ApoPharma Inc.

STATISTICAL ANALYSIS PLAN

LA38-EXT

Long-term Safety and Efficacy Study of Ferriprox® for the Treatment of Transfusional Iron Overload in Patients with Sickle Cell Disease or Other Anemias

Final Version 1.0

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LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
AE	Adverse event
AF	Assent form
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
CS	Clinically significant
CI	Confidence interval
CRA	Clinical research associate
CRF	Case report form
CRO	Contract research organization
DFO	Deferoxamine
DFP	Deferiprone
dw	Dry weight
ECG	Electrocardiogram
eCRF	Electronic case report form
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GGT	Gamma-glutamyl transferase
Hb	Hemoglobin
HIV	Human immunodeficiency virus
HR	Heart rate
ICF	Informed consent form
ICH	International Conference on Harmonisation
ID	Identification
IEC	Independent Ethics Committee
IRB	Institutional Review Board
ITT	Intent-to-treat
LIC	Liver iron concentration
MedDRA	Medical Dictionary for Regulatory Activities
mg	milligram
mg/g	milligram per gram
NCS	Not clinically significant

Abbreviation	Definition
OCRDC	Oracle Clinical Remote Data Capture
PDR	Patient Data Report
PP	Per protocol
RBC	Red blood cell
SAE	Serious adverse event
SAP	Statistical analysis plan
SCD	Sickle cell disease
t.i.d.	three times daily
ULN	Upper limit of normal
WHO	World Health Organization

1 INTRODUCTION

This document outlines the statistical analysis plan (SAP) for LA38-EXT, titled "Long-term Safety and Efficacy Study of Ferriprox® for the Treatment of Transfusional Iron Overload in Patients with Sickle Cell Disease or Other Anemias".

Once patients in LA38-0411 have completed the study, they have been invited to enroll in LA38-EXT, a 2-year extension study in which all patients have received deferiprone. The long-term data obtained from this study will provide additional information on the safety and efficacy of deferiprone in patients with sickle cell disease or other anemias.

2 STUDY OBJECTIVES

2.1 Primary Objective

To evaluate the long-term safety and tolerability of deferiprone in iron-overloaded patients with sickle cell disease or other anemias.

2.2 Secondary Objective

To evaluate the efficacy of deferiprone in the treatment of iron overload in patients with sickle cell disease or other anemias who have received deferiprone for up to 3 years.

3 STUDY DESIGN

LA38-EXT is a 2-year prospective, multi-center, single-arm, open-label extension of LA38-0411. All patients who have completed LA38-0411 have been offered the opportunity to continue in this extension study, with the final visit of LA38-0411 being Visit 1 of LA38-EXT. Patients who had been treated with deferiprone during LA38-0411 continued to receive deferiprone for up to 2 years (Group 1), while those who had been treated with deferoxamine were switched to deferiprone for treatment up to 2 years (Group 2) in LA38-EXT. The dosage of deferiprone was 25–33 mg/kg three times a day (t.i.d.).

4 STUDY PROCEDURES

The procedures and assessments to be conducted at each study visit are shown in Table 1.

Table 1 Table of study procedures

Procedure	Visit 1 [1]	Blood Draws [2]	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9 or Early Termination
Week:	0		13	26	39	52	65	78	91	104
Informed consent/assent	X									
Eligibility criteria	X									
Prior and concomitant medications	X		X	X	X	X	X	X	X	X
Transfusion information (if applicable) [3]	X	X	X	X	X	X	X	X	X	X
Serum pregnancy testing (if applicable) [4]	X		X	X	X	X	X	X	X	X
Physical examination	X					X				X
Vital signs (including weight and height) [5]	X		X	X	X	X	X	X	X	X
12-lead ECG	X					X				X
Contraceptive counseling	X		X	X	X	X	X	X	X	X
Serology	X									X
Hematology	X	X	X	X	X	X	X	X	X	X
Biochemistry [6]	X			X		X		X		X
Serum ferritin	X		X	X	X	X	X	X	X	X
Urinalysis	X					X				X
Liver MRI	X					X				X
Cardiac MRI T2*	X					X				X

Procedure	Visit 1 [1]	Blood Draws [2]	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9 or Early Termination
Week:	0		13	26	39	52	65	78	91	104
Dose calculation/verify and adjust dose level	X		X	X	X	X	X	X	X	
Collect used and unused study medication			X	X	X	X	X	X	X	X
Dispense study medication	X		X	X	X	X	X	X	X	
Dispense patient diary card	X		X	X	X	X	X	X	X	
Review and collect diary card			X	X	X	X	X	X	X	X
Adverse events	X		X	X	X	X	X	X	X	X

[1] Visit 1 of study LA38-EXT is also the final visit of study LA38-0411. It serves as the baseline visit for those patients who received deferoxamine in LA38-0411 and will now be receiving deferiprone for the first time. (For patients who received deferiprone in LA38-0411, the measures obtained at the baseline visit of the LA38-0411 study will be used as the baseline measures for LA38-EXT as well.)

[2] For Group 1, hematology testing is to be done monthly throughout the study. For Group 2, it is to be done weekly up to Visit 3 (Week 26), biweekly up to Visit 5 (Week 52), and monthly thereafter. At the quarterly site visits, this testing will be done as part of the routine procedures, and at the other time points it can be done at a local laboratory instead of at the site.

[3] Record volume of blood that the patient received during the transfusion, and the mean hematocrit of the packed red blood cell units transfused

[5] Females of childbearing potential only

[5] Height will be measured only at Visits 1, 5, and 9

[6] At Visits 1, 3, 5, 7, and 9, the blood sample must be drawn following a 10-hour fast

4.1 Method of Assignment to Treatment

Not applicable. All patients in this extension study received deferiprone.

4.2 Blinding Procedures

Not applicable.

4.3 Allocation of Patient Numbers

All patients in LA38-0411 were assigned a unique 6-digit number, where the first 3 digits represent the site code and the last 3 were sequentially assigned to each patient who signed the ICF. These assigned numbers were maintained when patients continued on to this extension study of LA38-EXT.

4.4 Treatment Compliance

Compliance reported in the eCRF was based on the patient's diary and on the return of used and unused medication containers. If compliance was greater than 100% and the patient reported taking all doses as prescribed, compliance would be reported as 100% in the eCRF. Under-compliance < 80% and over-compliance >120% were to be reported as a protocol deviation, unless under-compliance was due to treatment interruption because of infection or neutropenia or other extenuating circumstances.

5 MEASUREMENTS AND EVALUATIONS

5.1 Efficacy Measurements

5.1.1 Liver Iron Concentration

MRI scans for liver iron were performed at Visit 1, Visit 5, and Visit 9 (or early termination).

5.1.2 Cardiac MRI T2*

MRI scans for the assessment of cardiac MRI T2* were performed at Visit 1, Visit 5, and Visit 9 (or early termination).

5.1.3 Serum Ferritin

Serum ferritin was assessed at the start of the extension study and quarterly thereafter.

