CLINICAL TRIAL CONSULTANTS AB

CONFIDENTIAL

Statistical analysis plan (SAP)

Sponsor:	*Empros Pharma AB*
Study code:	*EP-002*
CTC project no:	*263-21-2019*
Study title:	*Lean Efficacy Phase IIa Proof of concept trial (LEAAP) A multi-centre, double-blind, placebo-controlled, randomised study in overweight and obese patients during twenty-six weeks, investigating the effect of EMP16-02 on body weight, safety and clinical biomarkers*
SAP version and date:	*Draft version 1.0 20JAN2021*

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2 VERSION HISTORY

This statistical analysis plan (SAP) for study EP-002 is based on the protocol dated 03APR2020.

Table 1 SAP version history summary

SAP version	Approval date	Changes	Rationale
0.1	02SEP2020	-	Version ready for internal review
0.2	30SEP2020	-	Version ready for Sponsor review
0.3	23OCT2020	Minor updates	Updated version after Sponsor review
0.4	18JAN2021	Minor updates	Updated version after Sponsor review
0.5	20JAN2021	Minor updates	Updated version after Sponsor review
1	20JAN2021	NA	Original version

3 INTRODUCTION

This SAP gives details regarding the statistical analyses and data presentation outlined in the final clinical study protocol (CSP) for the study *EP-002*. Any changes from the final CSP are given in Section 9.

4 CLINICAL STUDY DETAILS

4.1 Clinical study objectives and endpoints

Objects	Estimands/Endpoints
Primary	
1.1.1 To evaluate the effect of the study drug EMP16-02 (120 mg orlistat [O]/40 mg acarbose [A]) on relative body weight loss after a 26-week period of oral treatment as compared to placebo.	1.1 Relative (%) change from baseline in body weight after 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A) as compared to placebo.
Secondary	
2.1 To assess the effect of two different doses of EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) on relative and absolute body weight loss during a 26-week period of oral treatment as compared to placebo.	2.1.1 Proportion of subjects with ≥5% and ≥10% decrease in body weight compared to baseline after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo. 2.1.2 Relative (%) and absolute change from baseline in body weight after 14 and 26 weeks of treatment with EMP16-02 (150 mg O/50 mg A) as compared to placebo. 2.1.3 Absolute change from baseline in body weight after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A) as compared to placebo.
2.2 To assess the effect of two different doses of EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) on other anthropometric characteristics during a 26-week period of oral treatment as compared to placebo.	2.2.1 Relative (%) and absolute change from baseline in body mass index (BMI) after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo. 2.2.2 Absolute change from baseline in waist circumference after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo. 2.2.3 Absolute change from baseline in sagittal diameter after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo. 2.2.4 Relative (%) and absolute change from baseline in percentage body fat after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo.
2.3 To assess the effect of two different doses of EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) on satiety and meal pattern during a 26-week period of oral treatment as compared to placebo.	2.3.1 Satiety and craving after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo, corrected for satiety and craving after standardised breakfast at baseline.

2.4 To assess the effect of two different doses of EMP16-02 (120 mg O/40 mg acarbose (A) and 150 mg O/50 mg A) on fasting insulin, glucose metabolism markers, lipid metabolism markers and inflammation markers during a 26-week period of oral treatment as compared to placebo.	2.4.1 Relative (%) and absolute change from baseline in fasting haemoglobin A1c (HbA1c), glucose, insulin, total cholesterol, high-density lipoprotein (HDL), low-density lipoprotein (LDL), triglycerides, liver enzymes, albumin and high-sensitivity C-reactive protein (hs-CRP) after 7, 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo. 2.4.2 Change from baseline in the proportion of diabetic (fasting glucose ≥ 7.0 mmol/L) and prediabetic subjects (fasting glucose ≥ 6.1 mmol/L and < 7.0 mmol/L) after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo.
2.5 To assess the effect of two different doses of EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) on blood pressure during a 26-week period of oral treatment as compared to placebo.	2.5.1 Relative (%) and absolute change from baseline in blood pressure after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo.
2.6 To assess the effect of two different doses of EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) on quality of life during a 26-week period of oral treatment as compared to placebo.	2.6.1 Change from baseline in quality of life after 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo.
2.7 To assess the relationship between drop-out(s) and tolerability for two different doses of EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) during a 26-week period of oral treatment as compared to placebo.	2.7.1 Dropout rate (overall and Gastrointestinal-related (GI)) following treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo.
2.8 To assess the safety and gastrointestinal (GI) tolerability of two different doses of EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) during a 26-week period of oral treatment as compared to placebo.	2.8.1 Frequency and severity of adverse events (AEs) during 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo. 2.8.2 Clinically significant relative (%) and absolute changes from baseline in safety laboratory parameters and ECG after 26 weeks of treatment, and in vital signs after 7, 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo. 2.8.3 GI tolerability after 2, 4, 6, 8, 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo. 2.8.4 Compliance after 7, 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40

	mg A and 150 mg O/50 mg A) as compared to placebo.
Tertiary/Exploratory	
3.1 To assess the effect of two different doses of EMP16-02 (120 mg O/40 mg A and 150 mg O /50 mg A) on fasting plasma/serum levels of apolipoprotein A1 (ApoA1) and apolipoprotein B (ApoB) during a 26-week period of oral treatment as compared to placebo.	3.1 The absolute difference in fasting plasma/serum levels of ApoA1 and ApoB from baseline after 7, 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo.
3.2 To assess the pre-dose plasma level of orlistat at steady state.	3.2 Pre-dose plasma concentrations of orlistat after 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A). The exploratory analyses may not be reported in the clinical study report (CSR).

