurgitation severity, and right ventricular (RV) function (original and indexed to BSA).

2.3 Exploratory Objectives

To evaluate the effects of multiple SC doses of elamipretide on:

- 6-minute walking distance
- Quality of life using the KCCQ
- N-terminal pro-brain natriuretic peptide (NT-pro-BNP) levels

3. STUDY DESIGN

3.1 Study Design

This is a randomized, double-blinded, placebo-controlled, multiple dose Phase 2 study in subjects with HFrEF. The objectives are to evaluate the effects of multiple SC doses of elamipretide on LV ESV, LV systolic and diastolic function, LV volumes, LV global longitudinal strain, LA volume, LV mass, mitral and tricuspid regurgitation severity, and RV function in subjects with stable heart failure with reduced ejection fraction. After completing the screening period, approximately 66 subjects will be randomized, in a 1:1:1 ratio, to receive either placebo, 4 mg elamipretide, or 40 mg elamipretide once daily for 28 consecutive days.

Efficacy will be assessed with the following measurements:

- LV ESV assessed by MRI
- Left ventricular ejection fraction (LVEF) and left ventricular end diastolic volume (LV EDV) assessed by MRI
- The following parameters by echocardiography:
    - E/A (ratio between early and late mitral inflow velocity),
    - E/e' (Ratio between early mitral inflow velocity and mitral annular early diastolic velocity)
    - LV EDV, LV ESV and biplane ejection fraction (EF)
    - LV global longitudinal strain
    - LA volume ○ LV mass
    - Mitral regurgitation severity ○ Tricuspid regurgitation severity ○ RV fractional area change ○ RV systolic pressure (RVSP)
- Distance walked (meters) on the 6-minute walk test (6MWT)

- Kansas City Cardiomyopathy Questionnaire (KCCQ) score
- Levels of NT-pro-BNP

Subjects will be screened for reduced EF, defined as LVEF ≤ 40%, by 2-D echocardiography.

There are 3 study treatment groups randomized in equal ratio:

- Elamipretide (MTP-131) 40 mg of 40 mg/1 mL of sterile solution, administered as a once daily SC injection for 28 consecutive days.
- Elamipretide (MTP-131) 4 mg of 40 mg/1 mL of sterile solution, administered as a once daily SC injection for 28 consecutive days.
- Placebo (excipients used to manufacture the investigational drug but without the active drug substance) administered as a once daily SC injection for 28 consecutive days.

3.2 Randomization

Randomization will be used in this study to avoid bias in the assignment of study treatments to subjects, to increase the likelihood that known and unknown subject attributes (e.g., demographics and baseline characteristics) are balanced across treatment groups, and to enhance the possible validity of statistical comparisons across treatment groups. Blinded treatment will be used to reduce potential bias during data collection and evaluation of endpoints. Only those subjects who meet protocol-specified criteria for stable heart failure with reduced ejection fraction will be randomized to study treatment.

At Day 1, after the eligibility criteria have been confirmed, a treatment kit number will be assigned to each subject on the basis of a centralized computer-generated randomization schedule administered by IWRS. Subjects will be randomized into 1 of 3 treatment groups in a 1:1:1 fashion to receive either elamipretide 4 mg, elamipretide 40 mg, or placebo, so that a target of 22 subjects will be randomized to the elamipretide 4 mg dose group, 22 subjects will be randomized to the elamipretide 40 mg dose group, and 22 subjects will be randomized to the placebo treatment group. Treatment kits for placebo will specify injection volumes of either 0.1 or 1 mL in order to maintain the blind. This will be accomplished by administering a randomization schedule in randomized blocks of 6 with a ratio of 2:2:1:1 (elamipretide 4 mg [0.1 mL], elamipretide 40 mg [1 mL], placebo [0.1 mL] or placebo [1 mL]). This design maintains the 1:1:1 ratio of elamipretide 4 mg, elamipretide 40 mg, and placebo in addition to ensuring the complete blind to study treatment.

3.3 Hypothesis Testing

Primary hypothesis:

Null hypothesis H_0: There is no difference between the elamipretide 40 mg and placebo treatment groups in change in LV ESV at Week 4 from baseline.

Alternative hypothesis H_a: There is a difference between the elamipretide 40 mg and placebo treatment groups in change in LV ESV at Week 4 from baseline.

The elamipretide 4 mg treatment will also be compared to placebo as a secondary hypothesis.

3.4 Interim Analysis

No formal interim analyses are planned for this study.

3.5 Sample Size

The target sample size of 22 subjects per treatment group provides 80% power to detect an 8 mL difference between treatment groups in LV ESV, as measured by MRI, assuming a standard deviation of 9.4 mL.

3.6 Schedule of Assessments and Study Procedures

	Screening Period	Treatment Period				Follow-Up Period
	Days -28 to -1 (Screening Visit)	**Day 1[a] (Baseline)**	**Week 1 (Day 8 + 3)**	**Week 2 (Day 15 ± 3)**	**Week 4/ED[b] (Day 29 + 3)**	**Week 6 (Day 43 ± 3)**
Informed Consent	X					
Demographics	X					
Randomization		X				
Review of Inclusion/Exclusion Criteria	X	X				
Relevant Medical History[c]	X	X				
Concomitant Medication Review	X	X	X	X	X	X
Review AEs		X	X	X	X	X
Cardiovascular Physical Examination[d]	X	X	X	X	X	X
Vital Signs[e]	X	X	X	X	X	X
12-Lead ECG	X	X	X	X	X	X
Blood Chemistry & Hematology	X	X	X	X	X	X
PK Samples[f]		X	X	X	X	X
Urinalysis	X	X			X	
Pregnancy Test[g]	X	X			X	
Echocardiography[h]	X	X			X	X
Cardiac MRI[i]	X		X		X	
KCCQ		X			X	
NT-pro-BNP		X	X	X	X	X
6-Minute Walk Test		X			X	
Study Medication Dispensing		X	X	X		
Study Medication Injection[j]		X----------X				
ISR Self-Assessment Questionnaire		X----------X				
Visiting Nurse/Investigator ISR Assessment[k]		X----------X				

[a] All Day 1 assessments should be performed prior to administering the first dose of study medication except the ISR assessments (as described in Section 6.3.9) and blood drawn for plasma analysis of elamipretide and metabolites (45 minutes post-injection ±15 minutes) (as described in Section 6.3.8.5) which should be completed after study medication administration. [b] If a subject discontinues study medication early, the subject will have an Early Discontinuation Visit and will be asked to complete the Week 4 assessments. [c] At the Screening Visit, a relevant medical history will be taken. Relevant medical history will be updated at the Day 1 visit. [d] Cardiovascular physical examination including lung auscultation and weight. Height will only be measured at the Screening Visit. [e] Vital signs measurements will include temperature, heart rate, respiration rate and blood pressure, recorded in the sitting position after at least 10 minutes rest.

[f] Blood samples for PK determinations of elamipretide and metabolites concentrations will be collected before administration of study medication and at 45 minutes (±15 minutes) post-dose at the Day 1, Week 1, and Week 2 visits, and at any time point at the Week 4 and 6 visit.

[g] Serum pregnancy test will be done for women of childbearing potential at the Screening visit. Urine pregnancy test will be done for women of childbearing potential on Day 1 and Week 4. The results of the Day 1 pre-dose pregnancy test must be evaluated before randomization to ensure eligibility.

[h] At the Screening Visit, only a 2-D echocardiography will be performed and it will be performed prior to Step 2 (blood draw, urinalysis) and Step 3 (cardiac MRI) screening procedures. Both 2-D and 3-D echocardiography will be performed at the Day 1, Week 4 and Week 6 visits.

[i] At the Screening visit, subjects will undergo delayed gadolinium-enhanced cardiac MRI prior to study medication injection. At the Week 1 visit, subjects will undergo cardiac MRI approximately 1 to 6 hours following injection of study medication.

[j] At Day 1, study medication injection will occur after the completion of baseline procedures (as noted in footnote a). Study medication will be administered daily by a Visiting Nurse, except on Study Visits, at Days 1 through 3 and during the Week 1 and Week 2 visits. The last dose of study medication will be administered on the day prior to the Week 4 visit.

[k] At each home visit, the Visiting Nurse will assess the current day's injection site. At Days 1 through 3, Week 1 and Week 2 visits, the Investigator (or designee) will assess the current day's injection site. The assessment will evaluate erythema, pain, swelling, and pruritus at the injection site at approximately 15 minutes post-injection. If any reaction is apparent, the injection site will also be evaluated at 30 minutes post-injection.

4. DATA AND ANALYTICAL QUALITY ASSURANCE

The overall quality assurance procedures for the study data, statistical programming and analyses are described in the Everest's Standard Operating Procedures. Detailed data management procedures are documented in the Data Management Plan, Data Validation Check Specifications, and Data Review Plan. Detailed statistical and programming quality control and quality assurance procedures are documented in the Statistical Analysis and Programming QC/QA Plan.

5. ANALYSIS POPULATIONS

5.1 Safety Population

Safety population includes all subjects receiving at least one dose of the investigational medicinal product (IMP). Safety analyses will be conducted on the safety population according to the treatment received.

5.2 Intent-to-Treat (ITT) Population

The Intent-To-Treat Population (ITT) will consist of all subjects who were randomized and receive at least 1 dose of IMP. The ITT population will be the primary analysis for efficacy assessments. Efficacy analyses will be conducted on the ITT Population according to the treatment group to which the subjects were randomized.

5.3 Per-Protocol (PP) Population

The Per-Protocol Population (PP) will consist of all randomized subjects receiving at least one dose of the IMP without major protocol violations/deviations. The list of major protocol violations/deviations will be identified by the Sponsor prior to final database lock for the study that would lead to exclusion from the PP analysis. The PP population will be a sensitivity analysis to the ITT analysis for efficacy assessments. If there are no major deviations which exclude data from the PP population, the PP analysis will not be reported.

6. SPECIFICATION OF ENDPOINTS AND VARIABLES

6.1 Demographic and Baseline Characteristics

Demographic variables consist of the following:

- Age in years (continuous) derived as the integer of (informed consent date – date of birth + 1)/365.25
- Gender

- Race
- Ethnicity

Baseline characteristics consist of the following:

- Weight (kg)
- Height (cm)
- BMI (kg/m^2) derived as
- weight in kg divided by (height in m)^2
- Vital signs (heart rate, systolic blood pressure, diastolic blood pressure, and temperature [oral or tympanic])
- Physical cardiovascular examination (any clinically significant abnormalities (yes, no))
- Medical and surgical history
- Prior medications

6.2 Efficacy

The effect of multiple SC doses of elamipretide on left ventricular end systolic volume is assessed using the change in LVESV between Baseline and Week 4.

6.2.1 Study Day and Visit Window Definitions

The date the subject is randomized and is expected to receive the first dose of study medication will be used as the Study Day 1.

Study day will be calculated as follows:

Before study day 1: Study Day = date of assessment – date of study day 1.
On or after study day 1: Study Day = date of assessment – date of study day 1 + 1.

The last study date is the last visit date of any scheduled, unscheduled or early discontinuation visits. The last Study Day is calculated as:

Last Study Day = last study date – date of study day 1 + 1.

The target study days are summarized in Table 1 below:

Table 1. Visit Windows for Efficacy Assessments

Scheduled Visit Number	Visit (label)	Time Interval (day)	Target Time Point (day)
0	Screening	-28 to -1	-28 to -1
1	Baseline/Day 1	1	1
2	Week 1	1 (postdose) to 11	8
3	Week 2	12 to 22	15
4	Week 4	23 to 36	29
5	Week 6	≥37	43

The baseline assessment is defined as the last assessment prior to the first dose of study medication. In some cases, these baseline measurements are obtained at the screening visit.

If multiple assessments fall in the same visit window, the non-missing assessment closest to target time point will be selected for analysis. Data obtained during unscheduled visits will be allocated to the scheduled visit corresponding to the visit window they fall in. If an unscheduled visit is closer to the target time point than the scheduled visit, a blinded review will be done at the end of the study to determine which visit to use. The choice will depend on how far off the scheduled visit occurred and what data was collected at each of the visits.

6.2.2 Primary Efficacy Variables

The primary efficacy endpoint is change in LV ESV assessed by MRI at Week 4 from baseline.

6.2.3 Secondary Efficacy Variables

Secondary efficacy endpoints are changes from baseline for the following measures:

- LVEF and LV EDV assessed by MRI
- The following parameters by echocardiography:
    - E/A (ratio between early and late mitral inflow velocity),
    - E/e' (Ratio between early mitral inflow velocity and mitral annular early diastolic velocity) ○ LV EDV, LV ESV and biplane ejection fraction (EF)

- LV global longitudinal strain
- LA volume
- LV mass
- Mitral regurgitation severity ○ Tricuspid regurgitation severity ○ RV fractional area change ○ RV systolic pressure (RVSP)

Change from baseline for the above MRI measures will be assessed at Week 1 (approximately 1 to 6 hours following injection of study medication) and at Week 4, and for the echocardiography measures at Weeks 4 and 6.

The measures of volume, LV ESV, LV EDV, LA volume, LV mass, RV ESV, RV EDV, and RV myocardial mass, will be indexed to body surface area (BSA) by dividing the measures by BSA. All analyses will be done on the indexed values. Listings will include both indexed and nonindexed values.

6.2.4 Exploratory Efficacy Variables

Exploratory efficacy endpoints are changes from screening for the following measures:

- Distance walked (meters) during 6MWT
- Levels of NT-pro-BNP
- KCCQ score

Change from baseline for the Distance walked measure will be assessed at Week 4, the levels of NT-pro-BNP measure at Weeks 1, 2, 4, and 6, and as an AUC for visits Baseline, Weeks 1, 2, 4, and 6, and for the KCCQ measure at Week 4.

6.2.5 Plasma Concentration

Blood samples for PK determinations of elamipretide and metabolites (M1, M2) concentrations will be collected before administration of study medication and at 45 minutes ±15 minutes postdose at the Day 1, Week 1 and Week 2 visits, and at any time point at the Week 4 and Week 6 visits.

Plasma samples will be analyzed for MTP-131 concentrations using a validated liquid chromatography/ tandem mass spectrometry assay.

6.3 Safety

The safety profile of elamipretide will be assessed through the recording, reporting, and analyzing of AEs, clinical evaluations, and laboratory tests. Safety variables include the following:

- Adverse events and serious adverse events
- Local laboratory measurements – clinical chemistry and hematology with specific attention to Na+ and K+
- Urinalysis
- Vital signs
- Electrocardiogram (ECG)
- Physical examination
- Pregnancy
- Concomitant medications/treatments
- Injection site reaction (ISR)

6.3.1 Study Day and Visit Window Definitions

The term "Safety analysis period" is from the first dose of study medication to 30 days after the last dose of study drug.

Study day is defined as in Section 6.2.1.

The date at the first dose of study medication is used as Study Day 1. The target study days are summarized in Table 2 below:

Table 2. Visit Windows for Safety Assessments

Scheduled Visit Number	Visit (label)	Time Interval (day)	Target Time Point (day)
0	Screening	-28 to -1	-28 to -1
1	Baseline/Day 1	1	1
2	Week 1	1 (postdose) to 11	8
3	Week 2	12 to 18	15
4	Week 4	23 to 36	29
5	Week 6	>37	43

Data obtained during unscheduled visits will be allocated to the scheduled visit corresponding to the visit window they fall in. If multiple assessments fall in the same visit window, the nonmissing assessment closest to target time point will be selected for analysis.

Baseline values for clinical laboratory tests, vital signs and ECGs will be defined as the last evaluation performed prior to the first dose of study medication.

6.3.2 Extent of Exposure to Study Medication

Elamipretide 4 mg or 40 mg, or Placebo (excipients used to manufacture the investigational drug but without the active drug substance) will be administered as a once daily SC injection for 28 consecutive days.

The study medication exposure variables include:

- Study treatment exposure (days) = Treatment end date - treatment start date – number of days of missed doses + 1
- Study treatment compliance (%) = Average over total time of exposure (Treatment start date to treatment end date):

For each day:

$$100 \times \frac{\text{~~Day X Total Volume Expected~~}}{\text{~~Day X To~~tal Volume Injected}}$$

The average calculation should include all days from the treatment start date to the treament end date, including days with missed doses.

6.3.3 Adverse Events

The AE reporting period begins when the subject signs the ICF and continues through the clinical study's post treatment follow-up period, defined as 14 days after last administration of study medication. Within the study, all subjects who took at least 1 dose of IMP, whether they completed the treatment period or not, should enter the 14-day period as defined above. If a subject is documented as lost-to follow-up, ongoing/unknown outcome AEs will not be followedup.

Adverse events will be collected and coded using the latest version of the Medical Dictionary for

Regulatory Activities (MedDRA 19.1 or newer). An adverse event is considered treatmentemergent if the date of onset is on or after the date of first dose of study medication, or worsening during the treatment period (intensity/severity changed to worsen grades). All reported AEs will be listed, but only treatment-emergent adverse events (TEAEs) will be summarized. All adverse events are assessed by investigators on intensity, relationship to study drug, and seriousness according to the definitions in protocol Sections 9.7.1.1 and 9.7.1.2.

Intensity: AEs will be rated as Mild, Moderate or Severe.

Relationship to study drug: AEs will be qualified as either related (unlikely, probably or possibly related) or non-related (unrelated) to study drug. Seriousness: AEs will be categorized as serious or non-serious

Adverse Events Counting Rules:

1. A subject with more than one different adverse event in a particular system organ class (SOC) will be counted only once in the total of subjects experiencing adverse events in that particular SOC.
2. A subject having experienced the same event (AE preferred term) more than once during the study will be counted only once in the number of subjects with that event.
3. A subject having experienced the same event (AE preferred term) more than once during the study with a different intensity or seriousness, it will be counted only once with the worst grade and seriousness respectively.
4. A subject having experienced the same event (AE preferred term) more than once during the study with a different causal relationship to the study drug, it will be counted only once by considering the most-related documented degree of relationship.

Events with Irregular Start or End Dates:

Partial dates may be imputed when appropriate. Imputed dates will be used to determine Study Day.

If a partial date is reported for the start of an adverse event, a complete date will be estimated by the following algorithm:

1. Only the year is reported: If the subject started receiving study medication in the previous year, then January 1 will be used as the starting date of the event. If the subject started receiving study medication in the year reported, then the date of the first dose of study medication will be used as the start of the event.
2. The month and year is reported: If the subject started receiving study medication prior to the month and year reported, then the first day of the month will be used as the starting date

of the event. If the subject started receiving study medication during the month and year reported, then the date of the first dose of study medication will be used as the start of the event.

If a partial date is reported for the end of an adverse event and the adverse event is not continuing, a complete date will be estimated by the following algorithm:

1. Only the year is reported: If the subject started receiving study drug in the previous year, then the date of final study contact with the subject will be used as the end of the adverse event. If the subject started receiving study medication in the year reported, then the earlier of December 31 or the date of final study contact with the subject will be used as the end of the adverse event.
2. The month and year reported: The earlier of the last date of the month or the date of final contact with the subject will be used as the end of the adverse event.

The above rules are subject to logical sense (for example, imputed start date should be on or prior to imputed end date and vice-versa).

6.3.4 Laboratory Data

Clinical laboratory tests on hematology, chemistry, urinalysis, and HF biomarkers will be performed according to the schedule in Section 3.6. Investigators will assess whether there are any clinically significant abnormalities and record the abnormality on medical and surgical history or adverse event forms. The lists of laboratory parameters collected are as follows:

Hematology:

- Hemoglobin
- Hematocrit
- Erythrocyte count (RBC)
- Leukocytes (WBC)
- Neutrophils, segmented
- Lymphocytes
- Monocytes
- Eosinophils
- Basophils
- Platelets

Clinical Chemistry (Serum Concentrations of):

- Sodium
- Potassium

- Total bilirubin

- Alkaline phosphatase (ALP)
- Alanine aminotransferase (ALT)
- Aspartate aminotransferase (AST)
- Blood urea nitrogen (BUN)
- Creatinine
- Calcium
- Glucose, nonfasting
- Albumin
- Chloride
- Bicarbonate
- Total Protein
- Triglycerides
- eGFR calculated with the MDRD study equation
- hsTroponin I Urinalysis:

- Specific gravity
- pH
- Protein
- Glucose
- Ketones
- Blood
- Sodium
- Chloride
- Creatinine
- Microalbuminuria HF Biomarker:

- NT-pro-BNP

Conversion to the International System of Units

All laboratory data will be stored in the database with the units in which they are originally reported. Laboratory data in summary tables and subject data listings will be presented in the International System of Units (SI units; Système International d'Unités). Laboratory data not reported in SI units will be converted to SI units before further processing or data analysis.

Abnormal Values

Based upon laboratory normal ranges, laboratory test results will be categorized according to the normal range as low, normal and high. Subjects with laboratory data outside the normal range will be listed with abnormal values flagged.