5.2 Safety Measurements

5.2.1 Adverse Events

An adverse event (AE) is any untoward medical occurrence in a patient who is administered a pharmaceutical or other therapeutic product in a clinical study, not necessarily having a causal relationship with the product. An AE can therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a product, whether or not considered related to that product.

5.2.2 Serious Adverse Events

An SAE is an adverse event occurring at any dose that results in any of the following outcomes:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability or incapacity
- A congenital anomaly in the offspring of a patient who received the study treatment
- An important adverse event that does not result in death, is not life-threatening, and does not necessitate hospitalization but which in the investigator's judgment may jeopardize the patient and may necessitate medical or surgical intervention to prevent one of those outcomes. Examples include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or treatment-related substance abuse.

5.2.3 Adverse Events of Special Interest

5.2.3.1 Neutropenia

Patients taking deferiprone were monitored for neutropenia, defined as a confirmed absolute neutrophil count (ANC) less than 1.5×10^9/L. Categories of neutropenia are as follows:

- Mild: A confirmed ANC $< 1.5 \times 10^9$/L but $\geq 1.0 \times 10^9$/L
- Moderate: A confirmed ANC $< 1.0 \times 10^9$/L but $\geq 0.5 \times 10^9$/L
- Severe: A confirmed ANC $< 0.5 \times 10^9$/L. Severe neutropenia is also referred to as agranulocytosis.

For a case of neutropenia to be confirmed, there must be 2 consecutive counts, a maximum of 3 days apart, that are both less than the specified value. If both counts are below 1.5 x 10^9/L but are not in the same severity category, a third count was required to determine the severity.

5.2.3.2 Infections

If the patient developed fever or any type of infection during the study, deferiprone was to be interrupted immediately and neutrophil count should be obtained and monitored more frequently (every 2 days if ANC <1.5 x 10^9/L). Patients should be advised to report immediately to their physician any symptoms indicative of infection such as fever, sore throat, and flu-like symptoms. Patients has been provided with an emergency services card with contact information, and the patient/legal guardian will be advised to carry this card at all times. In presence of confirmed fever and/or infection, they would be required to have their neutrophil counts tested as soon as possible and no later than 24 hours after the symptoms of infection was detected. Therapy with deferiprone could be re-initiated once all symptoms had been resolved and it was deemed safe by the investigator.

5.2.4 Laboratory Measurements

The following laboratory tests had been performed:

- **Hematology** (for Group 1, monthly throughout the study; for Group 2, weekly for the first 6 months, biweekly for the next 6 months, and monthly thereafter): hemoglobin, total WBC count, ANC, and platelet count
- **Biochemistry** (semi-annually; Visits 1, 3, 5, 7, and 9): total protein, GGT, lactate dehydrogenase (LDH), sodium, potassium, chloride, fasting glucose, total and direct bilirubin (indirect bilirubin will be calculated by the sponsor), AST, ALT, albumin, blood urea nitrogen, calcium, creatinine, uric acid, alkaline phosphatase, and amylase
- **Serology** (Visits 1 and 9): Hepatitis B and C and HIV testing
- **Urinalysis** (annually; Visits 1, 5, and 9): pH, specific gravity, glucose, protein, ketones, blood, and (if indicated by the dipstick results), sediment microscopy. If there is blood in the urine or three or more "plus signs" for protein, samples must be sent for microscopy.
- **Pregnancy** (quarterly; Visits 1–9): serum pregnancy test

5.2.5 Other Safety Measurements

5.2.5.1 Physical Examination

At Visits 1, 5, and 9, the investigator or a qualified delegate performed a physical examination of the following organs and systems: head, ears, eyes, nose, throat and neck, respiratory system, cardiovascular system, gastrointestinal system, musculoskeletal system, central and peripheral nervous system, skin, thyroid, and general constitution.

5.2.5.2 Vital Signs

Temperature, heart rate, respiration rate, and systolic and diastolic blood pressure were measured at each visit.

Weight was measured at each visit, and height was measured at Visits 1, 5, and 9.

5.2.5.3 Electrocardiogram

A standard 12-lead ECG was performed at Visits 1, 5, and 9. As a minimum, the following parameters had been assessed: HR, PR, QRS, QT, QTcF, QTcB. The results were interpreted by the investigator, and the overall interpretation had been documented.

5.2.5.4 Concomitant Medications

Information about prior and concomitant medications was collected at each visit. The following was to be recorded in the source documents and eCRFs:

- Any medications that the patient continues to take during the trial
- Any medications that the patient starts to take during the trial

6 STATISTICAL ANALYSIS

6.1 Endpoints

6.1.1 Primary Endpoints

- Adverse events (AEs): Frequency, severity, time to onset (the start date of AE minus the start date of exposure to treatment), duration (the stop date of AE minus the start date of AE), and relatedness to study product
- Serious adverse events (SAEs): Frequency and relatedness to study product
- Number of discontinuations due to AEs

6.1.2 Secondary Endpoints

The time points for the efficacy assessments are defined below. Since the baseline measures are by definition those taken prior to the start of deferiprone therapy, "baseline" is defined differently for the two groups, as follows:

- **Group 1:** For patients who received deferiprone in LA38-0411, the baseline visit of that study will be treated as the baseline visit of LA38-EXT as well. Thus, Week 0 of the extension study will be Year 1 (i.e., the completion of one year of deferiprone treatment), Week 52 will be Year 2, and Week 104 will be Year 3 of deferiprone treatment.

- **Group 2:** For patients who received deferoxamine in LA38-0411, the start of the extension study (Week 0) will be treated as the baseline visit. For this group, therefore, Week 52 will be Year 1, and Week 104 will be Year 2 of deferiprone treatment.

Efficacy endpoints for deferiprone therapy are provided below. For Group 1, the change from baseline to Year 1 is derived from study LA38-0411. For Group 2, there is no Year 3 of deferiprone treatment.

- The change from baseline to Year 1 (both groups; Group 1 data are from LA38-0411), from baseline to Year 2 (both groups), and from baseline to Year 3 (Group 1 only) in liver iron concentration (LIC), as measured by magnetic resonance imaging (MRI)
- The change from baseline to Year 1 (both groups; Group 1 data are from LA38-0411), from baseline to Year 2 (both groups), and from baseline to Year 3 (Group 1 only) in cardiac MRI T2*
- The change from baseline to Year 1 (both groups; Group 1 data are from LA38-0411 data), from baseline to Year 2 (both groups), and from baseline to Year 3 (Group 1 only) in serum ferritin
- Responder analysis, defined as the percentage of patients who show a ≥20% decline from baseline in LIC or serum ferritin or a ≥20% increase from baseline in cardiac MRI T2* at Year 1 (both groups; Group 1 data are from LA38-0411), at Year 2 (both groups), and at Year 3 (Group 1 only)

In addition to the above analyses, the change from baseline to end of LA38-041 for deferoxamine and the change from baseline to end of LA38-EXT for deferiprone in Group 2 will be compared. The purpose of this analysis is to assess if deferiprone could maintain or even further improve LIC and MRI T2* after the patients were switched therapy.

