Appendix 16.1.9

Documentation of statistical methods

Contents

Statistical Analysis Plan

A Phase II, Multicenter, Double-blind, Placebo-controlled, Efficacy and Safety Study of Two Oral Doses (150 mg bid / 300 mg bid) of MP1032 in Male and Female Patients with Moderate-to-Severe Chronic Plaque Psoriasis.

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SIGNATURE PAGE

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Abbreviations and definitions

AE	adverse event
AP	alkaline phosphatase
ALT	alanine aminotransferase
AST	aspartate aminotransferase
$AUC_{(0,t)}$	area under the curve
BMI	body mass index
BSA	body surface area
C_{max}	maximal plasma concentration
CMH	Cochran-Mantel-Haenszel
CRP	C-reactive protein
eCRF	electronic case report form
EoT	end of treatment
FAS	full analysis set
FU	follow up
γGT	gamma-glutamyltransferase
GOT	glutamic oxaloacetic transaminase
GPT	glutamic pyruvic transaminase
hCG	human chorionic gonadotrpin
HIV	human immunodeficiency virus
ICH	international conference on harmonisation
IL-6	interleukin 6
IMP	investigational medicinal product
ITT	Intent-To-Treat
IWRS	Interactive Web Response Systems
LOCF	last observation carried forward
LLQ	lower limit of quantification
MCH	mean corpuscular hemoglobin
MCHC	mean corpuscular hemoglobin concentration
MCV	mean corpuscular volume#
MedDRA	medical dictionary for regulatory activities
NCA	non-compartmental analysis
PGA	physician's global assessment
PASI	psoriasis area severity index
PK	pharmacokinetic
PKS	pharmacokinetic-evaluation-set
PP	per-protocol
PT	preferred term
RBC	red blood cell
SAE	serious adverse event
SAP	statistical analysis plan
SAS	Statistical Analysis System
SES	safety evaluation set
SOC	system organ class
t_{max}	time point of maximal plasma concentration
TEAE	treatment emergent adverse event
TNF-α	tumor necrosis factor α
VCS	valid cases set
WBC	white blood cell
WHO	world health organization

1 Overview

This Statistical Analysis Plan (SAP) is issued to provide a comprehensive and detailed description of strategy, rationale, and statistical technique that will be used to evaluate the clinical efficacy and safety of two oral doses of MP1032 (150 mg bid and 300 mg bid) when taken for 12 weeks by patients with moderate-to-severe chronic plaque psoriasis.

The credibility of the study findings will be ensured by pre-specifying the statistical approaches to the analysis of the study data prior to unblinding of the randomization schedule. This SAP is based on the clinical trial protocol number MP1032-CT04, version 2.0 dated October 19, 2018.

1.1 Background / rationale

MP1032 is a small-molecule macrophage modulator currently not available as a registered or approved medicinal product within the borders of the European economic area, the United States, or Japan. Experimental data have shown that MP1032 can inhibit inflammation by reducing Tumor Necrosis Factor α (TNF-α) and Interleukin 6 (IL-6) [1]. MetrioPharm AG is developing MP1032 as an anti-inflammatory compound. The first target indication is psoriasis.

Psoriasis is a relatively common skin condition, affecting 1.5 to 3% of the general population in Europe [2]. Psoriasis can have a particularly negative effect on quality of life, affecting a sufferer's physical, social, and psychological functioning so the need for effective therapies is high. Psoriasis is characterized by outbreaks of skin inflammation interspersed by varying periods of remission. The underlying mechanisms of the inflammatory flares in psoriasis are poorly understood, but the therapeutic potency of anti-TNF-α and anti-IL-17 biologics is evidence of immune modulation's potential to reduce disease severity [1]

However, antibody-based biologics therapies are not optimal therapies for life-long treatment of psoriasis, due to decreasing efficacy over time and relatively high costs. Furthermore, the use of immune-suppressive drugs, such as methotrexate, cyclosporine, or anti TNF-α / IL-12 / IL-17/ IL-23 biologics increases the risk of opportunistic infections and/or requires regular laboratory checks on blood and liver function [1].

MP1032 has been shown to reduce TNF-α and IL-6 levels in vitro (human peripheral blood mononuclear cells and differentiated human promyelocytic leukemia cells), and in vivo, and its anti-inflammatory potential has been shown in mouse and rat arthritis models. Other anti-inflammatory compounds usually exhibit immune-suppressive effects resulting in an increased vulnerability to infections. MP1032, on the other hand, has shown an anti-infective potential in animal infection models.

As a multi-target small-molecule macrophage modulator, MP1032 seems to avoid the problems of tolerance and reduced long-term efficacy that biologics have. An important potential safety advantage of MP1032 lies in the observation from animal models that the compound reduces rather than increases susceptibility to bacterial and viral infections. This may be due to the fact that MP1032 is reducing – rather than completely suppressing – TNF-α and IL-6 levels.

MetrioPharm considers these molecular and safety characteristics along with the ease of an oral therapy over topical therapies as strong arguments for MP1032 to become an effective therapy option in moderate-to-severe psoriasis, where topical agents are not effective enough or too tedious for patients to apply them regularly.

1.2 Objectives

The trial is designed with two primary endpoints as described in the EMA guideline [2].

Table 1 Objectives and endpoints:

Primary objective	Primary endpoint
The primary objective of this trial is to evaluate the clinical efficacy and safety of two oral doses of MP1032 (150 mg bid and 300 mg bid) when taken for 12 weeks by patients with moderate-to-severe chronic plaque psoriasis.	Efficacy: MP1032 300 mg bid vs. placebo 1.1 Percentage of patients who achieve a 75% improvement (response) in their PASI score (PASI 75) at Week 12 (Day 84) compared to baseline in patients treated with 300 mg bid of MP1032 compared to placebo 1.2 Improvement (1 or more points on a 7 Point Scale) in PGA at Week 12 (Day 84) compared to baseline in patients treated with 300 mg bid of MP1032 compared to placebo Efficacy: MP1032 150 mg bid vs. placebo 2.1 Percentage of patients who achieve a 75% improvement (response) in their PASI score (PASI 75) at Week 12 (Day 84) compared to baseline in patients treated with 150 mg bid of MP1032 compared to placebo 2.2 Improvement (1 or more points on a 7 Point Scale) in PGA Score at Week 12 (Day 84) compared to baseline in patients treated with 150 mg bid of MP1032 compared to placebo Safety: 3 Incidence of adverse events
Secondary objectives	**Secondary endpoints**
To evaluate the effect of each oral doses of MP1032 (150 mg bid and 300 mg bid) compared to placebo on the PASI score	• Percentage of patients who achieve a 50% improvement (response) in their PASI score (PASI 50) at Week 12 (Day 84) compared to baseline in patients treated with 300 mg bid of MP1032 compared to placebo • Percentage of patients who achieve a 50% improvement (response) in their PASI score (PASI 50) at Week 12 (Day 84) compared to baseline in patients treated with 150 mg bid of MP1032 compared to placebo • Mean PASI score and change from baseline at Week 4 (Day 28), 8 (Day 56), 12 (Day 84) and week 16 (Day 112) • Time to achieve PASI 50 and PASI 75
To evaluate the effect of each oral dose of MP1032 (150 mg bid and 300 mg bid) compared to placebo on the PGA score	• Mean score and change from Baseline at Week 4 (Day 28), 8 (Day 56), 12 (Day 84) and 16 (Day 112) in the PGA
To evaluate the effect of each oral dose of MP1032 (150 mg bid and 300 mg bid) compared to placebo on the BSA	• Mean value and change from Baseline at Week 4 (Day 28), 8 (Day 56), 12 (Day 84) and 16 (Day 112) in the BSA

Secondary objectives (continued)	Secondary endpoints (continued)
To evaluate systemic exposure of two oral doses of MP1032 (150 mg bid and 300 mg bid) when taken for 12 weeks by patients with moderate-to-severe chronic plaque psoriasis	• PK data analy i

1.3 Modifications from the statistical section in the protocol

Not applicable.

2 Investigational plan

2.1 Study design and randomization

This trial is a randomized, double-blind, parallel, placebo-controlled trial to evaluate the efficacy and safety of two oral doses of MP1032 (150 mg bid and 300 mg bid) in adult patients with moderate-to-severe chronic plaque psoriasis.

The trial design consists of a 28-day screening period, a 12-week treatment period, and subsequently a 28-day follow-up period. Each patient will have 6 visits and unscheduled visits as needed.

Approximately 150 patients (2 × 50 patients MP1032 and 50 patients placebo) who meet the entry criteria will be randomized on Day 1 to receive either 150 mg MP1032, 300 mg MP1032 or placebo orally twice daily for 12 weeks.

Efficacy and safety will be assessed as outlined in the trial flow chart (see Table 2)

Patient Identification

Upon signature of informed consent (screening period) each patient receives a 5-digit patient identification number, which is composed of:

Digits 1 and 2:	trial center (01, 02, 03, etc.) 01 – 10 for German sites and 11 – 20 for Polish sites
Digits 3, 4 and 5:	individual screening number within the center (consecutively in the order of screening within the center: 001, 002, etc.)

Treatment Assignment

Patients will be randomized on a 1:1:1 basis to one of three treatment groups:

- MP1032 300 mg bid
- MP1032 150 mg bid
- Placebo bid

The trial will use a block randomization scheme. Enrollment will be performed competitively between all 14 centers (Germany and Poland) until approximately 150 patients are enrolled in the trial in order to have 120 evaluable patients.

Patients who are eligible for enrollment into the trial will be randomized at Visit 2/Day 1 and will be assigned the lowest random number available at the site. Patient kits will be dispensed according to the kit number assigned by the Interactive Web Response System (IWRS). The kit numbers will be assigned to the treatment kits by a simple randomization.

The treatment group designation will remain blinded until the final database is locked. If the blind is broken via IWRS, the date, time, person who broke the blind and the reason must be recorded in the patient's eCRF, and any associated AE report.

The random list, assigning the randomization number to the treatment groups, and the kit number list, assigning the kit number to the treatment groups will be generated by psy consult scientific services.

2.2 Sample size justification

It is planned to recruit approximately 150 patients for this clinical trial in Germany and Poland (each country approximately 75 patients) to achieve 120 evaluable patients.

No formal sample size calculations were performed for this explorative trial. A sample size of 40 in each group is adequate to detect a difference in rates (in PASI 75% or PGA improvement) of at least 0,274, e.g. a success rate of 0,674 (67,4%) in the active group and 0,4 (40%) in the placebo group, with 80% power, using a two group χ^2 test with a 0,100 two-sided significance level.

2.3 Study plan

Table 2 Trial flow chart

Trial Period	Screening	Treatment phase				Follow-up	Unscheduled visit[g]
Day	(Day - 28 to -3)	Day 1	Day 28 (±2 days)	Day 56 (±2 days)	Day 84 (+5 days)	Day 112 (±2 days)	
Visit Number / Procedure	1	2	3	4	5	6	Unscheduled
Informed consent	X						
In-/exclusion criteria	X	X					
Demographics/medical history	X						
Physical examination	X	X			X	X	
Height, body weight, BMI	X						
Smoking history/ alcohol consumption	X						
Vital signs	X	X	X	X	X	X	
Pregnancy test in female patients[a]	X	X[b]			X		
Safety laboratory, incl. urine dipstick	X	X	X	X	X	X	X
HIV, Hepatitis	X						
Randomization		X					
Localization of photographic documentation test field[c]		X					
Photographic documentation[c]		X	X	X	X	X	
PK sample[d]		X			X		
PASI	X	X	X	X	X	X	
PGA	X	X	X	X	X	X	
BSA	X	X	X	X	X	X	
Dispensing of IMP		X	X	X			
IMP administration[e]		X	X	X	X		
Diary dispensing		X	X	X			
Drug return / accountability			X	X	X		
Diary return and check			X	X	X		
Prior and concomitant therapy	X	X	X	X	X	X	X
Adverse events[f]	X	X	X	X	X	X	X

a) A serum pregnancy test will be done for all women at screening and urine test for all other visits.
b) A urine pregnancy test on Day 1 will be performed prior to the first administration of IMP for all women.
c) Only performed in a subgroup of approx. 2 sites (approx. 30 patients); on Day 1 Photographic documentation will be performed prior to the first administration of IMP
d) Only performed in a subgroup of approx. 4 sites (approx. 30 patients); on Day 1 and Day 84 first PK sample will be performed prior to the first administration of IMP. PK samples will be collected before IMP administration, and 15, 30, 60 and 120 minutes after administration of IMP.
e) IMP administration will start on Day 1 after randomization and will continue as self-administration by trial patients at home until Day 84. Patients included in the PK analysis will administrate the first treatment (Day 1) at the site. All patients will administrate the last treatment (Day 84) at the sites.
f) AE reporting starts after the signature of informed consent form and finishes at the End of Study Follow-Up Visit.
g) Perform assessments which are relevant to the reason for the unscheduled visit (e.g. Photographic documentation, Lab analysis, PASI, PGA, BSA, etc.).