6.3.5 Vital Signs

Vital signs include heart rate (beats per minute [BPM]), respiration rate, systolic and diastolic blood pressure (mmHg) and oral or tympanic temperature (°C). Vital signs will be collected at each scheduled visit.

Baseline values are those measured at last evaluation prior to the first dose of study medication.

Change from baseline to time point t, denoted Changet, will be calculated as:

$$Change_t = Value_t - Value_{Baseline}.$$

6.3.6 Electrocardiogram (ECG)

Baseline ECGs will be defined as the last evaluation performed prior to the first dose of study medication. Electrocardiogram results (normal versus abnormal), intervals of HR, PR, QRS, QT, and RR in msec are reported on eCRF at screening, Day 1 (Baseline), Week 1, Week 2, Week 4, and Week 6. The Fridericia corrected QT interval (QTcF) will be calculated as: $QTcF = QT/(RR)^{1/3}$.

6.3.7 Physical Examination

A cardiovascular physical examination, including lung auscultation and weight, will be measured at screening, Day 1 (Baseline), Week 1, Week 2, Week 4, and Week 6. Height will only be measured at the Screening Visit.

The results of the physical examination with any clinical significant abnormalities (yes/no) are reported on the eCRF.

6.3.8 Pregnancy Test

All pregnancies with an estimated conception date that occurred during the AE reporting period, as defined in Section 6.3.3, must be recorded in the AE section of the eCRF. For this study, this applies to pregnancies in female subjects and in female partners of male subjects.

6.3.9 Concomitant Medications/Treatments

Prior and concomitant medications will be recorded at Screening and during the study. Prior medication is defined as any medication taken before the first dose of the IMP. Concomitant

medication is defined as any medication taken during the study between the date of the first dose of IMP and the last study date of the subject. Any medications started after the last study date of the subject will not be considered concomitant medications.

All relevant information, including reason for use, dose, frequency and route, will be recorded for any medication administered or received prior and during the study.

Summaries of all concomitant therapies taken during the course of the study will be presented in tabular form using Anatomical Therapeutic Chemical 3 classification codes and preferred drug name via the World Health Organization Drug Dictionary (WHO-DD) with latest version to be specified in the Clinical Study Report.

All medications will be summarized by treatment group and sorted alphabetically by medication class and medication subclass. For the summary tables, if a subject has taken a concomitant medication more than once, the subject will be counted only once in the total.

The concomitant medication listing will be reviewed as part of the identification of protocol deviations to identify subjects who took medications which may affect the efficacy of the study drug. Medications of interest include beta blockers, ACE or ARBS, Spironolactone, diuretics (specifically furosemide), and oral long acting nitrates.

Medications with Incomplete Dates:

For medications with incomplete dates, imputation will be used to convert to a complete date. Imputed dates will be used to determine Study Day.

Partial medication start dates will be imputed as follows:

1. Only the year is reported: If the subject started to receive study drug in the year reported, then the date of the first dose of study drug will be used as the starting date of the medication. Otherwise, January 1 will be used as the start of the medication.
2. The month and year is reported: If the subject started to receive study drug during the month and year reported, then the date of first dose of study drug will be used as the starting date of the medication. Otherwise, the first day of the month will be used as the start of the medication.

Partial medication end dates will be imputed for non-ongoing medications as follows:

1. Only the year is reported: If the subject stopped to receive study drug in the year reported, then the date of the last dose of study drug will be used as the end date of the medication. Otherwise, December 31 will be used as the end of the medication.
2. The month and year is reported: If the subject stopped to receive study drug during the month and year reported, then the date of last dose of study drug will be used as the end date of the medication. Otherwise, the last day of the month will be used as the end of the medication.

The above rules are subject to logical sense (for example, imputed start date should be on or prior to imputed end date and vice-versa).

7. STATISTICAL ANALYSIS

7.1 General Data Handling Rules and Definitions

All data collected on case report forms will be provided in listings, except data collected only for confirmation of study entry criteria and for study administrative purposes. If any randomized subject is found to not have valid documented informed consent, the subject's data will be excluded from the report, except as necessary to document the error.

Except where specified all continuous variables will be summarized with descriptive statistics (the number of non-missing values, mean, standard deviation, median, minimum and maximum) and all categorical variables will be summarized with frequency counts and percentages, by treatment group. Unless otherwise specified, the mean and median will be displayed to one more decimal place than the original data, and standard deviation and standard error of the mean should be displayed to two more decimal place than the original data. All percentages for frequencies will be rounded to 1 decimal place.

When statistical hypothesis testing is performed, the treatment comparison will be two-sided and tested at an alpha=0.05 level of significance. Although, this provides for experiment-wise alpha at the strict 0.05 level, for the primary endpoint (LV ESV), significant results on LV EF would also be considered positive. In addition, if both endpoints are statistically significant at the 0.10 level of statistical significance, the study will similarly be considered positive. This effectively implements a Hochberg's adjustment for a primary endpoint family (of LV ESV and LV EF) at the 0.10 family-wise alpha-level.

Missing data will be maintained as missing unless specified otherwise. For variables where missing data is imputed, the analysis dataset will contain one variable with the imputed value and the original variable with missing maintained as missing.

7.2 Subject Disposition

Subject disposition summaries will include the number of subjects randomized and the numbers included in the Safety, ITT, and Per-Protocol populations by treatment group for all subjects. The number and percentage of subjects who complete or discontinue from the study will be summarized by reason for discontinuation for each treatment group.

The frequency distribution of the extent of subject participation in the study (last study date – randomization date – number of days of missed doses + 1) will be provided by treatment group for all randomized subjects.

7.3 Demographic and Baseline Characteristics

Subject's age, gender, race, ethnicity, weight, height, BMI, and baseline characteristics, vital signs, cardiovascular physical examination results (any clinically significant abnormalities (yes, no)), and ischemic/non-ischemic status will be summarized by treatment group and for all subjects in the Safety, ITT, and Per-Protocol populations. The medical and surgical history will be listed.

7.4 Efficacy Analyses

Efficacy analyses will be conducted on the ITT population, along with the Per-Protocol population for sensitivity; according to the treatment the subjects were assigned.

Since imaging may be performed after a clinic visit there will be an allowable 5 day window from the clinic visit. Any imaging that is collected more than 5 days after the clinic visit will not be included in the analysis.

7.4.1 Primary Efficacy

The primary efficacy endpoint is change in LV ESV assessed by MRI at Week 4 from baseline.

Actual values and change from baseline values will be summarized by treatment group in the ITT and Per-Protocol populations. Mean change in LV ESV measurements of all three treatment groups together will be analyzed using a mixed-effect model for repeated measures (MMRM), in order to study trends in the treatment effects over 4 weeks, with the primary time point of interest

being at Week 4. The model will include treatment (4 mg elamipretide, 40 mg elamipretide, placebo), visit (week numbers), treatment-by-visit interaction, and ischemic/non-ischemic as fixed effects, baseline LV ESV and baseline LV ESV by visit interaction as covariates, and subject as a random effect. An unstructured covariance matrix will be used to model the covariance of withinpatient results. The Kenward Roger method will be used to compute the denominator degrees of freedom. All LV ESV data at Week 1 and Week 4 will be included in the MMRM model. All pairwise comparisons among treatment groups for change from baseline in LV ESV and the corresponding 2-sided 95% confidence interval (CI) will be calculated based on the MMRM model for each visit. In addition a linear contrasts (at each visit) will be constructed to test for trend over dose levels, such that differences in contrast coefficients are proportional to differences in dose level (0 mg, 4 mg and 40 mg).

The primary comparison for the primary analysis involves the comparison of 40 mg elamipretide vs. placebo at Week 4. This provides for experiment-wise alpha at the strict 0.05 alpha-level for this comparison, only.

Nevertheless, a failure of the primary comparison for the primary endpoint will not automatically be considered a "failed study" for internal decision making, where the decision will necessarily be made based on the totality of the data. Accordingly, nominal significance on key secondary endpoints (such as LV EF) or even strong trends in a preponderance of endpoints with key secondary endpoints significant at a slightly inflated alpha-level of, say, 0.10, may be considered sufficient for progression of the compound in this indication, despite an outcome not generally considered to represent "substantial evidence of effectiveness".

The normality and homogeneity of variances assumptions will be checked graphically by residual plot. If these model assumptions fail despite data transformation (e.g. log) a non-parametric approach (e.g. Kruskal-Wallis test) may be used.

7.4.2 Secondary Efficacy

Secondary analyses to address the secondary objective will include comparisons in change from baseline between treatment groups for the following endpoints. The MRI endpoints will be analyzed in the same manner as the primary efficacy measures. The model will include the same terms as for the primary analysis, but will include the baseline (pre-treatment) assessment of the same endpoint. The echocardiography endpoints (except those endpoints noted below) will be analyzed with the same MMRM model as the primary endpoint, with the exception that Week 4

and Week 6 (two week post-treatment follow-up visit) will be included in the model (instead of Week 1 and Week 4). The model will include the same terms as for the primary analysis, but will include the baseline (pre-treatment) assessment of the same endpoint. Due to the high degree of measurement error associated with echocardiography measurements, only descriptive statistics will be produced for select echocardiography parameters as described below.

Secondary Endpoints Assessed by MRI:

- LVEF ○ LV EDV ○ LVSV
- LVCO
- LV myocardial mass ○ RV ESV ○ RV EDV
- RVEF

Secondary Endpoints Assessed by Echocardiography:

- E/A (ratio between early and late mitral inflow velocity),
- E/e' (Ratio between early mitral inflow velocity and mitral annular early diastolic velocity)
- LA volume ○ LV GLS

The following secondary endpoints assessed by echocardiography with descriptive statistics only:

- LV EDV ○ LV ESV ○ LVEF (biplane)
- LV mass
- Mitral regurgitation severity
- Tricuspid regurgitation severity ○ RV fractional area change ○ RV systolic pressure (RVSP)

7.4.3 Exploratory Efficacy

Exploratory analyses to address the exploratory objective will include comparisons in change from baseline between treatment groups for the following endpoints. hsTroponin and the log of NT-proBNP levels will be analyzed in the same manner as the primary efficacy measures, with a MMRM model. The distance walked (meters) during 6MWT and the KCCQ score only have one postbaseline assessment so they will not be analyzed as repeated measures. Instead, the change

from baseline of these two endpoints will be analyzed with an ANCOVA model. The model terms will include terms for treatment, baseline (pre-treatment) value, and ischemic/non-ischemic. Treatment difference estimates using least square means along with the 95% confidence intervals for the estimates will be presented for scheduled visits. The difference in mean change from baseline between the elamipretide treatment groups and placebo will be tested at a 2-sided significance level of 0.05.

- Distance walked (meters) during 6MWT
- Levels of NT-pro-BNP (log transformed)
- KCCQ score

Additionally, the LV myocardial mass, LV stroke volume, LV cardiac output, RV end systolic volume, RV end diastolic volume, RV myocardial mass, and the RV ejection fraction, assessed by MRI, will be analyzed in the same manner as the primary efficacy measures, including comparisons in change from baseline between treatment groups.

7.4.4 Efficacy Subgroup Analyses

The primary efficacy endpoint, change in LV ESV assessed by MRI at Week 4 from baseline, will be summarized by treatment group for subgroups of subjects with baseline ischemic/non-ischemic status, high versus low baseline hsTroponin, subgroups of baseline NT-pro-BNP levels. The values of the endpoint for the subgroups will also be plotted by treatment group over time for Screening, Week 1, and Week 4. The analyses and plots will be done using the ITT population.

7.5 Plasma Concentration Analyses

Plasma concentration analyses will be conducted on the Safety population. Plasma samples will be analyzed for elamipretide, M1, and M2 concentrations. No formal statistical analyses will be performed.

Individual concentration time data for elamipretide will be listed, sorted by subject, and summarized for each nominal time point (as determined by nominal hour).

The plasma concentration data for elamipretide, M1, and M2 at each time point will be listed and summarized for the safety population. Descriptive statistics will include the number of observations (n), mean, standard deviation, coefficient of variation, median, minimum, maximum, geometric mean, and geometric coefficient of variation.

The plasma concentration-time profiles for individual and mean (+/-SD) plasma concentrations of elamipretide, M1, and M2 will be presented on both linear/linear and semi-logarithmic (log/linear) scales. For individual profiles, three figures will be presented with all individual profiles, one each for elamipretide, M1, and M2, superimposed on a same profile panel. For the mean linear-linear and semi-logarithmic profiles, three figures will be created with the mean concentrations of elamipretide, M1, and M2 at each nominal time-point for all subjects displayed.

7.6 Safety Analyses

Except where otherwise specified, safety analyses will be performed using the safety population. Safety measurements will include AEs, clinical laboratory tests (i.e. serum chemistry, hematology, urinalysis, and hsTroponin), ECGs, physical exams and vital signs. All safety data will be summarized by treatment group. Baseline values for clinical laboratory tests, vital signs and ECGs will be defined as the last evaluation performed prior to administration of study drug.

7.6.1 Extent of Exposure to Study Medication

The following study medication exposure variables as listed in Section 6.3.2 will be summarized by treatment groups.

- Study treatment exposure (days)
- Study treatment compliance (%)

Study medication dosing information will be listed by subject.

7.6.2 Adverse Events

All AEs will be coded to system organ class (SOC) and preferred term (PT) using the Medical Dictionary for Regulatory Activities (MedDRA version 19.1 or newer) coding dictionary (version to be specified in the clinical study report). All reported AEs will be listed, but only treatmentemergent adverse events (TEAEs) will be summarized.

Frequency and percentage of subjects experiencing a specific adverse event will be tabulated by system organ class, preferred term, and treatment group. Summary tables will be provided for adverse events by maximum intensity, relationship to study drug, serious adverse events, and adverse events causing discontinuation of study medication.

The incidence of all TEAEs, drug relationship with TEAEs, and severity of TEAE will be summarized by treatment group and all subjects in the safety population with frequencies and

percentages. In the summary tables, subjects may be counted under multiple SOCs and PTs, but for each SOC and PT, subjects are only counted once. If a subject has the same AE on multiple occasions, the highest intensity (severe > moderate > mild) or drug relationship (probable > possibly related > unlikely related > unrelated) recorded for the event will be presented. If severity is missing, subjects will be included as Grade 3 (for severity). If drug relationship is missing, subjects will be included in related tables (i.e., considered related). Summary tables will be sorted by SOC, and then PT.

The following summaries will be presented for TEAEs:

1. Summary of Adverse Events by Treatment Group;
2. Incidence of Adverse Events by System Organ Class and Preferred Term;
3. Incidence of Serious Adverse Events by System Organ Class and Preferred Term;
4. Incidence of Adverse Events by System Organ Class, Preferred Term and Intensity;
5. Incidence of Study Drug Related Adverse Events by System Organ Class, Preferred Term and Intensity;
6. Incidence of Adverse Events by System Organ Class, Preferred Term and Relationship to Study Drug;
7. Incidence of Adverse Events Leading to Discontinuation of Study Drug by System Organ Class and Preferred Term

7.6.3 Deaths

Summary of deaths will be provided as a listing, displaying treatment group, date of death, study day of death and reason for death.

7.6.4 Clinical Laboratory Evaluations

Summary tables for laboratory parameters (including hematology, chemistry, urinalysis, and hsTroponin) will include descriptive statistics for values and change from baseline for all continuous variables for each treatment group. Subjects with laboratory data outside the normal range will be listed with abnormal values flagged.

Shift tables (i.e., tables that show the number of subjects who are low, normal, or high at baseline versus each post-baseline scheduled assessment, Section 3.6) will be produced.

The number and percentage of subjects with urinalysis results outside the normal range will be presented by parameter and time point for each treatment group. Shift tables for urinalysis will

show the number of subjects who are normal/abnormal at baseline and normal/abnormal at the end of study.

Laboratory test reference ranges, flags for values outside of the normal ranges, as well as investigators assessment of these values as non-clinically or clinically significant are all displayed in subject data listings by treatment group and measurement time point for all subjects from the safety population.

7.6.5 Vital Signs

Vital sign changes from baseline tables will be summarized by treatment group and visit time point. Listing of vital signs will be provided for all subjects in the safety population.

7.6.6 Electrocardiogram (ECG)

ECG changes from baseline tables will be summarized by treatment group and visit time point, and a subgroup table for low and high QRS interval duration. ECG results (normal versus abnormal) and an assessment of the clinical significance of any abnormalities (in the opinion of the Investigator) will be listed for individual subjects. Intervals of HR, PR, QRS, QT, and QTc will also be listed. Patients who have either an increase of >60 msec between baseline and end of treatment in their QT or an absolute QT value >500 msec at any point in time during the study will be listed separately.

7.6.7 Physical Examination

The number and percentage of subjects experiencing clinically significant abnormalities (yes, no, not done) in the cardiovascular physical examination will be tabulated at every visit by treatment group and for all subjects combined. The number and percentage of subjects experiencing clinically significant abnormalities (yes, no, not done), and the weight, height, and BMI, in the physical measurements will be summarized at every visit by treatment group and for all subjects combined. Physical examinations results will be presented in individual subject data listings.

7.6.8 Concomitant Medications/Treatments

The number and percentage of subjects have reported concomitant therapies during the course of the study will be tabulated by using Anatomical Therapeutic Chemical 3 classification codes and preferred drug name via the World Health Organization Drug Dictionary (WHO-DD) in latest version (version 3Q2016 WHODRUG DDE in addition to WHODRUG HD, or later), with version to be specified in the Clinical Study Report.

All medications will be summarized by treatment group and sorted alphabetically by medication class and medication subclass. For the summary tables, if a subject has taken a concomitant medication more than once, the subject will be counted only once in the total.

All prior and concomitant medication data will be presented in individual subject data listings.

8. ANALYSES PERFORMED BEFORE DATABASE CLOSURE

No interim analyses are planned for this study.

9. CHANGES FROM METHODS PLANNED IN THE PROTOCOL

Any changes to methods planned in this statistical analysis plan will be documented in a revision to this statistical plan prior to database lock, or identified in the clinical study report.

10. STATISTICAL SOFTWARE

The statistical software to be used for generation of the tables, listings, and figures is SAS® version 9.3 or higher.

11. REFERENCES

APPENDIX 1 DATA HANDLING RULES

Category	Description	Data Handling Rules
Demographics	Age at informed consent	Age = integer ((date of informed consent signed – date of birth+1)/365.25) For some sites (Italy and U.K.) only month and year of birth are collected, and day of birth is imputed as the 1st of the month. For some sites (Netherlands) only year of birth is collected, and day and month of birth are imputed as the 1st of January. This same imputation rule will apply for all missing day of birth to the 1st of the month, and month of birth to January.
Baseline	Baseline assessment	Baseline assessment is defined as last assessment prior to first dose of study medication.
Timing	Study Day 1	Date subject is randomized and expected to receive the first dose of study medication.

Timing	Study Day	Before study day 1: study day = date of assessment – date of study day 1. On or after study day 1: study day = date of assessment – date of study day 1 + 1.
Timing	Day 1 and Hour 0	The date and time at first dose of study medication.
Timing	Time from first dose of study medication	The time from first dose of study medication = time of assessment – time of first dose of study medication.
Outcome measures/Vital Signs/Lab	Change from baseline	$Change_t = Value_t – Value_{Baseline}$.
Exposure	Extent of study drug exposure	Extent of exposure to study medication (days) = Treatment end date – treatment start date – number of days of missed doses + 1.

APPENDIX 2 SAS CODE FOR STATISTICAL ANALYSES

The following table presents the SAS code for the statistical analyses. This section will be finalized after examining the existing data and prior to the final signoff of this SAP.

Test	Table/Figure	SAS Codes
MMRM with baseline value as covariate	*Primary and secondary MRI and exploratory endpoints- requiring MMRM*	*proc mixed;* *class treatment timepoint patient;* *model cfb = treatment baseline timepoint baseline*timepoint treatment*timepoint ischemic / residual ddfm=kenwardroger; ** cfb is change from baseline **;* *repeated timepoint / type=un subject=patient; lsmeans treatment*timepoint / pdiff cl; run;*
ANCOVA with baseline value as covariate	*Secondary and Exploratory endpoints requiring ANCOVA*	*proc glm; class treatment;* *model cfb = treatment baseline baseline_MRI ischemic;* ***cfb is change from baseline;* *lsmeans treatment / cl pdiff; run;*

Linear trend test for MMRM models	*Primary, and secondary MRI, and exploratory endpoints-requiring MMRM*	*proc mixed; class treatment timepoint patient; model cfb = treatment baseline timepoint baseline*timepoint treatment*timepoint ischemic; **A contrast 'linear trend test' will involve the following coefficients to test treatment effects at each visit -0.470757 -0.342368 0.8131249; ** coefficients calculated from SAS PROC IML; ** in order of placebo, 4, 40; If treatment=3 is placebo, code treatment as 0 so placebo will go first. Coefficients are applied to estimates of treatment effect for each treatment group at each visit, which will consist of main effect and interaction terms, specific for the visit under consideration. run;*
Linear trend test for ANCOVA models	*Secondary and Exploratory endpoints requiring ANCOVA*	*proc glm; class treatment; model cfb = treatment baseline baseline_MRI ischemic; contrast 'linear trend test' treatment -0.470757 -0.342368 0.8131249; ** coefficients calculated from SAS PROC IML; ** in order of placebo, 4, 40; If treatment=3 is placebo, code treatment as 0 so placebo will go first. run;*

APPENDIX 3 REFERENCE RANGES AND CLINICALLY RELEVANT CHANGES FROM BASELINE FOR MARKED LABORATORY ABNORMALITIES

Not applicable.