6.2 Study Populations

Study populations intended for analysis are defined as follows: Intent-to-Treat (ITT), Per-Protocol (PP), and Safety. The ITT population will represent the primary analysis population

to evaluate all efficacy endpoints. The efficacy endpoints will also be analyzed for the PP population, which is the secondary analysis population.

6.2.1 Intent-to-Treat Population

The ITT population will include all randomized patients who received at least one dose of study drug and have a baseline and at least one post-baseline efficacy assessment.

6.2.2 Per Protocol Population

The Per-Protocol (PP) population will include all enrolled patients who complete the study, have no major protocol violations, and have an efficacy assessment at the end of the study. Prior to database lock, patients with major protocol violations will be reviewed and excluded, where appropriate, from the PP population. Major protocol violations will include (but not be limited to) the following:

- Patients who were not compliant with the treatment (<80% compliance)
- Patients who took iron chelator medications other than the assigned study medication during the course of the study

6.2.3 Safety Population

The safety population will include all enrolled patients who took at least one dose of study drug.

6.3 Data Analysis

6.3.1 Patient Disposition and Drug Exposure

Patient disposition will be summarized and presented, including the number and percentages of patients who were enrolled, received at least one dose of study medication, completed the study, and withdrew (including reasons for withdrawals). For each patient, the number of doses taken will be computed from the study drug dispensing and accountability eCRFs obtained at each visit. The overall mean of total daily dose taken during the study will be summarized with descriptive statistics.

6.3.2 Patient Characteristics

Baseline characteristics for continuous variables will be summarized with descriptive statistics such as mean, standard deviation, minimum, median and maximum values. Baseline characteristics for discrete variables will be summarized with frequency tables.

6.3.3 Analysis of Efficacy

Changes in LIC, in cardiac MRI T2*, and in serum ferritin from baseline to Year 1 (both groups; Group 1 data are from LA38-0411), from baseline to Year 2 (both groups), and from

baseline to Year 3 (Group 1 only) will be summarized with descriptive statistics and will be tested against no change using a one-sample t-test. The changes in these 3 efficacy measures from the start of deferiprone therapy to the last visit of LA38-EXT in all patients, irrespective of whether deferiprone therapy was initiated in LA38-0411 or in LA38-EXT, will also be tested using a one-sample t-test. In addition, the percentages of responders will be tabulated for Year 1 (both groups; Group 1 data are from LA38-0411), for Year 2 (both groups), and for Year 3 (Group 1 only) of deferiprone therapy. The change from baseline to end of LA38-041 for deferoxamine and the change from baseline to end of LA38-EXT for deferiprone in Group 2 will be compared.

6.3.4 Analysis of Safety

The incidences of AEs and SAEs reported from the start of deferiprone therapy for all patients will be tabulated. For patients continuing on deferiprone, this time period will be from the start of LA38-0411 to the completion of LA38-EXT; for those switching to deferiprone, it will be from the start of LA38-EXT to the completion of LA38-EXT. AEs will be summarized by worst severity and by relationship to the study medication. Time to onset and duration of all SAEs, of AEs of special interest such as neutropenia, agranulocytosis, increased ALT, and arthralgia: 1) the mean time to the first onset and the mean time to the last recurrence will be calculated, and 2) the mean duration for the first episode and the mean duration for any recurrent episodes, excluding the first episode, will be calculated for all SAEs and AEs of special interest.

The percentage of discontinuations due to AEs will be calculated, and the AEs leading to discontinuation will be summarized in a frequency table.

Laboratory data (hematology and chemistry) will be summarized using descriptive statistics for continuous variables and frequency tables for discrete variables. The incidences of out-of-range data will be tabulated, and the changes from baseline to the end of study will be presented in shift tables.

14 SUMMARY TABLES AND FIGURES

Note: The final numberings for tables and/or figures in the clinical study report can be changed if more tables and/or figures are added in addition to those in the SAP.

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Note: Similar tables will be produced for PR, QRS, QT, QTcF, and QTcB.

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Note: Similar graphs will be produced for total white blood cell (WBC), absolute neutrophil count (ANC), and platelets.

14.3.2 Biochemistry

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Note: Similar tables will be produced for GGT, lactate dehydrogenase (LDH), sodium, potassium, chloride, glucose (fasting at screening visit only), total, direct and indirect bilirubin, AST, ALT, albumin; blood urea nitrogen, calcium, creatinine, uric acid, alkaline phosphatase, and amylase.

16 DATA LISTINGS

Note: The final numberings for patient data listings in the clinical study report can be changed if more patient data listings are made in the addition to those in the SAP.

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17 TABLE SHELLS

The following table shells provide a framework for the display of data from this study. These tables may not be produced exactly as shown in the shells, but are intended to reflect the general layout of the data that will be included in the clinical study report.

Note that 'c' in the table shells indicates an alphanumeric character and 'x' indicates a number from 0 to 9.

If the same data points are collected at more than one visit, the results will be summarized in Table x.x for baseline, x.x-1 for visit 1, x.x-2 for visit 2 and so on.

Table 14.1.1 Patient disposition

	Treatment	
	DFP+ DFP	DFO+DFP
Enrolled	Xxx	xxx
Exposed*	xxx (xx%)	xxx (xx%)
Completed*	xxx (xx%)	xxx (xx%)
Withdrawn*	xxx (xx%)	xxx (xx%)

Data source: 16.2.18 Listing of disposition
Note: *Percentages are based on the number of enrolled patients in each treatment group.

Table 14.1.2 Number of patients in the ITT, PP, and safety populations

		Treatment	
		DFP+DFP	DFO+DFP
ITT population	LIC	xxx	xxx
	Cardiac MRI T2*	xxx	xxx
	Serum Ferritin	xxx	xxx
PP population	LIC	xxx	xxx
	Cardiac MRI T2*	xxx	xxx
	Serum Ferritin	xxx	xxx
Safety population		xxx	xxx

Data source: 16.2.10 Listing of LIC, 16.2.11 Listing of cardiac MRI T2*, and 16.2.16 Listing of serum ferritin, and 16.2.24 Listing of exposure

Table 14.1.3 Number of patients by study site

	Treatment	
Study Site	DFP+DFP	DFO+DFP
001	xxx	xxx
002	xxx	xxx
…	…	…
Total	xxx	xxx

Data source: 16.2.2 Listing of demographics

Table 14.1.4 Reasons for not completing the study

		Treatment	
		DFP+DFP	DFO+DFP
N (%)		xx (100)	xx (100)
Reason	Detail		
Adverse event	Ccccc	xx (xx)	xx (xx)
	Ccccc	xx (xx)	xx (xx)
Voluntary withdrawal	Ccccc	xx (xx)	xx (xx)
	Ccccc	xx (xx)	xx (xx)
Lost to follow-up	Ccccc	xx (xx)	xx (xx)
	Ccccc	xx (xx)	xx (xx)
Investigator decision	Ccccc	xx (xx)	xx (xx)
	Ccccc	xx (xx)	xx (xx)
Protocol violation	Ccccc	xx (xx)	xx (xx)
	Ccccc	xx (xx)	xx (xx)
Other	Ccccc	xx (xx)	xx (xx)
	Ccccc	xx (xx)	xx (xx)
Total		xx (xx)	xx (xx)