3 Statistical and analytical procedures

3.1 Definitions

The following definitions apply:

- Baseline: The latest non-missing observation prior to first treatment with IMP.

Baseline data definition	obtained on/at
Age, race, height, body weight, BMI	Screening
Relevant medical history (last 5 years) including psoriasis history, relevant surgical history (last 5 years) and relevant previous medication (last 6 weeks) including psoriatic treatment taken (last 6 weeks)	Screening
Smoking and alcohol consumption	Screening
Concomitant medication	Day 1
Adverse events	Day 1
Physical examination	Day 1, Screening*
Vital signs (blood pressure, pulse rate)	Day 1, Screening*
Safety laboratory parameters	Day 1, Screening*
PASI, PGA, BSA	Day 1, Screening*

*only in case of missing Day 1 assessment

- Change from baseline = post baseline value – baseline value
- Percent change from baseline = 100 * change from baseline / baseline value
- Last observation carried forward (LOCF): The last observed value (either scheduled or unscheduled) carried forward and used for all directly subsequent and missing scheduled points.
- Current medical conditions – medical conditions ongoing at first dosing.
- Prior therapy: Any medication or therapy taken prior to start of first IMP dosing.
- Concomitant therapy: A medication or therapy ongoing at start of first IMP dosing, or starting after the first IMP dosing.
- Treatment emergent adverse event (TEAE): Adverse event with an onset (or worsening) on or after the time of the first IMP dosing.
- Time to achievement of PASI 50 (75): Day of first visit were PASI 50 (75) is observed.
- Analysis centers: Pooled small centers for analyses, as described in section 3.5.4.

3.2 Analysis variables

3.2.1 Efficacy variable(s)

3.2.1.1 Psoriasis Area Severity Index (PASI)

The PASI quantifies the severity and extent of the disease and weighs these with the body surface area involvement. It involves the assessment of erythema (E), infiltration (I),

desquamation (D), and body surface area involvement (A) over 4 body regions: head (h), trunk (t), upper (u) and lower extremities (l).

Degree of severity (for E, I, D) per body region	Value given
No symptoms	0
Slight	1
Moderate	2
Marked	3
Very marked	4

Surface involved (A), per body region	Value given
<10%	1
10-29%	2
30-49%	3
50-69%	4
70-89%	5
90-100%	6

Because the head (h), upper extremities (u), trunk (t), and lower extremities (l) correspond to approximately 10%, 20%, 30%, and 40% of body surface area, respectively, the PASI score is calculated by the formula:

PASI = 0.1*(Eh + Ih +Dh)*Ah + 0.2*(Eu + Iu + Du)*Au + 0.3*(Et + It + Dt)*At + 0.4*(El +Il +Dl)*Al

The PASI score ranges from 0 to 72, with a higher score indicating increased disease severity and will be assessed at the time points specified in Table 2.

3.2.1.2 Physician`s Global Assessment (PGA)

The PGA provides an overall evaluation of the severity of the disease. The PGA is a 7-point physician's assessment of psoriasis that is a therapeutic standard in clinical studies for this disease.

Disease severity	Value given
Clear	0
Almost clear	1
Mild	2
Mild to moderate	3
Moderate	4
Moderate to severe	5
Severe	6

The PGA will be completed by the Investigator (or designee) at the time points specified in Table 2.

3.2.1.3 Assessment of body surface area (BSA)

The total surface area of the body affected with psoriasis plaques will be determined by the Investigator at the time points specified in Table 2. The investigator will calculate the approximate BSA by assuming that 1% BSA is approximately equal to the surface area of one outstretched hand (with fingers) of the patient [2]. Calculation should include psoriasis on the palms of the hands and soles of the feet as well as on the face and scalp.

The assessment of BSA by the Investigator serves to describe the change in % BSA affected by psoriasis after 12 weeks of treatment.

3.2.1.4 Primary efficacy variable(s)

The primary efficacy variables are:

1. 75% improvement (response) in their PASI score (PASI 75) and
2. Improvement (1 or more points on a 7 point scale) in their PGA score

The secondary efficacy variables are:

3. 50% improvement (response) in their PASI score (PASI 50)
4. Mean PASI score and change to baseline
5. Time to achieve PASI 50 and PASI 75
6. Mean score and change from baseline in the PGA
7. Mean score and change from baseline in the BSA
8. PK data

3.2.2 Safety variables

3.2.2.1 Adverse events

All noted complaints will be recorded with duration, intensity/severity, seriousness, probability of relatedness to the study preparation and outcome (see study protocol, section 7.3., Reporting/documentation of adverse events).

As it is the case for expedited reporting (see study protocol section 7.3.1) adverse events with a causal relationship to IMP described as “probable” or “possible” will like a “certain” causality be considered as “related” whereas an “unlikely” causality will be considered as “not related”, if applicable.

3.2.2.2 Laboratory variables

The following laboratory parameters will be collected at every visit (except serology):

Table 3 Laboratory Parameter per visit

Parameter	Screening	Day 1	Day 28 / 56	Day 84 (EoT)	Day 112 (FU)
Serology					
Hepatitis A IgG-antibody-test	X	--	--	--	--
Hepatitis A IgM-antibody-test	X	--	--	--	--
Hepatitis B core antibody-test	X	--	--	--	--
Hepatitis B surface antibody-test	X	--	--	--	--
Hepatitis B surface antigen-test	X	--	--	--	--
Hepatitis C virus antibody-test	X	--	--	--	--
HIV-1 antibody-test	X	--	--	--	--
HIV-2 antibody-test	X	--	--	--	--
Hematology					
RBC	X	X	X	X	X
WBC* including differential	X	X	X	X	X
Hemoglobin	X	X	X	X	X
Hematocrit	X	X	X	X	X

Parameter	Screening	Day 1	Day 28 / 56	Day 84 (EoT)	Day 112 (FU)
MCH	X	X	X	X	X
MCV	X	X	X	X	X
MCHC	X	X	X	X	X
Platelets	X	X	X	X	X
Clinical Chemistry					
AST (GOT)	X	X	X	X	X
ALT (GPT)	X	X	X	X	X
γGT	X	X	X	X	X
AP	X	X	X	X	X
Creatinine	X	X	X	X	X
Total bilirubin	X	X	X	X	X
CRP	X	X	X	X	X
hCG serum	X	--	--	--	--
Urine					
Urine dip stick test**	X	X	X	X	X

* including lymphocyte, neutrophils count, and eosinophils
** leukocytes, nitrite, pH, protein, glucose, ketones, urobilinogen, bilirubin, blood/hemoglobin

3.2.2.3 Pharmacokinetic variables

To evaluate systemic concentrations of MP1032 PK samples will be analyzed in a subgroup at selected trial sites, approximately 30 patients in total.

Blood will be collected before morning dose and 15, 30, 60 and 120 minutes after morning dose at visit 2 (Day 1, baseline) and at visit 5 (Day 84, end of treatment [EoT]). The date and time of the last application of IMP prior to the PK sample taken and the date and time of the PK sample will be documented in the electronic case report form (eCRF).

Samples will be analyzed at Prolytic GmbH, Frankfurt and the results of blood MP1032 concentration will be transferred to bioskin for statistical analysis.

3.2.2.4 Other safety variables

Physical examination focusing on the skin is done at screening, Day 1, Day 84, and at follow up visit (Day 112).

Vital signs (blood pressure and pulse rate) will be assessed at all visit days planned.

3.3 Analysis populations

3.3.1 Efficacy populations

Intent-To-Treat (ITT)

The full-analysis-set (FAS) will include all randomized patient who received at least one dose of IMP, and had at least one post-baseline assessment. The intention-to-treat (ITT) analysis will be based on the FAS. The FAS is considered primary analysis set for the efficacy analysis.

Per-Protocol (PP)

The valid-cases-set (VCS) will include all patients from the FAS, who completed the assessments of the co-primary endpoints without any protocol violation interfering with the precise evaluation of treatment efficacy and with sufficient exposure to IMP, i.e.

- who completed the visit 5 (Day 84) assessments of PASI and PGA;
- who did not take any prohibited concomitant medications up to the visit 5 (Day 84).

  During the blind data review meeting (BDRM) concomitant medications will be reviewed considering timing, duration of concomitant treatment, and influence on the efficacy assessments to determine prohibited medication usage that warrants exclusion from the VCS;
- who were compliant with the dosing regimen. A subject will be considered compliant, if the subject administered ≥ 80% of the planned capsules.

Subjects who prematurely discontinue the treatment due to an adverse event at least possibly related to IMP will not be excluded from the VCS.

Prior to breaking the blind, other additional criteria may be added to the list to accommodate for unforeseen events that occurred during the conduct of the trial that result in noteworthy study protocol violations.

The per-protocol (PP) analysis will be based on the VCS. Primary efficacy endpoints will be evaluated on VCS to assess the sensitivity.

3.3.2 Safety populations

Safety-evaluation-set (SES)

The safety-evaluation-set (SES) will include all patients who received any trial medication at least once; all safety analyses will be based on the SES.

Pharmacokinetic-evaluation-set (PKS)

All subjects without any protocol deviations that could interfere with the administration of the treatment or the evaluation of systemic concentrations of MP1032, who received at least one dose of IMP and who have any completed determination of MP1032 levels will be included in the pharmacokinetic-evaluation-set (PKS).

3.4 Statistical methods

Statistical analyses will be performed using two-sided tests, without adjustment for multiplicity. All p-values will be interpreted descriptively.

Data will be summarized by treatment group (and by visit when applicable), with respect to demographic and baseline characteristics, efficacy variables, and safety variables.

Summary statistics will include the mean, number of non-missing cases (n), standard deviation, median, minimum, and maximum values for continuous variables, and frequencies and percentages for categorical variables.

Categorical efficacy variables will be analyzed using the Cochran-Mantel-Haenszel (CMH) test with stratification by (pooled) analysis center and the Fisher's exact test in case of analyses without stratification (mainly for safety assessment).

Selected scores will be analyzed using an analysis of covariance (ANCOVA) model, with treatment group and (pooled) analysis center as factors and baseline outcome as covariate.

Time to event data will be analyzed using the Kaplan-Meier method, and treatment group differences will be tested by the log-rank test.

3.4.1 Demographics and baseline characteristics

Demographic data (age, sex, race) and background data (height, weight, BMI, years of psoriasis), including smoking and alcohol consumption, will be summarized using descriptive statistical methods by treatment group for the ITT, Safety, and PP populations. Years of psoriasis at screening visit will be determined with one decimal (see section 3.5.1).

3.4.2 Discontinuations and dropouts

Subjects discontinuing the study will be listed in the clinical study report with reason for discontinuation and last study day given.

A summary will be presented for the reason for discontinuation from the trial and for discontinuation from the treatment phase, i.e. discontinuation prior to Day 84/Week 12 visit.

3.4.3 Current medical conditions

Relevant medical history of the past five years and psoriasis history will be assessed at screening and will be classified on the basis of the Medical Dictionary for Regulatory Activities (MedDRA) (see section 3.5). Current medical conditions, i.e. medical conditions ongoing at first dosing, will be presented by system organ class (SOC) and preferred term (PT) for each treatment group in the FAS. In any given category (e.g., SOC) a subject will be counted only once. Descriptive summaries of subject's years of psoriasis will be presented (see section 3.4.1).

3.4.4 Prior and concomitant therapies

All concomitant medications, therapies and procedures taken in the 6 weeks before the first dose are collected. Previous and concomitant therapies (drug treatments und non-drug therapies) will be classified on the basis of the WHO Drug Dictionary Enhanced (see section 3.5). Medical procedures will be classified on the basis of MedDRA (see section 3.5).

Previous and concomitant therapies will be presented by WHO-drug Level 3 ATC categories (therapeutic/pharmacological subgroup) and preferred term for each treatment group in the FAS. In any given category (e.g., drug category) a subject will be counted only once.

Concomitant medical procedures will be listed with MedDRA SOC and PT.

3.4.5 Compliance

The % treatment compliance will be determined as the number of performed treatment applications in relation to the planned applications within the individual subjects treatment phase:

- total number of applications =
  # planned applications – # missed applications + # overdose applications
- % treatment compliance =
  100 * total number of applications / # planned applications

The % dosing compliance will be determined as the number of dosed capsules in relation to the number of planned capsules within the individual subjects treatment phase:

- total number of dosed capsules =
  6 * # planned applications – # missed capsules + # overdose capsules
- % dosing compliance =
  100 * total number of dosed capsules / (6 * # planned applications)

The % treatment compliance and % dosing compliance will be summarized by descriptive statistics and frequency counts will be given for sufficient (≥80%) and insufficient (<80%) compliance.