APPENDIX 4 MOCKUP TABLES, LISTINGS, AND GRAPHS (TLGS)

Mockup tables, listings, and graphs are presented in a separate document.

SPECIFICATION OF END OF TEXT STANDARD OUTPUT TABLES, LISTINGS, AND FIGURES (TLFs)

Trial Sponsor: Stealth BioTherapeutics, Inc.

Protocol Number: SPIHF-201 **IND Number:** N/A **EUDRACT Number:** 2014-005724-10

Investigational Drug: Elamipretide™ (MTP-131)

Indication: Heart Failure with reduced Ejection Fraction (HFrEF)

Dosage Form/Strength: Elamipretide™ (MTP-131) 40 mg/1 mL of sterile solution for subcutaneous injection with doses of 4 mg or 40 mg administered as a once daily SC injection

Protocol Title: A Phase 2 Randomized, Double-Blinded, Placebo-Controlled Study to Evaluate the Effects of Multiple Subcutaneous Injections of Elamipretide on Left Ventricular Function in Subjects with Stable Heart Failure with Reduced Ejection Fraction

CHANGE LOG FOR CHANGES MADE AFTER THE INITIAL APPROVAL

Revision Date**	Section(s) Modified	Brief Description of Revision(s) or Reason(s) for Revision	Modifications Reviewed and Approved by*
			Sponsor, Everest

* Provide person's initial and last name. ** Update the Last Revision Dates on the cover page and the document header.

General Instructions for End-of-Text TFLs

Following are the specifications for end-of-text standard tables, figures and listings (TFLs).

Header

The following header should appear at the very top of each page of a table, a figure, or a listing (TFL):

```
Stealth Protocol SPIBioTherapeuticsHF-201                                                    ,
Inc. ElamipretidePage n of N ™ (MTP-131 for SC Injection)
```

Footer

The following footer should appear at the bottom of each page of a TFL generated in SAS:

```
Program: /sasdir/pgname.sas                                    Version 2014-01-25 13:37
```

where: PGNAME = SAS program name. Version will be replaced by “Draft” or “Final”.

Title

At least three (3) lines should be reserved for the whole title. The first line is for the TFL number (i.e., title index #); the second line is for the actual title (title); and the third line is reserved for the analysis population descriptor (population). All titles should be centered, as shown in the following example:

```
Table 1.1
Demographics
Safety Population
```

Footnotes

In general, a footnote serves as a brief explanation/clarification/definition/concept of a flag symbol or a character, an abbreviation, a terminology, etc., that appears in, or related directly to the displayed content of a TFL. Detailed/technical elaboration of, for example, a mathematical/statistical formula, a statistical term/test, or an algorithm for deriving a parameter value, should be addressed in the text of the statistical analysis plan (SAP).

All footnotes should follow immediately after a horizontal solid line. There should be one and only one space between the last footnote and the footer.

When an abbreviation (e.g., TEAE, SAE, etc.) appears for the first time in the entire set of TFLs for a study, a footnote should be provided at least once; it is up to the Study Biostatistician, Scientist, and Study Programmer to decide whether there is a need to repeat the same footnote for the rest of TFLs (if applicable).

Each line of a complete footnote should end with a period. When a footnote needs more than 1 line, one (1) period is needed.

Footnotes should be in the format shown in the following example:

```
<abbreviations> <notes>

[a]
[b]
[c]
Source: Listings 2.1.1, 2.1.2, 2.3
```

Page Layout

All output should be in landscape orientation.

All efforts should be made to present all treatment groups in one page.

The Scientist and Study Biostatistician will pre-determine the order for the display of the treatment groups.

Page Format

There should be a solid line at the top of the tables and listings just below the title.

There should be a solid line just below the column headings that runs completely across the width of the tables and listings.

There should be a solid line at the bottom of the tables and listings just above the footnote(s) on every page.

Font

The default font to be used in the actual study tables/listings should be Courier New 8 point which is approximately equivalent to the acceptable font size of Times New Roman 9-10 in accordance with the FDA's guidance on Electronic Common Technical Document Specification.

Descriptive Statistics

By default, descriptive statistics in this template covers: n, mean, median, standard deviation (SD), minimum (min), and maximum (max). Unless otherwise specified in the actual table shells, the mean and median should be displayed to one more decimal place than the original data, and standard deviation and standard error of the mean should be displayed to two more decimal place than the original data.

Rounding for Percentage

All percentages will be rounded to 1 decimal place in all TFLs. P-values

will be presented with 4 decimal places.

Alignment of Decimals

It is recommended that all the decimal places be aligned in summary tables, as shown in the following example:

	Decimal Align
n	xxx
Mean	xx.xx
SD	xx.xxx
Median	xx.xx
Min, Max	xx.x, xx.x

When numbers with decimal points are included in brackets (e.g., percentages), the brackets should be aligned to the right and then padded to allow for all possible percentages and then the left brackets will also be aligned. For example:

Brackets Align
(99.9%) (xx.x%)
(9.9%) (x.x%)

It is recommended that all column entries in a summary tables and listings are aligned to the center. Columns for text fields are all left justified. Columns with whole numbers are all right justified. For graphs, the lines are distinguishable and that the symbols for each line are appropriate. Legend is consistent across output for treatment names and abbreviations.

Use of N Versus n

N = total number of subjects in the defined analysis set. n

= total number of subjects in the specific category.

If N is specified in the column heading then any reference to the number of subjects in the body should be small n, as shown in the following example:

Demographic Parameter	Treatment Group A (N = xxx)	Treatment Group B (N = xxx)	Total (N = xxx)
	xx	xx	xx
Age (years) n	xx.x	xx.x	xx.x
Mean SD	x.xx	x.xx	x.xx
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

A Note for Subject Data Listings

Observed Dates/AE Severity/Relationship to investigational product are used in subject data listings.

Observed values or raw assessment scores are used in data listings along with their derived values used in analyses, e.g., raw assessment scores and derived total scores.

TABLE OF CONTENTS FOR TABLES, FIGURES AND LISTINGS

1. SUBJECT DISPOSITION

Table 1.1
Subject Disposition
All Randomized Subjects

	Elamipretide 4 mg (N=xx)		Elamipretide 40 mg (N=xx)		Placebo (N=xx)		All Subjects (N=xx)	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects Randomized	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Safety Population [a]	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
ITT Population [b]	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Per-Protocol Population [c]	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Not Treated	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Completed Study	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Early Discontinuation from the Study	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Primary Reason for Discontinuation Adverse Event	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Subject Withdrawal of Consent	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Sponsor Decision	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Investigator Decision	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Pregnancy	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Subject Lost to Follow-up	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)

% = 100*n/N, where n = number of subjects in the specific row category and N = number of subjects in the column category.
[a] Safety Population = all subjects who received at least 1 dose of the investigational medicinal product (IMP), summarized according to the treatment received.
[b] ITT Population = all subjects who were randomized and receive at least 1 dose of IMP, summarized according to the treatment group to which the subjects were randomized
[c] Per-Protocol Population = all randomized subjects receiving at least one dose of the IMP without major protocol violations/deviations, summarized according to the treatment group to which the subjects were randomized. Source: Listing 1.1

Table 1.2
Extent of Participation in the Study
All Randomized Subjects

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)	All Subjects (N=xx)
Extent of Participation in the study [a]				
Treatment Period				
n		xx		xx
1-5 days	xx	(xx.x%)	xx	(xx.x%)
6-10 days	(xx.x%)	xx	(xx.x%)	xx
11-15 days	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
16-20 days	(xx.x%)	xx	(xx.x%)	xx
21-25 days	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
26-28 days	(xx.x%)	xx	(xx.x%)	xx
>28 days	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Follow-up Period				
n	xx	xx	xx	xx
1-5 days after last dose	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
6-10 days after last dose		xx		xx
11-14 days after last dose		(xx.x%)		(xx.x%)
>14 days after last dose		xx		xx
		(xx.x%)		(xx.x%)

[a] Extent of Participation in the Study = Treatment Period: last treatment date – randomization date + 1. Follow-up Period: last study date – last treatment date + 1.

Source: Listing 1.1

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

2. DEMOGRAPHIC AND BASELINE CHARACTERISTICS

Table 2.1a
Demographic and Non-Imaging Baseline Characteristics Safety Population

	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)	All Subjects (N=xx)

Age (years)	xx	xx	xx	xx
n Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx,	xx,	xx,	xx,
Age (years)	xx	xx	xx	xx
n	xx xx	xx xx	xx xx	xx xx
< 65	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
≥ 65	xx	xx	xx	xx
Gender	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
n	xx xx	xx xx	xx xx	xx xx
Male	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
Female	xx	xx	xx	xx
Race	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
n	xx xx	xx xx	xx xx	xx xx
White	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
Black or African American	xx	xx	xx	xx
Asian	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
American Indian or Alaska Native	xx	xx	xx	xx
Native Hawaiian or other Pacific Islander	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
Other	xx	xx	xx	xx
Unknown	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
Ethnicity	xx	xx	xx	xx
n	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
Hispanic or Latino	xx	xx	xx	xx
Not Hispanic or Latino	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
Not reported	xx xx	xx xx	xx xx	xx xx
Unknown	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
	xx	xx	xx	xx
Baseline Weight (kg)	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
n Mean SD	xx	xx	xx	xx
Median	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
Min, Max	xx	xx	xx	xx
	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
	xx	xx	xx	xx
	xx.x	xx.x	xx.x	xx.x
	xx.xx	xx.xx	xx.xx	xx.xx
	xx.x	xx.x	xx.x	xx.x
	xx,	xx,	xx,	xx,
	xx	xx	xx	xx
	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)	All Subjects (N=xx)

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Baseline Height (cm) n Mean SD Median Min, Max	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx
Body Mass Index (kg/m^2) Baseline n Mean SD Median Min, Max	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx
Body Surface Area (m^2) n Mean SD Median Min, Max	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx
Non-Imaging Efficacy Assessments				
Baseline Distance Walked (meters) During 6-minute Walking Test n Mean SD Median Min, Max	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx
Baseline Levels of Log10 [NT-pro-BNP (ng/mL)] n Mean SD Median Min, Max	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx
Baseline Levels of NT-pro-BNP (ng/mL) n Geometric Mean (CV%) Mean SD Median Min, Max	xx xx.x (xx.xx) xx.x xx.xx xx.x xx, xx	xx xx.x (xx.xx) xx.x xx.xx xx.x xx, xx	xx xx.x (xx.xx) xx.x xx.xx xx.x xx, xx	xx xx.x (xx.xx) xx.x xx.xx xx.x xx, xx

Report generated by program: /sasdir/xxxx.sas
-MM-DD HH:MM

D r a f t Y Y Y Y

Baseline eGFR (ml/min) n < 60 ≥ 60 Mean SD Median Min, Max	xx xx (xx.x%) xx (xx.x%) xx.x xx.xx xx.x xx, xx	xx xx (xx.x%) xx (xx.x%) xx.x xx.xx xx.x xx, xx	xx xx (xx.x%) xx (xx.x%) xx.x xx.xx xx.x xx, xx	xx xx (xx.x%) xx (xx.x%) xx.x xx.xx xx.x xx, xx
Baseline Kansas City Cardiomyopathy Questionnaire (KCCQ) Overall Summary Score n [redacted] Min, Max	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx
Vital Signs				
Baseline Heart Rate (bpm) n Mean SD Median Min, Max	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx
Baseline Respiration Rate (breaths/min) n Mean SD Median Min, Max	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx
Baseline Systolic Blood Pressure (mmHg) n Mean SD Median Min, Max	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx
Baseline Diastolic Blood Pressure (mmHg) n Mean SD Median Min, Max	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx	xx xx.x xx.xx xx.x xx, xx

Report generated by program: /sasdir/xxxx.sas
-MM-DD HH:MM

D r a f t Y Y Y Y

	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)	All Subjects (N=xx)

	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)	All Subjects (N=xx)
Baseline Temperature (Oral or Tympanic) (°C)				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Cardiovascular Physical Examination with Clinically Significant Abnormalities				
n	xx	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Baseline value is the last available measure prior to treatment.
SD = Standard deviation. Age is age at informed consent. n represents the number of subjects contributing to summary statistics. Percentages are based on n for each characteristic.

Source: Listings 1.4, 2.3, 7.1, 7.4.

Table 2.1b
Baseline Characteristics from MRI Safety Population

	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)	All Subjects (N=xx)

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)	All Subjects (N=xx)
Baseline Left Ventricular End Systolic Volume (LV ESV) (mL) [a]				
n Mean SD	xx xx.x		xx	
Median	xx.xx		xx.x	
Min, Max	xx.x		xx.xx	
	xx, xx		xx.x	
			xx, xx	
Baseline Left Ventricular Ejection Fraction (LVEF) (%)				
n Mean				
SD	xx xx.x		xx	
Median	xx.xx		xx.x	
Min, Max	xx.x		xx.xx	
	xx, xx		xx.x	
			xx, xx	
Baseline Left Ventricular End Diastolic Volume (LV EDV) (mL) [a]				
n Mean SD				
Median	xx xx.x		xx	
Min, Max	xx.xx		xx.x	
	xx.x		xx.xx	
	xx, xx		xx.x	
			xx, xx	
Percent Scarring of LV Mass (%)				
n Mean SD	xx			
Median	xx.x		xx	
Min, Max	xx.xx		xx.x	
	xx.x		xx.xx	
	xx, xx		xx.x	
Ischemic/Non-ischemic Status [b]			xx,	
n			xx	
Ischemic			xx xx	
Non-ischemic			(xx.x%)	
			xx	
	xx xx		(xx.x%)	
	(xx.x%) xx			
	(xx.x%)			

Baseline value is the last available measure prior to treatment.

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

SD = Standard deviation. n represents the number of subjects contributing to summary statistics.
Percentages are based on n for each characteristic.
[a] Value indexed by body surface area [BSA].
[b] Ischemic status as determined by scar pattern.
Source: Listings 2.1.

Table 2.1c
Baseline Characteristics from Echocardiography Safety Population

	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)	All Subjects (N=xx)

Baseline E/A (Ratio Between Early And Late Mitral Inflow Velocity)		
n Mean SD	xx xx.x	xx
Median	xx.xx	xx.x
Min, Max	xx.x	xx.xx
	xx, xx	xx.x
		xx, xx
Baseline E/e' (Ratio Between Early Mitral Inflow Velocity And Mitral Annular Early Diastolic Velocity)		
n Mean	xx xx.x	xx
SD	xx.xx	xx.x
Median	xx.x	xx.xx
Min, Max	xx, xx	xx.x
		xx, xx
Baseline Left Ventricular Ejection Fraction (LVEF) Biplane (%)		
n Mean SD		
Median	xx xx.x	xx
Min, Max	xx.xx	xx.x
	xx.x	xx.xx
	xx, xx	xx.x
Baseline Left Ventricular Global Longitudinal Strain (%)		xx, xx
n Mean		
SD		
Median	xx xx.x	xx
Min, Max	xx.xx	xx.x
	xx.x	xx.xx
	xx, xx	xx.x
Baseline Left Atrial Volume (mL) [a]	xx	xx, xx
n Mean SD	xx.x	xx
Median	xx.xx	xx.x
Min, Max	xx.x	xx.xx
	xx, xx	xx.x
Baseline Left Ventricular Mass (g) [a]		xx, xx

	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)	All Subjects (N=xx)
n Mean	xx xx.x	xx xx.x	xx xx.x	xx xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	xx	xx	xx	xx
Baseline Mitral Regurgitation Severity (cm^2)	xx.x	xx.x	xx.x	xx.x
n Mean SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	xx	xx	xx	xx
Baseline Tricuspid Regurgitation Severity (cm^2)	xx.x	xx.x	xx.x	xx.x
n Mean SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Baseline Right Ventricular Fractional Area Change (%) n	xx xx.x	xx xx.x	xx xx.x	xx xx.x
Mean	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx, xx	xx, xx	xx, xx	xx, xx
Min, Max				
Baseline Right Ventricular Systolic Pressure (RVSP) (mmHg)				
n Mean SD	xx xx.x	xx xx.x	xx xx.x	xx xx.x
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x	xx.x	xx.x	xx.x
	xx, xx	xx, xx	xx, xx	xx, xx

Baseline value is the last available measure prior to treatment.
SD = Standard deviation. Age is
age at informed consent.
n represents the number of subjects contributing to summary statistics. Percentages are based on n for each characteristic.
[a] Value indexed by body surface area [BSA].

Source: Listings 2.2.

Table 2.2a

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Demographic and Non-Imaging Baseline Characteristics ITT Population

Table 2.2b
Baseline Characteristics from MRI
ITT Population

Table 2.2c
Baseline Characteristics from Echocardiography
ITT Population

Table 2.3a
Demographic and Non-Imaging Baseline Characteristics Per-Protocol Population

Table 2.3b
Baseline Characteristics from MRI
Per-Protocol Population

Table 2.3c
Baseline Characteristics from Echocardiography
Per-Protocol Population

3. EFFICACY ANALYSIS

3.1 EFFICACY ANALYSIS

Point [a]	Elamipretide (mL) (N=xx)	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo	Elamipretide 4 mg and Placebo (95% CI), P-value [b]	Elamipretide 40 mg and Placebo (95% CI), P-value [b]	Difference Between Elamipretide 40 mg and Elamipretide 4 mg (95% CI), P-value [b]	Difference Between Test and Placebo [c]	Linear Trend P-value Time
Baseline	n	xx	xx			Mean	xx.x	xx.x	
SD	xx.xx	xx.xx				Median	xx.x	xx.x	
	Min, Max	xx, xx			xx, xx				
						Week 1	n	xx	xx
Mean	xx.x	xx.x				SD	xx.xx	xx.xx	
	xx.x								Median xx.x
	Min, Max	xx, xx			xx, xx				
						Change		from Baseline to Week 1	
[d]	n	xx			xx				
	Mean	xx.x			xx.x	xx.x (xx.x, xx.x)	x.xxxx	xx.x (xx.x, xx.x)	x.xxxx xx.x
(xx.x, xx.x)	x.xxxx	x.xxxx							
SD	xx.xx	xx.xx	Median	xx.x	xx.x				
	Min, Max	xx, xx			xx, xx				
						Week 4	n	xx	xx
Mean	xx.x	xx.x				SD	xx.xx	xx.xx	
	xx.x								Median xx.x
	Min, Max	xx, xx			xx, xx				
						Change	n	xx	xx

Table 3.1
Summary of Change From Baseline in Left Ventricular End Systolic Volume (LV ESV), Assessed by MRI ITT Population

Time Point	LV ESV (mL) [a]	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)	Difference Between Elamipretide 4 mg and Placebo (95% CI), P-value [b]	Difference Between Elamipretide 40 mg and Placebo (95% CI), P-value [b]	Difference Between Elamipretide 40 mg and Elamipretide 4 mg (95% CI), Pvalue [b]	Linear Trend Test Pvalue [c]
from Baseline to Week 4 [d]								
					xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	x.xxxx
					x.xxxx	x.xxxx	x.xxxx	
	Mean	xx.x		xx.x				
	SD	xx.xx						
	Median	xx.x	xx.xx	xx.x				
	Min, Max	xx, xx						

ITT Population = all subjects who were randomized and receive at least 1 dose of IMP, according to the treatment group to which the subjects were randomized.
Baseline value is the last available measure prior to treatment.
[a] Value indexed by body surface area [BSA].
[b] 95% confidence interval is based on the t-distribution and Lsmean of between treatment group difference from a mixed model repeated measures for the change from baseline which includes treatment group, treatment-by-visit interaction, and ischemic/non-ischemic as factors and the baseline value and baseline value-by-visit interaction as continuous covariates. P-value corresponds to a 2-sided significance level of the between treatment group difference from the mixed model repeated measures. [c] Linear trend test.
[d] Change from Baseline at time point t: $Change_t = Value_t - Value_{Baseline}$. Source:
Listings 2.1