4.2 Clinical study design

This was an exploratory, randomised, double-blind, placebo-controlled study in overweight and obese patients (henceforth referred to as subjects) in which the effect of two doses of EMP16-02 on body weight loss were tested versus placebo. The study was conducted during 26 weeks at two study centres in Sweden.

4.3 Statistical hypotheses

No formal hypothesis for the primary endpoint was defined in the protocol.

4.4 Number of subjects

A total of 156 subjects were randomised in the study. 52 subjects were randomised to each treatment arm to achieve at least 41 evaluable subjects per treatment arm assuming a dropout rate of 20%.

An evaluable subject was defined as a subject that completed 26 weeks of treatment with the investigational medicinal product (IMP).

4.5 Randomisation

On Day 1, subjects were randomised in a 1:1:1 ratio to receive either EMP16-02 150 mg O/50 mg A (n=52), EMP16-02 120 mg O/40 mg A (n=52), or placebo (n=52).

A computer-generated randomisation list was created using `proc plan`, in SAS Version 9.4. The randomisation list contained subject number and treatment and was kept by the randomiser in a sealed envelope until database lock. A copy of the randomisation list was delivered to Recipharm, who packaged the IMP individually based on the randomisation list.

If needed for emergency unblinding, sealed individual treatment code envelopes were kept at the clinic and at CTC's pharmacovigilance department (CTC PV) in locked and restricted areas.

4.6 Blinding

This is a double-blind study, and the allocation of treatments will not be disclosed until clean file has been declared and the database has been locked.

Active treatment and placebo capsules are identical in appearance.

5 STATISTICAL AND ANALYTICAL PLANS

5.1 Sample size determination

The hypothesis is that subjects treated with EMP16-02 have a greater relative change (reduction) in body weight compared to placebo. The estimated treatment difference should be 5% with a standard deviation of 8%, assuming statistical power of 80% and a significance level of 5% based on two-sided hypothesis testing. Using PASS, Power Analysis & Sample Size Software, V16.0 (method compare means), the number of evaluable subjects needed per treatment arm was calculated to be 41 subjects. An evaluable subject is defined as a subject who has completed 26 weeks of treatment with the IMP. assuming a drop-out rate of 20%, a total of 156 subjects needs to be randomised.

5.2 Definition of analysis sets

5.2.1 Full analysis set (FAS)

The FAS will consist of all subjects who have been randomised and received at least one dose of the IMP and who have at least one post-baseline assessment of efficacy data.

5.2.1 Safety analysis set

The Safety analysis set will consist of all subjects who received at least one dose of the IMP.

5.2.2 Per protocol analysis set (PPS)

The PPS will consist of all subjects who have been randomised and completed the study without any major protocol deviations that are judged to compromise the analysis of the data. All protocol violations will be judged as major or minor prior to database lock.

5.2.1 Use of analysis set

The safety population will be used for safety evaluations. The FAS and PPS population will be used for efficacy evaluation. If any of the analysis sets have identical population, only one will be used.

5.3 Definition of baseline

The baseline measurement is defined as the latest measurement prior to first dose of the IMP.

5.4 Summary statistics

In general, all data collected will be presented with descriptive statistics. Descriptive statistics will include at least the number of subjects, mean, standard deviation (SD), median, minimum, maximum, Q1 and Q3 for continuous data. Frequency and percentage will be provided for categorical data. Tables with descriptive statistics will be divided by treatment and assessment time, where applicable. Subject data listings will be sorted by treatment, subject, and timing of assessments.

5.5 Significance level

All hypothesis testing will use a 5% significance level (α=0.05).

5.6 Multiple comparisons/multiplicity

No adjustment for multiple comparison/multiplicity will be performed. All significant findings will be reviewed for medical relevance.

5.7 Handling of dropouts, missing data, and outliers

Outliers will be included in summary tables and listings and will not be handled separately in any analyses. No imputation of data will be performed for descriptive statistics. Imputations using last observation carried forward (LOCF) will be performed for analysis using analysis of variance and analysis of covariance.

5.8 Adjustment for covariates

In general, treatment and body weight will be used as covariates for analysis of covariates.

5.9 Multicentre studies

Two clinical sites are used in this study: one in Linköping and one in Uppsala. No calculations will be performed to adjust for potential differences between sites.

5.10Examination of subgroups

Subgroups of gender will be performed for the primary endpoint 1.1 and secondary endpoint 2.1.1 and 2.1.2.

5.11Blind review

Not applicable.

6 SUBJECTS

6.1 Subject disposition

The subject disposition table will include the number of screened subjects, reasons for withdrawal prior to treatment with the IMP, number of subjects for each IMP, reasons for withdrawal, and the number of completed subjects in the study. The table will also summarise the number of subjects in each study population. See tables and listings in the statistical output layout, section 14.

6.2 Baseline characteristics and demographics

The following baseline characteristics will be summarised by treatment:

- Gender
- Age
- Ethnicity
- Race
- Weight
- Height
- Body mass index (BMI)
- Medical/surgical history
- HIV and Hepatitis B/C
- Alcohol breath test
- Pregnancy test
- Urine drug screen

7 TREATMENT INFORMATION AND EXTENT OF EXPOSURE

7.1 Active treatment

The number of subjects on each IMP will be tabulated with start time and stop time. Duration of application will be tabulated using listings and descriptive statistics.