Data source: 16.2.18 Listing of disposition

Table 14.1.5 Demographics data

	Treatment		
	DFP+DFP	DFO+DFP	
N	Xxx	xxx	p-value§
Age (years): Mean ± SD (Min, Median, Max)	 xx.x ± xx.x (xx.x, xx.x, xx.x)	 xx.x ± xx.x (xx.x, xx.x, xx.x)	0.xxxx
Sex: n (%) Female Male	 xx (xx) xx (xx)	 xx (xx) xx (xx)	0.xxxx
Ethnic Origin: n (%) Hispanic/Latino Other	 xx (xx) xx (xx)	 xx (xx) xx (xx)	0.xxxx
Racial Origin: n (%) White Black Asian Native American Native Hawaiian/Other Pacific Islander Multi-Racial	 xx (xx) xx (xx) xx (xx) xx (xx) xx (xx) xx (xx)	 xx (xx) xx (xx) xx (xx) xx (xx) xx (xx) xx (xx)	0.xxxx

§ T-test for age; Fisher's exact test for sex, ethnic origin, and racial origin
Data source: 16.2.2 Listing of demographics

Table 14.1.6 LIC, cardiac MRI T2*, and serum ferritin at baseline

	Treatment		
	DFP+DFP	DFO+DFP	
N	xxx	xxx	
	Mean ± SD (Min, Max)	Mean ± SD (Min, Max)	P-value (t-test)
LIC (mg/g dw)	xx.x ± xx.x (xx.x, xx.x)	xx.x ± xx.x (xx.x, xx.x)	0.xxxx
Cardiac MRI T2* (ms)	xx.x ± xx.x (xx.x, x.xx)	xx.x ± xx.x (xx.x, xx.x)	0.xxxx
Serum Ferritin (µg/L)	xxxx ± xxxx (xxxx, xxxx)	xxxx ± xxxx (xxxx, xxxx)	0.xxxx

Data source: 16.2.10 Listing of LIC, 16.2.11 Listing of cardiac MRI T2*, 16.2.16 Listing of serum ferritin

Table 14.1.7 Medical history

	Treatment			
	DFP+DFP		DFO+DFP	
N	xxx		xxx	
Illness/Event by MedDRA Primary System Organ Class and Preferred Term	Resolved n (%)	Ongoing n (%)	Resolved n (%)	Ongoing n (%)
Cccccc	xx (xx)	xx (xx)	xx (xx)	xx (xx)
Cccccc	xx (xx)	xx (xx)	xx (xx)	xx (xx)
cccccc	xx (xx)	xx (xx)	xx (xx)	xx (xx)
cccccc	xx (xx)	xx (xx)	xx (xx)	xx (xx)

Data source: 16.2.20 Listing of medical history

Table 14.1.8 Vital signs at baseline

	Treatment		
	DFP+DFP	DFO+DFP	
N	xxx	xxx	
Vital Sign:	Mean ± SD (Min, Max)	Mean ± SD (Min, Max)	P-value (T-test)
Temperature (°C)	xx.x ± xx.x (xx, xx)	xx.x ± xx.x (xx, xx)	0.xxxx
Resting Heart Rate (/min)	xxx.x ± xxx.x (xxx, xxx)	xxx.x ± xxx.x (xxx, xxx)	0.xxxx
Respiration (/min)	xx.x ± xx.x (xx, xx)	xx.x ± xx.x (xx, xx)	0.xxxx
Systolic Blood Pressure (mmHg)	xxx.x ± xxx.x (xxx, xxx)	xxx.x ± xxx.x (xxx, xxx)	0.xxxx
Diastolic Blood Pressure (mmHg)	xxx.x ± xxx.x (xxx, xxx)	xxx.x ± xxx.x (xxx, xxx)	0.xxxx

Data source: 16.2.5 Listing of vital signs including height and weight

Table 14.1.9 Weight and height at baseline

	Treatment		
	DFP+DFP	DFO+DFP	
N	xxx	xxx	
	Mean ± SD (Min, Max)	Mean ± SD (Min, Max)	P-value (T-test)
Weight (kg)	xx.x ± xx.x (xx, xx)	xx.x ± xx.x (xx, xx)	0.xxxx
Height (cm)	xxx.x ± xxx.x (xxx, xxx)	xxx.x ± xxx.x (xxx, xxx)	0.xxxx

§For patients who had separate screening and baseline visits, height was measured only at screening
Data source: 16.2.5 Listing of vital signs including height and weight

Table 14.2.1.1 LIC at each assessment

		Treatment		
		DFP+DFP	DFO+DFP	
	Visit	N Mean ± SD (Min, Max)	N Mean ± SD (Min, Max)	P-value (T-test)
LIC (mg/g dw)	Baseline	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx .
	Month 6	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Year 1	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Year 2	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Year 3	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx

Data source: 16.2.10 Listing of LIC

Table 14.2.1.2 Change in LIC at each follow-up assessment

		Treatment		
		DFP+DFP	DFO+DFP	
	Visit	N Mean ± SD (Min, Max)	N Mean ± SD (Min, Max)	P-value (T-test)
Change in LIC (mg/g dw)	Month 6	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Year 1	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Year 2	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Year 3	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx

Data source: 16.2.10 Listing of LIC

Table 14.2.1.3 Change in LIC for DFO+DFP group – Data from the extension study

		DFO+DFP	
	Visit	N Mean ± SD (Min, Max)	P-value (One sample T-test)
Change in LIC (mg/g dw)	From Year 1 to Year 2	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	From Year 1 to Year 3	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx

Data source: 16.2.10 Listing of LIC

Table 14.2.1.4 Change in LIC for DFO and DFO+DFP groups

		Treatment		
		DFO*	DFO+DFP*	
	Visit	N Mean ± SD (Min, Max)	N Mean ± SD (Min, Max)	P-value (T-test)
Change in LIC (mg/g dw)	End of Study	xxx xx.x ± xx.x (xx.x, xx.x)	Xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx

Data source: 16.2.10 Listing of LIC
Note: *Patients in DFO come from LA38-0411 and patients in DFO+DFP comes from LA38-EXT.

Table 14.2.1.5 Responder analysis in LIC defined as ≥ 20% decline in LIC from baseline.

	Treatment				
	DFP+DFP		DFO+DFP		P-value (Fisher's exact test)
	N	n (%)	N	n (%)	0.xxxx
Year 1	xxx	xx (xx%)	xxx	xx (xx%)	0.xxxx
Year 2	xxx	xx (xx%)	xxx	xx (xx%)	0.xxxx
Year 3	xxx	xx (xx%)	xxx	xx (xx%)	0.xxxx

Data source: 16.2.10 Listing of LIC

Table 14.2.1.6 Responder analysis in LIC defined as ≥ 20% decline in LIC from baseline for DFO+DFP group – Data from the extension study.