Table 3.2
Summary of Change From Baseline in Left Ventricular End Systolic Volume (LV ESV), Assessed by MRI
Per-Protocol Population

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.3
Summary of Change From Baseline in Left Ventricular Ejection Fraction (LVEF), Assessed by MRI
ITT Population

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

[*Change 2nd column header to: LVEF*]

[*Remove footnote for indexing to BSA*]

Table 3.4
Summary of Change From Baseline in Left Ventricular Ejection Fraction (LVEF), Assessed by MRI
Per-Protocol Population

[*Change 2nd column header to: LVEF*]

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

[*Remove footnote for indexing to BSA*]

Table 3.5
Summary of Change From Baseline in Left Ventricular End Diastolic Volume (LV EDV), Assessed by MRI
ITT Population

[*Change 2nd column header to: LV EDV*]

Table 3.6
Summary of Change From Baseline in Left Ventricular End Diastolic Volume (LV EDV), Assessed by MRI
Per-Protocol Population

[*Change 2nd column header to: LV EDV*]

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.7
Summary of Change From Baseline in Left Ventricular Stroke Volume (LVSV), Assessed by MRI
ITT Population

[*Change 2nd column header to: LVSV*]

[*Remove footnote for indexing to BSA*]

Table 3.8
Summary of Change From Baseline in Left Ventricular Stroke Volume (LVSV), Assessed by MRI
Per-Protocol Population

[*Change 2nd column header to: LVSV*]

[*Remove footnote for indexing to BSA*]

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.9
Summary of Change From Baseline in Left Ventricular Cardiac Output (LVCO), Assessed by MRI
ITT Population

[*Change 2nd column header to: LVCO*]

[*Remove footnote for indexing to BSA*]

Table 3.10
Summary of Change From Baseline in Left Ventricular Cardiac Output (LVCO), Assessed by MRI
Per-Protocol Population

[*Change 2nd column header to: LVCO*]

[*Remove footnote for indexing to BSA*]

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.11
Summary of Change From Baseline in Left Ventricular Myocardial Mass (LV Mass), Assessed by MRI
ITT Population

[*Change 2nd column header to: LV Mass*]

Table 3.12
Summary of Change From Baseline in Left Ventricular Myocardial Mass (LV Mass), Assessed by MRI
Per-Protocol Population

[*Change 2nd column header to: LV Mass*]

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.13
Summary of Change From Baseline in Right Ventricular End Systolic Volume (RV ESV), Assessed by MRI
ITT Population

[*Change 2nd column header to: RV ESV*]

Table 3.14
Summary of Change From Baseline in Right Ventricular End Systolic Volume (RV ESV), Assessed by MRI
Per-Protocol Population

[*Change 2nd column header to: RV ESV*]

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.15
Summary of Change From Baseline in Right Ventricular End Diastolic Volume (RV EDV), Assessed by MRI
ITT Population

[*Change 2nd column header to: RV EDV*]

Table 3.16
Summary of Change From Baseline in Right Ventricular End Diastolic Volume (RV EDV), Assessed by MRI
Per-Protocol Population

[*Change 2nd column header to: RV EDV*]

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.17
Summary of Change From Baseline in Right Ventricular Ejection Fraction (RVEF), Assessed by MRI
ITT Population

[*Change 2nd column header to: RVEF*]

[*Remove footnote for indexing to BSA*]

Table 3.18
Summary of Change From Baseline in Right Ventricular Ejection Fraction (RVEF), Assessed by MRI
Per-Protocol Population

[*Change 2nd column header to: RVEF*]

[*Remove footnote for indexing to BSA*]

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.19
Summary of Change From Baseline in E/A (Ratio Between Early And Late Mitral Inflow Velocity), Assessed by Echocardiography
ITT Population

[*Change 2nd column header to: E/A, Change Timepoints to Weeks 4 and 6, Change footnote to Listing 2.2*]

[*Remove footnote for indexing to BSA*]

Table 3.20
Summary of Change From Baseline in E/A (Ratio Between Early And Late Mitral Inflow Velocity), Assessed by Echocardiography
Per-Protocol Population

[*Change 2nd column header to: E/A, Change Timepoints to Weeks 4 and 6, Change footnote to Listing 2.2*]

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*] [*Remove footnote for indexing to BSA*]

Table 3.21
Summary of Change From Baseline in E/e' (Ratio Between Early Mitral Inflow Velocity and Mitral Annular Early Diastolic Velocity), Assessed by Echocardiography
ITT Population

[*Change 2nd column header to: E/e', Change Timepoints to Weeks 4 and 6, Change footnote to Listing 2.2*]

[*Remove footnote for indexing to BSA*]

Table 3.22
Summary of Change From Baseline in E/e' (Ratio Between Early Mitral Inflow Velocity and Mitral Annular Early Diastolic Velocity), Assessed by Echocardiography Per-Protocol Population

[*Change 2nd column header to: E/e', Change Timepoints to Weeks 4 and 6, Change footnote to Listing 2.2*]

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

[*Remove footnote for indexing to BSA*]

Table 3.23
Summary of Change From Baseline in Left Atrial Volume, Assessed by Echocardiography
ITT Population

[*Change 2nd column header to: LAV, Change Timepoints to Weeks 4 and 6, Change footnote to Listing 2.2*]

Table 3.24
Summary of Change From Baseline in Left Atrial Volume, Assessed by Echocardiography
Per-Protocol Population

[*Change 2nd column header to: LAV, Change Timepoints to Weeks 4 and 6, Change footnote to Listing 2.2*]

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.25
Summary of Change From Baseline in Left Ventricular Global Longitudinal Strain, Assessed by Echocardiography
ITT Population

[*Change 2nd column header to: LV GLS, Change Timepoints to Weeks 4 and 6, Change footnote to Listing 2.2*]

[*Remove footnote for indexing to BSA*]

Table 3.26
Summary of Change From Baseline in Left Ventricular Global Longitudinal Strain, Assessed by Echocardiography
Per-Protocol Population

[*Change 2nd column header to: LV GLS, Change Timepoints to Weeks 4 and 6, Change footnote to Listing 2.2*]

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

[*Remove footnote for indexing to BSA*]

Table 3.27
Summary of Change From Baseline in Left Ventricular End Diastolic Volume (LV EDV), Assessed by Echocardiography ITT Population

LV EDV (mL)	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)
Time Point [a]			

	Baseline	n	xx	xx
		Mean	xx.x	xx.x
		SD	xx.xx	xx.xx
		Median	xx.x	xx.x
		Min, Max	xx, xx	xx, xx
	Week 4	n	xx	xx
		Mean	xx.x	xx.x
		SD	xx.xx	xx.xx
		Median	xx.x	xx.x
		Min, Max	xx, xx	xx, xx
	Change from Baseline to Week 4 [a]	n	xx	xx
		Mean	xx.x	xx.x
		SD	xx.xx	xx.xx
		Median	xx.x	xx.x
		Min, Max	xx, xx	xx, xx
	Week 6	n	xx	xx
		Mean	xx.x	xx.x
		SD	xx.xx	xx.xx
		Median	xx.x	xx.x
		Min, Max	xx, xx	xx, xx
	Change from Baseline to Week 6 [a]			

Time Point	LV EDV (mL) [a]	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)
	Min, Max	xx, xx		xx, xx

ITT Population = all subjects who were randomized and receive at least 1 dose of IMP, according to the treatment group to which the subjects were randomized.
Baseline value is the last available measure prior to treatment.

[Source: Listings 2.2a] Change from Baseline at time point t: Change $_t$ = Value $_t$ – Value$_{Baseline}$.

Table 3.28
Summary of Change From Baseline in Left Ventricular End Diastolic Volume (LV EDV), Assessed by Echocardiography
Per-Protocol Population

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.29
Summary of Change From Baseline in Left Ventricular End Systolic Volume (LV ESV), Assessed by Echocardiography
ITT Population

Table 3.30
Summary of Change From Baseline in Left Ventricular End Systolic Volume (LV ESV), Assessed by Echocardiography
Per-Protocol Population

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.31
Summary of Change From Baseline in Biplane Ejection Fraction (EF), Assessed by Echocardiography
ITT Population

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Table 3.32
Summary of Change From Baseline in Biplane Ejection Fraction (EF), Assessed by Echocardiography
Per-Protocol Population

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.33
Summary of Change From Baseline in Left Ventricular Mass, Assessed by Echocardiography
ITT Population

Table 3.34
Summary of Change From Baseline in Left Ventricular Mass, Assessed by Echocardiography
Per-Protocol Population

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.35
Summary of Change From Baseline in Mitral Regurgitation Severity, Assessed by Echocardiography
ITT Population

Table 3.36
Summary of Change From Baseline in Mitral Regurgitation Severity, Assessed by Echocardiography
Per-Protocol Population

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.37

Summary of Change From Baseline in Tricuspid Regurgitation Severity, Assessed by Echocardiography
ITT Population

Table 3.38
Summary of Change From Baseline in Tricuspid Regurgitation Severity, Assessed by Echocardiography
Per-Protocol Population

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.39
Summary of Change From Baseline in Right Ventricular Fractional Area Change, Assessed by Echocardiography
ITT Population

Table 3.40
Summary of Change From Baseline in Right Ventricular Fractional Area Change, Assessed by Echocardiography
Per-Protocol Population

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.41
Summary of Change From Baseline in Right Ventricular Systolic Pressure (RVSP), Assessed by Echocardiography
ITT Population

Table 3.42
Summary of Change From Baseline in Right Ventricular Systolic Pressure (RVSP), Assessed by Echocardiography
Per-Protocol Population

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.43
Summary of Change From Baseline in Distance Walked (meters) During 6-minute Walking Test (6MWT)
ITT Population

[From Table 3.1 mock, *Change 2nd column header to: 6MWT, Change Timepoints to Week 4, Change footnote to Listing 2.3*] [*Remove footnote for indexing to BSA*]

[*Change footnote [b] to:*
[b] 95% confidence interval is based on the t-distribution and Lsmean of between treatment group difference from an ANCOVA model for the change from baseline which includes treatment group, ischemic/non-ischemic, and treatment-by-ischemic/non-ischemic interaction as factors and the baseline value as a continuous covariate. P-value corresponds to a 2-sided significance level of the between treatment group difference from the ANCOVA model.]

Table 3.44
Summary of Change From Baseline in Distance Walked (meters) During 6-minute Walking Test (6MWT)
Per-Protocol Population

[From Table 3.1 mock, *Change 2nd column header to: 6MWT, Change Timepoints to Week 4, Change footnote to Listing 2.3*]

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*] [*Remove footnote for indexing to BSA*]

[*Change footnote [b] to:*
[b] 95% confidence interval is based on the t-distribution and Lsmean of between treatment group difference from an ANCOVA model for the change from baseline which includes treatment group, ischemic/non-ischemic, and treatment-by-ischemic/non-ischemic interaction as factors and the baseline value as a continuous covariate. P-value corresponds to a 2-sided significance level of the between treatment group difference from the ANCOVA model.]

Table 3.45
Summary of Change From Baseline in Levels of NT-pro-BNP
ITT Population

[From Table 3.1 mock, *Change 2nd column header to: NT-pro-BNP, Change Timepoints to Weeks 1, 2, 4, and 6, Change footnote to Listing 2.3]* [*Remove footnote for indexing to BSA*]

[*Change footnote [b] to:*

[a] Difference between treatments and inferential statistics based on log10 (NT-pro-BNP). 95% confidence interval is based on the t-distribution and Lsmean of between treatment group difference from a mixed model repeated measures for the change from baseline which includes treatment group, treatment-by-visit interaction, ischemic/non-ischemic as factors and the baseline value and baseline value-by-visit interaction as continuous covariates. P-value corresponds to a 2-sided significance level of the between treatment group difference from the mixed model repeated measures.]

[Change footnote [c] to:

[b] Linear trend test of log10 (NT-pro-BNP).]

Table 3.46
Summary of Change From Baseline in Levels of NT-pro-BNP
Per-Protocol Population

[From Table 3.1 mock, *Change 2nd column header to: NT-pro-BNP, Change Timepoints to Weeks 1, 2, 4, and 6, Change footnote to Listing 2.3]* [*Remove footnote for indexing to BSA*]

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

[*Change footnote [b] to:*

[a] Difference between treatments and inferential statistics based on log10 (NT-pro-BNP). 95% confidence interval is based on the t-distribution and Lsmean of between treatment group difference from a mixed model repeated measures for the change from baseline which includes treatment group, treatment-by-visit interaction, ischemic/non-ischemic as

factors and the baseline value and baseline value-by-visit interaction as continuous covariates. P-value corresponds to a 2-sided significance level of the between treatment group difference from the mixed model repeated measures.]

[Change footnote [c] to:

[b] Linear trend test of log10 (NT-pro-BNP).]

Table 3.47
Summary of Change From Baseline in Levels of hsTroponin
ITT Population

[From Table 3.1 mock, *Change 2nd column header to: hsTroponin, Change Timepoints to Weeks 1, 2, 4, and 6, Change footnote to Listing 6.4]*

[*Remove footnote for indexing to BSA*]

Table 3.48
Summary of Change From Baseline in Levels of hsTroponin
Per-Protocol Population

[From Table 3.1 mock, *Change 2nd column header to: hsTroponin, Change Timepoints to Weeks 1, 2, 4, and 6, Change footnote to Listing 6.4]* [*Remove footnote for indexing to BSA*]

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

Table 3.49
Summary of Change From Baseline in Kansas City Cardiomyopathy Questionnaire (KCCQ) Overall Summary Score
ITT Population

[From Table 3.1 mock, *Change 2nd column header to: KCCQ, Change Timepoints to Week 4, Change footnote to Listing 2.3*] [*Remove footnote for indexing to BSA*]

[*Change footnote [b] to:*
[b] 95% confidence interval is based on the t-distribution and Lsmean of between treatment group difference from an ANCOVA model for the change from baseline which includes treatment group, ischemic/non-ischemic, and treatment-by-ischemic/non-ischemic interaction as factors and the baseline value as a continuous covariate. P-value corresponds to a 2-sided significance level of the between treatment group difference from the ANCOVA model.]

Table 3.50
Summary of Change From Baseline in Kansas City Cardiomyopathy Questionnaire (KCCQ) Overall Summary Score
Per-Protocol Population

[From Table 3.1 mock, *Change 2nd column header to: KCCQ, Change Timepoints to Week 4, Change footnote to Listing 2.3*] [*Remove footnote for indexing to BSA*]

[*Change first footnote to: Per-Protocol Population = all subjects who were randomized and receive at least 1 dose of IMP, without major protocol violations/deviations, according to the treatment group to which the subjects were randomized.*]

[*Change footnote [b] to:*

[b] 95% confidence interval is based on the t-distribution and Lsmean of between treatment group difference from an ANCOVA model for the change from baseline which includes treatment group, ischemic/non-ischemic, and treatment-by-ischemic/non-ischemic interaction as factors and the baseline value as a continuous covariate. P-value corresponds to a 2-sided significance level of the between treatment group difference from the ANCOVA model.]

4. PLASMA CONCENTRATION ANALYSIS

Table 4.1
Summary of Plasma Concentrations of Elamipretide and Metabolites (M1, M2) by Time Point
Safety Population

Concentration (unit)			Elamipretide (N=xx)	M1 (N=xx)	M2 (N=xx)
Day 1					
Pre-dose					
n			xx	xx	xx
Mean (CV%)			xx.x (xx.xx)	xx.x (xx.x)	xx.x (xx.xx)
SD			xx.xx	xx.x	xx.xx
Median			xx.x	xx	xx.x
Min, Max			xx, xx	xx, xx	xx, xx
Geometric Mean (CV%)			xx.x (xx.xx)	xx.x (xx.x)	xx.x (xx.xx)
	Post-dose				
N			xx	xx	xx
Mean (CV%)			xx.x (xx.xx)	xx.x (xx.x)	xx.x (xx.xx)
SD			xx.xx	xx.x	xx.xx
Median			xx.x	Xx	xx.x
Min, Max			xx, xx	xx, xx	xx, xx
Geometric Mean (CV%)			xx.x (xx.xx)	xx.x (xx.x)	xx.x (xx.xx)
	Week 1	Pre-dose			
n			xx	xx	xx
Mean (CV%)			xx.x (xx.xx)	xx.x (xx.x)	xx.x (xx.xx)
SD			xx.xx	xx.x	xx.xx
Median			xx.x	xx	xx.x
Min, Max			xx, xx	xx, xx	xx, xx
Geometric Mean (CV%)			xx.x (xx.xx)	xx.x (xx.x)	xx.x (xx.xx)
	Post-dose				
N			xx	xx	xx
Mean (CV%)			xx.x (xx.xx)	xx.x (xx.x)	xx.x (xx.xx)
SD			xx.xx	xx.x	xx.xx

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Min, Max	xx, xx xx.x	xx, xx xx.x	xx, xx xx.x	
Geometric Mean (CV%)	(xx.xx)	(xx.x)	(xx.xx)	
	xx xx.x	xx xx.x	xx xx.x	
Post-dose	(xx.xx)	(xx.x)	(xx.xx)	
N	xx.xx xx.x	xx.x Xx	xx, xx xx.x	
Mean (CV%)	xx, xx xx.x	xx, xx	(xx.xx)	
SD	(xx.xx)	xx.x	xx xx.x	
Median	xx xx.x	(xx.x)	(xx.xx)	
Min, Max	(xx.xx)	xx xx.x	xx xx.x	Median
Geometric Mean (CV%)	xx.xx xx.x	(xx.x)	xx, xx xx.x	xx.x
Week	xx, xx xx.x	xx.x xx	(xx.xx)	Xx
4 n	(xx.xx)	xx, xx	xx xx.x	xx.x
Mean (CV%)	xx xx.x	xx.x	(xx.xx)	Min, Max
SD	(xx.xx)	(xx.x)	xx.xx xx.x	xx, xx
Median	xx.xx xx.x	xx xx.x	xx, xx xx.x	xx, xx
Min, Max	xx, xx xx.x	(xx.x)	(xx.xx)	xx, xx
Geometric Mean (CV%)	(xx.xx)	xx.x xx		
Week		xx, xx		Geometric
6 n		xx.x		Mean (CV%)
Mean (CV%)		(xx.x)		xx.x
SD				(xx.xx)
Median				xx.x
Min, Max				(xx.x)
Geometric Mean (CV%)				xx.x
				(xx.xx)
Week 2	Pre-dose			
n	xx	xx	xx	
Mean (CV%)	xx.x (xx.xx)	xx.x (xx.x)	xx.x (xx.xx)	
SD xx.xx xx.x xx.xx Median xx.x xx xx.x				

N = number of subjects treated with Elamipretide. n = number of subjects with data.
SD = standard deviation.
CV = coefficient of variation.
Values below Lower Limit of Quantification (LLQ) are set to LLQ/2.
Source: Listing 4.1

5. EXTENT OF EXPOSURE TO STUDY MEDICATION

Table 5.1
Extent of Exposure to Study Medication by Treatment Group
Safety Population

	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)	All Subjects (N=xx)

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Study Treatment Exposure (days) [a]	xx	xx	xx	xx
N	xxx.x	xxx.x	xxx.x	xxx.x
Mean SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x	xxx.x
Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx
Study Treatment Compliance (%)	xx	xx	xx	xx
n	xxx.x	xxx.x	xxx.x	xxx.x
Mean SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.x	xxx.x	xxx.x	xxx.x
Min, Max	xxx, xxx	xxx, xxx	xxx, xxx	xxx, xxx

SD = Standard deviation.
n represents the number of subjects contributing to summary statistics. Percentages are based on n for each characteristic. Percentages are based on n.
[a] Study treatment exposure (days) = Treatment end date - treatment start date – number of days of missed doses + 1. Source: Listing 3.1

6. ADVERSE EVENTS

Table 6.1
Overall Summary of Treatment-Emergent Adverse Events by Treatment Group
Safety Population

	Elamipretide 4 mg (N=xx)		Elamipretide 40 mg (N=xx)		Placebo (N=xx)		All Subjects (N=xx)	
	# of Subjects n (%)	E	# of Subjects n (%)	E	# of Subjects n (%)	E	# of Subjects n (%)	E
Subjects with at least one TEAE	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx
Subjects with TEAEs Related to Study Treatment [a]	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx
Subjects with Serious TEAEs	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Subjects with Serious TEAEs Related to Study Treatment [a]	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx
Subjects with TEAEs Leading to Discontinuation of Study Drug	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx
Deaths – All Causes	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx

Percentages are based on N.
TEAE = Treatment-Emergent Adverse Event. An adverse event is considered treatment-emergent if the date of onset is on or after the date of first dose of study medication, or worsening during the treatment period + 30 days.
E = number of events
[a] Related = unlikely related, probably related or possibly related to study drug.