7.2 Prior and concomitant medications

Prior and concomitant medication data will be listed and tabulated by Anatomical Therapeutic Chemical (ATC) code.

8 STATISTICAL METHODOLOGY

All parameters will be presented by treatment and assessment timepoint using descriptive statistics. Additional statistical analyses are specified below.

8.1 Primary endpoint(s) analysis

8.1.1 Definition of endpoint(s)

8.1.1.1 Body weight after 26 weeks

This section refers to primary objective #1 and endpoint 1.1.

Relative (%) change from baseline in body weight after 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A) as compared to placebo will be analysed using analysis of variance with treatment as the independent variable.

See tables and listings in statistical output layout, section 14.

8.1.2 Sensitivity analysis

No sensitivity analysis is planned to be performed.

8.1.3 Supplementary analyses

No supplementary analyses are planned to be performed.

8.2 Secondary endpoint(s) analysis

8.2.1 Definition of endpoint(s)

8.2.1.1 Body weight

This section refers to secondary objective #2.1 and endpoints 2.1.1, 2.1.2 and 2.1.3.

The proportion of subjects with ≥5% and ≥10% decrease in body weight compared to baseline after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo will be analysed using chi-square test without continuity correction.

The absolute change from baseline in body weight after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A) as compared to placebo will be analysed using analysis of covariance with treatment as independent variable and body weight at baseline as covariate.

The relative (%) change from baseline in body weight after 14 and 26 weeks of treatment with EMP16-02 (150 mg O/50 mg A) as compared to placebo will be analysed using analysis of variance with treatment as independent variable. The absolute change from baseline in body weight will be analysed using analysis of covariance with treatment and body weight at baseline as covariates.

See tables and listings in statistical output layout, section 14.

8.2.1.2 Anthropometric measurements

This section refers to secondary objective #2.2 and endpoints 2.2.1, 2.2.2, 2.2.3 and 2.2.4.

The relative change from baseline in BMI after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo will be analysed using analysis of variance with treatment as independent variable. The absolute change from baseline in BMI will be analysed using analysis of covariance with treatment as independent variable and body weight at baseline as covariate.

The absolute change from baseline in waist circumference after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo will be analysed using analysis of covariance with treatment as independent variable and body weight at baseline as covariate.

The absolute change from baseline in sagittal diameter after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo will be analysed using analysis of covariance with treatment as independent variable and body weight at baseline as covariate.

The relative (%) change from baseline in percentage body fat after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo will be analysed using analysis of variance with treatment as independent variable.

The absolute change from base line in percentage of body fat will be analysed using analysis of covariance with treatment and body weight at baseline as covariates.

See tables and listings in statistical output layout, section 14.

8.2.1.3 Satiety and craving

This section refers to secondary objective #2.3 and endpoint 2.3.1.

Satiety and craving questionnaire include seven questions, with a scale 0 (not at all) to 9 (extremely much). Note, the second and third question in the questionnaire will be reversed before calculating the total score. Satiety and craving as total score after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo, corrected for hunger and craving after standardised breakfast at baseline will be analysed using the Wilcoxon Rank Sum test.

8.2.1.4 Glucose metabolism markers, lipid metabolism markers and inflammation markers

This section refers to secondary objective #2.4 and endpoint 2.4.1 and 2.4.2.

The relative (%) change from baseline in fasting HbA1c, glucose, insulin, total cholesterol, HDL, LDL, triglycerides, liver enzymes, albumin and hs-CRP after 7, 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo will be analysed using analysis of variance with treatment as independent variable.

The absolute change from baseline in these markers will be analysed using analysis of covariance with treatment as independent variable and body weight at baseline as covariate.

The proportions of diabetic subjects (subjects with a fasting glucose ≥ 7.0 mmol/L) and prediabetic subjects (fasting glucose ≥ 6.1 and < 7.0 mmol/L) and non-diabetic subjects

(fasting glucose < 6.1 mmol/L) after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) will be presented using shift tables. The change from baseline in the proportion of diabetic and prediabetic subjects after 14 and 26 weeks of treatment with EMP16-02 as compared to placebo will be analysed using Chi-square test without continuity correction.

See tables and listings in statistical output layout, section 14.

8.2.1.5 Blood pressure

This section refers to secondary objective #2.5 and endpoint 2.5.1.

The relative (%) change from baseline in blood pressure, systolic and diastolic blood pressure, after 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo will be analysed using analysis of variance with treatment as independent variable. The absolute change from baseline in blood pressure will be analysed using analysis of covariance with treatment as independent variable and body weight at baseline as covariates.

See tables and listings in statistical output layout, section 14.

8.2.1.6 Meal pattern questionnaire

This section refers to secondary objective #2.6 and endpoint 2.6.1.

Meal pattern questionnaire include five questions, all with score 0 to 3 points. Note, question 5 will be given the score 0-3; 3 points for “Every morning”, 2 points for “Almost every morning”, 1 point “Several times a week” and 0 points for “Once a week or less”. For each treatment group, the absolute and percent change from baseline in total score of the Meal pattern questionnaire will be calculated and analysed using the Wilcoxon Rank Sum test at each visit. The absolute change for each question will be compared between the treatment groups by using the Wilcoxon Rank Sum test.

Question 4 will also be presented separately with absolute and percent change from baseline.