3.4.6 Efficacy analyses

3.4.6.1 Hypotheses

Since this is an exploratory trial no formal hypotheses are postulated. The data will be evaluated descriptively.

3.4.6.2 Statistical analyses

Primary efficacy endpoints

The co-primary endpoint response in PASI 75 at Week 12 (Day 84) is defined as 75% improvement in PASI score compared to baseline (i.e. percent of change from baseline ≤ 75%). The co-primary endpoint improvement in PGA at Week 12 (Day 84) is defined as reduction by 1 or more points on the PGA scale in comparison to baseline.

The comparisons of the treatment groups MP1032 300 mg bid and MP1032 150 mg bid, each vs. the placebo treatment, with respect to each, the PASI 75 rate and PGA improvement rate, at Week 12 (Day 84) will be evaluated by the CMH test stratified by (pooled) analysis center. The common odds-ratio with 95% confidence interval will be provided. The homogeneity of the individual odds-ratios will be assessed by the Breslow-Day test.

Secondary efficacy endpoints

Secondary efficacy endpoints will be evaluated descriptively. The methodology outlined at the top of this section 3.4.6.2 will be applied for pairwise treatment comparisons vs. placebo:

The PASI 50 responder rate at Week 12 (Day 84) will be evaluated according to the primary efficacy endpoints, as well as the PASI 75, PASI 50 and PGA improvement at Week 4 (Day 28) and Week 8 (Day 56) of the treatment phase and at follow-up, 4 weeks after end of treatment.

The change in the PASI score from baseline to each post baseline visit, respectively, will be evaluated using an analysis of covariance (ANCOVA) model, with treatment group and (pooled) analysis center as factors and baseline outcome as covariate, in both analysis sets, FAS and VCS.

The time to achievement of PASI 50 and PASI 75, respectively, will be evaluated using the Kaplan-Meier method. The study day of first achievement of PASI 50 and PASI 75, respectively, will be the considered event, with study day of last assessment as the time point of censoring, in case of no occurrences of PASI 50 or PASI 75. Pairwise treatment group differences will be tested by the log-rank test.

Location shift in change from baseline in PGA will be assessed using Hodges-Lehmann Estimation with comparison by the Wilcoxon rank sum test, in both analysis sets, FAS and VCS.

Descriptive summaries will be provided for each parameter by treatment group and by visit, if applicable. Percentages will be provided based on the number of non-missing cases, if not otherwise stated. For PASI and PGA the descriptive summaries will be performed in both analysis sets, FAS and VCS.

Subgroup analyses

The following subgroups, based on baseline parameter, will be evaluated with respect to the primary efficacy variables PASI and PGA for each post-baseline visit within the FAS:

Table 4 Subgroups

Center:	• Analysis (pooled) centers		
Age:	• 18 to 40	• >40	
Sex:	• Male	• Female	
BMI:	• ≤ 24.9 (normal)	• 25.0 - 29.9 (pre-obesity)	• ≥ 30.0 (obesity)
Years of psoriasis:	• 1 to 10	• >10	
Smoking	• Current	• Never or former	
Cigarette smoking:	• <1 to 10	• >10	
PGA:	• 3 to 4	• 5 to 6	
PASI:	• ≤ 15	• > 15	
CRP:	• <10 mg/dl	• ≥ 10 mg/dl	

The change in PASI and PGA will be evaluated utilizing following analyses:

- mean change from baseline in PASI by ANCOVA model
- location shift in change from baseline in PGA by Wilcoxon rank sum test and Hodges-Lehmann Estimation

If applicable, the analyses will be stratified by country.

3.4.7 Safety analyses

3.4.7.1 Adverse events

All AEs reported during the trial will be listed, documenting course, severity, investigator assessment of the relationship to the IMPs, and outcome. AEs will be coded using the MedDRA mapping system for PTs and SOC.

TEAEs, i.e. AEs with an onset (or worsening) on or after the time of the first IMP application will be summarized by the number of TEAEs and number (percent) of patients reporting TEAEs by primary SOC, PT, severity, and relationship to IMP. When summarizing TEAEs by severity or relationship to IMP, each subject will be counted once within a SOC or a PT by using the event with the greatest severity or with the strongest relationship to IMP, respectively, within each category.

Listings of serious adverse events (SAE) and patients who prematurely discontinued treatment due to AEs will be given.

3.4.7.2 Laboratory analyses

All safety laboratory parameters of hematology and clinical chemistry, as scheduled in Table 3, will be summarized descriptively, including their changes from baseline (see section 3.1). Shift tables of low, normal and high outcomes, determined with respect to the normal ranges, will be presented for each post-baseline visit, in comparison to the baseline outcome. Incidence of any clinically significant outcome, i.e. number of subjects having any clinically significant outcome during the trial will be presented for each laboratory parameter.

Urinalysis outcomes will be summarized by frequency counts and by shift tables of normal and abnormal outcomes. Incidence of clinically significant urinalysis parameter will be presented.

Individual subject's listings of all assessed safety laboratory parameters, scheduled or unscheduled, will be provided.

3.4.7.3 Pharmacokinetic analyses

Blood MP1032 concentration-time data for both MP1032 treatment groups in the PKS will be listed, summarized and displayed graphically, including the nominal and actual blood sampling time relative to the corresponding IMP administration time.

Summary statistics of MP1032 levels by nominal sampling time will be provided with following summary statistics for each nominal sampling time: geometric mean, geometric standard deviation (re-transformed standard deviation of the logarithms) and geometric coefficient of variation (CV), arithmetic mean, standard deviation, CV, minimum, median, maximum value and the number of measurements.

Generally, summary statistics will only be presented if at least 6 quantifiable outcomes are available, i.e. if at least 6 concentrations were above the lower limit of quantification (LLQ). For the calculation of the summary statistics, pre-dose/through levels below LLQ will be substituted by zero and post-dose levels will be substituted by LLQ/2.

Individual and mean concentration versus time curves of M1032 concentration (using the actual sampling times for individual plots and the planned sampling times for mean plots) will be plotted by treatment. Plots of geometric means on linear concentration scale and of geometric means on semilogarithmic scale with will be presented.

Based on the concentration-time data the following non-compartmental analysis (NCA) parameter will be derived for both visits separately:

- C_{max}: Maximum MP1032 concentration observed
- t_{max}: Time point (effective) at which the C_{max} is observed
- $AUC_{(0,t)}$: Area under the concentration-time curve (AUC) up to the last quantifiable sample drawn.

The AUC will be approximated using the trapezoid formula and calculated with the effective time points 0, … t. The pre-dose value will be defined as 0 for calculation of $AUC_{(0,t)}$ and missing intermediate concentrations will be excluded from the calculations.

Pharmacokinetic characteristics will be listed and summarized by the statistics mentioned above in the PKS for each treatment and visit. The parameter t_{max} will be described utilizing minimum, maximum and median.

3.4.7.4 Other safety analyses

Vital signs will be summarized descriptively, including changes from baseline. Shift tables of normal and abnormal outcomes and incidence of clinically significant vital sign parameter will be presented.

Findings in the physical examination will be listed.

3.4.7.5 Extent of exposure to study drug

The overall extent of exposure to study drug will be summarized by

- total number of applications =
  # planned applications – # missed applications + # overdose applications
- total number of dosed capsules =
  6 * # planned applications – # missed capsules + # overdose capsules
- average number of capsules per application =
  total number of dosed capsules / total number of applications

- duration of the treatment (days of treatment) =
  duration from first dose to last dose in days, start and end day included.
- average number of capsules per day =
  total number of dosed capsules / days of treatment
- % exposure =
  100 * total number of dosed capsules / (84 * 2 * 6)

For each treatment descriptive statistics will be given. Duration of treatment will additionally be presented by a frequency table for categorized numbers of days (less than 26 days, 26 to 53 days, 54 to 83 days, 84 days and more) and % exposure will be presented by exposure of less than 80% and 80% and more. .

3.5 Data handling conventions

In general, data from the source documents will be captured in an eCRF by a software package that can be customized for remote data entry procedure and that maintains an electronic audit trail. The eCRFs will be developed in the EDC system in accordance with bioskin SOPs under supervision and in agreement with the sponsor. The database structure will be validated.

Only authorized site personnel will be able to enter/modify/correct data to the eCRF. The investigator/coordinator or designee must enter the information required by the protocol as soon as possible after the visit into the eCRF.

The data will be checked for consistency. Queries for discrepant data may be generated automatically by the system upon entry or generated manually by the monitor or the trial data manager. All queries, whether generated by the system or by a user, will be in an electronic format. Once all the queries are closed and data have been verified by the CRA, the eCRF will be signed (eSignature) by the investigator and the database will be locked.

All data management procedures will be detailed in a separate, specifically identified file that collectively will be referenced as the data management plan (DMP).

Adverse event, medical history terms, and procedures from the concomitant medications page will be coded using the MedDRA dictionary (Version 20.1 from September 2017) according to the ICH MedDRA Term Selection: Points to Consider release 4.14 from September 2017. All MedDRA coded terms will be provided with all 5 levels, from System Organ Class to Lowest level term, including associated codes.

Previous and concomitant medication and non-drug therapies will be coded using the WHO Drug Global Dictionary in its latest available version at the time point of coding. Product Name, Preferred Base Name, Drug Code and ATC Levels 1-4 with associated codes will be reported.

The locked SAS Database will be used to generate the subject listings, tabulations, and analyses.

All data associated with the clinical database, including eCRF data, all external data such as medical coding, third party data, and others i.e. randomization unblinding, analysis population definition, all transferred to study data tabulation model (CDISC SDTM, v1.4; IG v3.2). The SDTM data sets will be used to generate analysis data model (CDISC ADaM, v2.1; IG v1.1) data sets, subject listings, tabulations, and analyses.

3.5.1 Missing data

A description of missing data will be provided in the clinical study report.

For the evaluation of success rates of the primary efficacy variables PASI and PGA missing PGA assessments and/or any parts of the PASI assessments will be evaluated as failure to achieve improvement.

For descriptive analyses of PASI, PGA and BSA the last observation carried forward (LOCF) principle will be applied to impute the missing assessments, up to the Day 84 visit. Follow-up assessments will not be imputed.

Sensitivity of the primary efficacy analyses will be evaluated applying PP analyses.

Regarding incomplete recordings for adverse events the following rules apply:

- For start and stop dates no imputation will be applied. If any, start or stop date, is not complete, but required for the classification, i.e. the occurrence of the AE is not explicitly reported as occurring prior first dose (see eCRF), the AE will be considered treatment emergent.
- Missing assessments of severity, intensity and causal relationship to the IMP will be reported as a separate category.

For the determination of the number of years from start of psoriasis to the screening visit missing starting days will be imputed by the first day of month and missing months will be imputed by the first month (January) of the year.

For concomitant therapies (see section 3.2.2.4) incomplete dates will not be imputed. If an incomplete start or stop date does not allow for the classification as prior and/or concomitant therapy - despite of information in eCRF if taken/used prior to first dosing and/or if ongoing at first dosing - the treatment will be reported as prior and as concomitant therapy.

Pharmacokinetic data below LLQ will be replaced as described in 3.4.7.3 for descriptive statistics and for the derivation of $AUC_{(0,t)}$. Missing pre-dose levels will be imputed by zero. Missing intermediate samples, i.e. missing values in between non-missing levels (quantifiable or substituted by LLQ/2) will be imputed by linear interpolation between the last preceding and the next following available value. The last value will be imputed by LLQ/2, if missing.

3.5.2 Window for time points

A strict adherence to the visit schedule will be required. Visit schedule violations will be documented as protocol deviations and assessed within the BDRM.

Assessments performed out of the planned visit schedule will be assigned to the nearest, directly preceding or following planned visit, if that visit is missing. If both planned visits are missing and the distances are equal, the assignment is performed to the following one. Otherwise an assessment performed out of the planned visit schedule will not be included in the statistical evaluation and will be listed only.

3.5.3 Unscheduled visits

If applicable, the reason for unscheduled visit assessments will be given together with the results. For the statistical analysis the unscheduled assessments will be assigned as described in section 3.5.2.

In case of premature withdrawal from the trial, efficacy assessments performed at the time point of withdrawal, will be assigned to a planned visit as described in section 3.5.2.

Safety assessments performed at the time point of withdrawal will be reported together with the last visit in treatment phase (Day 84 / End of Treatment [EoT]).