Source: Listing 5.1
Program: /data/dev/client29/SPIHF201/programs/statout/xxxxxxx.sas DDMMMYYYY:HH:MM (Page x of y)

Table 6.2
Incidence of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population

System Organ Class Preferred Term	Elamipretide 4 mg (N=xx) n (%)	Elamipretide 40 mg (N=xx) n (%)	Placebo (N=xx) n (%)	All Subjects (N=xx) n (%)
At Least One TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
MedDRA SOC1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				
MedDRA SOC2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%) xx
Preferred Term 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	(xx.x%) xx
Preferred Term 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	(xx.x%)
… Etc.				

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Percentages are based on N.
TEAE = Treatment Emergent Adverse Event. An adverse event is considered treatment-emergent if the date of onset is on or after the date of first dose of study medication, or worsening during the treatment period + 30 days.
If more than one adverse event is coded to the same preferred term for a subject, the subject will be counted only once for that preferred term. If more than one preferred term is coded to the same System Organ Class for a subject, the subject will be counted only once for that System Organ Class. Adverse events coded using MedDRA version 20.0.
Source: Listing 5.1

Note to Programmer: SOCs sorted alphabetically. PTs sorted within SOCs in decreasing order of frequency in the all subject group.

Subjects having several AEs with the same SOC will be counted only once for that particular SOC.

Subjects having several AEs with the same PT will be counted only once for that particular PT.

Table 6.3
Incidence of Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Safety Population

System Organ Class Preferred Term	Elamipretide 4 mg (N=xx) n (%)	Elamipretide 40 mg (N=xx) n (%)	Placebo (N=xx) n (%)	All Subjects (N=xx) n (%)
At Least One TESAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
MedDRA SOC1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

MedDRA SOC2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%) xx
Preferred Term 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	(xx.x%) xx
Preferred Term 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	(xx.x%)
… Etc.				

TESAE (Treatment Emergent Serious Adverse Event) = serious adverse events occurring on or after the date of first dose of study medication, or worsening during the treatment period + 30 days. The definition of serious adverse event is in Protocol Section 9.6. If more than one serious adverse event is coded to the same preferred term for a subject, the subject will be counted only once for that preferred term. If more than one preferred term is coded to the same System Organ Class for a subject, the subject will be counted only once for that System Organ Class.
Percentages are based on N.
Adverse events coded using MedDRA version 20.0.
Source: Listings 5.2

Note to Programmer: SOCs sorted alphabetically. PTs sorted within SOCs in decreasing order of frequency in the all subject group.

Subjects having several SAEs with the same SOC will be counted only once for that particular SOC. Subjects having several SAEs with the same PT will be counted only once for that particular PT.

Table 6.4
Incidence of Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Intensity
Safety Population

System Organ Class / Preferred Term	Elamipretide 4 mg (N=xx)			Elamipretide 40 mg (N=xx)			Placebo (N=xx)			All Subjects (N=xx)		
	Mild n (%)	Moderate n (%)	Severe n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	Mild n (%)	Moderate n (%)	Severe n (%)
xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	At Least One	xx	
TEAE	(xx.x%)	(xx.x%)	(xx.x%)		(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
MedDRA SOC1	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	(xx.x%)	(xx.x%)	(xx.x%)		(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Preferred Term 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…															
MedDRA SOC2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…													Etc.		

Percentages are based on N.
TEAE = Treatment Emergent Adverse Event. An adverse event is considered treatment-emergent if the date of onset is on or after the date of first dose of study medication, or worsening during the treatment period + 30 days. Only the worst grade of intensity is counted for multiple occurrences of the same adverse event for a given subject. Adverse events coded using MedDRA version 20.0.
Source: Listing 5.1

Note to Programmer: SOCs and PTs sorted alphabetically.

Table 6.5
Incidence of Study Treatment Related Adverse Events by System Organ Class, Preferred Term, and Intensity Safety Population

System Organ Class	Elamipretide 4 mg (N=xx)			Elamipretide 40 mg (N=xx)			Placebo (N=xx)			All Subjects (N=xx)		
Preferred Term	Mild n (%)	Moderate n (%)	Severe n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	Mild n (%)	Moderate n (%)	Severe n (%)
At Least One Study Treatment Related AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Report generated by program: /sasdir/xxxx.sas
-MM-DD HH:MM

D r a f t Y Y Y Y

	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)			xx (xx.x%)	xx (xx.x%)			xx (xx.x%)	xx (xx.x%)	xx (xx.x%)		
MedDRA SOC1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)		
Preferred Term 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)		
Preferred Term 2																
…																
MedDRA SOC2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)		
Preferred Term 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)		
Preferred Term 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)			xx (xx.x%)	xx (xx.x%)			xx (xx.x%)	xx (xx.x%)	xx (xx.x%)		
…																
Etc.																

Percentages are based on N.
Study Treatment Related AE is a treatment-emergent adverse event classified by investigators as unlikely related,probably related or possibly related to study drug.
Only the worst grade of intensity is counted for multiple occurrences of the same adverse event for a given subject. Adverse events coded using MedDRA version 20.0.
Source: Listing 5.1

Note to Programmer: SOCs and PTs sorted alphabetically.

Table 6.6
Incidence of Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Relationship to Study Drug
Safety Population

	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)	All Subjects (N=xx)

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

System Organ Class Preferred Term	Not Related (%) n (%)	Related n	Not Related (%) n (%)	Related n	Not Related (%) n (%)	Related n	Not Related (%) n (%)	Related n
At Least One TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
MedDRA SOC1	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 (xx.x%)
Preferred Term 1	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx	xx (xx.x%)
Preferred Term 2	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)	xx (xx.x%)
…								
MedDRA SOC2	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 (xx.x%)
Preferred Term 1	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx	xx (xx.x%)
Preferred Term 2	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)	xx (xx.x%)
…								
Etc.								

Percentages are based on N.
TEAE = treatment Emergent Adverse Event. An adverse event is considered treatment-emergent if the date of onset is on or after the date of first dose of study medication, or worsening during the treatment period + 30 days.
Not Related = unrelated to study drug; Related = unlikely related, probably related or possibly related to study drug. If a subject had more than one occurrence in the same event category, only the most related occurrence was counted. Adverse events coded using MedDRA version 20.0.
Source: Listing 5.1

Note to Programmer: SOCs sorted alphabetically. PTs sorted within SOCs in decreasing order of frequency in the related-all subject column.

Table 6.7
Incidence of Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by System Organ Class and Preferred Term
Safety Population

System Organ Class	Preferred Term	Elamipretide 4 mg (N=xx) n (%)	Elamipretide 40 mg (N=xx) n (%)	Placebo (N=xx) n (%)	All Subjects (N=xx) n (%)

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

					xx (xx.x%)
Any Adverse Event Leading to Discontinuation of Study Drug	Any	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
MedDRA SOC1	Any	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	PT1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	PT2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	…				
MedDRA SOC2	Any	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	PT1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	PT2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Etc.					

Percentages are based on N.
Adverse events coded using MedDRA version 20.0. Source: Listing 5.3

Note to Programmer: SOCs sorted alphabetically. PTs sorted within SOCs in decreasing order of frequency in the all subject group.

Table 6.8
Deaths
Safety Population

Subject ID	Study Treatment	Age/Sex [a]	Date of Death	Study Day of Death [b]	Was Autopsy Performed? (Yes/No)
xxxx	Elamipretide 4 mg	73/F	yyyy-mmm-dd	xx	Xxx

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

xxxx	Placebo	75/M	yyyy-mmm-dd	xx		Xx

[a] Age is age at informed consent in years. F = Female, M = Male.

[Source: b]Study Day = date of death – date of first dose + 1. Listing 5.2

7. CLINICAL LABORATORY EVALUATIONS

Table 7.1a
Change From Baseline in Hematology Parameters by Visit Safety Population

Parameter (unit)	Elamipretide 4 mg (N=xx)		Elamipretide 40 mg (N=xx)		Placebo (N=xx)		All Subjects (N = xxx)	
Time Point	Actual Value	Change From Baseline	Actual Value	Change From Baseline	Actual Value	Change From Baseline	Actual Value	Change From Baseline

Report generated by program: /sasdir/xxxx.sas
-MM-DD HH:MM

D r a f t Y Y Y Y

Baseline[a]	n	xx		xx		xx		xx			
	Mean	xx.xx		xx.xx		xx.xx		xx.xx			
	SD	xx.xxx		xx.xxx		xx.xxx		xx.xxx			
	Median	xx.xx		xx.xx		xx.xx		xx.xx			
	Min, Max	xx.x, xx.x		xx.x, xx.x		xx.x, xx.x		xx.x, xx.x			
Week 1	n	xx	xx xx.xx	xx	xx xx.xx	xx	xx xx.xx	xx	xx xx.xx		
	Mean	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx		
	SD	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx		
	Median	xx.xx	xx.x,	xx.xx	xx.x,	xx.xx	xx.x,	xx.xx	xx.x,		
	Min, Max	xx.x, xx.x	xx.x	xx.x, xx.x	xx.x	xx.x, xx.x	xx.x	xx.x, xx.x	xx.x		
Week 2	n	xx	xx xx.xx	xx	xx xx.xx	xx	xx xx.xx	xx	xx xx.xx		
	Mean	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx		
	SD	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx		
	Median	xx.xx	xx.x,	xx.xx	xx.x,	xx.xx	xx.x,	xx.xx	xx.x,		
	Min, Max	xx.x, xx.x	xx.x	xx.x, xx.x	xx.x	xx.x, xx.x	xx.x	xx.x, xx.x	xx.x		
Week 4	n	xx	xx xx.xx	xx	xx xx.xx	xx	xx xx.xx	xx	xx xx.xx		
	Mean	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx		
	SD	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx		
	Median	xx.xx	xx.x,	xx.xx	xx.x,	xx.xx	xx.x,	xx.xx	xx.x,		
	Min,	xx.x,	xx.x	xx.x,	xx.x	xx.x,	xx.x	xx.x,	xx.x		
Week 6											

<Parameter 1> *(unit)*

Parameter (unit) Time Point		Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)		All Subjects (N = xxx)
		Actual Change From Value Baseline	Actual Change From Value Baseline	Actual Value	Change From Baseline	Actual Change From Value Baseline
	Max	xx.x	xx.x	xx.x		xx.x

SD = Standard deviation.
n represents the number of subjects contributing to summary statistics.

[Source: Listinga] Baseline assessment is defined as last assessment prior to the first dose of study medication. 6.1

Parameter (unit) Treatment Group <Parameter 1> (unit)	Baseline	Week 1			Week 2			Week 4			Week 6		
		Low n (%)	Normal n (%)	High n (%)	Low n (%)	Normal n (%)	High n (%)	Low n (%)	Normal n (%)	High n (%)	Low n (%)	Normal n (%)	High n (%)
Elamipretide 4 mg	N												
	Low	xx xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Elamipretide 40 mg	N												
	Low	xx xx (xx.x%)			xx xx (xx.x%)			xx xx (xx.x%)			xx xx (xx.x%)		
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Placebo	N												
	Low	xx xx (xx.x%)			xx xx (xx.x%)			xx xx (xx.x%)			xx xx (xx.x%)		
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Report generated by program: /sasdir/xxxx.sas
-MM-DD HH:MM

D r a f t Y Y Y Y

<Parameter 2> (unit)

Table 7.1b
Shift Table of Hematology Parameters From Baseline to Post Baseline Visits

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Safety Population

Parameter (Treatment unit)		Week 1			Week 2			Week 4			Week 6		
Group	Baseline	Low n (%)	Normal n (%)	High n (%)	Low n (%)	Normal n (%)	High n (%)	Low n (%)	Normal n (%)	High n (%)	Low n (%)	Normal n (%)	High n (%)

Percentages are based on N, number of subjects with assessment value at both the post-baseline visit and baseline. Source: Listing 6.1

Table 7.2a
Change From Baseline in Blood Chemistry Parameters by Visit
Safety Population

Note to Programmer: Same layout as Table 7.1a.

Source: Listing 6.2

Table 7.2b
Shift Table of Blood Chemistry Parameters From Baseline to Post Baseline Visits
Safety Population

Note to Programmer: Same layout as Table 7.1b.

Source: Listing 6.2

Table 7.3a
Change From Baseline in Urinalysis Parameters by Visit
Safety Population

Note to Programmer: Table layout is similar to Table 7.1a. The time points are baseline and Week 4. Only the parameters with continuous values will be presented.

Source: Listing 6.3

Table 7.3b
Shift Table of Urinalysis Parameters From Baseline to Post Baseline Visits Safety Population

Note to Programmer: Table layout is similar Table 7.1b. Low, Normal, High replaced with Normal and Abnormal. Time points are baseline and Week 4. All the parameters in urinalysis will be presented. Source: Listing 6.3

Table 7. 4a
Change From Baseline in Levels of hsTroponin by Visit
Safety Population

Note to Programmer: Same layout as Table 7.1a. Include parameters: hsTroponin, Log hsTroponin. For Log hsTroponin, use Log Ratio for Change from Baseline.

Source: Listing 6.4

8. ELECTROCARDIOGRAM EVALUATIONS

Table 8.1
Change From Baseline in Electrocardiogram (ECG) Parameters by Visit Safety Population

	Elamipretide 4 mg (N=xx)		Elamipretide 40 mg (N=xx)		Placebo (N=xx)		All Subjects (N = xxx)	
Parameter (unit)	Actual	Change From	Actual	Change From	Actual	Change From	Actual	Change From
Time Point	Value	Baseline	Value	Baseline	Value	Baseline	Value	Baseline
<Parameter 1>								

(unit)

Baseline[a]	n	xx		xx		xx		xx			
	Mean	xx.xx		xx.xx		xx.xx		xx.xx			
	SD	xx.xxx		xx.xxx		xx.xxx		xx.xxx			
	Median	xx.xx		xx.xx		xx.xx		xx.xx			
	Min, Max	xx.x, xx.x		xx.x, xx.x		xx.x, xx.x		xx.x, xx.x			
Week 1	n	xx	xx xx.xx	xx	xx xx.xx	xx	xx xx.xx	xx	xx xx.xx		
	Mean	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx		
	SD	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx		
	Median	xx.xx	xx.x, xx.x	xx.xx	xx.x, xx.x	xx.xx	xx.x, xx.x	xx.xx	xx.x, xx.x		
	Min, Max	xx.x, xx.x		xx.x, xx.x		xx.x, xx.x		xx.x, xx.x			
Week 2	n	xx	xx xx.xx	xx	xx xx.xx	xx	xx xx.xx	xx	xx xx.xx		
	Mean	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx		
	SD	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx	xx.xxx	xx.xx		
	Median	xx.xx	xx.x, xx.x	xx.xx	xx.x, xx.x	xx.xx	xx.x, xx.x	xx.xx	xx.x, xx.x		
	Min, Max	xx.x, xx.x		xx.x, xx.x		xx.x, xx.x		xx.x, xx.x			
Week 4	n	xx	xx	xx	xx	xx	xx	xx	xx		
	Mean	xx.xx		xx.xx		xx.xx		xx.xx			
	SD										
	Median										
	Min, Max										
Week 6	n										
	Mean										

Parameter (unit) Time Point		Elamipretide 4 mg (N=xx) Actual Value	Elamipretide 4 mg (N=xx) Change From Baseline	Elamipretide 40 mg (N=xx) Actual Value	Elamipretide 40 mg (N=xx) Change From Baseline	Placebo (N=xx) Actual Value	Placebo (N=xx) Change From Baseline	All Subjects (N = xxx) Actual Value	All Subjects (N = xxx) Change From Baseline
	SD	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
	Median	xx.xx	xx.xx xx.x,	xx.xx	xx.xx xx.x,	xx.xx	xx.xx xx.x,	xx.xx	xx.xx xx.x,
	Min, Max	xx.x, xx.x	xx.x	xx.x, xx.x	xx.x	xx.x, xx.x	xx.x	xx.x, xx.x	xx.x

SD = Standard deviation. n represents the number of subjects contributing to summary statistics.

[Source: Listinga] Baseline assessment is defined as last assessment prior to the first dose of study medication. 7.2

9. VITAL SIGNS

Table 9.1
Change From Baseline in Vital Signs Safety
Population

Parameter (unit) / Time Point		Elamipretide 4 mg (N=xx)		Elamipretide 40 mg (N=xx)		Placebo (N=xx)		All Subjects (N=xx)	
		Actual Value	Change From Baseline	Actual Value	Change From Baseline	Actual Value	Change From Baseline	Actual Value	Change From Baseline
Heart Rate (bpm)									
Baseline	n	xx		xx		xx		xx	
	Mean	xx.x		xx.x		xx.x		xx.x	
	SD	xx.xx		xx.xx		xx.xx		xx.xx	
	Median	xx.x		xx.x		xx.x		xx.x	
	Min, Max	xx.x, xx.x		xx.x, xx.x		xx.x, xx.x		xx.x, xx.x	
Week 1	n	xx	xx	xx	xx	xx	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Week 2	n	xx	xx	xx	xx	xx	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Week 4	n	xx	xx	xx	xx	xx	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y
-MM-DD HH:MM

Week 6	n Mean SD Median Min, Max	xx xx.x xx.xx xx.x xx.x, xx.x	xx.x xx.x xx.x	xx xx.xx xx.x,	n Mean SD Median Min, Max	xx xx.x xx.xx xx.x xx.x, xx.x	xx xx.x xx.xx xx.x xx.x, xx.x	xx xx.x xx.xx xx.x xx.x, xx.x	xx xx.x xx.xx xx.x xx.x, xx.x	xx xx.x xx.xx xx.x xx.x, xx.x	

Parameter (unit) Time Point	Elamipretide 4 mg (N=xx) Actual Value	 Change From Baseline	Elamipretide 40 mg (N=xx) Actual Value	 Change From Baseline	Placebo (N=xx) Actual Value	 Change From Baseline	All Subjects (N=xx) Actual Value	 Change From Baseline

SD = Standard deviation, BP = Blood pressure.

n represents the number of subjects contributing to summary statistics. Source: Listing 7.1

Note to Programmer: Repeat for Respiration Rate (breaths/min), Systolic BP (mmHg), Diastolic BP (mmHg), and Temperatures(°C)

10. PHYSICAL EXAMINATION

Table 10.1
Cardiovascular Physical Examination Results by Visit
Safety Population

	Elamipretide 4 mg (N=xx)		Elamipretide 40 mg (N=xx)		Placebo (N=xx)		All Subjects (N=xx)	
	n	(%)	n	(%)	n	(%)	n	(%)
Screening								
Clinical Significant Abnormality Noted		(xx.x%)		(xx.x%)		(xx.x%)		(xx.x%)
Yes	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
No	xx		xx		xx		xx	
Not Done	xx		xx		xx		xx	
Baseline								
Clinical Significant Abnormality Noted		(xx.x%)		(xx.x%)		(xx.x%)		(xx.x%)
Yes	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
No	xx		xx		xx		xx	
Not Done	xx		xx		xx		xx	
Week 1								
Clinical Significant Abnormality Noted		(xx.x%)		(xx.x%)		(xx.x%)		(xx.x%)
Yes	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
No	xx		xx		xx		xx	
Not Done	xx		xx		xx		xx	
Week 2								
Clinical Significant Abnormality Noted								
Yes	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
No	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Not Done	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Week 4								
Clinical Significant Abnormality Noted								
Yes	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
No								

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Not Done	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Week 6								
Clinical Significant Abnormality Noted								
Yes	xx		xx		xx		xx	(xx.x%)
No	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
Not Done	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)	xx	(xx.x%)
		(xx.x%)		(xx.x%)		(xx.x%)		

% = 100*n/N, where n = number of subjects in the specific row category and N = number of subjects in the column category. Source: Listing 7.3

Table 10.2
Physical Measurement Results by Visit Safety
Population

	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)	All Subjects (N=xx)
Screening	xx xx (xx.x%)			xx xx (xx.x%)
Clinical Significant Abnormality Noted n Yes	xx (xx.x%)	xx xx (xx.x%)	xx xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Done		xx (xx.x%)		
Weight (kg)	xx	xx	xx	xx
n	xx.x	xx.x	xx.x	xx.x
Mean	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx, xx	xx, xx	xx, xx	xx, xx
Min, Max				
Height (cm)	xx	xx	xx	xx
n	xx.x	xx.x	xx.x	xx.x
Mean	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx, xx	xx, xx	xx, xx	xx, xx
Min, Max				
Body Mass Index (kg/m2)	xx	xx	xx	xx
n	xx.x	xx.x	xx.x	xx.x
Mean	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.x	xx.x	xx.x	xx.x
Median	xx, xx	xx, xx	xx, xx	xx, xx
Min, Max				
Baseline	xx xx	xx xx	xx xx	xx xx
Clinical Significant Abnormality Noted n Yes	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx
No	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx
Not Done	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
Weight (kg)	xx	xx	xx	xx
n	xx.x	xx.x	xx.x	xx.x
Mean	xx.xx	xx.xx	xx.xx	xx.xx
SD				
Median	xx.x	xx.x	xx.x	xx.x