See tables and listings in statistical output layout, section 14.

8.2.1.7 Activity and sleep questionnaire

This section refers to secondary objective #2.6 and endpoint 2.6.1.

The two questions (both with answer option Yes or No) included in the Activity and Sleeping questionnaire will be analysed pairwise at each visit using a Chi-square test without continuity correction and presented in frequency tables.

See tables and listings in statistical output layout, section 14.

8.2.1.8 Health and quality of life (RAND-36)

This section refers to secondary objective #2.6 and endpoint 2.6.1.

The RAND-36 QoL questionnaire will be analysed in accordance with the manual.

8.2.1.9 Drop-out rate

This section refers to secondary objective #2.7 and endpoint 2.7.1.

The drop-out rate (overall and GI-related) following treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo will be analysed using Chi-square test without continuity correction.

See tables and listings in statistical output layout, section 14.

8.2.1.10 Adverse events

This section refers to secondary objective #2.8 and endpoint 2.8.1.

An overview of all AEs, including SAEs, intensity, relationship to IMP, withdrawals due to AEs and deaths will be presented by treatment, SOC and PT.

Incidence of AEs and SAEs will be summarised by SOC and PT by treatment and overall. All AE data will be listed by treatment and subject and include the verbatim term entered by the Investigator.

8.2.1.11 Physical examination

This section refers to secondary objective #2.8 and no endpoint.

Clinically significant and non-clinically significant abnormal findings will be specified and presented by subject and summarised by treatment.

Changes over time will be presented using shift tables, if considered appropriate.

See tables and listings in statistical output layout, section 14.

8.2.1.12 Vital signs

This section refers to secondary objective #2.8 and endpoint 2.8.2.

Vital signs (systolic/diastolic BP and pulse) will be summarised by treatment. Data will be presented with absolute and percent change from baseline at each visit.

See tables and listings in statistical output layout, section 14.

8.2.1.13 Resting 12-lead ECG

This section refers to secondary objective #2.8 and endpoint 2.8.2.

All ECGs will be categorised as ”normal”, ”abnormal, not clinically significant”, or ”abnormal, clinically significant” (as judged by the Investigator) and summarised by treatment using frequency tables.

Changes over time will be presented using shift tables, if considerate appropriate.

See tables and listings in statistical output layout, section 14.

8.2.1.14 Laboratory safety assessments

This section refers to secondary objective #2.8 and endpoint 2.8.2.

Safety laboratory data will be summarised by treatment with absolute and percent change from baseline at each visit.

Abnormal, clinically significant values will be summarised separately if considered appropriate.

See tables and listings in statistical output layout, section 14.

8.2.1.15 Gastrointestinal tolerability questionnaire

This section refers to secondary objective #2.8 and endpoint 2.8.3.

GSRS (GI tolerability) include 15 questions. For each treatment group, the absolute and percent change from baseline in total score of the calculated and analysed using analysis of covariance with at least treatment as independent variable, body weight at baseline as covariate.

Subscore will be analysed in accordance with the manual and will be presented separately for each treatment with absolute and percent change from baseline.

See tables and listings in statistical output layout, section 14.

8.2.1.16 Compliance

This section refers to secondary objective #2.8 and endpoint 2.8.4.

The compliance of the IMP will be measured as follow:

$$compliance = \frac{number\ of\ delivered\ capsules - number\ of\ returned\ capsules}{number\ of\ delivered\ capsules}$$

The measured compliance and ViedocMe IMP compliance questions will be presented using descriptive statistics.

See tables and listings in statistical output layout, section 14.

8.2.1 Sensitivity analysis

No sensitivity analysis is planned to be performed.

8.2.2 Supplementary analyses

No supplementary analyses are planned to be performed.

8.3 Tertiary/exploratory endpoint(s) analysis

8.3.1.1 Plasma/serum profile of ApoA1 and ApoB

The absolute difference in fasting plasma/serum levels of ApoA1 and ApoB from baseline after 7, 14 and 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) as compared to placebo will be presented using descriptive statistics.

See tables and listings in statistical output layout, section 14.

8.3.1.2 Orlistat plasma values

Pre-dose plasma concentrations of orlistat after 26 weeks of treatment with EMP16-02 (120 mg O/40 mg A and 150 mg O/50 mg A) will be presented using descriptive statistics.

See tables and listings in statistical output layout, section 14.

8.4 Discontinuation

Subjects who discontinue from the IMP treatment will be tabulated. The reason for discontinuation will be given. For discontinuation due to AEs, the AEs will be given.

8.5 Other Analyses

No other analyses are planned to be performed.

8.6 Interim Analysis

No interim analysis is planned to be performed.

8.7 Top-line data

Top-line data will be delivered within 48h after database lock.

The top-line data will include primary objective #1 (endpoint 1.1), secondary objective #2.1 and #2.8 (endpoints 2.1.1, 2.1.2 ,2.1.3 and 2.8.4).

9 CHANGES FROM THE CSP

The endpoint for the proportion of decreased body weight have been reordered to the top of the secondary endpoints.

10 STATISTICAL DELIVERABLES

The following documents will be delivered:

- SAP
- Statistical analyses and summary tables

11 SOFTWARE

All statistical analyses will be performed using SAS Version 9.4 (SAS institute, Cary, NC).

