Statistical Analysis Plan (SAP)

Purpose of Analysis:	Clinical Study Report (CSR)
Investigational Product:	D-LYSERGIC ACID DIETHYLAMIDE (LSD) D-TARTRATE (MM-120)
Protocol Number:	MMED007
Document Status/ Version Number	Final 2.0
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SAP FOR CSR

Trial Statistician:	[redacted]
Statistical programmer:	[redacted]

SIGNATURES

TITLE: Safety And Efficacy of Repeated Low Dose D-Lysergic Acid Diethylamide (LSD) D-Tartrate (MM-120) as Treatment for Adhd in Adults: a Multi-Center, Randomized, Double- Blind, Placebo-Controlled Phase 2A Proof of Concept Trial

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DOCUMENT: SAP for Clinical Study Report

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[redacted]	19.12.2023	[redacted]
[redacted]		[redacted]
[redacted]		

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LIST OF ABBREVIATIONS AND ACRONYMS

ADHD	Attention-deficit/hyperactivity disorder
AE	Adverse event
AISRS	Adult ADHD investigator symptom rating scale
ADHD-RS	Attention-deficit/hyperactivity disorder-rating scale
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
ASRS	Adult attention-deficit/hyperactivity disorder self-reporting rating scale
AUC	Area under the curve concentration in plasma
BMI	Body mass index
BP	Blood pressure
CBD	Cannabidiol
CAARS	Connors' adult ADHD rating scale
CAARS-L-SR	Connors' adult ADHD rating scale self-report long form
CAARS-S-OR	Connors' adult ADHD rating scale observer-rated short screening
CKD-EPI	Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation
CGI-S	Clinical Global Impression - Severity of Illness Scale
Cmax	Maximum observed drug concentration
COVID-19	Coronavirus disease 2019
CRF	Case report form
CSR	Clinical study report
C-SSRS SCN	Columbia-suicide severity rating scale at screening
C-SSRS-SLV	Columbia-Suicide Severity Rating Scale-Since Last Visit
CYP	Cytochrome P450
5D-ASC	5 dimensions of altered states of consciousness scale
DMT	Dimethyltryptamine
DSM-5	Diagnostic and statistical manual version 5
ECG	Electrocardiogram
eCRF	Electronic case report form
EDC	Electronic data capture
EOS	End of Study
EOT	End of Treatment
ET	Early Termination
FA	Factor Analysis
GGT	Gamma-glutamyl transferase
HR	Heart rate
IE	Intercurrent event
IMP	Investigational medicinal product
LSD	Lysergic acid diethylamide
MAOI	Monoamine oxidase inhibitor
MCH	Mean corpuscular hemoglobin
MCV	Mean corpuscular volume
MDMA	3,4-methylenedioxymethamphetamine
MEQ30	Mystical experience questionnaire 30 items
MINI	Mini International Neuropsychiatric Interview
Ml	Milliliter

MM-120	Mind Medicine, Inc. compound dose for D-lysergic acid diethylamide D-tartrate
PCA	Principal Component Analysis
PGX	Pharmacogenomics
PK	Pharmacokinetic
QTcF	QT interval corrected using Fridericia's formula
RR	Respiratory rate
SAE	Serious adverse events
SNDRI	Serotonin-norepinephrine-dopamine reuptake inhibitor
SNRI	Selective serotonin reuptake inhibitor
SSRI	Selective serotonin reuptake inhibitor
SUSAR	Unexpected serious adverse reaction
T1/2	Terminal elimination half-life (h)
TCA	Tricyclic antidepressant
THC	Tetrahydrocannabidiol
Tmax	Time of peak plasma concentration
ULN	Upper limit of normal
VAS	Visual analog scale
WOCBP	Women of childbearing potential

1 INTRODUCTION

This Statistical Analysis Plan (SAP) is based on the study protocol MMED007, final version 5.0, dated 10 February 2022.

The purpose of this document is to provide details concerning the data analyses and presentation of the study data in line with the objectives of the study. All the definitions, derivation rules and handling of missing data procedures will be detailed as well as references to the variables and datasets provided; details regarding efficacy analysis will be given.

Table, figure and listing layouts will also be provided in this document.

2 TRIAL DESIGN, STUDY DOCUMENTS, DATABASE CODING

2.1 TRIAL DESIGN

2.1.1 Trial design

This is a randomized, double-blind, placebo-controlled, Phase 2a study on the efficacy and safety of repeated low dose D-lysergic acid diethylamide (LSD) D-Tartrate (MM-120) in adult subjects aged ≥ 18 and ≤ 65 with attention-deficit/hyperactivity disorder (ADHD).

Eligible subjects that consent to participate will be randomized in a 1:1 allocation to placebo or MM-120.

There will be 2 arms:

- Arm 1-Placebo: a total of 26 subjects will receive a placebo identical in appearance to the IMP administered orally twice weekly for 6 weeks. Subjects and site staff will remain blinded to the treatment group.
- Arm 2-MM-120: a total of 26 subjects will receive 20 µg of MM-120 twice weekly for 6 weeks. Subjects and site staff will remain blinded to the treatment group.

Potential study subjects who provide informed consent will have eligibility evaluated/confirmed at 2 visits: 1) Screening, and 2) Baseline. The screening visit occurs up to 4 weeks prior to Baseline. An assessment will be made to confirm or make the ADHD diagnosis with the Mini International Neuropsychiatric Interview (MINI). The subject must have an Adult Attention Deficit Investigator Symptom Rating Scale (AISRS) score of ≥ 26 and a Clinical Global Impression - Severity of Illness Scale (CGI-S) score of ≥ 4 at screening and must meet all other eligibility criteria:

Inclusion criteria

1. Ability and willingness to provide written, informed consent prior to initiation of any study-related procedures and to adhere to all study requirements. NOTE: The subject (i.e., not a legally authorized representative) must be cognitively able to understand the requirements of the study and provide the informed consent.
2. Age ≥ 18 and ≤ 65 years at Screening.