3.5.4 Pooling of centers for statistical analyses

For the purpose of statistical analyses of efficacy, a small center is defined as a center with less than 3 VCS subjects in at least one treatment arm (MP1032 150 mg bid arm, MP1032 300 mg bid arm or the Vehicle Lotion arm). Small centers will be pooled in the order of the total number of VCS subjects in each center, from smallest to largest, until all centers have at least 3

VCS subjects in each treatment arm. A small center will be pooled with the next center (small or not) in the fixed order given in the beginning of pooling. In case of equally sized centers the center with the lower center number will be considered as smaller. The pooling will be performed for German and Polish centers, separately.

3.5.5 Statistical technical issues

Not applicable.

3.5.6 Database related issues

Not applicable.

4 Interim analysis

Not applicable.

5 Software documentation

The statistical evaluation will be performed at bioskin using the software package SAS (Statistical Analysis System, SAS Inc., Cary, NC).

6 References

[1] Nast A. Boehncke WH. Mrowietz U et al. S3-Leitlinie zur Therapie der Psoriasis vulgaris Update 2011. JDDG; 2011; 9 (Suppl. 2):S1-S104.

[2] EMA Guideline on Psoriasis. Guideline on Clinical Investigation of Medicinal Products Indicated for the Treatment of Psoriasis. Issued by the European Medicines Agency, London, 18 November 2004. Accessed 27 Jan 2016.

Statistical Analysis Plan - Appendix

A Phase II, Multicenter, Double-blind, Placebo-controlled, Efficacy and Safety Study of Two Oral Doses (150 mg bid / 300 mg bid) of MP1032 in Male and Female Patients with Moderate-to-Severe Chronic Plaque Psoriasis.

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SIGNATURE PAGE

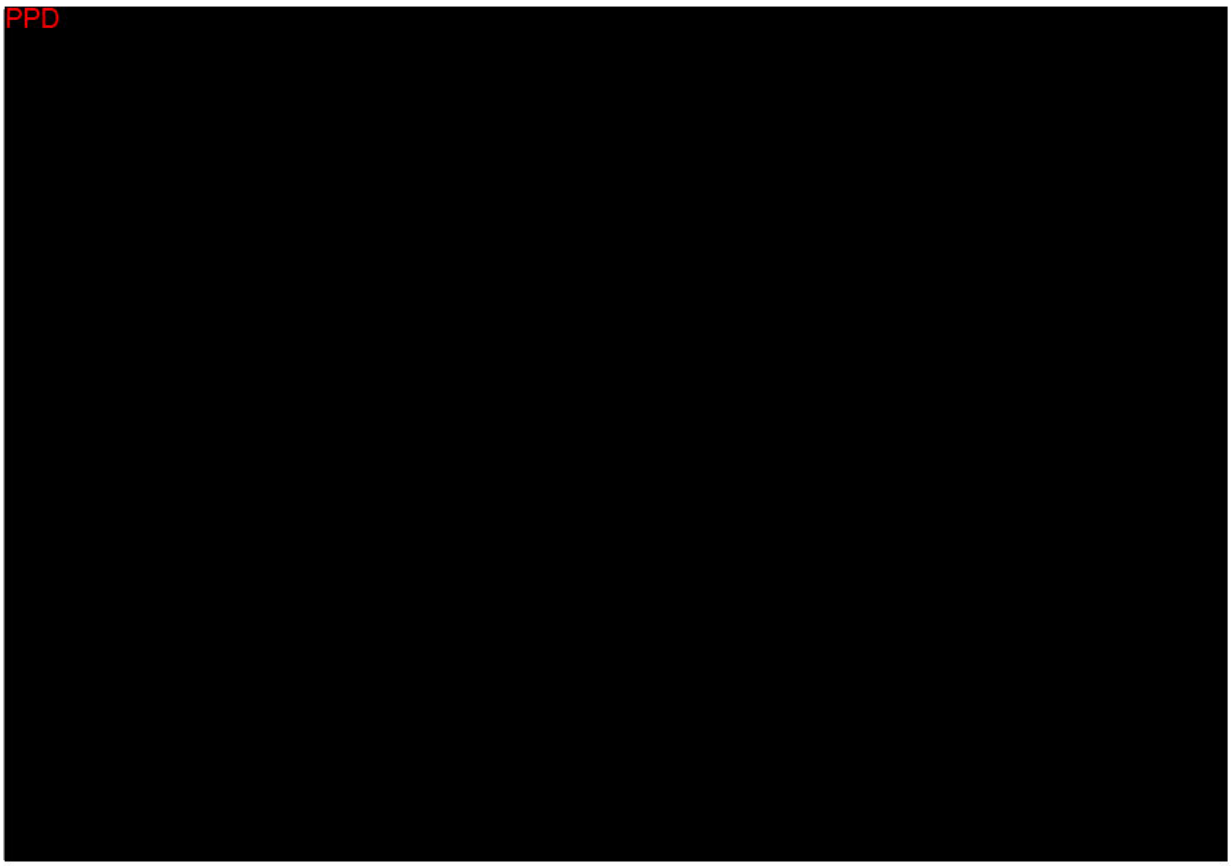

Table of Contents

Abbreviations and Definitions

AE	adverse event
ATC	anatomical therapeutic chemical
ANCOVA	analysis of covariance
bid	twice daily
BLQ	below level of quantification
BMI	body mass index
BSA	body surface area
C_{max}	maximum MP1032 concentration observed
CMH	Cochran-Mantel-Haenszel
EoT	end of treatment
FAS	full analysis set
IMP	investigational medical product
LLQ	lower level of quantification
LOCF	last observation carried forward
Max	maximum
MedDRA	Medical Dictionary for Regulatory Activities
Min	Minimum
PASI	psoriasis area severity index
PGA	physician's global assessment
PKS	pharmacokinetic evaluation set
SD	standard deviation
SE	Standard error of means
SES	safety evaluation set
SOC	system organ class
TEAE	treatment-emergent adverse event
t_{max}	time point at which the C_{max} is observed
VCS	valid cases set
WHO	World Health Organization

Table 14.1.1: Subject enrollment and evaluability
(Part 1 of 5)

	MP1032 300 mg bid	MP1032 150 mg bid	Placebo bid	Total
Total				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in FAS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in VCS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
01 - Universitaetsmedizin Mainz				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in FAS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in VCS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
03 - CentroDerm GmbH				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in FAS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in VCS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
04 - MensingDerma research GmbH				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in FAS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in VCS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

SES: safety evaluation set; FAS: full-analysis-set; VCS: valid-cases-set; PKS: pharmacokinetic-evaluation-set
[1] Percentages calculated on number of subjects randomized

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.1.1: Subject enrollment and evaluability
(Part 2 of 5)

	MP1032 300 mg bid	MP1032 150 mg bid	Placebo bid bid	Total
05 - Rothhaar Studien				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in FAS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in VCS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
06 - Klinische Forschung Dresden GmbH				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in FAS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in VCS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
08 - Hautzentrum im Jahrhunderthaus				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in FAS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in VCS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
09 - Fachklinik Bad Bentheim				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in FAS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in VCS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

SES: safety evaluation set; FAS: full-analysis-set; VCS: valid-cases-set; PKS: pharmacokinetic-evaluation-set
[1] Percentages calculated on number of subjects randomized

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.1.1: Subject enrollment and evaluability
(Part 3 of 5)

	MP1032 300 mg bid	MP1032 150 mg bid	Placebo bid	Total
10 - Klinische Forschung Schwerin GmbH				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in FAS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in VCS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
11 - Kliniczny Szpital Wojewodzki nr 1, Klinika Dermatologii				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in FAS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in VCS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
12 - MULTIKLINIKA SALUTE Sp. z o. o.				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in FAS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in VCS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
13 - Provita Sp. z o.o				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in FAS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in VCS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

SES: safety evaluation set; FAS: full-analysis-set; VCS: valid-cases-set; PKS: pharmacokinetic-evaluation-set
[1] Percentages calculated on number of subjects randomized

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.1.1: Subject enrollment and evaluability
(Part 4 of 5)

	MP1032 300 mg bid	MP1032 150 mg bid	Placebo bid	Total
14 - Laser Clinic s.c. Andrzej Krolicki, Tomasz Kochanowski				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in FAS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in VCS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
15 - dermMedica Sp. z o.o.				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in FAS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in VCS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
16 - CENTRUM MEDYCZNE PLEJADY Sp. z o. o. spolka komandytowa				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in FAS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in VCS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
17 - Dermedic Jacek Zdybski				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in FAS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in VCS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

SES: safety evaluation set; FAS: full-analysis-set; VCS: valid-cases-set; PKS: pharmacokinetic-evaluation-set
[1] Percentages calculated on number of subjects randomized

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.1.1: Subject enrollment and evaluability
(Part 5 of 5)

	MP1032 300 mg bid	MP1032 150 mg bid	Placebo bid	Total
18 - Dermoklinika Centrum Medyczne s.c. M.Kierstan, J.Narbutt, A.Lesiak				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in FAS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in VCS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
19 - GynCentrum Sp. Z o.o.				
Number of subjects screened	XX	XX	XX	XX
Number of subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects included in SES[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in FAS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in VCS[1]	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
Subjects included in PKS[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

SES: safety evaluation set; FAS: full analysis set; VCS: valid cases set; PKS: pharmacokinetic evaluation set
[1] Percentages calculated on number of subjects randomized

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.1.2: Subject completion / discontinuation (Not randomized subjects)
(Part 1 of 1)

	Total
Subjects screened	N = XXX
Subjects not randomized	XXX (XXX.X%)
Screening failures[1]	XXX (XXX.X%)
Associated reasons for not randomized	
Not all inclusion criteria met	XXX (XXX.X%)
At least one exclusion criterion met	XXX (XXX.X%)
Withdrawal by subject	XXX (XXX.X%)
Other	XXX (XXX.X%)

[1] Subjects not meeting all inclusion criteria or meeting any exclusion criteria.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.1.3: Subject completion / discontinuation (Randomized subjects)
(Part 1 of 2)

	MP1032 300 mg bid	MP1032 150 mg bid	Placebo bid	Total
Subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects with trial completion on Week 16 / Follow up	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects with premature discontinuation before Week 16 / Follow up	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Reasons for trial discontinuation before Week 16 / Follow up				
Adverse event	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Death	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Lost to follow-up	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Non-compliance with study drug	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Physician decision	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Pregnancy	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Protocol-defined stopping criteria	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Protocol deviation	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Site terminated by sponsor	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Study terminated by sponsor	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Withdrawal by subject	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Other	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

EoT: End of treatment.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.1.3: Subject completion / discontinuation (Randomized subjects
(Part 2 of 2)

	MP1032 300 mg bid	MP1032 150 mg bid	Placebo bid	Total
Subjects randomized	N = XX	N = XX	N = XX	N = XX
Subjects with trial completion on Week 12 / EoT[1]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects discontinued before Week 12 / EoT[2]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Reasons for trial discontinuation before Week 12 / EoT				
Adverse event	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Death	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Lost to follow-up	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Non-compliance with study drug	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Physician decision	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Pregnancy	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Protocol-defined stopping criteria	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Protocol deviation	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Site terminated by sponsor	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Study terminated by sponsor	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Withdrawal by subject	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Other	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

EoT: End of treatment.
[1] Week 12/EoT visit of PASI within the time range 80 ≤ study day ≤ 91 and exposure ≥ 80% planned exposure
[2] Week 12/EoT visit of PASI at a study day ≤ 79 or exposure < 80% planned exposure

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.1.4: Excluded subjects from the analysis populations (Randomized subjects)
(Part 1 of 1)

	MP1032 300 mg bid	MP1032 150 mg bid	Placebo bid	Total
Number of randomized subjects	N = XX	N = XX	N = XX	N = XX
Subjects excluded from the SES	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Primary exclusionary reason / protocol deviation[1]				
Subject did not receive any IMP	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects excluded from the FAS	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Primary exclusionary reason / protocol deviation[1]				
Subject did not receive any IMP	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subject has no post-baseline assessment	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects excluded from the VCS	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Primary exclusionary reason / protocol deviation[1]				
Subject did not receive any IMP	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subject has no post-baseline assessment	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subject took interfering concomitant medication	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subject did not complete Week 12 visit (EoT)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subject not compliant with dosing regimen[2]	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Other major protocol deviations	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subjects excluded from the PKS	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Primary exclusionary reason / protocol deviation[1]				
Subject did not receive any IMP	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subject has no completed determination of MP1032 levels	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Subject took interfering concomitant medication	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Other major protocol deviations	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

[1] In case of multiple deviations, only the primary exclusionary reason / protocol deviation is counted;
[2] Subjects who had less than 80% of the expected oral doses.
Exception: Treatment related discontinuations, i.e. discontinuations due to adverse events at least possibly related to IMP.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.2.1: Subject demographics (SES)
(Part 1 of 1)