12 APPROVAL

Issued by:

DocuSigned by:
Linnéa Eriksson
Signer Name: Linnéa Eriksson
Signing Reason: I approve this document
Signing Time: 21-Jan-2021 | 14:37 CET
1C5E24B4BE5B4603BB47B4A82FACB244

21-Jan-2021 | 14:37 CET

Responsible Biostatistician

Date (dd-Mmm-yyyy)

CTC Representative

Approved by:

DocuSigned by:
Ulf Holmbäck
Signer Name: Ulf Holmbäck
Signing Reason: Jag godkänner dokumentet
Signing Time: 20-jan-2021 | 05:55 PST
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20-jan-2021 | 05:55 PST

Sponsor Representative

Date (dd-Mmm-yyyy)

13 SUPPORTIVE DOCUMENTATION

13.1 Appendix 1 –list of abbreviations

Abbreviation of term	Explanation
AE	Adverse event
ApoA1	Apolipoprotein A1
ApoB	Apolipoprotein B
ATC	Anatomical-Therapeutic-Chemical
APTT	Activated partial thromboplastin time
BMI	Body mass index
CF	Clean file
CRF	Case report form
CSP	Clinical study protocol
ECG	Electrocardiogram
FAS	Full analysis set
GI	Gastrointestinal
GSRS	Gastrointestinal symptom rating scale
HbA1c	Haemoglobin A1
HDL	High-density lipoprotein
HIV	Human immunodeficiency virus
Hs-CRP	High sensitivity C-reactive protein
LDL	Low-density lipoprotein
MedDRA	Medical Dictionary for Regulatory Affairs
mg	Milligram
PPS	Per protocol set
PT	Preferred term
SAE	Serious adverse event
SAP	Statistical analysis plan
SAS	Statistical analysis system
SD	Standard deviation
WHO	World Health Organization

13.2Appendix 2 – changes to protocol-planned analyses

14 STATISTICAL OUTPUT LAUOUT

14.1Template tables

Template tables includes template tables and will be adjusted depending on the collected data.

14.1.1 Descriptive statistic table – continuous variables

Assessment (unit)	Result category	Assessment timepoint		EMP16-02 120mg O/40mg A	EMP16-02 150mg O/50mg A	Placebo	Total
[Parameter 1] (unit)	Measured value	[Assessment timepoint 1]	n	x	x	x	x
			Mean (SD)	x.xxx (x.xxx)	x.xxx (x.xxx)	x.xxx (x.xxx)	x.xxx (x.xxx)
			Median (Min, Max)	x.xxx (x.xx, x.xx)	x.xxx (x.xx, x.xx)	x.xxx (x.xx, x.xx)	x.xxx (x.xx, x.xx)
			Q1, Q3	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx
		[Assessment timepoint 2]	n	x	x	x	x
			Mean (SD)	x.xxx (x.xxx)	x.xxx (x.xxx)	x.xxx (x.xxx)	x.xxx (x.xxx)
			Median (Min, Max)	x.xxx (x.xx, x.xx)	x.xxx (x.xx, x.xx)	x.xxx (x.xx, x.xx)	x.xxx (x.xx, x.xx)
			Q1, Q3	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx
	Absolute change from baseline	[Assessment timepoint 2]	n	x	x	x	x
			Mean (SD)	x.xxx (x.xxx)	x.xxx (x.xxx)	x.xxx (x.xxx)	x.xxx (x.xxx)
			Median (Min, Max)	x.xxx (x.xx, x.xx)	x.xxx (x.xx, x.xx)	x.xxx (x.xx, x.xx)	x.xxx (x.xx, x.xx)
			Q1, Q3	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx
			Between groups p-value (Wilcoxon)	x.xxxx	x.xxxx		
			Ancova p-value	x.xxxx	x.xxxx		
	Relative change from baseline (%)	[Assessment timepoint 2]	n	x	x	x	x
			Mean (SD)	x.x (x.x)	x.xxx (x.xxx)	x.xxx (x.xxx)	x.xxx (x.xxx)

Assessment (unit)	Result category	Assessment timepoint		EMP16-02 120mg O/40mg A	EMP16-02 150mg O/50mg A	Placebo	Total
			Median (Min, Max)	x.x (x, x)	x.xxx (x.xx, x.xx)	x.xxx (x.xx, x.xx)	x.xxx (x.xx, x.xx)
			Q1, Q3	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx	x.xxx, x.xxx
			Between groups p-value (Wilcoxon)	x.xxxx	x.xxxx		
			Acova p-value	x.xxxx	x.xxxx		

Data based on [ANALYSIS SET]. Baseline at [Assessment timepoint 1]. ND: Not defined - no evaluable observations. NA: Not available - no non-missing observations. NC: Not calculated - number of non-missing observations less than 3
[STUDYID] [DOMAIN]: [PARAMETER CATEGORY], SAS program: descriptive_stat_tables.sas. Run by: [USERNAME], [USER EMAIL] [TIMESTAMP]

14.1.2 Descriptive statistic table – discrete variables

Assessment	Assessment timepoint	Result	EMP16-02 120mg O/40mg A	EMP16-02 150mg O/50mg A	Placebo	Total
[Parameter 1]	[Assessment timepoint 1]	[RESULT 1]	x(x.x%)/X	x(x.x%)/X	x(x.x%)/X	x(x.x%)/X
		[RESULT 2]	x(x.x%)/X	x(x.x%)/X	x(x.x%)/X	x(x.x%)/X
		Chi-Square p-value				x.xxxx
	[Assessment timepoint 2]	[RESULT 1]	x(x.x%)/X	x(x.x%)/X	x(x.x%)/X	x(x.x%)/X
		[RESULT 2]	x(x.x%)/X	x(x.x%)/X	x(x.x%)/X	x(x.x%)/X
		Chi-Square p-value				x.xxxx