	Treatment	
	DFO+DFP	
	N	n (%)
Year 1	xxx	xx (xx%)
Year 2	xxx	xx (xx%)

Data source: 16.2.10 Listing of LIC

Table 14.2.2.1 Cardiac MRI T2* at each assessment

		Treatment		
		DFP+DFP	DFO+DFP	
	Visit	N Mean ± SD (Min, Max)	N Mean ± SD (Min, Max)	P-value (T-test)
Cardiac MRI T2* (ms)	Baseline	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 6	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Year 1	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Year 2	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Year 3	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx

Data source: 16.2.11 Listing of cardiac MRI T2*

Table 14.2.2.2 Change in cardiac MRI T2* at each follow-up assessment

		Treatment		
		DFP+DFP	DFO+DFP	
	Visit	N Mean ± SD (Min, Max)	N Mean ± SD (Min, Max)	P-value (T-test)
Change in cardiac MRI T2* (ms)	Month 6	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Year 1	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Year 2	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Year 3	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx

Data source: 16.2.11 Listing of cardiac MRI T2*

Table 14.2.2.3 Change in cardiac MRI T2* for DFO+DFP group – Data from the extension study

		DFO+DFP	
	Visit	N Mean ± SD (Min, Max)	P-value (One sample T-test)
Change in cardiac MRI T2* (ms)	From Year 1 to Year 2	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	From Year 1 to Year 3	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx

Data source: 16.2.11 Listing of cardiac MRI T2*

Table 14.2.2.4 Change in cardiac MRI T2* for DFO and DFO+DFP groups

		Treatment		
		DFO*	DFO+DFP*	
	Visit	N Mean ± SD (Min, Max)	N Mean ± SD (Min, Max)	P-value (T-test)
Change in cardiac MRI T2* (ms)	End of Study	xxx xx.x ± xx.x (xx.x, xx.x)	Xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx

Data source: 16.2.11 Listing of cardiac MRI T2*
Note: *Patients in DFO come from LA38-0411 and patients in DFO+DFP comes from LA38-EXT.

Table 14.2.2.5 Responder analysis in cardiac MRI T2* defined as ≥ 20% increase in cardiac MRI T2* from baseline.

	Treatment				
	DFP+DFP		DFO+DFP		P-value (Fisher's exact test)
	N	n (%)	N	n (%)	0.xxxx
Year 1	xxx	xx (xx%)	xxx	xx (xx%)	0.xxxx
Year 2	xxx	xx (xx%)	xxx	xx (xx%)	0.xxxx
Year 3	xxx	xx (xx%)	xxx	xx (xx%)	0.xxxx

Data source: 16.2.11 Listing of cardiac MRI T2*

Table 14.2.2.6 Responder analysis in cardiac MRI T2* defined as ≥ 20% increase in cardiac MRI T2* from baseline for DFO+DFP group – Data from the extension study.

	Treatment	
	DFO+DFP	
	N	n (%)
Year 1	xxx	xx (xx%)
Year 2	xxx	xx (xx%)

Data source: 16.2.11 Listing of cardiac MRI T2*

Table 14.2.3.1 Serum ferritin each assessment

		Treatment		
		DFP+DFP	DFO+DFP	
	Visit	N Mean ± SD (Min, Max)	N Mean ± SD (Min, Max)	P-value (T-test)
Serum Ferritin (µg/L)	Baseline	xxx, xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx .
	Month 3	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 6	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 9	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 12	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 15	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx .
	Month 18	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 21	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 24	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 27	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 30	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 33	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx

		Treatment		
		DFP+DFP	DFO+DFP	
	Month 36	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx

Data source: 16.2.16 Listing of serum ferritin

Table 14.2.3.2 Change in serum ferritin at each follow-up assessment

		Treatment		
		DFP+DFP	DFO+DFP	
	Visit	N Mean ± SD (Min, Max)	N Mean ± SD (Min, Max)	P-value (T-test)
Change in serum ferritin (µg/L)	Month 3	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 6	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 9	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 12	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 15	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 18	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 21	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 24	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx

		Treatment		
		DFP+DFP	DFO+DFP	
	Month 27	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 30	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 33	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	Month 36	xxx xx.x ± xx.x (xx.x, xx.x)	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx

Data source: 16.2.16 Listing of serum ferritin

Table 14.2.3.3 Change in serum ferritin for DFO+DFP group – Data from the extension study

		DFO+DFP	
	Visit	N Mean ± SD (Min, Max)	P-value (One sample T-test)
Change in serum ferritin (µg/L)	From Month 12 to Month 15	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	From Month 12 to Month 18	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	From Month 12 to Month 21	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	From Month 12 to Month 24	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	From Month 12 to Month 27	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	From Month 12 to Month 30	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx

		DFO+DFP	
	Visit	N Mean ± SD (Min, Max)	P-value (One sample T-test)
	From Month 12 to Month 33	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx
	From Month 12 to Month 36	xxx xx.x ± xx.x (xx.x, xx.x)	0.xxxx

Data source: 16.2.16 Listing of serum ferritin

Table 14.2.3.4 Responder analysis in serum ferritin as defined ≥ 20% decline in serum ferritin from baseline.

	Treatment				
	DFP+DFP		DFO+DFP		P-value (Fisher's exact test)
	N	n (%)	N	n (%)	0.xxxx
Year 1	xxx	xx (xx%)	xxx	xx (xx%)	0.xxxx
Year 2	xxx	xx (xx%)	xxx	xx (xx%)	0.xxxx
Year 3	xxx	xx (xx%)	xxx	xx (xx%)	0.xxxx

Data source: 16.2.16 Listing of serum ferritin

Table 14.2.3.5 Responder analysis in serum ferritin defined as ≥ 20% decline in serum ferritin from baseline for DFP+DFO group – Data from the extension study.

	Treatment	
	DFO+DFP	
	N	n (%)
Year 1	xxx	xx (xx%)
Year 2	xxx	xx (xx%)

Data source: 16.2.16 Listing of serum ferritin

Table 14.3.1.1 Overall summary of adverse events

	Treatment		
	DFP+DFP	DFO+DFP**	
N	xxx	xxx	P-value (Fisher's exact test)
Number of patients experiencing at least one AE	xx (xx%)	xx (xx%)	0.xxxx
Number of patients experiencing at least one severe AE	xx (xx%)	xx (xx%)	0.xxxx
Number of patients experiencing at least one serious AE	xx (xx%)	xx (xx%)	0.xxxx
Number of patients experiencing at least one related* AE	xx (xx%)	xx (xx%)	0.xxxx
Number of patient deaths	xx (xx%)	xx (xx%)	0.xxxx
Number of patient withdrawals due to AEs	xx (xx%)	xx (xx%)	0.xxxx

*Includes possibly, probably, and definitely related. Worst case scenario of causality between the investigator and company's assessment.