	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)	Total (N = XX)
Age [years]				
N	XX	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX X	XX X	XX X	XX X
Min , max	XX , XX	XX , XX	XX , XX	XX , XX
Sex				
N	XX	XX	XX	XX
Male	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Female	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Race				
N	XX	XX	XX	XX
American Indian or Alaska Native	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Asian	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Black or African American	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Multiple Races	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Native Hawaiian or Other Pacific Islander	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
White	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Other	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.2.2: Subject demographics (FAS)
Analog to Table 14.2.1 for FAS

Table 14.2.3: Subject demographics (VCS)
Analog to Table 14.2.1 for VCS

Table 14.2.4: Subject demographics (PKS)
Analog to Table 14.2.1 for PKS

Table 14.2.5: Subject baseline characteristics (SES)
(Part 1 of 1)

	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)	Total (N = XX)
Height [cm]				
N	XX	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX X	XX X	XX X	XX X
Min , max	XX , XX	XX , XX	XX , XX	XX , XX
Weight [kg]				
N	XX	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X	XX.X
Min , max	XX , XX	XX , XX	XX , XX	XX , XX
BMI [kg/m²]				
N	XX	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X	XX.X
Min , max	XX , XX	XX , XX	XX , XX	XX , XX

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.2.6: Subject baseline characteristics (FAS)
Analog to Table 14.2.5 for FAS

Table 14.2.7: Subject baseline characteristics (VCS)
Analog to Table 14.2.5 for VCS

Table 14.2.8: Subject baseline characteristics (PKS)
Analog to Table 14.2.5 for PKS

Table 14.2.9: Baseline psoriasis (SES)
(Part 1 of 1)

	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)	Total (N = XX)
Psoriasis history [years]				
N	XX	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX X	XX X	XX X	XX X
Min , max	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
PASI				
N	XX	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X	XX.X
Min , max	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
PGA				
N	XX	XX	XX	XX
0 – Clear	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
1 – Almost clear	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
2 – Mild	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
3 – Mild to moderate	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
4 – Moderate	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
5 – Moderate to severe	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
6 – Severe	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.2.10: Baseline psoriasis (FAS)
Analog to Table 14.2.9 for FAS

Table 14.2.11: Baseline psoriasis (VCS)
Analog to Table 14.2.9 for VCS

Table 14.2.12: Baseline psoriasis (PKS)
Analog to Table 14.2.9 for PKS

Table 14.2.13: Alcohol Consumption: Average glasses per day (SES)
(Part 1 of 1)

	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)	Total (N = XX)
Beer (up to 5% alcohol) gla e (200 mL)				
N	XX	XX	XX	XX
< 0 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< <1 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< ≥1 - <2 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< ≥2 - <3 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
…	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< ≥10 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Unknown >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Wine, wine-based (up to 12% alcohol) glasses (200 mL)				
N	XX	XX	XX	XX
< 0 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< <1 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< ≥1 - <2 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< ≥2 - <3 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
…	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< ≥10 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Unknown >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Liqueur (15-40% alcohol) glasses (200 mL)				
N	XX	XX	XX	XX
< 0 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< <1 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
…	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< ≥10 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Unknown >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Spirits (up to 40% alcohol and more) glasses (200 mL)				
N	XX	XX	XX	XX
< 0 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< <1 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
…	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< ≥10 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Unknown >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

PROGRAMMING: ONLY REPORTED OUTCOMES ARE PRESENTED

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.2.14: Alcohol Consumption: Average glasses per day (FAS)
Analog to Table 14.2.13 for FAS

Table 14.2.15: Alcohol Consumption: Average glasses per day (VCS)
Analog to Table 14.2.13 for VCS

Table 14.2.16: Alcohol Consumption: Average glasses per day (PKS)
Analog to Table 14.2.13 for PKS

Table 14.2.17: Smoking history and tobacco use (SES)
(Part 1 of 1)

	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)	Total (N = XX)
Status of habitual cigarette smoking[1]				
N	XX	XX	XX	XX
Never	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Former	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Current	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Unknown	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Number of cigarettes[1]				
N	XX	XX	XX	XX
< 1	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
1 - 10	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
11 - 20	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
21 - 40	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
> 40	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Other habitual tobacco use[2]				
N	XX	XX	XX	XX
Pipe	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Cigar	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Cigarillo	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Other tobacco	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

[1] Smoking status for the last 6 months prior to Visit 1. Current: if any cigarettes were smoked during this time period.
[2] Other habitual tobacco use, if any were smoked during the last 6 months.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.2.18: Smoking history and tobacco use (FAS)
Analog to Table 14.2.17 for FAS

Table 14.2.19: Smoking history and tobacco use (VCS)
Analog to Table 14.2.17 for VCS

Table 14.2.20: Smoking history and tobacco use (PKS)
Analog to Table 14.2.17 for PKS

Table 14.2.21: Current medical conditions (SES)
(Part 1 of 1)

Current medical conditions[1] **Incidence[2] (Incidence rate%[3])**	**MP1032 300 mg bid** **(N = XX)**	**MP1032 150 mg bid** **(N = XX)**	**Placebo bid** **(N = XX)**	**Total** **(N = XX)**
Subjects with any medical condition	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
System Organ Class[5] / Preferred Term				
< SOC >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< SOC >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< SOC >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

[1] Medical conditions ongoing at first dosing
[2] Incidence determined as the number of subjects with any respective MedDRA category (system organ class or preferred term).
[3] Incidence rate is determined as the incidence divided by the number of subjects at risk, i.e. size of the SES
[4] Coded using WHO MedDRA dictionary (Version 21.0 from March 2018).

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.2.22: Prior medications or therapies (SES)
(Part 1 of 1)

Prior medications or therapies[1] **Incidence[2] (Incidence rate%[3])**	**MP1032 300 mg bid** **(N = XX)**	**MP1032 150 mg bid** **(N = XX)**	**Placebo bid** **(N = XX)**	**Total** **(N = XX)**
Subjects with any prior medication or therapy	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
ATC Level 3 / Preferred term[4]				
< ATC Level 3 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< ATC Level 3 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< ATC Level 3 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< No Preferred term specified >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< No ATC Level 3 specified >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< No Preferred term specified >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

[1] Medication or therapy taken prior to start of first IMP dosing.
[2] Incidence is determined as the number of subjects with any respective concomitant medication, therapy, ATC level or preferred term
[3] Incidence rate is determined as the incidence divided by the number of subjects at risk, i.e. size of the SES
[4] Coded using WHO Coded using WHO MedDRA dictionary (Version 21.0 from March 2018).

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.2.23: Concomitant medications or therapies (SES)
(Part 1 of 1)

Concomitant medications or therapies[1] **Incidence[2] (Incidence rate%[3])**	**MP1032 300 mg bid** **(N = XX)**	**MP1032 150 mg bid** **(N = XX)**	**Placebo bid** **(N = XX)**	**Total** **(N = XX)**
Subjects with any concomitant medication or therapy	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)	XXX (XXX.X%)
ATC Level 3 / Preferred term[4]				
< ATC Level 3 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< ATC Level 3 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< ATC Level 3 >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< Preferred term >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< No Preferred term specified >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< No ATC Level 3 specified >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
< No Preferred term specified >	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

[1] Medications or therapies present after the first IMP dosing
[2] Incidence is determined as the number of subjects with any respective concomitant medication, therapy, ATC level or preferred term
[3] Incidence rate is determined as the incidence divided by the number of subjects at risk, i.e. size of the SES
[4] Coded using WHO Coded using WHO MedDRA dictionary (Version 21.0 from March 2018).

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.3.1: Treatment compliance (SES)
(Part 1 of 1)

	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
Total number of planned applications			
N	XXX	XXX	XXX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X
Min , max	XX , XX	XX , XX	XX , XX
% Treatment compliance[1]			
N	XX	XX	XX
Mean ± SD	XXX.X ± XXX.X	XXX.X ± XXX.X	XXX.X ± XXX.X
Median	XXX.X	XXX.X	XXX.X
Min , max	XXX , XXX	XXX , XXX	XXX , XXX
Insufficient (< 80%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Sufficient (≥ 80%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
% Dosing compliance[2]			
N	XX	XX	XX
Mean ± SD	XXX.X ± XXX.X	XXX.X ± XXX.X	XXX.X ± XXX.X
Median	XXX.X	XXX.X	XXX.X
Min , max	XXX , XXX	XXX , XXX	XXX , XXX
Insufficient (< 80%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Sufficient (≥ 80%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

[1] % Treatment compliance = 100 * # applications / # planned applications, with # applications = # planned applications – # missed applications + # overdose applications.
[2] % Dosing compliance = 100 * # dosed capsules / (6 * # planned applications), with # dosed capsules = 6 * # planned applications – # missed capsules + # overdose capsules

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.3.2: PASI – Descriptive statistics – LOCF (FAS)
(Part 1 of 2)

PASI – LOCF (FAS)	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
Day 1 / Baseline[1]			
N	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX X	XX X	XX X
Min , max	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
Week 4			
N	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X
Min , max	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
Change from Baseline[1]			
N	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X
Min , max	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
Week 8			
N	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X
Min , max	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
Change from Baseline[1]			
N	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X
Min , max	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X

[1] Baseline: Last observation collected prior to first dose of any IMP, i.e. Day 1 assessment or, if missing, Screening assessment.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.3.2: PASI – Descriptive statistics – LOCF (FAS)
(Part 2 of 2)

PASI – LOCF (FAS)	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
Day 1 / Baseline[1]			
N	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX X	XX X	XX X
Min , max	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
Week 12 / EoT			
N	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X
Min , max	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
Change from Baseline[1]			
N	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X
Min , max	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
Week 16 / Follow-up			
N	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X
Min , max	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
Change from Baseline[1]			
N	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X
Min , max	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X

[1] Baseline: Last observation collected prior to first dose of any IMP, i.e. Day 1 assessment or, if missing, Screening assessment.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Figure 14.1: PASI – Lineplot: Mean values by treatment over time – LOCF (FAS)
Mean values per visit and treatment (visits on x-axis)

Figure 14.2: PASI – Lineplot: Mean change from baseline by treatment over time – LOCF (FAS)
Mean change from baseline per visit and treatment (visits on x-axis)

Table 14.3.3: PASI – PASI 75 responders – LOCF (FAS)
(Part 1 of 2)

PASI 75[1] – LOCF	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
Week 4			
N	XX	XX	XX
Responder	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Non re ponder	XX (XXX X%)	XX (XXX X%)	XX (XXX X%)
Comparison vs Placebo[2]			
p-value	X.XXX	X.XXX	--
Odds ratio	X.XX	X.XX	--
Confidence interval	X.XX, X.XX	X.XXX	--
Breslow-Day test[3]	X.XXX	X.XXX	--
Week 8			
N	XX	XX	XX
Responder	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Non-responder	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Comparison vs Placebo[2]			
p-value	X.XXX	X.XXX	--
Odds ratio	X.XX	X.XX	--
Confidence interval	X.XX, X.XX	X.XXX	--
Breslow-Day test[3]	X.XXX	X.XXX	--
Week 12 / EoT			
N	XX	XX	XX
Responder	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Non-responder	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Comparison vs Placebo[2]			
p-value	X.XXX	X.XXX	--
Odds ratio	X.XX	X.XX	--
Confidence interval	X.XX, X.XX	X.XXX	--
Breslow-Day test[3]	X.XXX	X.XXX	--

[1] 75% improvement in PASI score
[2] Cochran-Mantel-Haenszel (CMH) test: p-value for the hypothesis, that all within-stratum odds ratios equal to 1 and estimate of the common odds ratio with 95% confidence interval
[3] p-value of Breslow-Day test for the hypothesis that all individual odds-ratios are equal

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.3.3: PASI – PASI 75 responders – LOCF (FAS)
(Part 2 of 2)

PASI 75[1] – LOCF	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
Week 16 / Follow up			
N	XX	XX	XX
Responder	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Non-responder	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Comparison vs Placebo[2]			
p-value	X.XXX	X.XXX	--
Odds ratio	X.XX	X.XX	--
Confidence interval	X.XX, X.XX	X.XXX	--
Breslow-Day test[3]	X.XXX	X.XXX	--

[1] 75% improvement in PASI score
[2] Cochran-Mantel-Haenszel (CMH) test: p-value for the hypothesis, that all within-stratum odds ratios equal to 1 and estimate of the common odds ratio with 95% confidence interval
[3] p-value of Breslow-Day test for the hypothesis that all individual odds-ratios are equal

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.3.4: PASI – PASI 50 responsers – LOCF (FAS)
Analog to Table 14.3.3 for PASI 50

Table 14.3.5: PASI – Time to PASI 75 (FAS)
(Part 1 of 1)