Data based on [ANALYSIS SET].
[STUDYID] [DOMAIN]: [PARAMETER CATEGORY], SAS program: descriptive_stat_tables.sas. Run by: [USERNAME], [USER EMAIL] [TIMESTAMP]

14.1.3 Shift table

Assessment	Assessment timepoint	Result	NORMAL n (%)	ABNORMAL CS n (%)	ABNORMAL NCS n (%)	MISSING n (%)	TOTAL n (%)
[Parameter 1]	[Assessment timepoint 1]	NORMAL	x (x%)	x (x%)	x (x%)	x (x%)	x (x%)
		ABNORMAL CS	x (x%)	x (x%)	x (x%)	x (x%)	x (x%)
		ABNORMAL NCS	x (x%)	x (x%)	x (x%)	x (x%)	x (x%)
		MISSING	x (x%)	x (x%)	x (x%)	x (x%)	x (x%)
		TOTAL	x (x%)	x (x%)	x (x%)	x (x%)	x (x%)

Data based on [ANALYSIS SET].
[STUDYID] [DOMAIN]: [PARAMETER CATEGORY], SAS program: descriptive_stat_tables.sas. Run by: [USERNAME], [USER EMAIL] [TIMESTAMP]

14.2Tables

Table 14.1.1 Baseline characteristics and demographics (analysis set)

		EMP16-02 120mg O/40mg (N=X)	EMP16-02 150mg O/50mg (N=X)	Placebo (N=X)	Total (N=X)
Age (years)	n/nmiss	x/x	x/x	x/x	x/x
	Mean (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)
	Median (Min, Max)	x.x (x, x)	x.x (x, x)	x.x (x, x)	x.x (x,x)
Body Mass Index (kg/m^2)	n/nmiss	x/x	x/x	x/x	x/x
	Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
	Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
Height (cm)	n/nmiss	x/x	x/x	x/x	x/x
	Mean (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)
	Median (Min, Max)	x.x (x, x)	x.x (x, x)	x.x (x, x)	x.x (x,x)
Weight (kg)	n/nmiss	x/x	x/x	x/x	x/x
	Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
	Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x,x.x)
Sex	Female	x (x.x%)	x (x.x%)	x (x.x%)	x (x.x%)
	Male	x (x.x%)	x (x.x%)	x (x.x%)	x (x.x%)
Ethnicity	Hispanic Or Latino	x (x.x%)	x (x.x%)	x (x.x%)	x (x.x%)
	Not Hispanic Or Latino	x (x.x%)	x (x.x%)	x (x.x%)	x (x.x%)
Race	American Indian Or Alaska Native	x (x.x%)	x (x.x%)	x (x.x%)	x (x.x%)
	Asian	x (x.x%)	x (x.x%)	x (x.x%)	x (x.x%)
	Black or African American	x (x.x%)	x (x.x%)	x (x.x%)	x (x.x%)
	Native Hawaiian or other Pacific Islander	x (x.x%)	x (x.x%)	x (x.x%)	x (x.x%)

	EMP16-02 120mg O/40mg (N=X)	EMP16-02 150mg O/50mg (N=X)	Placebo (N=X)	Total (N=X)
White	x (x.x%)	x (x.x%)	x (x.x%)	x (x.x%)

[STUDYID] Summarised demographics data.
Data based on the [analysis set].
SAS program: summary_demographics.sas. Run by: [USERNAME], [USER EMAIL] [TIMESTAMP]

Table 14.1.2 Subject disposition (all subjects)

	Total
Screened subjects	x
Withdrawn prior to [dose]	x
--- Withdrawal reason x	x
--- Withdrawal reason x	x
--- Withdrawal reason x	x
Included subjects	x
--- EMP16-02 120mg O/40mg	x
--- EMP16-02 150mg O/50mg	x
--- Placebo	x
Withdrawn subjects	x
--- Withdrawal reason x	x
--- Withdrawal reason x	x
--- Withdrawal reason x	x
Completed subjects	x
--- EMP16-02 120mg O/40mg	x
--- EMP16-02 150mg O/50mg	x
--- Placebo	x
Included in full analysis set	x
Included in safety analysis set	x
Included in per protocol set	x
Subjects at VISIT 1	x
Subjects at VISIT 2	x
Subjects at VISIT 3	x

	Total
Subjects at VISIT 4	x
Subjects at VISIT 5	x
Subjects at VISIT 6	x

[STUDYID] Disposition, SAS program: disposition.sas. Run by: [USERNAME], [USER EMAIL] [TIMESTAMP]

Table 14.1.4.x Medical history events by system organ class and preferred term (analysis set)