**AEs occurred while on DFP treatment.

Data source: 16.2.23 Listing of adverse events

Table14.3.1.2 Adverse events

	Treatment		
	DFP+DFP (N=xxx)	DFO+DFP (N=xxx)	
	Exposure (patient-years): x.xx	Exposure (patient-years):x.xx	
	Total Events: xxx	Total Events: xxx	
System Organ Class Preferred Term	n Patients (%)	n Patients (%)	P-value (Fisher's exact test)
CCCCCC	x (x.x)	x (x.x)	0.xxxx
Cccccc	x (x.x)	x (x.x)	0.xxxx
Cccccc	x (x.x)	x (x.x)	0.xxxx
Cccccc	x (x.x)	x (x.x)	0.xxxx
.....	.....	.....	.....

Note: Similar tables will be produced from Table 14.3.1.3 to Table 14.3.1.7
Data source: 16.2.23 Listing of adverse events

Table 14.3.1.8 Adverse events by causality

		Treatment	
		DFP+DFP (N=xxx)	DFO+DFP (N=xxx)
System Organ Class Preferred Term	Relatedness (worst case)	Patients reporting (n=xx)	Patients reporting (n=xx)
CCCCCCCC		x (x.x)	x (x.x)
cccccc	Not Related*	x (x.x)	x (x.x)
	Related**	x (x.x)	x (x.x)
cccccc	Not Related	x (x.x)	x (x.x)
	Related*	x (x.x)	x (x.x)
.....	.....	.....	.....

*Not related
**Possibly, Probably, or Definitely Related
Data source: 16.2.23 Listing of adverse events

Table 14.3.1.9 Time to the first onset of SAEs

	Treatment				
	DFP+DFP		DFO+DFP		
SAE	N	Mean ± SD (Min, Max)	N	Mean ± SD (Min, Max)	P-value (T-test)
Cccccc	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Cccccc	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
....	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Cccccc	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

Note: Similar table will be produced for Table 14.3.1.10.
Data source: 16.2.23 Listing of adverse events

Table 14.3.1.11 Time to the last recurrence of SAEs

	Treatment				
	DFP+DFP		DFO+DFP		
SAE	N	Mean ± SD (Min, Max)	N	Mean ± SD (Min, Max)	P-value (T-test)
Cccccc	xxx	xx.x ± xx.x (xx, xx)	Xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Cccccc	xxx	xx.x ± xx.x (xx, xx)	Xxx	xx.x ± xx.x (xx, xx)	0.xxxx
....	xxx	xx.x ± xx.x (xx, xx)	Xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Cccccc	xxx	xx.x ± xx.x (xx, xx)	Xxx	xx.x ± xx.x (xx, xx)	0.xxxx

Note: Similar table will be produced for Table 14.3.1.12.
Data source: 16.2.23 Listing of adverse events

Table 14.3.1.13 Duration of the first onset of SAEs

	Treatment				
	DFP+DFP		DFO+DFP		
SAE	N	Mean ± SD (Min, Max)	N	Mean ± SD (Min, Max)	P-value (T-test)
Cccccc	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Cccccc	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
....	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Cccccc	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

Note: Similar table will be produced for Table 14.3.1.14.
Data source: 16.2.23 Listing of adverse events

Table 14.3.1.15 Duration of the last recurrence of SAEs

	Treatment				
	DFP+DFP		DFO+DFP		
SAE	N	Mean ± SD (Min, Max)	N	Mean ± SD (Min, Max)	P-value (T-test)
Cccccc	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Cccccc	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
....	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Cccccc	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

Note: Similar table will be produced for Table 14.3.1.16.
Data source: 16.2.23 Listing of adverse events

Table 14.3.2.1 Temperature at each assessment

	Treatment				
	DFP+DFP		DFO+DFP		
Visit	N	Mean ± SD (Min, Max)	N	Mean ± SD (Min, Max)	P-value (T-test)
Baseline	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 1	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 2	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 3	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 4	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 5	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 6	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 7	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 8	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 9	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 10	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 11	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 12	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 15	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 18	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 21	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 24	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 27	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

	Treatment				
	DFP+DFP		DFO+DFP		
Month 30	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 33	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 36	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

Note: Similar tables will be produced for resting heart rate, respiration, systolic and diastolic blood pressures.
Data source: 16.2.5 Listing of vital signs including height and weight

Table 14.3.2.2 Change in temperature from baseline to each follow-up assessment

	Treatment				
	DFP+DFP		DFO+DFP		
Visit	N	Mean ± SD (Min, Max)	N	Mean ± SD (Min, Max)	P-value (T-test)
Month 1	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 2	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 3	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 4	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 5	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 6	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 7	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 8	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 9	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 10	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 11	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

	Treatment				
	DFP+DFP		DFO+DFP		
Month 12	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 15	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 18	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 21	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 24	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 27	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 30	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 33	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 36	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

Note: Similar tables will be produced for resting heart rate, respiration, systolic and diastolic blood pressures.
Data source: 16.2.5 Listing of vital signs including height and weight

Table 14.3.3.1 Weight (kg) at each assessment

	Treatment				
	DFP+DFP		DFO+DFP		
Visit	N	Mean ± SD (Min, Max)	N	Mean ± SD (Min, Max)	P-value (T-test)
Baseline	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 1	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxx
Month 2	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 3	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 4	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 5	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 6	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 7	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 8	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 9	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 10	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 11	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 12	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 15	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 18	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 21	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 24	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 27	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

	Treatment				
	DFP+DFP		DFO+DFP		
Month 30	xxx	xx.x ± xx.x (xx, xx)	Xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 33	xxx	xx.x ± xx.x (xx, xx)	Xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 36	xxx	xx.x ± xx.x (xx, xx)	Xxx	xx.x ± xx.x (xx, xx)	0.xxxx

Data source: 16.2.5 Listing of vital signs including height and weight

Table 14.3.3.2 Change in weight from baseline to last assessment

		Treatment		
		DFP+DFP	DFO+DFP	
	N	xxx	xxx	P-value (T-test)
Change in weight (kg) Mean ± SD (Min, Max)	Baseline	xxx.x ± xxx.x (xxx, xxx)	xxx.x ± xxx.x (xxx, xxx)	0.xxxx
	Last assessment	xxx.x ± xxx.x (xxx, xxx)	xxx.x ± xxx.x (xxx, xxx)	0.xxxx
	Change at last assessment	xxx.x ± xxx.x (xxx, xxx)	xxx.x ± xxx.x (xxx, xxx)	0.xxxx

Data source: 16.2.5 Listing of vital signs including height and weight

Table 14.3.3.1 Height (cm) at each assessment

	DFP+DFP		DFO+DFP		
Visit	N	Mean ± SD (Min, Max)	N	Mean ± SD (Min, Max)	P-value (T-test)
Baseline	xxx	xxx ± xxx (xxx, xxx)	xxx	xxx ± xxx (xxx, xxx)	0.xxxx
Month 6	xxx	xxx ± xxx (xxx, xxx)	xxx	xxx ± xxx (xxx, xxx)	0.xxxx
Month 12	xxx	xxx ± xxx (xxx, xxx)	xxx	xxx ± xxx (xxx, xxx)	0.xxxx
Month 24	xxx	xxx ± xxx (xxx, xxx)	xxx	xxx ± xxx (xxx, xxx)	0.xxxx
Month 36	xxx	xxx ± xxx (xxx, xxx)	xxx	xxx ± xxx (xxx, xxx)	0.xxxx