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Min, Max	xx, xx	xx, xx	xx, xx
Week 1			
Clinical Significant Abnormality Noted			
n	xx	xx xx	xx xx
Yes	xx (xx.x%)	(xx.x%)	(xx.x%)
No	xx (xx.x%)	xx	xx
Not Done	xx (xx.x%)	(xx.x%)	(xx.x%)
		xx	xx
		(xx.x%)	(xx.x%)
Weight (kg)			
n xx Mean xx.x	SD	xx	xx
xx.xx		xx.x	xx.x
Median	xx.x	xx.xx	xx.xx
Min, Max	xx, xx	xx.x	xx.x
		xx,	xx,
Week 2		xx	xx
Clinical Significant Abnormality Noted			
n	xx	xx xx	xx xx
Yes	xx (xx.x%)	(xx.x%)	(xx.x%)
No	xx (xx.x%)	xx	xx
Not Done	xx (xx.x%)	(xx.x%)	(xx.x%)
		xx	xx
		(xx.x%)	(xx.x%)
Weight (kg)			
n xx Mean xx.x	SD	xx	xx
xx.xx		xx.x	xx.x
Median	xx.x	xx.xx	xx.xx
Min, Max	xx, xx	xx.x	xx.x
		xx,	xx,
Week 4		xx	xx
Clinical Significant Abnormality Noted			
n	xx	xx xx	xx xx
Yes	xx (xx.x%)	(xx.x%)	(xx.x%)
No	xx (xx.x%)	xx	xx
Not Done	xx (xx.x%)	(xx.x%)	(xx.x%)
		xx	xx
		(xx.x%)	(xx.x%)
Weight (kg)			
n xx Mean xx.x	SD	xx	xx
xx.xx		xx.x	xx.x
Median	xx.x	xx.xx	xx.xx
Min, Max	xx, xx	xx.x	xx.x
		xx,	xx,
Week 6		xx	xx
Clinical Significant Abnormality Noted			
n	xx	xx xx	xx xx
Yes	xx (xx.x%)	(xx.x%)	(xx.x%)
No	xx (xx.x%)		

xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Not Done					xx (xx.x%)			xx (xx.x%)			xx (xx.x%)			xx (xx.x%)	
				Weight (kg)						n	xx	xx	xx	xx	Mean
xx.x	xx.x	xx.x	xx.x	SD	xx.xx	xx.xx	xx.xx	xx.xx	Median	xx.x	xx.x	xx.x	xx.x		
Min, Max					xx, xx			xx, xx			xx, xx			xx, xx	

% = 100*n/N, where n = number of subjects in the specific row category and N = number of subjects in the column category. Source: Listing 7.3

11. CONCOMITANT MEDICATIONS/TREATMENTS

Table 11.1
Concomitant Medications by ATC and Preferred Drug Name Safety Population

ATC Class / Preferred Drug Name	Elamipretide 4 mg (N=xx)	Elamipretide 40 mg (N=xx)	Placebo (N=xx)	All Subjects (N=xx)
	n (%)	n (%)	n (%)	n (%)
Taking at Least One Concomitant Medication	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATC Highest Level Class 1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Medication 1[a]	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx
Medication 2	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
…				
ATC Highest Level Class 2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Medication 1	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx	(xx.x%) xx
Medication 2	(xx.x%)	(xx.x%)	(xx.x%)	(xx.x%)
Etc.				

ATC = Anatomic-Therapeutic-Chemical 3 Classification code.
[a] Preferred drug name via the World Health Organization Drug Dictionary (WHO-DD).
Percentages are based on N.
Included any medications taken during the study (from the date of first dose of investigational product to the date of last visit).
Source: Listing 3.2

Note to Programmer: ATCs sorted alphabetically. All medications will be sorted alphabetically by medication class and medication subclass.

LISTINGS

LISTINGS – SUBJECT DISPOSITION, DEMOGRAPHICS, AND BASELINE CHARACTERISTICS

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Listing 1.1
Study Completion or Early Discontinuation Status
All Randomized Subjects

Subject ID	Age/Sex[a]	Date of Randomization/ Treatment Assigned	Study Drug Administered	Treatment Start/End Date	Study Completion Status/ Last Study Date [b] (Study Day) [c]	Reason for Early Discontinuation	Included in Safety/ITT/Per-Protocol Population?
xxx-xxx	73/F	yyyy-mmm-dd	Elamipretide 4 mg	yyyy-mmm-dd/	Completed yyyy-mmm-dd		Yes/Yes/Yes
xxx-xxx		Elamipretide 4 mg		yyyy-mmm-dd	(xxx) Discontinued		
xxx-xxx		yyyy-mmm-dd	Elamipretide 40		yyyy-mmm-dd (xxx)		
xxx-xxx	66/M 69/F	Elamipretide 40	mg	yyyy-mmm-dd/	Discontinued yyyy-	Adverse event	Yes/Yes/No
xxx-xxx	xx/X xx/X	mg		yyyy-mmm-dd	mmm-dd (xxx)		
		yyyy-mmm-dd	Elamipretide 40		Discontinued yyyy-		
		Elamipretide 4 mg	mg Placebo	yyyy-mmm-dd/	mmm-dd (xxx)	Sponsor decision,	No/No/No
		yyyy-mmm-dd		yyyy-mmm-dd	Discontinued yyyy-	specific reason	
		Placebo yyyy-mmm-	Placebo		mmm-dd (xxx)	Withdrawal of	No/No/No
		dd				consent	
		Placebo		yyyy-mmm-dd /		Investigator	Yes/Yes/No
				yyyy-mmmdd		reason, specific	
						reason	

[a] Age is age at informed consent. Sex: M = Male, F = Female.
[b] Last Study Date = date of last visit.
[c] Study Day = study date – date of randomization + 1.

Note to Programmer: Listing is sorted by Treatment Group and Subject ID.

Listing 1.2
Violations of Inclusion/Exclusion Criteria
All Subjects

Subject ID	Informed Consent Form Signed	Date Informed Consent Signed	Satisfied All Inclusion/ Exclusion Criteria	Inclusion/Exclusion Criteria Failed

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

xxx-xxx	Yes	yyyy-mmm-dd	No	INCL. # 3, EXCL # 6, Other: xxxxxxxx
xxx-xxx	Yes	yyyy-mmm-dd	Yes	

Note to Programmer: Listing is sorted by Randomized Treatment Group and Subject ID.

Listing 1.3
Randomization Status
All Subjects

Subject ID	Randomized?	Randomized Treatment Assignment	Randomization Number	Randomization Date	Reason not Randomized
xxx-xxx	Yes	Elamipretide 4 mg	xxxxx	yyyy-mmm-dd	
xxx-xxx	No				xxxxxxxxxxxxxxxxxxxx

Note to Programmer: Listing is sorted by Subject ID.

Listing 1.4
Demographic Information
All Randomized Subjects

Subject ID	Treatment Assignment	Age/Sex [a]	Race	Ethnicity	Height (cm)	Weight (kg)	BMI (kg/m2)
	Elamipretide						
xxx-xxx	4 mg	73/F	White	Hispanic or Latino	xxx.x	xxx.x	xx.x
xxx-xxx	Placebo	66/M	Black	Not Hispanic or Latino	xxx.x	xxx.x	xx.x
	Randomized					Baseline	

[a] Age is age at informed consent. Sex: M = Male, F = Female.

Note to Programmer: Listing is sorted by Randomized Treatment Group and Subject ID.

Listing 1.5
Medical and Surgical History
All Randomized Subjects

Subject ID	Randomized Treatment Assignment [a]	Age/Sex	Any Medical/ Surgical History	Category	Diagnosis or Surgery	Start Date	Is Condition Still Present at Screening?	End Date
xxx-xxx	Elamipretide 4 mg	73/F	Yes	Drug Allergy	xxxxxxxxx	yyyy-mmm-dd	No	yyyy-mmm-dd
				Hepatic	xxxxxxxxx	yyyy-mmm-dd	Yes	
xxx-xxx	Elamipretide 40 mg	66/M	Yes	Psychiatric	xxxxxxxxxx	yyyy-mmm-dd	No	yyyy-mmm-dd
xxx-xxx	Placebo	78/F	No					

[a] Age is age at informed consent. Sex: M = Male, F = Female.

Note to Programmer: Listing is sorted by Randomized Treatment Group and Subject ID.

LISTINGS – EFFICACY

Listing 2.1
Cardiac MRI Assessments – Actual and Change from Baseline Values
ITT Population

Subject ID	Treatment Assignment [a]	Age/Sex	Visit	Visit date	Parameter	Value	Change from Screening (Baseline value)
xxx-xxx	Elamipretide		Screening	yyyy-mmm-dd	Left Ventricular End Systolic Volume	xxx.xx	
					Left Ventricular End Systolic Volume (LV ESV), Indexed by BSA	xxx.xx	xxx.xx
					Left Ventricular Ejection Fraction (LVEF)	xxx.xx	xxx.xx
					Left Ventricular End Diastolic Volume (LV EDV)	xxx.xx	xxx.xx
					Left Ventricular End Diastolic Volume (LV EDV), Indexed by BSA	xxx.xx	xxx.xx
					Left Ventricular Myocardial Mass (LV Mass)	xxx.xx	xxx.xx
					Left Ventricular Myocardial Mass (LV Mass), Indexed by BSA	xxx.xx	xxx.xx
					Left Ventricular Stroke Volume (LVSV)	xxx.xx	
					Left Ventricular Cardiac Output (LVCO)	Xxxxxxx	
					Right Ventricular End Systolic Volume (RV ESV)	xxx.xx	
					Right Ventricular End Systolic Volume (RV ESV), Indexed by BSA	xxx.xx	
					Right Ventricular End Diastolic Volume (RV EDV)	xxx.xx	
					Right Ventricular End Diastolic Volume (RV EDV), Indexed by BSA		
					Right Ventricular Myocardial Mass (RV Mass)		
					Right Ventricular Myocardial Mass (RV Mass), Indexed by BSA		
					Right Ventricular Ejection Fraction (RVEF)		
					Ischemic/Non-ischemic Status		
					LV ESV		xxx.xx
					LV ESV, Indexed by BSA		xxx.xx
					LVEF		xxx.xx
			Week 1	yyyy-mmm-dd			
	4 mg	73/F			(LV ESV)		

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

		LV EDV	xxx.xx	xxx.xx
		LV EDV, Indexed by BSA	xxx.xx	xxx.xx
		LV Mass	xxx.xx	xxx.xx
		LV Mass, Indexed by BSA	xxx.xx	xxx.xx
		LVSV	xxx.xx	xxx.xx
		LVCO	xxx.xx	xxx.xx
		RV ESV	xxx.xx	xxx.xx
		RV ESV, Indexed by BSA	xxx.xx	xxx.xx
		RV EDV	xxx.xx	xxx.xx
		RV EDV, Indexed by BSA	xxx.xx	xxx.xx
		RV Mass	xxx.xx	xxx.xx
		RV Mass, Indexed by BSA	xxx.xx	xxx.xx
		RVEF	xxx.xx	xxx.xx
		LV ESV	xxx.xx	xxx.xx
		LV ESV, Indexed by BSA	xxx.xx	xxx.xx
		LVEF	xxx.xx	xxx.xx
		LV EDV	xxx.xx	xxx.xx
		LV EDV, Indexed by BSA	xxx.xx	xxx.xx
		LV Mass	xxx.xx	xxx.xx
	yyyy-mmm-dd	LV Mass, Indexed by BSA	xxx.xx	xxx.xx
		LVSV	xxx.xx	xxx.xx
Week 4		LVCO	xxx.xx	xxx.xx
		RV ESV	xxx.xx	xxx.xx
		RV ESV, Indexed by BSA	xxx.xx	xxx.xx
		RV EDV	xxx.xx	xxx.xx
		RV EDV, Indexed by BSA	xxx.xx	xxx.xx
		RV Mass	xxx.xx	xxx.xx
		RV Mass, Indexed by BSA		
		RVEF		

xxx-
xxx

Elamipretide 40 mg	65/M	Screening

[a] Age is age at informed consent. Sex: M = Male, F = Female.

Note to Programmer: Listing is sorted by Randomized Treatment Group, Subject ID, and Visit Date. Ischemic/Non-ischemic status only needs to be reported at Screening.

Listing 2.2

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Echocardiography Assessments– Actual and Change from Baseline Values
ITT Population

Subject	Treatment	Age/Sex					Change from
xxx-xxx	Elamipretide mg	73/F 4	Screening	yyyy-mmm-dd	E/A (Ratio Between Early And Late Mitral Inflow Velocity)	xxx.xx	xxx.xx
					E/e' (Ratio Between Early Mitral Inflow Velocity and Mitral Annular Early Diastolic Velocity)		xxx.xx
					Left Ventricular End Systolic Volume (LV ESV)		xxx.xx
					Left Ventricular End Systolic Volume (LV ESV), Indexed by BSA		
					Biplane Ejection Fraction (EF)		
					Left Ventricular End Diastolic Volume (LV EDV)	xxx.xx	xxx.xx
					Left Ventricular End Diastolic Volume (LV EDV), Indexed by BSA		xxx.xx
					Left Ventricular Global Longitudinal Strain (LV GLS)		xxx.xx
					Left Atrial Volume (LAV)		
					Left Atrial Volume (LAV), Indexed by BSA	xxx.xx	xxx.xx
					Left Ventricular Mass (LVM)		
					Left Ventricular Mass (LVM), Indexed by BSA	xxx.xx	xxx.xx
					Mitral Regurgitation Severity (MRS)		
					Tricuspid Regurgitation Severity (TRS)		
					Right Ventricular Fractional Area Change (RV FAC)	xxx.xx	xxx.xx
					Right Ventricular Systolic Pressure (RVSP)		xxx.xx
					E/A		
					E/e'		
					LV ESV		xxx.xx
					LV ESV, Indexed by BSA		xxx.xx
					EF		xxx.xx

Report generated by program: /sasdir/xxxx.sas
-MM-DD HH:MM

D r a f t Y Y Y Y

		Baseline	yyyy-mmm-dd	LV EDV	xxx.xx	ID
				LV EDV, Indexed by BSA	xxx.xx	
				LV GLS	xxx.xx	
				LAV	xxx.xx	
				LAV, Indexed by BSA	xxx.xx	
				LVM	xxx.xx	
				LVM, Indexed by BSA	xxx.xx	
				MRS	xxx.xx	
					xxx.xx	
					xxx.xx	

Assignment	[a]	Visit	Visit date	Parameter	Value	Baseline

			TRS	xxx.xx	
			RV FAC	xxx.xx	
			RVSP	xxx.xx	
			E/A	xxx.xx	
			E/e'	xxx.xx	xxx.xx
		yyyy-mmm-dd	LV ESV	xxx.xx	xxx.xx
	Week 4		LV ESV, Indexed by BSA	xxx.xx	xxx.xx
			EF	xxx.xx	xxx.xx
			LV EDV	xxx.xx	xxx.xx
			LV EDV, Indexed by BSA	xxx.xx	xxx.xx
			LV GLS	xxx.xx	xxx.xx
			LAV	xxx.xx	xxx.xx
			LAV, Indexed by BSA	xxx.xx	xxx.xx
			LVM	xxx.xx	xxx.xx
			LVM, Indexed by BSA	xxx.xx	xxx.xx
			MRS	xxx.xx	xxx.xx
			TRS	xxx.xx	xxx.xx
			RV FAC	xxx.xx	xxx.xx
			RVSP	xxx.xx	xxx.xx
			E/A	xxx.xx	xxx.xx
			E/e'	xxx.xx	xxx.xx
			LV ESV	xxx.xx	xxx.xx
			LV ESV, Indexed by BSA	xxx.xx	xxx.xx
			EF	xxx.xx	xxx.xx
			LV EDV	xxx.xx	xxx.xx
			LV EDV, Indexed by BSA	xxx.xx	xxx.xx
			LV GLS	xxx.xx	xxx.xx
			LAV	xxx.xx	xxx.xx
		yyyy-mmm-dd	LAV, Indexed by BSA	xxx.xx	xxx.xx
			LVM	xxx.xx	xxx.xx
			LVM, Indexed by BSA	xxx.xx	xxx.xx
	Week 6		MRS	xxx.xx	xxx.xx
			TRS		xxx.xx
			RV FAC		
			RVSP		

xxx-
xxx

Elamipretide 65/M Screening
40 mg

[a] Age is age at informed consent. Sex: M = Male, F = Female.

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Note to Programmer: Listing is sorted by Randomized Treatment Group, Subject ID, and Visit Date.

Listing 2.3
Exploratory Assessments – Actual and Change from Baseline Values
ITT Population

Subject ID	Treatment Assignment	Age/Sex [a]	Visit	Visit date	Parameter	Value	Change from Baseline [b]	Was a 6MWT performed? [c]

xxx-xxx	Elamipretide 4 mg	73/F	Baseline	yyyy-mmmdd									Yes	

					Distance Walked (meters) During 6-minute Walking Test (6MWT)	xxx.xx	xxx.xx							
					Levels of NT-pro-BNP (Log value)	xxx.xx (xx.xx)	xxx.xx (xx.xx)							
					Kansas City Cardiomyopathy Questionnaire (KCCQ) Score	xxx.xx	xxx.xx							
			Week 1	yyyy-mmmdd	NT-pro-BNP (Log value)	xxx.xx (xx.xx)	xxx.xx (xx.xx)							
			Week 2	yyyy-mmmdd	NT-pro-BNP (Log value)	xxx.xx (xx.xx)	xxx.xx (xx.xx)							
			Week 4	yyyy-mmmdd	6MWT								No	
					NT-pro-BNP (Log value)	xxx.xx	xxx.xx							
					KCCQ	xxx.xx (xx.xx)	xxx.xx (xx.xx)							
			Week 6	yyyy-mmmdd	NT-pro-BNP (Log value)	xxx.xx (xx.xx)	xxx.xx (xx.xx)							
xxx-xxx	Elamipretide 40 mg	65/M	Baseline											

[a] Age is age at informed consent. Sex: M = Male, F = Female.
[b] Log ratio for log-transformed parameters.
[c] Assessed only at Baseline and Week 4.

Note to Programmer: Listing is sorted by Randomized Treatment Group, Subject ID, and Visit Date.

Listing 2.4.1
Six-Minute Walk Test – Part I
ITT Population

Subject ID	Treatment Assignment	Age/Sex [a]	Visit Baseline	Visit date yyyymmm-dd	Was a 6MWT performed? Yes	If No, Reason	Supplemental oxygen used	If Yes, O_2 Flow,	Time Pre	Vitals Time HH:MM	Blood Pressure (mmHg)	Heart Rate (beats/	Respiratory Rate (breaths / min)	SpO_2 (%)	Dyspnea (Borg)	Fatigue (Borg)
Report generated by program: /sasdir/xxxx.sas													D r a f t		Y Y Y Y	
-MM-DD HH:MM																

xxxxxx	Elamipretide 4 mg	73/F				during test?	Yes	Type xx.x, xxxxx	xxx/xxx	min) xxx	xx	xx	xx.x	xx.x	
xxxxxx	Elamipretide 40 mg	65/M	Week 4 Baseline	yyyymmm-dd	No	New unstable angina or MI	No								

[a] Age is age at informed consent. Sex: M = Male, F = Female.

Note to Programmer: Listing is sorted by Randomized Treatment Group, Subject ID, and Visit Date.

Listing 2.4.2
Six-Minute Walk Test – Part II
ITT Population

[a]	Visit	Vis	Sta	Sto	Total	any	If	Other	Point	Subje	n	Require	Subject Sit at any	If Yes, Time	Treatment	Age/S	Any Interruptio	it	Any Clinically rt p	Distan
Interrupti	Yes,	,	Durin	ct	Discontinua	t	Subje	Assignmen	ex dat	Tim	Tim	Tim	ce	ons	During	Reas	Speci	g	First	tion of	Abnormalit	ct ID	t
xxx-xxx		Elamipretide 4 mg	Baseline	yyyymmm-dd	Pre-ps	HH:MM	HH:MM	xxx	Yes		Leg Cramps		Yes	HH:MM	Yes							

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y-MM-DD HH:MM

73/F -dd

Week 4 yyy y- mmm - dd Pos t HH: MM HH: MM xxx No

Elamipret Baseli xxx xxx- ide 40 mg 65/M ne

[a] Age is age at informed consent. Sex: M = Male, F = Female.

Note to Programmer: Listing is sorted by Randomized Treatment Group, Subject ID, and Visit Date.