	EMP16-02 120mg O/40mg N=X		EMP16-02 150mg O/50mg N=X		Placebo N=X		Total N=X	
System organ class Preferred term	n(%)	m	n(%)	m	n(%)	m	n(%)	m
Total	**x(x.x%)**	**x**	**x(x.x%)**	**x**	**x(x.x%)**	**x**	**x(x.x%)**	**x**
SOC 1s	**x(x.x%)**	**x**	**x(x.x%)**	**x**	**x(x.x%)**	**x**	**x(x.x%)**	**x**
SOC 1 PT 1	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
SOC 1 PT 2	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
SOC 1 PT 3	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
SOC 2	**x(x.x%)**	**x**	**x(x.x%)**	**x**	**x(x.x%)**	**x**	**x(x.x%)**	**x**
SOC 2 PT 1	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
SOC 2 PT 2	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x

n, number of subjects; m, number of events
Percentages are based on the number of subjects in the treatment period included in the [analysis set]
[STUDYID] Medical history events by system organ class and preferred term, [analysis set], SAS program: mh_summary_by_soc_and_pt.sas. Run by: [USERNAME], [USER EMAIL] [TIMESTAMP]

Table 14.2.x.x. Body weight loss proportion (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x. Body weight measurements (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x. BMI measurements (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x. Waist circumference measurements (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x. Sagittal diameter measurements (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x. Body fat measurements (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x. Satiety and craving measurements (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x. Fasting insulin, glucose metabolism markers, lipid metabolism marker and inflammation markers measurements (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x. Proportion of diabetic and prediabetic measurements (analysis set)

See appendix table – 14.1.3 Descriptive statistic table – shift table

Table 14.3.x.x. Blood pressure measurements (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x. Meal pattern measurements (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x. Meal pattern measurements (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x. Activity and sleep measurements (analysis set)

See appendix table – 14.1.2 Descriptive statistic table – discrete variables

Table 14.3.x.x. Quality of life measurements (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x. Dropout rate (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x Overview of adverse events (analysis set)

	EMP16-02 120mg O/40 N=X		EMP16-02 150mg O/50mg N=X		Placebo N=X		Total N=X	
	n(%)	m	n(%)	m	n(%)	m	n(%)	m
Any AE	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
Any SAE	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
Any AE leading to withdrawal	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
Any AE leading to death	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
Causality								
Possibly Related	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
Probably Related	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
Unlikely Related	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
Severity								
Mild	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
Moderate	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
Severe	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
Life-threatening	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
Death	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x

n, number of subjects; m, number of events
Percentages are based on the number of subjects in the treatment period included in the [analysis set].
Adverse events that occurred during [ELEMENTS] are omitted from summary.
[STUDYID] Overview of adverse events, [analysis set], SAS program: ae_summary_tables.sas. Run by: [USERNAME], [USER EMAIL] [TIMESTAMP]

Table 14.3.x.x Adverse events by system organ class and preferred term (analysis set)

	EMP16-02 120mg O/40mg N=X		EMP16-02 150mg O/50mg N=X		Placebo N=X		Total N=X	
System organ class Preferred term	n(%)	m	n(%)	m	n(%)	m	n(%)	m
SOC 1s	**x(x.x%)**	**x**	**x(x.x%)**	**x**	**x(x.x%)**	**x**	**x(x.x%)**	**x**
SOC 1 PT 1	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
SOC 1 PT 2	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
SOC 1 PT 3	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
SOC 2	**x(x.x%)**	**x**	**x(x.x%)**	**x**	**x(x.x%)**	**x**	**x(x.x%)**	**x**
SOC 2 PT 1	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x
SOC 2 PT 2	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x	x(x.x%)	x

n, number of subjects; m, number of events
Percentages are based on the number of subjects in the treatment period included in the [analysis set]
Adverse events that occurred during [ELEMENTS] are omitted from summary.
[STUDYID] Adverse events by system organ class and preferred term, [analysis set], SAS program: ae_summary_by_soc_and_pt.sas. Run by: [USERNAME], [USER EMAIL] [TIMESTAMP]

Table 14.3.x.x. Physical examinations interpretation (analysis set)

See appendix table – 14.1.2 Descriptive statistic table – discrete variables

Table 14.3.x.x. Physical examinations interpretation with shift (analysis set)

See appendix table – 14.1.3 Descriptive statistic table – shift table

Table 14.3.x.x. Vital signs measurements (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x. ECG measurements (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x. ECG interpretation (analysis set)

See appendix table – 14.1.2 Descriptive statistic table – discrete variables

Table 14.3.x.x. ECG interpretation with shift table (analysis set)

See appendix table – 14.1.3 Descriptive statistic table – shift table

Table 14.3.x.x. Safety laboratory measurements (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x. Safety laboratory interpretation (analysis set)

See appendix table – 14.1.2 Descriptive statistic table – discrete variables

Table 14.3.x.x. Safety laboratory – shift table (analysis set)

See appendix table – 14.1.3 Shift table

Table 14.3.x.x. GSRS measurements (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.3.x.x. Compliance measurements (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.4.x.x. Plasma levels of ApoA1 and ApoB (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

Table 14.4.x.x. Plasma concentration of orlistat (analysis set)

See appendix table – 14.1.1 Descriptive statistic table – continuous variables

14.3Figures

Figure 14.3.x.x. Body weight measurements (analysis set)

No template. Line plot with mean values and SD for each treatment arm. For both absolute and relative change from baseline.

Figure 14.3.x.x. Body fat measurements (analysis set)

No template. Line plot with mean values and SD for each treatment arm. For both absolute and relative change from baseline.

Figure 14.3.x.x. Fasting glucose measurements (analysis set)

No template. Line plot with mean values and SD for each treatment arm. For absolute change from baseline.

Figure 14.3.x.x. HbA1c measurements (analysis set)

No template. Line plot with mean values and SD for each treatment arm. For absolute change from baseline.

Figure 14.3.x.x. Waist measurements (analysis set)

No template. Line plot with mean values for each treatment arm.