Data source: 16.2.5 Listing of vital signs including height and weight

Table 14.3.3.4 Change in height from baseline to last assessment

		Treatment		
		DFP+DFP	DFO+DFP	
	N	xxx	xxx	P-value (T-test)
Change in height (cm) Mean ± SD (Min, Max)	Baseline	xxx.x ± xxx.x (xxx, xxx)	xxx.x ± xxx.x (xxx, xxx)	0.xxxx
	Last assessment	xxx.x ± xxx.x (xxx, xxx)	xxx.x ± xxx.x (xxx, xxx)	0.xxxx
	Change at last assessment	xxx.x ± xxx.x (xxx, xxx)	xxx.x ± xxx.x (xxx, xxx)	0.xxxx

Data source: 16.2.5 Listing of vital signs including height and weight

Table 14.3.4.1 Concomitant medications

	Treatment	
	DFP+DFP (N=xxx)	DFO+DFP (N=xxx)
	Exposure (patient-years): x.xx	Exposure (patient-years): x.xx
	Total Patients Reporting: xx	Total Patients Reporting: xx
Preferred Name	n Patients (%)	n Patients (%)
Cccccc	x (x.x)	x (x.x)
Cccccc	x (x.x)	x (x.x)
Cccccc	x (x.x)	x (x.x)
.....	.....	.....

Data source: 16.2.21 Listing of medication

Table 14.3.5.1 Heart rate of 12-lead ECG at each assessment

	Treatment				
	DFP+DFP		DFO+DFP		
Visit	N	Mean ± SD (Min, Max)	N	Mean ± SD (Min, Max)	P-value (T-test)
Baseline	xxx	xxx ± xxx (xxx, xxx)	xxx	xxx ± xxx (xxx, xxx)	0.xxxx
Month 6	xxx	xxx ± xxx (xxx, xxx)	xxx	xxx ± xxx (xxx, xxx)	NA
Month 12	xxx	xxx ± xxx (xxx, xxx)	xxx	xxx ± xxx (xxx, xxx)	0.xxxx
Month 24	xxx	xxx ± xxx (xxx, xxx)	xxx	xxx ± xxx (xxx, xxx)	0.xxxx
Month 36	xxx	xxx ± xxx (xxx, xxx)	xxx	xxx ± xxx (xxx, xxx)	NA

Note: Similar tables will be produced for PR (ms), QRS (ms), QT (ms), QTcF (ms), and QTcB (ms), respectively.
Data source: 16.2.7 Listing of 12-lead electrocardiogram

Table 14.3.5.2 Change in heart rate of 12-lead ECG at each follow-up assessment

	Treatment				
	DFP+DFP		DFO+DFP		
Visit	N	Mean ± SD (Min, Max)	N	Mean ± SD (Min, Max)	P-value (T-test)
Month 6	xxx	xxx ± xxx (xxx, xxx)	xxx	xxx ± xxx (xxx, xxx)	NA
Month 12	xxx	xxx ± xxx (xxx, xxx)	xxx	xxx ± xxx (xxx, xxx)	0.xxxx
Month 24	xxx	xxx ± xxx (xxx, xxx)	xxx	xxx ± xxx (xxx, xxx)	0.xxxx
Month 36	xxx	xxx ± xxx (xxx, xxx)	xxx	xxx ± xxx (xxx, xxx)	NA

Note: Similar tables will be produced for PR (ms), QRS (ms), QT (ms), QTcF (ms), and QTcB (ms), respectively.
Data source: 16.2.7 Listing of 12-lead electrocardiogram

Table 14.3.5.3 Shift table for clinically significant abnormality for 12-lead ECG: DFP+DFP group

		Last Assessment		
	n (%)	Normal	Abnormal	P-value (McNemar's test)
Baseline	Normal	xx (xx)	xx (xx)	0.xxxx
	Abnormal	xx (xx)	xx (xx)	

P-value = Data source: 16.2.7 Listing of 12-lead electrocardiogram

Table 14.3.5.4 Shift table for clinically significant abnormality for 12-lead ECG: DFO+DFP group

		Last Assessment		
	n (%)	Normal	Abnormal	P-value (McNemar's test)
Baseline	Normal	xx (xx)	xx (xx)	0.xxxx
	Abnormal	xx (xx)	xx (xx)	

P-value = Data source: 16.2.7 Listing of 12-lead electrocardiogram

Table 14.3.6.1.1 Hemoglobin at each assessment

	Treatment				
Hemoglobin	DFP+DFP		DFO+DFP		P-value (T-test)
Visit	N	Mean ± SD (Min, Max)	N	Mean ± SD (Min, Max)	
Baseline	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 1	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 2	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 3	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 4	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 5	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 6	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 7	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 8	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 9	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 10	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 11	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 12	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 13	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 14	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 15	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 16	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 17	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

	Treatment				
Hemoglobin	DFP+DFP		DFO+DFP		P-value (T-test)
Week 18	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 19	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 20	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 21	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 22	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 23	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 24	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 25	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 26	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 27	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 28	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 29	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 30	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 31	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 32	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 33	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 34	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 35	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 36	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

	Treatment				
Hemoglobin	DFP+DFP		DFO+DFP		P-value (T-test)
Week 37	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 38	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 39	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 40	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 41	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 42	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 43	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 44	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 45	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 46	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 47	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 48	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 49	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 50	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 51	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 12	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 15	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 18	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 21	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

	Treatment				
Hemoglobin	DFP+DFP		DFO+DFP		P-value (T-test)
Month 24	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 27	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 30	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 33	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 36	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

Note: Similar tables will be produced for total white blood cell (WBC), absolute neutrophil count (ANC), and platelets.
Data source: 16.2.9 Listing of hematology

Table 14.3.6.1.2 Change in hemoglobin at each follow-up assessment

	Treatment				
Hemoglobin	DFP+DFP		DFO+DFP		P-value (T-test)
Visit	N	Mean ± SD (Min, Max)	N	Mean ± SD (Min, Max)	
Week 1	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 2	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 3	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 4	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 5	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 6	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 7	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 8	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

	Treatment				
Hemoglobin	DFP+DFP		DFO+DFP		P-value (T-test)
Week 9	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 10	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 11	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 12	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 13	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 14	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 15	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 16	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 17	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 18	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 19	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 20	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 21	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 22	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 23	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 24	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 25	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 26	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 27	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

	Treatment				
Hemoglobin	DFP+DFP		DFO+DFP		P-value (T-test)
Week 28	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 29	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 30	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 31	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 32	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 33	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 34	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 35	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 36	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 37	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 38	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 39	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 40	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 41	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 42	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 43	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 44	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 45	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 46	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

	Treatment				
Hemoglobin	DFP+DFP		DFO+DFP		P-value (T-test)
Week 47	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 48	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 49	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 50	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Week 51	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 12	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 15	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 18	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 21	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 24	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 27	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 30	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 33	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 36	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

Note: Similar tables will be produced for total white blood cell (WBC), absolute neutrophil count (ANC), and platelets.