Report generated by program: /sasdir/xxxx.sas Draft YYYY-MM-DD HH:MM

Listing 2.5.1
Kansas City Cardiomyopathy Questionnaire – Page 1
ITT Population

Subject Assignment	Treatment	Age/Sex [a]	Visit	Visit date	Activity: Dressing Yourself	Activity: Showering / Bathing	Activity: Level Ground	Activity: Walking 1 Block on Groceries	Activity: Doing Yardwork, Housework, or Carrying	Activity: Climbing a Flight of Stairs Without Stopping	Activity: Hurrying or Jogging (as if to Catch a Bus)	Activity: Compared with 2 Weeks Ago, Have Symptoms Changed?
xxx-xxx	Elamipretide 4 mg	73/F	Baseline	yyyy-mmmdd	Extremely Limited							Much Worse
			Week 4	yyyy-mmmdd				Moderately Limited				Much Better
			Baseline									
xxx-xxx	Elamipretide 40 mg	65/M								Not at All Limited		

[a] Age is age at informed consent. Sex: M = Male, F = Female.

Note to Programmer: Listing is sorted by Randomized Treatment Group, Subject ID, and Visit Date.

Listing 2.5.2
Kansas City Cardiomyopathy Questionnaire – Page 2
ITT Population

Report generated by program: /sasdir/xxxx.sas
-MM-DD HH:MM

D r a f t Y Y Y Y

Subject ID	Treatment Assignment	Age/Sex [a]	Visit	How Many Times Visit Did you Have date Swelling?	How Much Has Swelling Bothered You?	How Many Times Has Fatigue Limited Your Ability?	How Much Has Fatigue Bothered You?	How Many Times Has Shortness of Breath Limited Your Ability?
xxx-xxx	Elamipretide 4 mg	73/F	Baseline	Every morning	Quite a bit bothersome	All of the time	Quite a bit bothersome	All of the time
			yyyymmmdd					
			Week 4 yyyymmmdd	1-2 times a week	Slightly bothersome	Less than once a week	Slightly bothersome	Less than once a week
xxx-xxx	Elamipretide Baseline 40 mg	65/M						

[a] Age is age at informed consent. Sex: M = Male, F = Female.

Note to Programmer: Listing is sorted by Randomized Treatment Group, Subject ID, and Visit Date.

Listing 2.5.3
Kansas City Cardiomyopathy Questionnaire – Page 3
ITT Population

Subject ID	Treatment Assignment	Age/Sex [a]	Visit	Visit date	How Much Has Shortness of Breath Bothered You?	How Many Times Forced to Sleep Sitting Up Because of Shortness of Breath?	How Sure Are You That You Know What to Do if Heart Failure Gets Worse?	How Well You Understand What Things You are Able to Do to Keep Heart Failure Symptoms from Getting Worse?	Heart Failure Limited Enjoyment of Life?	If You Had to Spend the Rest of Your Life with Heart Failure, How Would You Feel?
xxx-xxx	Elamipretide 4 mg	73/F	Baseline	yyyymmmdd	Quite a bit bothersome	Every night	Not very sure	Somewhat understand	It has limited my enjoyment of life quite a bit	Mostly dissatisfied
			Week 4	yyyymmmdd	Slightly bothersome	1-2 times a week	Mostly sure	Mostly understand	It has slightly limited my enjoyment of life	Mostly satisfied
xxx-xxx	Elamipretide 40 mg	65/M	Baseline							

[a] Age is age at informed consent. Sex: M = Male, F = Female.

Note to Programmer: Listing is sorted by Randomized Treatment Group, Subject ID, and Visit Date.

Listing 2.5.4
Kansas City Cardiomyopathy Questionnaire – Page 4
ITT Population

Treatment Assignment	Age/Sex [a]	Visit	How Often Have	Activity

Subject ID xxx-xxx	Elamipretide 4 mg	73/F	Baseline	Visit date yyyymmmdd	You Felt Discouraged?	Hobbies, Recreational Activities Severely Limited	Working or Doing Household Chores	Visiting Family or Friends Out of Your Home	Intimate Relationships with Loved Ones
			Week 4				Moderately Limited		
xxx-xxx	Elamipretide 40 mg	65/M	Baseline	yyyymmmdd					Did not limit at all

[a] Age is age at informed consent. Sex: M = Male, F = Female.

Note to Programmer: Listing is sorted by Randomized Treatment Group, Subject ID, and Visit Date.

Listing 2.5.5
Kansas City Cardiomyopathy Questionnaire – Summary Scores
ITT Population

Subject ID	Treatment Assignment	Age/Sex [a]	Visit	Visit date	Physical Limitation Score	Symptom Stability Score	Symptom Frequency Score	Symptom Burden Score	Total Symptom Score	Self-Efficacy Score	Quality of Life	Social Limitation Score	Overall Summary Score	Clinical Summary Score
xxx-Baseli	Elamipretide 4 mg	73/F	Week 4	yyyy-mmm-dd	xxx				xxx		xxx-65/M			
xxx-Baseli	Elamipretide 40 mg	65/M	Week 4	yyyy-mmm-dd	xxx				xxx		xxx-65/M			

[a] Age is age at informed consent. Sex: M = Male, F = Female.

Note to Programmer: Listing is sorted by Randomized Treatment Group, Subject ID, and Visit Date.

Report generated by program: /sasdir/xxxx.sas
-MM-DD HH:MM

Draft YYYY

LISTINGS – STUDY DRUG AND PRIOR/CONCOMITANT MEDICATIONS

Listing 3.1
Study Drug Injection Records Safety
Population

Subject	Study Drug	Dose	Study Drug Injections?	Vial Number(s)	Date of Injection	Time of Injection	Incomplete Injection	% of Dose Injected	Incomplete Dose Injected (mg)	ID	Any Treatment Used	If Incomplete Injection, Total Volume Injected (mL, Expected)	Reason(s) for Incomplete Injection	Entire Injection
xxx-xxx	Elamipretide	4 mg	Yes	xxx-xxx xxxx, xxxx-xxxx	xxxx- dd	yyyy-mmm-	hh:mm	Yes	xxx.xx	xxxx-	Yes	0.5 mL, 50%	xxxxxxxxxxxxxxx Reason: xxxxxx	Yes
										xxx-xxx	Placebo	No,		

Note to Programmer: Listing is sorted by Randomized Treatment Group and Subject ID.

Listing 3.2
Prior and Concomitant Medications by Subject
Safety Population

Subject ID	Study Treatment	Age/Sex [a]	Medication Class/Preferred Term (Investigator Text)	Reason	Dose	Unit	Route	Frequency	Prior/ Concomitant[b]	Start Date End Date / Ongoing	Date of First dose of Study Treatment
xxx-xxx	Elamipretide 4 mg	73/F	XXXXXXXXXXXX XXXXXXXX (XXXXXXXXXX)	xxxxxxx xxxx	xxxxx	xxxxx	xxxxx	xxx	Y/N	yyyy-mmm-dd Ongoing	yyyy-mmm-dd
			XXXXXXXXXXXX XXXXXXXX (XXXXXXXXXX)	xxxxxxx xxxx	xxxxx	xxxxx	xxxxx	xxx	N/Y	yyyy-mmm-dd yyyy-mmm-dd	yyyy-mmm-dd
xxx-xxx	Placebo	65/M	XXXXXXXXXXXX XXXXXXXX (XXXXXXXXXX)	xxxxxxx xxxx	xxxxx	xxxxx	xxxxx	xxx	Y/Y	yyyy-mmm-dd yyyy-mmm-dd	yyyy-mmm-dd

[a] Age is age at informed consent. Sex: M = Male, F = Female.
[b] Prior = any medications taken prior to the date of first dose of investigational product.
Concomitant = any medications taken during the study (from the date of first dose of investigational product to the date of last visit).

Note to Programmer: Listing is sorted by Study Treatment, Subject ID

LISTINGS – PLASMA CONCENTRATION

Listing 4.1
Plasma Concentrations of Elamipretide and Metabolites (M1, M2)
Safety Population

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

					Plasma Concentration (unit)		
Subject ID	Treatment Assignment	Age/Sex [a]	Date	Time label	Elamipretide	M1	M2
xxx-xxx	Elamipretide 4 mg	73/F	yyyy-mmm-dd	Day 1 Pre-dose	xxx.xx	xxx.xx	xxx.xx
				Day 1 Post-dose	xxx.xx	xxx.xx	xxx.xx
				Week 1 Pre-dose	xxx.xx	xxx.xx	xxx.xx
				Week 1 Post-dose	xxx.xx	xxx.xx	xxx.xx
				Week 2 Pre-dose	xxx.xx	xxx.xx	xxx.xx
				Week 2 Post-dose	xxx.xx	xxx.xx	xxx.xx
				Week 4	xxx.xx	xxx.xx	xxx.xx
				Week 6	xxx.xx	xxx.xx	xxx.xx
xxx-xxx							
	Elamipretide 40 mg						

[a] Age is age at informed consent. Sex: M = Male, F = Female.

Note to Programmer: Listing is sorted by Subject ID, Visit Date, and Time.

LISTINGS – ADVERSE EVENTS

Listing 5.1
Adverse Events
Safety Population

Subject ID	Study Treatment	Age/ Sex [a]	System Organ Class/Preferred Term (Investigator Term)	Onset Date (Study day)/ Resolution Date(Study Day)/ ongoing [b]	Intensity/ Relationship to Study Drug	Outcome	Treatment for AE? Medication or Procedure	Action Taken with Study Drug	Serious AE [c]

Report generated by program: /sasdir/xxxx.sas -MM-DD HH:MM

D r a f t Y Y Y Y

xxx-xxx	Elamipretide 4 mg	73/F	XXXXXXXXXXXX XXXXXXXXX (XXXXXXXXXX) XXXXXXXXXXXX XXXXXXXXX (XXXXXXXXXX)	yyyy-mmm-dd (xxx) yyyy-mmm-dd (xxx) yyyy-mmm-dd (xxx) ongoing	Severe Probably related Severe Unlikely related	Recovered/Resolved Not recovered/not resolved	Yes Medication Yes	Interrupted None Procedure	Yes No
xxx-xxx	Placebo	65/M	XXXXXXXXXXXX XXXXXXXXX (XXXXXXXXXX) XXXXXXXXXXXX XXXXXXXXX (XXXXXXXXXX)	yyyy-mmm-dd (xxx) yyyy-mmm-dd (xxx) yyyy-mmm-dd (xxx) yyyy-mmm-dd (xxx)	xxxxx xxxxxxxxxxxx xxxxx/ xxxxxxxxxxxx	xxxx/xxxx xxxxxxxxx	xxx xxxx	xxxxxxxxx xxxxxxxx	xxx xxx

AE = adverse event.
[a] Age is age at informed consent in years. F = Female, M = Male.
[b] Study Day = Onset/Resolution date – date of first dose of study drug + 1. [c] Serious AE criteria are defined in protocol Section 9.6.

Note to Programmer: Listing is sorted by Subject ID, AE Onset Date.

Listing 5.2
Serious Adverse Events Safety Population

Subject ID	Study Treatment	Age/ Sex [a]	System Organ Class/Preferred Term (Investigator Term)	Onset Date (Study day)/Resolution Date(Study Day)/ ongoing [b]	Intensity/ Relationship to Study Drug/Date of last study treatment prior to the event	Outcome	Treatment for AE? Medication or Procedure	Action Taken with Study Drug	Seriousness criteria [c]

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

xxx-xxx	Elamipretide 4 mg	73/F	XXXXXXXXXXXX XXXXXXXXX (XXXXXXXXXX)	yyyy-mmm-dd (xxx) yyyy-mmm-dd (xxx)	Severe Recovered Probably related /Resolved yyyy-mmm-dd Additional case details Relevant diagnostic tests	Yes Medication	Interrupted Stopped: yyyy-mmm-dd hh:mm AE abated Restarted: yyyy-mmm-dd hh:mm AE reoccurred	Hospitalization/prolongation. Admission on yyyymmm-dd Discharged on yyyy-mmm-dd	
xxx-xxx	Placebo	65/M	XXXXXXXXXXXX XXXXXXXXX (XXXXXXXXXX)	yyyy-mmm-dd (xxx) ongoing	Severe Unlikely related /not yyyy-mmm-dd Additional case details Relevant diagnostic tests	Not recovered resolved Yes Procedure	None	Death on yyyy-mmm-dd Autopsy performed	
xxx-xxx	Placebo	65/M	XXXXXXXXXXXX XXXXXXXXX (XXXXXXXXXX)	yyyy-mmm-dd (xxx) ongoing	Severe Unlikely related /not yyyy-mmm-dd	Not recovered resolved Yes Procedure	Permanently discontinued Last dose date yyyy-mmm-dd	xxxxxxx	

[a] Age is age at informed consent in years. F = Female, M = Male.
[b] Study Day = Onset/Resolution date – date of first dose of study drug + 1. [c] Serious AE criteria are defined in protocol Section 9.6.

Note to Programmer: Listing is sorted by Study Treatment, and Subject ID.

Listing 5.3
Adverse Events Leading to Discontinuation of Study Drug
Safety Population

System Organ Class/Preferred Term (Investigator Term)	Subject ID	Study Treatment	Age/ Sex [a]	Onset Date (Study day)/Resolution Date(Study Day)/ ongoing [b]	Intensity/ Relationship to Study Drug	Outcome	Treatment for AE? Medication or Procedure AE	Serious [c]
XXXXXXXXXXXX XXXXXXXXX (XXXXXXXXXX)	xxx-xxx	Elamipretide 4 mg	73/F	yyyy-mmm-dd d (xxx) yyyy-mmm-dd (xxx)	Severe Probably related	Recovered/Resolved	Yes Medication	Yes
	xxx-xxx	Elamipretide 40 mg	78/M	yyyy-mmm-dd (xxx) ongoing	Severe Possibly related	Not recovered/not resolved	Yes Procedure	No
XXXXXXXXXXXX XXXXXXXXX (XXXXXXXXXX)	xxx-xxx xxx-xxx	Placebo	65/M	yyyy-mmm-dd (xxx) yyyy-mmm-dd (xxx)	xxxxx xxxxxxxxxxx	xxxx/xxxx xxxxxxxxx	xxx xxxx	xxx
		Elamipretide 4 mg	68/F	yyyy-mmm-dd (xxx) yyyy-mmm-dd (xxx)	xxxxx/ xxxxxxxxxxx			xxx

AE = adverse event.
[a] Age is age at informed consent in years. F = Female, M = Male.
[b] Study Day = Onset/Resolution date – date of first dose of study drug + 1. [c] Serious AE criteria are defined in protocol Section 9.6.

Note to Programmer: Include all AEs with Action taken with study drug = permanently discontinued. Sorted by PT in decreasing order of total frequency, Study Treatment, and Subject ID.

LISTINGS – LABORATORY DATA

Listing 6.1
Hematology Results by Subject and Visit Safety Population

Subject [a]	Study	Age/Sex	Parameter (Unit)	ID	Treatment	Timepoint	Sample Date yyyy-mmm-dd	Sample Time	Value xxx.xx	Markedly Abnormal Criteria	Result (N/H/L)
						Screening	yyyy-mmm-dd				

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Elamipretide			Baseline	yyyy-mmm-dd yyyy-	hh:mm	xxx.xx	Reference Range	N N
xxx-xxx 4 mg	73/F		Week 1	mmm-dd yyyy-mmm-dd	hh:mm	xxx.xx	Low - high	L
		XXXXXX	Week 2	yyyy-mmm-dd yyyy-	hh:mm	xxx.xx	xxxx - xxxx	N
		(xxx)	Week 4	mmm-dd yyyy-mmm-dd	hh:mm	xxx.xx	xxxx - xxxx	N
			Week 6	yyyy-mmm-dd yyyy-	hh:mm	xxx.xx	xxxx - xxxx	N
			Screening	mmm-dd yyyy-mmm-dd	hh:mm	xxx.xx	xxxx - xxxx	N
			Baseline	yyyy-mmm-dd	hh:mm	xxx.xx	xxxx - xxxx	N
			Week 1	yyyy-mmm-dd	hh:mm	xxx.xx	xxxx - xxxx	H
			Week 2	yyyy-mmm-dd	hh:mm	xxx.xx	xxxx - xxxx	N
		XXXXXX	Week 4	yyyy-mmm-dd	hh:mm	xxx.xx	xxxx - xxxx	N
		(xxx)	Week 6	yyyy-mmm-dd	hh:mm	xxx.xx	xxxx - xxxx	N
				yyyy-mmm-dd	hh:mm	xxx.xx	xxxx - xxxx	
				yyyy-mmm-dd	hh:mm	xxx.xx	xxxx - xxxx	
			Screening		hh:mm	xxx.xx	xxxx - xxxx	N
			Baseline		hh:mm	xxx.xx	xxxx -	N
			Week 1		hh:mm	xxx.xx	xxxx xxxx	N
			Week 2		hh:mm	xxx.xx	- xxxx	N
			Week 4		hh:mm	xxx.xx	xxxx -	N
xxx-xxx Placebo	65/M	XXXXXX	Week 6				xxxx xxxx	N
		(xxx)					- xxxx	
							xxxx -	
							xxxx xxxx	
							- xxxx	

N = Normal, H=High, L=Low are based on comparison to the reference ranges. [a] Age is age at informed consent. Sex: M = Male, F = Female.

Note to Programmer: Listing is sorted by Study Treatment, Subject ID, Parameter, and Timepoint.

Listing 6.2
Blood Chemistry Results by Subject and Visit
Safety Population

Note to Programmer: Same layout as Listing 6.1.

Listing 6.3
Urinalysis Results by Subject and Visit
Safety Population

Note to Programmer: Layout similar to Listing 6.1. The time points are Screening, Baseline, and Week 4.

Listing 6.4
Levels of hsTroponin by Subject and Visit Safety
Population

Note to Programmer: Layout similar to Listing 6.1. The time points are Baseline, Week 1, Week 2, Week 4, and Week 6. Change "Value" column to "Value (Log Value)".

LISTINGS – OTHER SAFETY DATA

Listing 7.1
Vital Signs by Subject and Visit Safety
Population

Subject ID	Study Treatment Elamipretide	Age/ Sex [a]	Timepoint	Date	Time	Temperature (°C)	Blood Pressure Systolic (mmHg)	Blood Pressure Diastolic (mmHg)	Heart Rate (BPM)	Respiration Rate (breaths/min)
xxx-xxx	4 mg	73/F	Screening	yyyy-mmm-dd	hh:mm	xx.x	xxx	xxx	xxx	xxx
			Baseline	yyyy-mmm-dd	hh:mm	xx.x	xxx	xxx	xxx	xxx
			Week 1	yyyy-mmm-dd	hh:mm	xx.x	xxx	xxx	xxx	xxx
			Week 2	yyyy-mmm-dd	hh:mm	xx.x	xxx	xxx	xxx	xxx
			Week 4	yyyy-mmm-dd	hh:mm	xx.x	xxx	xxx	xxx	xxx
			Week 6	yyyy-mmm-dd	hh:mm	xx.x	xxx	xxx	xxx	xxx
xxx-xxx	Placebo	65/M	Screening	yyyy-mmm-dd	hh:mm	xx.x	xxx	xxx	xxx	xxx
			Baseline	yyyy-mmm-dd	hh:mm	xx.x	xxx	xxx	xxx	xxx
			Week 1	yyyy-mmm-dd	hh:mm	xx.x	xxx	xxx	xxx	xxx
			Week 2	yyyy-mmm-dd	hh:mm	xx.x	xxx	xxx	xxx	xxx
			Week 4	yyyy-mmm-dd	hh:mm	xx.x	xxx	xxx	xxx	xxx
			Week 6	yyyy-mmm-dd	hh:mm	xx.x	xxx	xxx	xxx	xxx

BPM = Beats per minute.
[a] Age is age at informed consent. Sex: M = Male, F = Female.

Note to Programmer: Listing is sorted by Study Treatment, Subject ID, and Timepoint.

Listing 7.2a
Electrocardiogram (ECG) by Subject and Visit Safety Population

Subject ID	Study Treatment	Age/Sex [a]	Timepoint	Date yyyy-mmm-dd	Time	Heart Rate	PR (msec)	QRS (msec)	QT (msec)	QTcF (msec)
xxx-xxx	Elamipretide 4 mg	73/F	Screening		hh:mm	xxx	xxx	xxx	xxx	xxx
			Baseline	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Week 1	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Week 2	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Week 4	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Week 6	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
xxx-xxx	Placebo	65/M	Screening	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Baseline	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Week 1	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Week 2	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Week 4	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Week 6	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx

[a] Age is age at informed consent. Sex: M = Male, F = Female. QTcF = Fridericia corrected QT interval.

Note to Programmer: Listing is sorted by Study Treatment, Subject ID and Timepoint.