14.4Listings

Listing 16.2.1.1. Discontinued subjects (All subjects)

Listing 16.2.2.1. Protocol deviations (All subjects)

Listing 16.2.3.1 Subjects excluded from PPS (All subjects)

Listing 16.2.3.2 Population definitions (All subjects)

Listing 16.2.3.3. Non-eligible subjects (All subjects)

Listing 16.2.4.1. Demography (Full analysis set)

Listing 16.2.4.2 Medical history (Full analysis set)

Listing 16.2.5. Prior and concomitant medications (Full analysis set)

Listing 16.2.x.x. Body weight (Full analysis set)

Listing 16.2.x.x. BMI (Full analysis set)

Listing 16.2.x.x. Waist circumference (Full analysis set)

Listing 16.2.x.x. Sagittal diameter (Full analysis set)

Listing 16.2.x.x. Body fat (Full analysis set)

Listing 16.2.x.x. Satiety and craving (Full analysis set)

Listing 16.2.x.x. Fasting insulin, glucose metabolism markers, lipid metabolism markers and inflammation markers (Full analysis set)

Listing 16.2.x.x. Diabetic and prediabetic (Full analysis set)

Listing 16.2.x.x. Blood pressure (Full analysis set)

Listing 16.2.x.x. RAND-36 (Full analysis set)

Listing 16.2.x.x. Activity and sleep (Full analysis set)

Listing 16.2.x.x. Adverse events, part 1 (Full analysis set)

Listing 16.2.x.x. Adverse events, part 2 (Full analysis set)

Listing 16.2.x.x. Serious adverse events, part 1 (Full analysis set)

Listing 16.2.x.x. Serious adverse events, part 2 (Full analysis set)

Listing 16.2.x.x. Serious adverse events, seriousness criteria (Full analysis set)

Listing 16.2.x.x. Safety laboratory (Full analysis set)

Listing 16.2.x.x. Vital signs (Full analysis set)

Listing 16.2.x.x. ECG (Full analysis set)

Listing 16.2.x.x. Physical examinations (Full analysis set)

Listing 16.2.x.x. GSRS (Full analysis set)

Listing 16.2.x.x. Compliance (Full analysis set)

Listing 16.2.x.x. ApoA1 and ApoB (Full analysis set)

Listing 16.2.x.x. Plasma concentration orlistat (Full analysis set)

Listing 16.2.x.x. Disposition (All subjects)

Listing 16.2.x.x. Subject visits (All subjects)

Listing 16.2.x.x. Subject elements (All subjects)

Certifikat om färdigställande

Kuvert-ID: 3600BB83EA70405EABBCB65B3402E181
Ämne: Please DocuSign: EP-002_SAP_v1.0_20JAN2020.pdf
Källkuvert:
Dokumentsidor: 46
Certifikatsidor: 5
AutoNav: Aktiverat
Kuverterad stämpling: Inaktiverat
Tidszon: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna

Signaturer: 2
Initialer: 0

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Plats: DocuSign

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Linnéa Eriksson linnea.eriksson@ctc-ab.se CTC Clinical Trial Consultants AB Säkerhetsnivå: E-post, Kontoautentisering (obligatoriskt)	 Signaturantagande: Förvald stil Signatur-ID: 1C5E24B4-BE5B-4603-BB47-B4A82FACB244 Med IP-adress: 92.34.249.8 Med signeringsautentisering via DocuSign-lösenord Med Anledning till underskrift (på varje flik): I approve this document	Skickade: 2021-01-20 13:36:03 Visade: 2021-01-21 14:13:28 Signerade: 2021-01-21 14:37:20
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Ulf Holmbäck ulf.holmback@emprospharma.com Ulf Holmback Säkerhetsnivå: E-post, Kontoautentisering (obligatoriskt)	 Signaturantagande: Förvald stil Signatur-ID: 58054CCB-6419-495B-84DB-94201B6C8148 Med IP-adress: 158.174.109.209 Med signeringsautentisering via DocuSign-lösenord Med Anledning till underskrift (på varje flik): Jag godkänner dokumentet	Skickade: 2021-01-20 13:36:03 Visade: 2021-01-20 14:53:55 Signerade: 2021-01-20 14:55:37
Delgivande av elektronisk uppgift och signatur: Godkänt: 2021-01-20 14:53:55 ID: 012b9f90-1de5-4c2a-b5a8-d291d51c88ff		

Händelser med undertecknare på plats	Signatur	Tidsstämpel

Redigerarleveranshändelser	Status	Tidsstämpel

Agentleveranshändelser	Status	Tidsstämpel

Mellanhandsleveranshändelser	Status	Tidsstämpel

Certifierade leveranshändelser	Status	Tidsstämpel

Kopieringshändelser	Status	Tidsstämpel

Vittneshändelser	Signatur	Tidsstämpel

Notariehändelser	Signatur	Tidsstämpel

Sammanfattning av kuverthändelser	Status	Tidsstämplar
Kuvertet har skickats	Hashkodat/krypterat	2021-01-20 13:36:03
Certifierat levererat	Säkerhetskontrollerat	2021-01-20 14:53:55
Signeringen är slutförd	Säkerhetskontrollerat	2021-01-20 14:55:37
Färdigställda	Säkerhetskontrollerat	2021-01-21 14:37:20

Betalningshändelser	Status	Tidsstämplar

Delgivande av elektronisk uppgift och signatur

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