Data source: 16.2.9 Listing of hematology

Table 14.3.6.1.3 Shift table for hemoglobin in abnormal range at baseline vs last assessment: DFP+DFP group

		Last Assessment			
	n (%)	Low	Normal	High	P-value (McNemar's test)
Baseline	Low	xx (xx)	xx (xx)	xx (xx)	0.xxxx
	Normal	xx (xx)	xx (xx)	xx (xx)	
	High	xx (xx)	xx (xx)	xx (xx)	

Note: Similar tables will be produced for total white blood cell (WBC), absolute neutrophil count (ANC), and platelets.
Data source: 16.2.9 Listing of hematology

Table 14.3.6.1.4 Shift table for hemoglobin in abnormal range at baseline vs last assessment: DFO+DFP group

		Last Assessment			
	n (%)	Low	Normal	High	P-value (McNemar's test)
Baseline	Low	xx (xx)	xx (xx)	xx (xx)	0.xxxx
	Normal	xx (xx)	xx (xx)	xx (xx)	
	High	xx (xx)	xx (xx)	xx (xx)	

Note: Similar tables will be produced for total white blood cell (WBC), absolute neutrophil count (ANC), and platelets.
Data source: 16.2.9 Listing of hematology

Table 14.3.6.2.1 Total protein at each assessment

	Treatment				
	DFP+DFP		DFO+DFP		
Visit	N	Mean ± SD (Min, Max)	N	Mean ± SD (Min, Max)	P-value (T-test)
Baseline	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 1	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 2	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 3	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 4	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 5	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 6	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 7	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 8	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 9	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 10	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 11	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 12	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 18	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 24	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 30	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 36	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

Note: Similar tables will be produced for GGT, lactate dehydrogenase (LDH), sodium, potassium, chloride, glucose (fasting at screening visit only), total, direct and indirect bilirubin, AST, ALT, albumin; blood urea nitrogen, calcium, creatinine, uric acid, alkaline phosphatase, and amylase.
Data source: 16.2.12 Listing of chemistry

Table 14.3.6.2.2 Change in total protein at each follow-up assessment

	Treatment				
	DFP+DFP		DFO+DFP		
Visit	N	Mean ± SD (Min, Max)	N	Mean ± SD (Min, Max)	P-value (T-test)
Month 1	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 2	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 3	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 4	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 5	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 6	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 7	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 8	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 9	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 10	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 11	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 12	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 18	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 24	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 30	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx
Month 36	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

Note: Similar tables will be produced for GGT, lactate dehydrogenase (LDH), sodium, potassium, chloride, glucose (fasting at screening visit only), total, direct and indirect bilirubin, AST, ALT, albumin; blood urea nitrogen, calcium, creatinine, uric acid, alkaline phosphatase, and amylase.
Data source: 16.2.12 Listing of chemistry

Table 14.3.6.2.3 Shift table for total protein in abnormal range at baseline vs last assessment: DFP+DFP group

		Last Assessment			
	n (%)	Low	Normal	High	P-value (McNemar's test)
Baseline	Low	xx (xx)	xx (xx)	xx (xx)	0.xxxx
	Normal	xx (xx)	xx (xx)	xx (xx)	
	High	xx (xx)	xx (xx)	xx (xx)	

Note: Similar tables will be produced for GGT, lactate dehydrogenase (LDH), sodium, potassium, chloride, glucose (fasting at screening visit only), total, direct and indirect bilirubin, AST, ALT, albumin; blood urea nitrogen, calcium, creatinine, uric acid, alkaline phosphatase, and amylase.
Data source: 16.2.12 Listing of chemistry

Table 14.3.6.2.4 Shift table for total protein in abnormal range at baseline vs last assessment: DFO+DFP group

		Last Assessment			
	n (%)	Low	Normal	High	P-value (McNemar's test)
Baseline	Low	xx (xx)	xx (xx)	xx (xx)	0.xxxx
	Normal	xx (xx)	xx (xx)	xx (xx)	
	High	xx (xx)	xx (xx)	xx (xx)	

Note: Similar tables will be produced for GGT, lactate dehydrogenase (LDH), sodium, potassium, chloride, glucose (fasting at screening visit only), total, direct and indirect bilirubin, AST, ALT, albumin; blood urea nitrogen, calcium, creatinine, uric acid, alkaline phosphatase, and amylase.
Data source: 16.2.12 Listing of chemistry

Table 14.3.6.3.1 HIV Antibody at each assessment

	Treatment				
	DFP+DFP		DFO+DFP		P-value (Fisher's exact test)
	N	Positive n (%)	N	Positive n (%)	
Baseline	xxx	xx (xx)	xxx	xx (xx)	0xxxx
Month 6	xxx	xx (xx)	xxx	xx (xx)	0.xxxx
Year 1	xxx	xx (xx)	xxx	xx (xx)	0.xxxx
Year 3	xxx	xx (xx)	xxx	xx (xx)	0.xxxx

Note: Similar tables will be produced for Hepatitis B and C.
Data source: 16.2.13 Listing of serology

Table 14.3.7.1 Female patients with positive pregnancy test during the study

	Treatment	
Pregnancy test: Positive	DFP+DFP	DFO+DFP
Patient ID	xxxxxx xxxxxx xxxxxx xxxxxx	xxxxxx xxxxxx xxxxxx xxxxxx .....

Data source: 16.2.14 Listing of pregnancy

Table 14.4.1 The number and percent of patients who had compliance ≤80% or ≥120% during the study

	Treatment				
	DFP+DFP		DFO+DFP		
Compliance	N	Percent	N	Percent	P-value (Fisher's exact test)
< 80%	xx	xx.x%	xx	xx.x%	0.xxxx
> 120%	xx	xx.x%	xx	xx.x%	0.xxxx

Data source: 16.2.19 Listing of compliance

Table 14.5.1 Overall mean of transfusional iron input (mg/kg/day) during the study

	Treatment				
	DFP+DFP		DFO+DFP		P-value (T-test)
	N	Mean ± SD (Min, Max)	N	Mean ± SD (Min, Max)	
Overall mean of transfusional iron input (mg/kg/day)	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)	0.xxxx

Data source: 16.2.26 Listing of transfusion information

Table 14.6.1 Overall mean of total daily dose

	Treatment			
	DFP+DFP		DFO+DFP	
	N	Mean ± SD (Min, Max)	N	Mean ± SD (Min, Max)
Overall mean of total daily dose (mg/kg/day)	xxx	xx.x ± xx.x (xx, xx)	xxx	xx.x ± xx.x (xx, xx)

Data source: 16.2.24 Listing of exposure