Time to PASI 75	MP1032 300 mg bid (N = XX)		MP1032 150 mg bid (N = XX)		Placebo bid (N = XX)	
	PASI 75 reached	Censored	PASI 75 reached	Censored	PASI 75 reached	Censored
Week 4	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Week 8	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Week 12/ EoT	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Week 16 / Follow up	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Kaplan-Meier estimator (95%-CI)[1]	XX (XX, XX)		XX (XX, XX)		XX (XX, XX)	
Comparison vs Placebo (Log-rank test p-value)	X.XXXX		X.XXXX		--	

[1] Kaplan–Meier estimate of the median time [day] to reach the PASI 75 criterion. The study day of first achievement of PASI 75 considered, with study day of last assessment as the time point of censoring, in case of no occurrences of PASI 75.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.3.6: PASI – Time to PASI 50 (FAS)
Analog to Table 14.3.5 for the time to achieve PASI 50

Table 14.3.7: PASI – ANCOVA for change from baseline – LOCF (FAS)
(Part 1 of 2)

PASI changes from baseline	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
Week 4			
N	XX	XX	XX
Mean ± SE[1]	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
95%-CI[1]	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
Comparison vs Placebo			
Estimate ± SE[1]	XX.X ± XX.X	XX.X ± XX.X	--
95%-CI[1]	XX.X , XX.X	XX.X , XX.X	--
p-value[1]	X.XXX	X.XXX	--
Week 8			
N	XX	XX	XX
Mean ± SE[1]	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
95%-CI[1]	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
Comparison vs Placebo			
Estimate ± SE[1]	XX.X ± XX.X	XX.X ± XX.X	--
95%-CI[1]	XX.X , XX.X	XX.X , XX.X	--
p-value[1]	X.XXX	X.XXX	--
Week 12 / EoT			
N	XX	XX	XX
Mean ± SE[1]	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
95%-CI[1]	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
Comparison vs Placebo			
Estimate ± SE[1]	XX.X ± XX.X	XX.X ± XX.X	--
95%-CI[1]	XX.X , XX.X	XX.X , XX.X	--
p-value[1]	X.XXX	X.XXX	--

[1] Estimates and treatment comparison of least square means using an ANCOVA model, with treatment group and (pooled) analysis center as factors and baseline outcome as covariate.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.3.7: PASI – ANCOVA for change from baseline – LOCF (FAS)
(Part 2 of 2)

PASI changes from baseline	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
Week 16 / Follow up			
N	XX	XX	XX
Mean ± SE[1]	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
95%-CI[1]	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
Comparison vs Placebo			
Estimate ± SE[1]	XX.X ± XX.X	XX.X ± XX.X	--
95%-CI[1]	XX.X , XX.X	XX.X , XX.X	--
p-value[1]	X.XXX	X.XXX	--

[1] Estimates and treatment comparison of least square means using an ANCOVA model, with treatment group and (pooled) analysis center as factors and baseline outcome as covariate.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.3.8: PASI – Descriptive statistics – LOCF (VCS)
Analog to Table 14.3.2 for VCS

Table 14.3.9: PASI – PASI 75 responsers – LOCF (VCS)
Analog to Table 14.3.3 for VCS

Table 14.3.10: PASI – ANCOVA for change from baseline – LOCF (VCS)
Analog to Table 14.3.7 for VCS

Table 14.3.11: PGA – Descriptive statistics – LOCF (FAS)
Analog to Table 14.3.2 for PGA

Figure 14.3: PGA – Lineplot: Mean by treatment over time – LOCF (FAS)
Analog to Figure 14.1 for PGA

Figure 14.4: PGA – Lineplot: Mean change from baseline by treatment over time – LOCF (FAS)
Analog to Figure 14.1 for PGA

Table 14.3.12: PGA – Location shift in change from baseline – LOCF (FAS)
(Part 1 of 2)

PGA changes from baseline	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
Week 4			
N	XX	XX	XX
Mean ± SD	X.X ± X.XX	X.X ± X.XX	X.X ± X.XX
Median	X X	X X	X X
Min , max	XX , XX	XX , XX	XX , XX
Comparison vs Placebo			
Estimate ± SE[1]	XX.X ± XX.X	XX.X ± XX.X	--
95%-CI[1]	XX.X , XX.X	XX.X , XX.X	--
p-value[2]	X.XXX	X.XXX	--
Week 8			
N	XX	XX	XX
Mean ± SD	X.X ± X.XX	X.X ± X.XX	X.X ± X.XX
Median	X.X	X.X	X.X
Min , max	XX , XX	XX , XX	XX , XX
Comparison vs Placebo			
Estimate ± SE[1]	XX.X ± XX.X	XX.X ± XX.X	--
95%-CI[1]	XX.X , XX.X	XX.X , XX.X	--
p-value[2]	X.XXX	X.XXX	--
Week 12 / EoT			
N	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X
Min , max	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
Comparison vs Placebo			
Estimate ± SE[1]	XX.X ± XX.X	XX.X ± XX.X	--
95%-CI[1]	XX.X , XX.X	XX.X , XX.X	--
p-value[2]	X.XXX	X.XXX	--

[1] Estimates and confidence interval by Hodges-Lehmann estimation using location shift.
[2] Wilcoxon rank sum test.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.3.12: PGA – Location shift in change from baseline – LOCF (FAS)
(Part 2 of 2)

PGA changes from baseline	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
Week 16 / Follow-up			
N	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX X	XX X	XX X
Min , max	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
Comparison vs Placebo			
Estimate ± SE[1]	XX.X ± XX.X	XX.X ± XX.X	--
95%-CI[1]	XX.X , XX.X	XX.X , XX.X	--
p-value[2]	X.XXX	X.XXX	--

[1] Estimates and confidence interval by Hodges-Lehmann estimation using location shift.
[2] Wilcoxon rank sum test.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.3.13: PGA – Location shift in change from baseline – LOCF (VCS)
Analog to Table 14.3.12 for VCS

Table 14.3.14: PGA – Frequency counts – LOCF (FAS)
(Part 1 of 2)

PGA	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
Baseline / Day 1			
N	XX	XX	XX
0 – Clear	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
1 Almo t clear	XX (XXX X%)	XX (XXX X%)	XX (XXX X%)
2 – Mild	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
3 – Mild to moderate	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
4 – Moderate	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
5 – Moderate to severe	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
6 – Severe	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Week 4			
N	XX	XX	XX
0 – Clear	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
1 – Almost clear	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
2 – Mild	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
3 – Mild to moderate	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
4 – Moderate	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
5 – Moderate to severe	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
6 – Severe	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Week 8			
N	XX	XX	XX
0 – Clear	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
1 – Almost clear	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
2 – Mild	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
3 – Mild to moderate	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
4 – Moderate	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
5 – Moderate to severe	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
6 – Severe	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.3.14: PGA – Frequency counts – LOCF (FAS)
(Part 2 of 2)

PGA	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
Week 12 / EoT			
N	XX	XX	XX
0 – Clear	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
1 Almo t clear	XX (XXX X%)	XX (XXX X%)	XX (XXX X%)
2 – Mild	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
3 – Mild to moderate	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
4 – Moderate	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
5 – Moderate to severe	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
6 – Severe	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Week 16 / Follow-up			
N	XX	XX	XX
0 – Clear	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
1 – Almost clear	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
2 – Mild	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
3 – Mild to moderate	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
4 – Moderate	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
5 – Moderate to severe	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
6 – Severe	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.3.15: PGA – PGA improvement – LOCF (FAS)
Analog to Table 14.3.3 for PGA

Table 14.3.16: PGA – Descriptive statistics – LOCF (VCS)
Analog to Table 14.3.2 for PGA (VCS)

Table 14.3.17: PGA – Frequency counts – LOCF (VCS)
Analog to Table 14.3.14 for VCS

Table 14.3.18: PGA – PGA improvement – LOCF (VCS)
Analog to Table 14.3.3 for PGA (VCS)

Table 14.3.19: BSA [%] – Descriptive statistics – LOCF (FAS)
Analog to Table 14.3.2 for BSA score

Table 14.4.1: PASI – Subgroup: Analysis center – ANCOVA for change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: Analysis centers (pooled): 1; 2; …; <X>.

Table 14.4.2: PASI – Subgroup: Age – ANCOVA for change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: Age: 18 to 40; >40.

Table 14.4.3: PASI – Subgroup: Sex – ANCOVA for change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: Sex: Male; Female.

Table 14.4.4: PASI – Subgroup: BMI – ANCOVA for change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: BMI: Normal (≤ 24.9); Pre-obesity (25.0 - 29.9); Obesity (≥ 30.0).

Table 14.4.5: PASI – Subgroup: Years of psoriasis – ANCOVA for change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: Years of psoriasis: 1 to 10; >10.

Table 14.4.6: PASI – Subgroup: Smoking – ANCOVA for change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: Smoking: Current; Never or former.

Table 14.4.7: PASI – Subgroup: Cigarette smoking – ANCOVA for change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: Cigarette smoking: <1 to 10; >10.

Table 14.4.8: PASI – Subgroup: PGA – ANCOVA for change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: PGA: 3 to 4; 5 to 6.

Table 14.4.9: PASI – Subgroup: PASI – ANCOVA for change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: PASI: ≤ 15; > 15.

Table 14.4.10: PASI – Subgroup: CRP – ANCOVA for change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: CRP: <10 mg/dl; ≥ 10 mg/dl.

Table 14.4.11: PASI – Subgroup: % Exposure – ANCOVA for change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: % Exposure: < 80%; ≥ 80%.

Table 14.4.12: PGA – Subgroup: Analysis center – Location shift in change from baseline – LOCF (FAS)
(Part 1 of 2)

PGA changes from baseline **Analysis center (pooled): 01**	**MP1032 300 mg bid (N = XX)**	**MP1032 150 mg bid (N = XX)**	**Placebo bid (N = XX)**
Week 4			
N	XX	XX	XX
Mean ± SD	X.X ± X.X	X.X ± X.X	X.X ± X.X
Median	X.X	X.X	X.X
Min , max	X , X	X , X	X , X
Comparison vs Placebo			
Estimate ± SE[1]	X.X ± X.XX	X.X ± X.XX	--
95%-CI[1]	X.X , X.X	X.X , X.X	--
p-value[2]	X.XXX	X.XXX	--
Week 8			
N	XX	XX	XX
Mean ± SD	X.X ± X.X	X.X ± X.X	X.X ± X.X
Median	X.X	X.X	X.X
Min , max	X , X	X , X	X , X
Comparison vs Placebo			
Estimate ± SE[1]	X.X ± X.XX	X.X ± X.XX	--
95%-CI[1]	X.X , X.X	X.X , X.X	--
p-value[2]	X.XXX	X.XXX	--
Week 12 / EoT			
N	XX	XX	XX
Mean ± SD	X.X ± X.X	X.X ± X.X	X.X ± X.X
Median	X.X	X.X	X.X
Min , max	X , X	X , X	X , X
Comparison vs Placebo			
Estimate ± SE[1]	X.X ± X.XX	X.X ± X.XX	--
95%-CI[1]	X.X , X.X	X.X , X.X	--
p-value[2]	X.XXX	X.XXX	--

[1] Estimates and confidence interval by Hodges-Lehmann estimation using location shift.
[2] Wilcoxon rank sum test.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.4.12: PGA – Subgroup: Analysis center – Location shift in change from baseline – LOCF (FAS)
(Part 2 of 2)

PGA changes from baseline **Analysis center (pooled): 01**	**MP1032 300 mg bid (N = XX)**	**MP1032 150 mg bid (N = XX)**	**Placebo bid (N = XX)**
Week 16 / Follow up			
N	XX	XX	XX
Mean ± SD	X.X ± X.X	X.X ± X.X	X.X ± X.X
Median	X.X	X.X	X.X
Min , max	X , X	X , X	X , X
Comparison vs Placebo			
Estimate ± SE[1]	X.X ± X.XX	X.X ± X.XX	--
95%-CI[1]	X.X , X.X	X.X , X.X	--
p-value[2]	X.XXX	X.XXX	--

[1] Estimates and confidence interval by Hodges-Lehmann estimation using location shift.
[2] Wilcoxon rank sum test.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.4.13: PGA – Subgroup: Age – Location shift in change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: Age: 18 to 40; >40.

Table 14.4.14: PGA – Subgroup: Sex – Location shift in change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: Sex: Male; Female.

Table 14.4.15: PGA – Subgroup: BMI – Location shift in change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: BMI: Normal (≤ 24.9); Pre-obesity (25.0 - 29.9); Obesity (≥ 30.0).

Table 14.4.16: PGA – Subgroup: Years of psoriasis – Location shift in change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: Years of psoriasis: 1 to 10; >10.

Table 14.4.17: PGA – Subgroup: Smoking – Location shift in change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: Smoking: Current; Never or former.