Listing 7.2b
Electrocardiogram (ECG) by Subject and Visit with QRS Duration of <= 110 msec Safety Population

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Listing 7.2c
Electrocardiogram (ECG) by Subject and Visit with QRS Duration of >110 msec Safety Population

Listing 7.3
Electrocardiogram (ECG) by Subject and Visit
Subjects with Either an Increase of >60 msec Between Baseline and End of Treatment in Their QT or QTcF or an Absolute QT or QTcF value >500 msec at Any Point in Time During the Study
Safety Population

Subject ID	Study Treatment	Age/Sex [a]	Timepoint	Date	Time	Heart Rate	PR (msec)	QRS(msec)	QT (msec)	QTcF(msec)
xxx-xxx	Elamipretide 4 mg	73/F	Screening	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Baseline	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Week 1	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Week 2	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Week 4	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Week 6	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
xxx-xxx	Placebo	65/M	Screening	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Baseline	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Week 1	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Week 2	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Week 4	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx
			Week 6	yyyy-mmm-dd	hh:mm	xxx	xxx	xxx	xxx	xxx

[a] Age is age at informed consent. Sex: M = Male, F = Female. QTcF = Fridericia corrected QT interval.

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Note to Programmer: Listing is sorted by Study Treatment, Subject ID and Timepoint.

Listing 7.4
Cardiovascular Physical Examination and Physical Measurements by Subject and Visit Safety Population

Subject ID	Study Treatment [a]	Age/Sex	Visit	Cardiovascular Physical Examination		Physical Measurements					
				Date	Examination performed?	Clinical Significant abnormalities noted?	Weight (kg)	Height (cm)	BMI (kg/m$_2$)	Physical Measurements Performed?	Clinical Significant abnormalities noted?
xxx-xxx	Elamipretide 4 mg	73/F	Screening	mmm-dd	Yes	No	xxx.x	xxx.x	xxx.x	yyyy-mm-dd	Yes No
			Baseline	mmm-dd	Yes	No	xxx.x	xxx.x	xxx.x	yyyy-mm-dd	Yes No
			Week 1	mmm-dd	Yes	No	xxx.x	xxx.x	xxx.x	yyyy-mm-dd	Yes No
			Week 2	mmm-dd	Yes	No	xxx.x	xxx.x	xxx.x	yyyy-mm-dd	Yes No
			Week 4	mmm-dd	No	No				yyyy-mm-dd	
			Week 6	mmm-dd	Yes	No				yyyy-mm-dd	Yes No
xxx-xxx	Placebo	65/M	Screening								

Report generated by program: /sasdir/xxxx.sas
D r a f t
Y Y Y Y -MM-DD HH:MM

							Baseline	yyyy-mmm-dd
							Week 1	yyyy-mmm-dd
							Week 2	yyyy-mmm-dd
							Week 4	yyyy-mmm-dd
							Week 6	yyyy-mmm-dd
Yes	No	Yes	No	xxx.x	xxx.x	xxx.x		
Yes	No	Yes	No	xxx.x	xxx.x	xxx.x		
Yes	No	Yes	No	xxx.x	xxx.x	xxx.x		
No		No		No		No		
Yes	Yes	Yes	Yes	xxx.x	xxx.x	xxx.x		
No								
Yes								
No						xxx.x	xxx.x	xxx.x

[a] Age is age at informed consent. Sex: M = Male, F = Female.

Note to Programmer: Listing is sorted by Study Treatment, Subject ID, and Timepoint.

Listing 7.5
Injection Site Reaction (Nurse/Investigator Assessment)
Safety Population

Subject ID	Study Treatment	Age/Sex [a]	Date	Assessment Not Completed	Injection Site	Other, Specify	Parameter	Grade
xxx-xxx	Elamipretide 4 mg	73/F	yyyy-mmm-dd yyyy-mmm-dd		Upper Right		Pain or Tenderness	
			yyyy-mmm-dd		Upper Left		Erythema or Redness	1
			yyyy-mmm-dd yyyy-mmm-dd		Lower Right		Induration or Swelling	2
			yyyy-mmm-dd		Lower Left			3
			yyyy-mmm-dd yyyy-mmm-dd		Other	Xxxxxx	Pruritus	4
xxx-xxx	Placebo	65/M	yyyy-mmm-dd		Upper Right			
			yyyy-mmm-dd		Upper Left			
			yyyy-mmm-dd		Lower Right			

Report generated by program: /sasdir/xxxx.sas
D r a f t Y Y Y Y -MM-DD HH:MM

yyyy-mmm-dd		Lower Left	
yyyy-mmm-dd yyyy-mmm-dd		Other	Xxxxxx

[a] Age is age at informed consent. Sex: M = Male, F = Female.

Note to Programmer: Listing is sorted by Study Treatment, Subject ID, and Timepoint.

Listing 7.6
Injection Site Reaction Self-Assessment Questionnaire
Safety Population

Subject ID	Study Treatment	Age/Sex [a]	Date	Day	Was the ISR Self-Assessment Questionnaire completed by the subject?	Pain?	Burning Sensation?	Cold Sensation?	Itching?	Redness?	Swelling?	Bruising?
xxx-xxx	Elamipretide 4 mg	73/F		1	Yes	Not at all						
			yyyy-mmm-dd	2	Yes							
			yyyy-mmm-dd	3	Yes		A little	Moderately				
			yyyy-mmm-dd	4	Yes				Very	Extremely		
			yyyy-mmm-dd	5	No							
			yyyy-mmm-dd	6	Yes							

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

xxx-xxx					
	Placebo	65/M	yyyy-mmm-dd	1	Yes
			yyyy-mmm-dd	2	Yes
			yyyy-mmm-dd	3	No
			yyyy-mmm-dd	4	Yes
			yyyy-mmm-dd	5	Yes
			yyyy-mmm-dd	6	Yes

[a] Age is age at informed consent. Sex: M = Male, F = Female.

Note to Programmer: Listing is sorted by Study Treatment, Subject ID, and Timepoint.

Listing 7.7
Comments
All Subjects

Subject ID	Study Treatment	Age/Sex [a]	Visit	Comments Applies To	Comments
xxx-xxx	Elamipretide 4 mg	73/F	xxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
			xxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
			xxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxx-xxx					
	Placebo	65/M	xxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
			xxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

[a] Age is age at informed consent. Sex: M = Male, F = Female.

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Note to Programmer: Listing is sorted by Study Treatment, Subject ID, Visit and CRF page.

FIGURES

Figure 1a
Change From Baseline in Left Ventricular End Systolic Volume (LV ESV), Assessed by MRI, for Elamipretide 4 mg Group (By Subject) ITT Population

Note: x-axis: Change time points to Screening, Week 1, and Week 4

Figure 1a
Change From Baseline in Left Ventricular End Systolic Volume (LV ESV), Assessed by MRI, for Elamipretide 4 mg Group (By Subject)
ITT Population

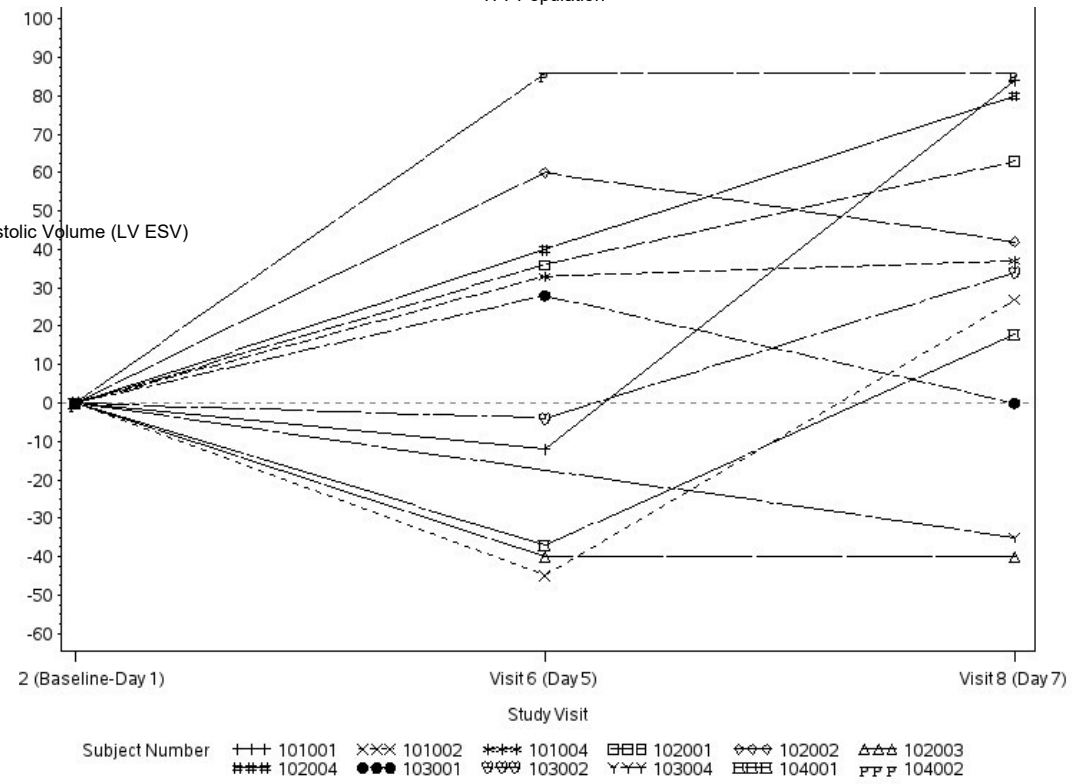


Figure 1b
Change From Baseline in Left Ventricular End Systolic Volume (LV ESV), Assessed by MRI, for Elamipretide 4 mg Group (By Subject)
Per-Protocol Population

Figure 1c
Change From Baseline in Left Ventricular End Systolic Volume (LV ESV), Assessed by MRI, for Elamipretide 40 mg Group (By Subject)
ITT Population

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Figure 1d
Change From Baseline in Left Ventricular End Systolic Volume (LV ESV), Assessed by MRI, for Elamipretide 40 mg Group (By Subject)
Per-Protocol Population

Figure 1e
Change From Baseline in Left Ventricular End Systolic Volume (LV ESV), Assessed by MRI, for Placebo Group (By Subject)
ITT Population

Figure 1f
Change From Baseline in Left Ventricular End Systolic Volume (LV ESV), Assessed by MRI, for Placebo Group (By Subject)
Per-Protocol Population

Figure 1g
LS Mean Change From Baseline in Left Ventricular End Systolic Volume (LV ESV), Assessed by MRI, (By Treatment Group)
ITT Population

Figure 1h
LS Mean Change From Baseline in Left Ventricular End Systolic Volume (LV ESV), Assessed by MRI, (By Treatment Group) Per-Protocol Population

Note: For Figures 1g and 1h, only 3 lines, one for Elamipretide 4mg, one for Elamipretide 40 mg, and one for Placebo group. Add SE bar to the plot. Change Subject Number legend to Treatment Group legend.

Figure 2a to Figure 2h (LVEF assessed by MRI)

Figure 3a to Figure 2h (LV EDV assessed by MRI)

Figure 4a to Figure 4h (LVSV assessed by MRI)

Figure 5a to Figure 5h (LVCO assessed by MRI)

Figure 6a to Figure 6h (LV Myocardial Mass assessed by MRI)

Figure 7a to Figure 7h (RV ESV assessed by MRI)

Figure 8a to Figure 8h (RV EDV assessed by MRI)

Figure 9a to Figure 9h (RVEF assessed by MRI)

Figure 10a to Figure 10h (E/A assessed by Echocardiography)

Figure 11a to Figure 11h (E/e' assessed by Echocardiography)

Figure 12a to Figure 12h (LA Volume assessed by Echocardiography)

Figure 13a to Figure 13h (LV GLS assessed by Echocardiography)

Figure 14a to Figure 14f (LV EDV assessed by Echocardiography)

Figure 15a to Figure 15f (LV ESV assessed by Echocardiography)

Figure 16a to Figure 16f (LVEF Biplane assessed by Echocardiography)

Figure 17a to Figure 17f (LV Mass assessed by Echocardiography)

Figure 18a to Figure 18f (Mitral Regurgitation Severity assessed by Echocardiography)

Figure 19a to Figure 19f (Tricuspid Regurgitation Severity assessed by Echocardiography)

Figure 20a to Figure 20f (RV fractional area change assessed by Echocardiography)

Figure 21a to Figure 21f (RV systolic pressure assessed by Echocardiography)

Figure 22a to Figure 22h (6MWT)

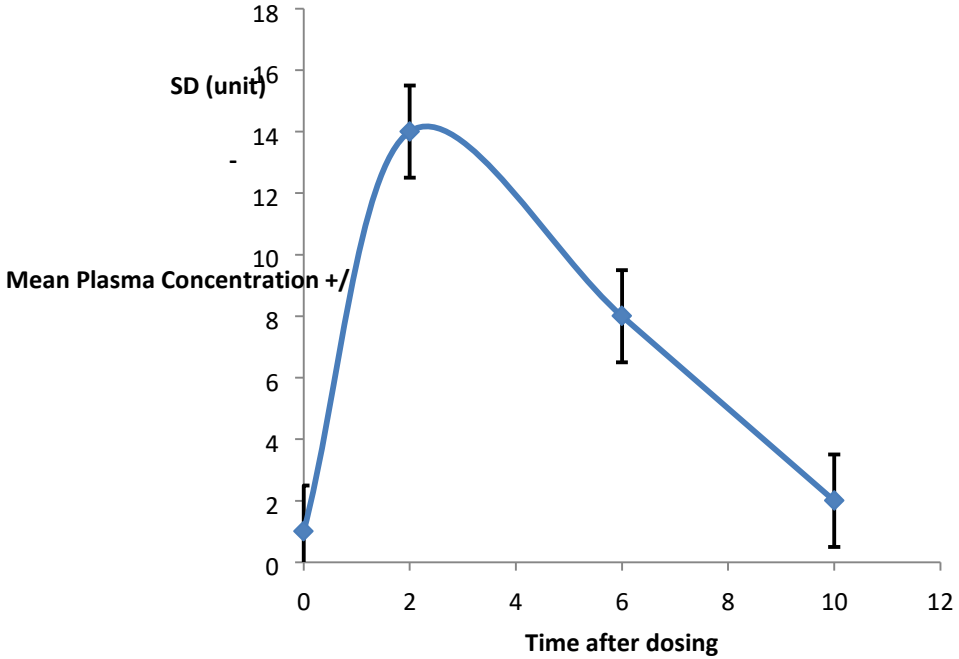
Figure 23a to Figure 23f (NT-pro-BNP)

Figure 24a to Figure 24h (Log10 NT-pro-BNP)

Figure 25a to Figure 25h (hs Troponin)

Figure 26a to Figure 26h (KCCQ)

Figure 27a
Mean Plasma Concentration-Time Profile of Elamipretide (Linear Scale) Safety Population



Source: Table 4.1

Programmer note:

1. *AXES: Display nominal time of sample on the X axis (label "Time After Dosing"). Display mean concentration value on the Y axis (label "Mean Plasma Concentration +/- SD <unit>")*
2. *Nominal time points marked on the x axis are Day 1 Pre-Dose, Day 1 45 min Post-Dose, Week 1 Pre-Dose, Week 1 45 min Post-Dose, Week 2 Pre-Dose, Week 2 45 min Post-Dose, Week 4, and Week 6*

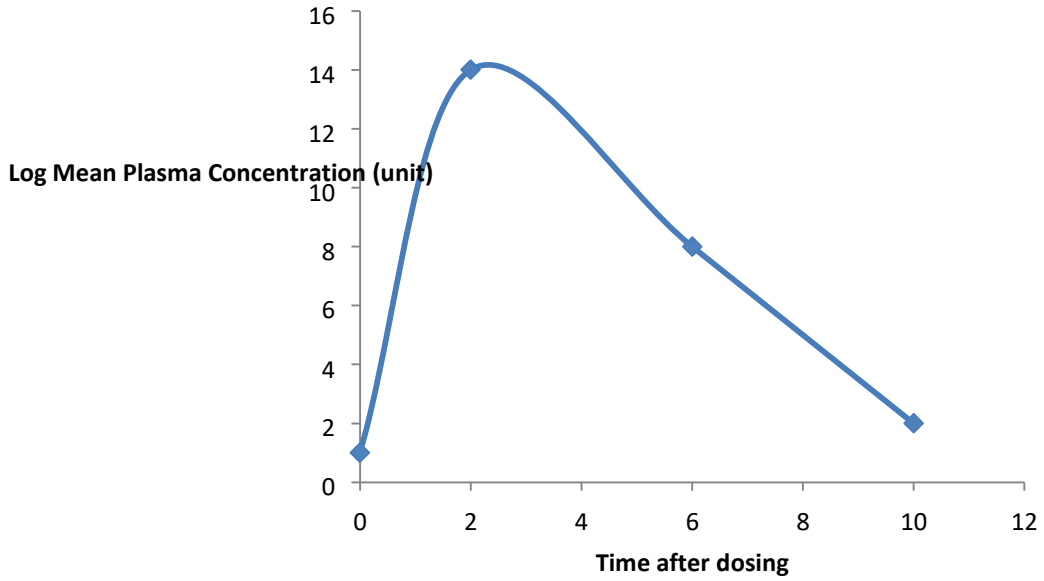
Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

3. PLOT TYPE: line and symbol plot with error bars (+/- SD)

Figure 27b
Mean Plasma Concentration-Time Profile of Elamipretide Metabolite M1 (Linear Scale) Safety Population

Figure 27c
Mean Plasma Concentration-Time Profile of Elamipretide Metabolite M2 (Linear Scale) Safety Population

Figure 27d
Log Mean Plasma Concentration-Time Profile of Elamipretide (Semi-logarithmic Scale)
Safety Population



Source: Table 4.1 and Listing 4.1

Programmer note:

1. *AXES: Display nominal time of sample on the X axis (label "Time After Dosing"). Display mean of log concentration value on the Y axis (label "Log Mean Plasma Concentration <unit>")*
2. *Nominal time points marked on the x axis are Day 1 Pre-Dose, Day 1 45 min Post-Dose, Week 1 Pre-Dose, Week 1 45 min Post-Dose, Week 2 Pre-Dose, Week 2 45 min Post-Dose, Week 4, and Week 6*
3. *PLOT TYPE: line and symbol plot*

Figure 27e
Log Mean Plasma Concentration-Time Profile of Elamipretide Metabolite M1 (Semi-logarithmic Scale)
Safety Population

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

Figure 27f
Log Mean Plasma Concentration-Time Profile of Elamipretide Metabolite M2 (Semi-logarithmic Scale)
Safety Population

Figure 27g
Individual Plasma Concentration-Time Profile of Elamipretide (Linear Scale)
Safety Population

Similar to Figure 27a without +/- SD Source:

Listing 4.1

Programmer note:

1. *All individual profiles superimpose on the same graph*
2. *AXES: Display actual time of sample on the X axis (label "Time After Dosing"). Display concentration value on the Y axis (label "Plasma Concentration, <unit>")*
3. *Nominal time points marked on the x axis are Day 1 Pre-Dose, Day 1 45 min Post-Dose, Week 1 Pre-Dose, Week 1 45 min Post-Dose, Week 2 Pre-Dose, Week 2 45 min Post-Dose, Week 4, and Week 6*
4. *PLOT TYPE: line plot.*

Figure 27h
Individual Plasma Concentration-Time Profile of Elamipretide Metabolite M1 (Linear Scale)
Safety Population

Figure 27i
Individual Plasma Concentration-Time Profile of Elamipretide Metabolite M2 (Linear Scale) Safety Population

Figure 27j
Individual Plasma Concentration-Time Profile of Elamipretide (Semi-logarithmic Scale)
Safety Population

Similar to Figure 27d

Source: Listing 4.1

Programmer note:

Report generated by program: /sasdir/xxxx.sas D r a f t Y Y Y Y -MM-DD HH:MM

1. *All individual profiles superimpose on the same graph*
2. *AXES: Display actual time of sample on the X axis (label "Time After Dosing"). Display log concentration value on the Y axis (label "Log Plasma Concentration, <unit>")*
3. *Nominal time points marked on the x axis are Day 1 Pre-Dose, Day 1 45 min Post-Dose, Week 1 Pre-Dose, Week 1 45 min Post-Dose, Week 2 Pre-Dose, Week 2 45 min Post-Dose, Week 4, and Week 6*
4. *PLOT TYPE: line plot.*

Figure 27k
Individual Plasma Concentration-Time Profile of Elamipretide Metabolite M1 (Semi-logarithmic Scale)
Safety Population

Figure 27l
Individual Plasma Concentration-Time Profile of Elamipretide Metabolite M2 (Semi-logarithmic Scale)
Safety Population

Similar to Figure 1a

Figure 28a
QTc for Subjects with a QTc value >500 msec at Any Point in Time During the Study (By Subject) Safety Population

Note:

1. *x-axis: Change time points to Screening, Baseline, Weeks 1,2, 4, and 6*
2. *Only generate figure if there is at least one subject who meets the criteria*