Table 14.4.18: PGA – Subgroup: Cigarette smoking – Location shift in change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: Cigarette smoking: <1 to 10; >10.

Table 14.4.19: PGA – Subgroup: PGA – Location shift in change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: PGA: 3 to 4; 5 to 6.

Table 14.4.20: PGA – Subgroup: PASI – Location shift in change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: PASI: ≤ 15; > 15.

Table 14.4.21: PGA – Subgroup: CRP – Location shift in change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: CRP: <10 mg/dl; ≥ 10 mg/dl.

Table 14.4.22: PGA – Subgroup: % Exposure – Location shift in change from baseline – LOCF (FAS)
Analog to Table 14.3.7 for Subgroups: % Exposure: < 80%; ≥ 80%.

Table 14.4.23: Extent of exposure (SES)
(Part 1 of 1)

	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
Total number of applications[1]			
N	XXX	XXX	XXX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X
Min , max	XX , XX	XX , XX	XX , XX
Total number of dosed capsules[2]			
N	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X
Min , max	XX , XX	XX , XX	XX , XX
Treatment duration[3]			
N	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X
Min , max	XX , XX	XX , XX	XX , XX
Less than 28 days	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
29 to 56 days	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
57 to 84 days	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
More than 84 days	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Average number of capsules per application[4]			
N	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X
Min , max	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
Average number of capsules per day[5]			
N	XX	XX	XX
Mean ± SD	XX.X ± XX.X	XX.X ± XX.X	XX.X ± XX.X
Median	XX.X	XX.X	XX.X
Min , max	XX.X , XX.X	XX.X , XX.X	XX.X , XX.X
% Exposure[6]			
N	XX	XX	XX
Mean ± SD	XXX.X ± XXX.X	XXX.X ± XXX.X	XXX.X ± XXX.X
Median	XXX.X	XXX.X	XXX.X
Min , max	XXX , XXX	XXX , XXX	XXX , XXX
Insufficient (< 80%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Sufficient (≥ 80%)	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

[1] Total number of applications = # planned applications – # missed applications +# overdose applications
[2] Total number of dosed capsules = 6 * # planned applications – # missed capsules" + # overdose capsules
[3] Treatment duration = date of last dose – date of first dose + 1.
[4] Average number of capsules per application = # dosed capsules / # applications
[5] Average number of capsules per day = # dosed capsules / days of treatment
[6] % Exposure = 100 * # dosed capsules / (84 * 2 * 6)

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.5.1: Overview on adverse events (SES)
(Part 1 of 1)

Adverse events **Count[1] / Incidence[2] (Incidence rate%[3])**	**MP1032 300 mg bid (N = XX)**	**MP1032 150 mg bid (N = XX)**	**Placebo bid (N = XX)**
TEAEs[4]	XXX / XX (XXX X%)	XXX / XX (XXX X%)	XXX / XX (XXX X%)
TEAEs by intensity[5]			
Severe	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
Moderate	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
Mild	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
TEAEs by relation to the IMP[5]			
Certain	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
Probable	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
Possible	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
Unlikely	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
Not related	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
Serious TEAEs	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
TEAEs leading to study discontinuation	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)

[1] Count of AEs reported
[2] Incidence determined as the number of subjects with respective AE
[3] Incidence rate determined as the incidence divided by the number of subjects at risk, i.e. size of the SES
[4] AEs not seen before treatment or, if already present before treatment, worsened after start of treatment
[5] Subjects counted once under the highest intensity or the strongest relation to the IMP

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.5.2: TEAEs by MedDRA terminology – Summary (SES)
(Part 1 of 1)

TEAEs[1] by MedDRA terminology Count[2] / Incidence[3] (Incidence rate%[4])	**MP1032 300 mg bid (N = XX)**	**MP1032 150 mg bid (N = XX)**	**Placebo bid (N = XX)**
System organ class / Preferred term[5]			
<System organ class A>	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
<Preferred term 1>	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
<Preferred term 2>	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
<System organ class B>	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
<Preferred term 1>	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
<Preferred term 2>	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
<System organ class C>	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
<Preferred term 1>	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
<Preferred term 2>	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)

[1] AEs not seen before treatment or, if already present before treatment, worsened after start of treatment
[2] Count of adverse events reported
[3] Incidence is determined as the number of subjects with any respective adverse event
[4] Incidence rate is determined as the incidence divided by the number of subjects at risk, i.e. size of the safety population
[5] Coded using MedDRA dictionary (version 20.1 from March 2018), sorted alphabetically.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.5.3: TEAEs by MedDRA terminology and severity – Summary (SES)
(Part 1 of 1)

TEAEs[1] by MedDRA terminology Count[2] / Incidence[3] (Incidence rate%[4])	Severity	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
System organ class / Preferred term[5]				
<System organ class A>	Mild	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Moderate	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Severe	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
<Preferred term 1>	Mild	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Moderate	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Severe	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
<System organ class B>	Mild	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Moderate	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Severe	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
<Preferred term 1>	Mild	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Moderate	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Severe	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)

[1] AEs not seen before treatment or, if already present before treatment, worsened after start of treatment
[2] Count of adverse events reported
[3] Incidence is determined as the number of subjects with any respective adverse event
[4] Incidence rate is determined as the incidence divided by the number of subjects at risk, i.e. size of the safety population
[5] Coded using MedDRA dictionary (version 20.1 from March 2018), sorted alphabetically.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.5.4: TEAEs by MedDRA terminology and relation to IMP – Summary (SES)
(Part 1 of 1)

TEAEs[1] by MedDRA terminology Count[2] / Incidence[3] (Incidence rate%[4])	Relation to IMP	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
System organ class / Preferred term[5]				
<System organ class A>	Certain	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Probable	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Possible	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Unlikely	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Not related	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
<Preferred term 1>	Certain	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Probable	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Possible	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Unlikely	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Not related	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
<System organ class B>	Certain	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Probable	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Possible	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Unlikely	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
	Not related	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)
<Preferred term 1>	(…)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)	XXX / XX (XXX.X%)

[1] AEs not seen before treatment or, if already present before treatment, worsened after start of treatment
[2] Count of adverse events reported
[3] Incidence is determined as the number of subjects with any respective adverse event
[4] Incidence rate is determined as the incidence divided by the number of subjects at risk, i.e. size of the safety population
[5] Coded using MedDRA dictionary (version 20.1 from March 2018), sorted alphabetically.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.6.1: Hematology – Hemoglobin [g/dL]: Summary (SES)
(Part 1 of 2)

Hemoglobin [g/dL]	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
Screening			
N	XXX	XXX	XXX
Mean ± SD	XXX.X ± XX.X	XXX.X ± XX.X	XXX.X ± XX.X
Median	XXX X	XXX X	XXX X
Min , max	XXX , XXX	XXX , XXX	XXX , XXX
Day 1			
N	XXX	XXX	XXX
Mean ± SD	XXX.X ± XX.X	XXX.X ± XX.X	XXX.X ± XX.X
Median	XXX.X	XXX.X	XXX.X
Min , max	XXX , XXX	XXX , XXX	XXX , XXX
Week 4			
N	XXX	XXX	XXX
Mean ± SD	XXX.X ± XX.X	XXX.X ± XX.X	XXX.X ± XX.X
Median	XXX.X	XXX.X	XXX.X
Min , max	XXX , XXX	XXX , XXX	XXX , XXX
Change from Baseline[1]			
N	XXX	XXX	XXX
Mean ± SD	XXX.X ± XX.X	XXX.X ± XX.X	XXX.X ± XX.X
Median	XXX.X	XXX.X	XXX.X
Min , max	XXX , XXX	XXX , XXX	XXX , XXX
Week 8			
N	XXX	XXX	XXX
Mean ± SD	XXX.X ± XX.X	XXX.X ± XX.X	XXX.X ± XX.X
Median	XXX.X	XXX.X	XXX.X
Min , max	XXX , XXX	XXX , XXX	XXX , XXX
Change from Baseline[1]			
N	XXX	XXX	XXX
Mean ± SD	XXX.X ± XX.X	XXX.X ± XX.X	XXX.X ± XX.X
Median	XXX.X	XXX.X	XXX.X
Min , max	XXX , XXX	XXX , XXX	XXX , XXX

[1] Baseline: Last observation collected prior to first dose of any IMP, i.e. Day 1 assessment or, if missing, Screening assessment.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.6.1: Hematology – Hemoglobin [g/dL]: Summary (SES)
(Part 2 of 2)

Hemoglobin [g/dL]	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
Week 12 / EoT			
N	XXX	XXX	XXX
Mean ± SD	XXX.X ± XX.X	XXX.X ± XX.X	XXX.X ± XX.X
Median	XXX X	XXX X	XXX X
Min , max	XXX , XXX	XXX , XXX	XXX , XXX
Change from Baseline[1]			
N	XXX	XXX	XXX
Mean ± SD	XXX.X ± XX.X	XXX.X ± XX.X	XXX.X ± XX.X
Median	XXX.X	XXX.X	XXX.X
Min , max	XXX , XXX	XXX , XXX	XXX , XXX
Week 16 / Follow up			
N	XXX	XXX	XXX
Mean ± SD	XXX.X ± XX.X	XXX.X ± XX.X	XXX.X ± XX.X
Median	XXX.X	XXX.X	XXX.X
Min , max	XXX , XXX	XXX , XXX	XXX , XXX
Change from Baseline[1]			
N	XXX	XXX	XXX
Mean ± SD	XXX.X ± XX.X	XXX.X ± XX.X	XXX.X ± XX.X
Median	XXX.X	XXX.X	XXX.X
Min , max	XXX , XXX	XXX , XXX	XXX , XXX

[1] Baseline: Last observation collected prior to first dose of any IMP, i.e. Day 1 assessment or, if missing, Screening assessment.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.6.2: Hematology – Hematocrit [%]: Summary (SES)
Analog to Table 14.6.1 for Hematocrit

Table 14.6.3: Hematology – Mean corpuscular hemoglobin [pg]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.4: Hematology – Mean corpuscular HGB concentration [g/dL]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.5: Hematology – Mean corpuscular volume [fL]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.6: Hematology – Erythrocytes [10^{12}/L]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.7: Hematology – Leukocytes [10^{9}/L]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.8: Hematology – Platelets [10^{9}/L]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.9: Hematology – Eosinophils [10^{9}/L]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.10: Hematology – Lymphocytes [10^{9}/L]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.11: Hematology – Neutrophils [10^{9}/L]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.12: Hematology – Eosinophils/Leukocytes [%]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.13: Hematology – Lymphocytes/Leukocytes [%]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.14: Hematology – Neutrophils/Leukocytes [%]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.15: Coagulation – International normalized ratio of prothrombin time: Summary (SES)
Analog to Table 14.6.1

Table 14.6.16: Clinical chemistry – Alkaline phosphatase [U/L]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.17: Clinical chemistry – Alanine aminotransferase [U/L]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.18: Clinical chemistry – Aspartate aminotransferase [U/L]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.19: Clinical chemistry – Bilirubin [mg/dL]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.20: Clinical chemistry – Creatinine [mg/dL]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.21: Clinical chemistry – C reactive protein [mg/L]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.22: Clinical chemistry – Gamma glutamyl transferase [U/L]: Summary (SES)
Analog to Table 14.6.1

Table 14.6.23: Urinalysis – Occult blood: Summary (SES)
(Part 1 of 2)

Urinalysis – Occult blood	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
Screening			
N	XXX	XXX	XXX
Negative	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 5-10 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 50 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 250 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 10 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 50 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 250 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Day 1			
N	XXX	XXX	XXX
Negative	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 5-10 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 50 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 250 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 10 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 50 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 250 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Week 4			
N	XXX	XXX	XXX
Negative	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 5-10 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 50 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 250 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 10 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 50 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 250 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.6.23: Urinalysis – Occult blood: Summary (SES)
(Part 2 of 2)

Urinalysis – Occult blood	MP1032 300 mg bid (N = XX)	MP1032 150 mg bid (N = XX)	Placebo bid (N = XX)
Week 8			
N	XXX	XXX	XXX
Negative	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 5-10 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 50 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 250 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 10 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 50 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 250 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Week 12 / EoT			
N	XXX	XXX	XXX
Negative	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 5-10 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 50 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 250 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 10 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 50 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 250 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Week 16 / Follow up			
N	XXX	XXX	XXX
Negative	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 5-10 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 50 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Erythrocytes ca 250 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 10 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 50 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)
Hemoglobin ca 250 ERY/uL	XX (XXX.X%)	XX (XXX.X%)	XX (XXX.X%)

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.6.24: Urinalysis – Leukocytes: Summary (SES)
Analog to Table 14.6.23 for Leukocytes
(Categories: Negative, Leukocytes ca 25 Leukocytes /uL, ca 75 Leukocytes /uL, ca 500 Leukocytes /uL)

Table 14.6.25: Urinalysis – Glucose: Summary (SES)
Analog to Table 14.6.23 for Glucose (Categories: Normal, 50 mg/dL, 150 mg/dL, 500 mg/dL, >=1000 mg/dL)

Table 14.6.26: Urinalysis – Ketones: Summary (SES)
Analog to Table 14.6.23 for Ketones (Categories: Negative, 25 mg/dL, 100 mg/dL, 300 mg/dL)

Table 14.6.27: Urinalysis – Bilirubin: Summary (SES)
Analog to Table 14.6.23 for Bilirubin (Categories: Negative, 1 mg/dL, 2 mg/dL, 4 mg/dL)

Table 14.6.28: Urinalysis – Urobilinogen: Summary (SES)
Analog to Table 14.6.23 for Urobilinogen (Categories: Normal, 2 mg/dL, 4 mg/dL, 8 mg/dL, 12 mg/dL)

Table 14.6.29: Urinalysis – Protein: Summary (SES)
Analog to Table 14.6.23 for Protein (Categories: Negative, 30 mg/dL, 100 mg/dL, 500 mg/dL)

Table 14.6.30: Urinalysis – Nitrite: Summary (SES)
Analog to Table 14.6.23 for Nitrite (Categories: Negative, Positive)

Table 14.6.31: Urinalysis – pH: Summary (SES)
Analog to Table 14.6.23 for pH (Categories: 5, 6, 7, 8, 9)

Table 14.7.1: Vital signs – Systolic blood pressure [mmHg]: Summary (SES)
Analog to Table 14.6.1 for systolic blood pressure

Table 14.7.2: Vital signs – Diastolic blood pressure [mmHg]: Summary (SES)
Analog to Table 14.6.1 for diastolic blood pressure

Table 14.7.3: Vital signs – Pulse rate [bpm]: Summary (SES)
Analog to Table 14.6.1 for pulse rate

Table 14.8.1: PK data – MP1032 concentration in blood (PKS) - MP1032 150 mg bid
(Part 1 of 1)

MP1032 150 mg bid (N = XX) MP1032 concentration [ng/mL]	Day 1					Week 12 / EoT				
	Pre-dose	15 min	30 min	60 min	120 min	Pre-dose	15 min	30 min	60 min	120 min
Subject ID										
XXX	<LLQ	<LLQ	<LLQ	<LLQ	<LLQ	<LLQ	<LLQ	XXX.X	XXX.X	<LLQ
XXX	<LLQ	<LLQ	XXX.X	<LLQ	<LLQ	<LLQ	<LLQ	XXX.X	XXX.X	<LLQ
XXX	<LLQ	<LLQ	XXX.X	XXX.X	<LLQ	<LLQ	<LLQ	XXX.X	XXX.X	<LLQ
XXX	<LLQ	XXX.X	XXX.X	XXX.X	<LLQ	<LLQ	<LLQ	XXX.X	XXX.X	<LLQ
XXX	<LLQ	XXX.X	XXX.X	XXX.X	<LLQ	<LLQ	XXX.X	XXX.X	XXX.X	XXX.X
XXX	<LLQ	XXX.X	XXX.X	XXX.X	<LLQ	<LLQ	XXX.X	XXX.X	XXX.X	XXX.X
XXX	<LLQ	XXX.X	XXX.X	XXX.X	XXX.X	<LLQ	XXX.X	XXX.X	XXX.X	XXX.X
XXX	<LLQ	XXX.X	XXX.X	XXX.X	XXX.X	<LLQ	XXX.X	XXX.X	XXX.X	XXX.X
XXX	<LLQ	XXX.X	XXX.X	XXX.X	XXX.X	<LLQ	XXX.X	XXX.X	XXX.X	XXX.X
XXX	<LLQ	XXX.X	XXX.X	XXX.X	XXX.X	<LLQ	XXX.X	XXX.X	XXX.X	XXX.X
N < LLQ	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
N > LLQ	XX	XX	XX	XX	XX[)]	XX	XX	XX	XX	XX
Geom. Mean	--	XXX.X	XXX.X	XXX.X	--	--	XXX.X	XXX.X	XXX.X	XXX.X
Geom. SD	--	XXX.X	XXX.X	XXX.X	--	--	XXX.X	XXX.X	XXX.X	XXX.X
Geom. CV [%]	--	XXX	XXX	XXX	--	--	XXX	XXX	XXX	XXX
Arithm. Mean	--	XXX.X	XXX.X	XXX.X	--	--	XXX.X	XXX.X	XXX.X	XXX.X
Arithm. SD	--	XXX.X	XXX.X	XXX.X	--	--	XXX.X	XXX.X	XXX.X	XXX.X
Arithm. CV [%]	--	XXX	XXX	XXX	--	--	XXX	XXX	XXX	XXX
Median	--	XXX.X	XXX.X	XXX.X	--	--	XXX.X	XXX.X	XXX.X	XXX.X
Minimum	--	XXX.X	XXX.X	XXX.X	--	--	XXX.X	XXX.X	XXX.X	XXX.X
Maximum		XXX X	XXX X	XXX X			XXX X	XXX X	XXX X	XXX X

Lower level of quantification (LLQ) = <XXX ng/mL>
Summary statistics presented only in case of at least 6 concentrations above the LLQ.
For the calculation of the summary statistics, pre-dose/through levels below LLQ substituted by zero and post-dose levels substituted by LLQ/2.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.8.2: PK data – MP1032 concentration in blood (PKS) - MP1032 300 mg bid
Analog to Table 14.8.1 for treatment MP1032 300 mg bid

Table 14.8.3: PK data – Relative blood sampling time (PKS) - MP1032 150 mg bid
(Part 1 of 1)

MP1032 150 mg bid (N = XX) **Relative blood sampling time[1] [min]**	**Day 1**					**Week 12 / EoT**				
	Pre-dose[2]	**15 min (±2 min)**	**30 min (±2 min)**	**60 min (±5 min)**	**120 min (±5 min)**	**Pre-dose[2]**	**15 min (±2 min)**	**30 min (±2 min)**	**60 min (±5 min)**	**120 min (±5 min)**
Subject ID										
XXX	0	XXX.X	XXX.X	XXX.X	XXX.X	0	XXX.X	XXX.X	XXX.X	XXX.X
XXX	0	XXX.X	XXX.X	XXX.X	XXX.X	0	XXX.X	XXX.X	XXX.X	XXX.X
XXX	0	XXX.X	XXX.X	XXX.X	XXX.X	0	XXX.X	XXX.X	XXX.X	XXX.X
XXX	0	XXX.X	XXX.X	XXX.X	XXX.X	0	XXX.X	XXX.X	XXX.X	XXX.X
XXX	0	XXX.X	XXX.X	XXX.X	XXX.X	0	XXX.X	XXX.X	XXX.X	XXX.X
XXX	0	XXX.X	XXX.X	XXX.X	XXX.X	0	XXX.X	XXX.X	XXX.X	XXX.X
XXX	0	XXX.X	XXX.X	XXX.X	XXX.X	0	XXX.X	XXX.X	XXX.X	XXX.X
XXX	0	XXX.X	XXX.X	XXX.X	XXX.X	0	XXX.X	XXX.X	XXX.X	XXX.X
XXX	0	XXX.X	XXX.X	XXX.X	XXX.X	0	XXX.X	XXX.X	XXX.X	XXX.X
XXX	0	XXX.X	XXX.X	XXX.X	XXX.X	0	XXX.X	XXX.X	XXX.X	XXX.X
Mean	--	XXX.X	XXX.X	XXX.X	XXX.X	--	XXX.X	XXX.X	XXX.X	XXX.X
SD	--	XXX.X	XXX.X	XXX.X	XXX.X	--	XXX.X	XXX.X	XXX.X	XXX.X
Median	--	XXX.X	XXX.X	XXX.X	XXX.X	--	XXX.X	XXX.X	XXX.X	XXX.X
Minimum	--	XXX.X	XXX.X	XXX.X	XXX.X	--	XXX.X	XXX.X	XXX.X	XXX.X
Maximum	--	XXX.X	XXX.X	XXX.X	XXX.X	--	XXX.X	XXX.X	XXX.X	XXX.X

[1] Time since morning dose [min]
[2] Relative pre-dose time is set to 0 for derivations.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.8.4: PK data – PK data – Relative blood sampling time (PKS) - MP1032 300 mg bid
Analog to Table 14.8.3 for treatment MP1032 300 mg bid

Figure 14.5: PK data – Profile plots for subject's MP1032 concentration over time (PKS) - MP1032 150 mg bid

Day 1	Week 12 / EoT
About 10 lines (=subjects) x-axis: actual time points y-axis linear scaled	About 10 lines (=subjects) x-axis: actual time points y-axis linear scaled

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Figure 14.6: PK data – Profile plots for subject's MP1032 concentration over time (PKS) - MP1032 300 mg bid
Analog to Figure 14.5 for treatment MP1032 300 mg bid.

Figure 14.7: PK data – Semi-logarithmic scaled profile plots for subject's MP1032 concentration over time (PKS) - MP1032 150 mg bid
Analog to Figure 14.5 with logarithmic scaled y-axis

Figure 14.8: PK data – Semi-logarithmic scaled profile plots for subject's MP1032 concentration over time (PKS) - MP1032 300 mg bid
Analog to Figure 14.5 for treatment MP1032 300 mg bid with logarithmic scaled y-axis

Figure 14.9: PK data – Mean profiles for treatments over time (PKS)
Analog to Figure 14.5, the lines represent geometric means of MP1032 concentrations over nominal time points, linear scale for y-axis.
NOTE: A line in this figure will only be generated if at least 6 subjects in the respective treatment arm have at least one concentration higher than LLQ.

Figure 14.10: PK data – Semi-logarithmic scaled mean profiles for treatments over time (PKS)
Analog to Figure 14.5, the lines represent geometric means of MP1032 concentrations over nominal time points, logarithmic scale for y-axis.
NOTE: A line in this figure will only be generated if at least 6 subjects in the respective treatment arm have at least one concentration higher than LLQ.

Table 14.8.5: Non-compartment parameters – C_{max}[ng/mL] (PKS) - MP1032 150 mg bid
(Part 1 of 1)

C_{max}[ng/mL]	MP1032 150 mg bid (N = XX)	
	Day 1	**Week 12 / EoT**
Subject ID		
XXX	XXX.X	XXX.X
XXX	XXX.X	XXX.X
XXX	XXX.X	XXX.X
XXX	XXX.X	XXX.X
XXX	XXX.X	XXX.X
XXX	XXX.X	XXX.X
XXX	XXX.X	XXX.X
XXX	XXX.X	XXX.X
N	XX	XX
Geom. Mean	XXX.X	XXX.X
Geom. SD	XXX.X	XXX.X
Geom. CV [%]	XXX	XXX
Arithm. Mean	XXX.X	XXX.X
Arithm. SD	XXX.X	XXX.X
Arithm. CV [%]	XXX	XXX
Median	XXX.X	XXX.X
Minimum	XXX.X	XXX.X
Maximum	XXX.X	XXX.X

Summary statistics presented only in case of at least 6 quantifiable values.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.8.6: Non-compartment parameters – C_{max}[ng/mL] (PKS) - MP1032 300 mg bid
Analog to Table 14.8.5 for treatment MP1032 300 mg bid

Table 14.8.7: Non-compartment parameters – t_{max}[min] (PKS) - MP1032 150 mg bid
(Part 1 of 1)

t_{max}[min]	MP1032 150 mg bid (N = XX)	
	Day 1	**Week 12 / EoT**
Subject ID		
XXX	XXX.X	XXX.X
XXX	XXX.X	XXX.X
XXX	XXX.X	XXX.X
XXX	XXX.X	XXX.X
XXX	XXX.X	XXX.X
XXX	XXX.X	XXX.X
XXX	XXX.X	XXX.X
XXX	XXX.X	XXX.X
N	XXX	XXX
Median	XXX.X	XXX.X
Min , max	XXX , XXX	XXX , XXX

Summary statistics presented only in case of at least 6 quantifiable values.

Source data: <DATASET> <DATE>
Program: <SAS PROGRAM> <DATE>

Table 14.8.8: Non-compartment parameters – t_{max}[min] (PKS) - MP1032 300 mg bid
Analog to Table 14.8.7 for treatment MP1032 300 mg bid

Table 14.8.9: Non-compartment parameters – $AUC_{(0,120)}$[ng/mL*min] (PKS) - MP1032 150 mg bid
Analog to Table 14.8.7for AUC

Table 14.8.10: Non-compartment parameters – $AUC_{(0,120)}$[ng/mL*min] (PKS) - MP1032 300 mg bid
Analog to Table 14.8.8 for AUC