3. Subjects with the diagnosis of Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5) ADHD, as determined by clinical evaluation and confirmed by structured interview (MINI).
4. AISRS total score of ≥26 at screening.
5. CGI-S score of ≥4 at screening.
6. Must be willing to receive IMP dose twice weekly. On Day 1, the subject will come to the clinic and must be willing to take a taxi or public transportation home or be accompanied by a caregiver and not drive a car, use heavy equipment, or participate in any other dangerous activity for the remainder of the day after receiving IMP (NOTE: at any protocol visit after Day 1 dosing, dosing visits may occur at the subject's home at the discretion of the PI, conducted by one of the study investigators or delegate and administered under supervision followed by the performance of the same procedures done at the clinic including safety monitoring. If early withdrawal is considered due to any safety issue identified, the Sponsor's medical monitor should be notified. If a remote visit is conducted due to any reason related to the COVID-19 pandemic, notification must be sent to the Medical Monitor's dedicated email address and Urgent Safety Measures as outlined in this protocol must be followed.)
7. Must be willing to refrain from more than 6 standard alcoholic drinks per week (1 standard drink corresponds to 0.1 L wine, 0.3 L beer, or 4 cL liquor), more than 10 cigarettes a day, and more than 2 cups of coffee a day throughout the study treatment period (6 weeks) and until the last study visit is complete (EOS or ET).

Exclusion criteria

1. Past or present diagnosis of a primary psychotic disorder or first-degree relative with a psychotic disorder.
2. Past or present bipolar disorder (DSM-5).
3. Other current psychiatric disorders that, in the opinion of the Investigator or medical supervisor, may confound the results of the study (e.g., obsessive-compulsive disorder,dysthymic disorder, panic disorder, dissociative disorder, anorexia nervosa or bulimia nervosa).
4. Subjects with [redacted] substance use disorder (except nicotine, provided subject does not smoke [redacted]
5. Somatic disorders including Central Nervous System (CNS) involvement of cancer, severe cardiovascular disease, untreated hypertension, severe liver disease (liver enzyme increase by more than 3x the upper limit of normal except unconjugated hyperbilirubinemia due to Gilbert's Disease, per Investigator), severely impaired renal function (estimated creatinine clearance < 50 mL/min by CKD-EPI formula), or anything else that, in the judgment of the Investigator or medical supervisor, poses too great a potential for side effects.
6. Any lifetime history of suicide attempt; [redacted] active suicidal thoughts or ideation (defined as a suicidal ideation score of 2 or greater in the Columbia-Suicide Severity Rating Scale [C-SSRS]); or endorsement of any suicidal behavior on the C-SSRS within the [redacted] the screening visit.

7. Likely to require psychiatric hospitalization during the course of the study.
8. Once consent is signed, subject not willing or able to stop any prescription or nonprescription ADHD medications during screening and prior to the baseline visit through final study visit (EOS or ET). *A list of prohibited medications is provided in APPENDIX C.*
9. Plan to start, stop, or alter the use of any medications, supplements, or other therapeutics from Baseline until EOS or ET (see Appendix 1 for list of prohibited medications).
10. Plan to start, stop or alter the use of psychotherapy, massage, meditation, acupuncture, hypnosis, yoga, or other similar therapy/activity from the time of providing informed consent until EOS or ET.
11. [redacted]
12. Likely to need use of any psychiatric medications with the potential to confound interpretation of study results or impact safety, at the discretion of the Investigator, in the 10 weeks following Baseline up to EOS or ET (see APPENDIX C for list of prohibited medications).
13. Use of investigational medication/treatment in the past 30 days prior to the screening visit.
14. [redacted]
15. Clinically significant abnormal baseline laboratory values, VSs, and ECG that include the following:
    a. Have evidence of clinically significant hepatic disorder (e.g., alanine aminotransferase [ALT] or aspartate aminotransferase [AST] > 3X ULN (except for Gilbert's disease), and
    b. Any clinically significant abnormal metabolic or hematologic screen, per Investigator or medical supervisor decision
    c. Exclusionary blood pressure: >140 mm Hg (systolic) or >90 mm Hg (diastolic); heart rate <45 beats/minute or >90 beats/minute after an approximately 5- minute supine or semi-supine rest NOTE: If the first measurement of a subject's heart rate is > 90 beats/minute, a second recording is allowed after an additional approximately 5-minute supine rest
    d. Exclusionary ECG parameters: QTcF > 450 msec (men), QTcF >470 msec (women)
    e. Any clinically significant abnormal electrocardiogram (ECG) finding (e.g., uncontrolled atrial fibrillation, ischemia) at Screening (Visit 1) or Baseline (Visit 2), as determined by the Investigator or medical supervisor (in consultation with a cardiologist, if needed.
16. Any other condition, therapy, laboratory abnormality, or other circumstance that, in the opinion of the Investigator or medical supervisor, may pose additional risk to the subject from participation in the study, may interfere with the subject's ability to comply with study procedures, may make participation in the study not in the subject's best interest or may confound the results of the study.
17. Prior history or ongoing neuropsychiatric signs or symptoms associated with COVID-19 such as development of, or current disorder, during or after a

COVID-19 infection including anxiety, memory loss, confusion, depression, delirium, agitation, or psychosis.

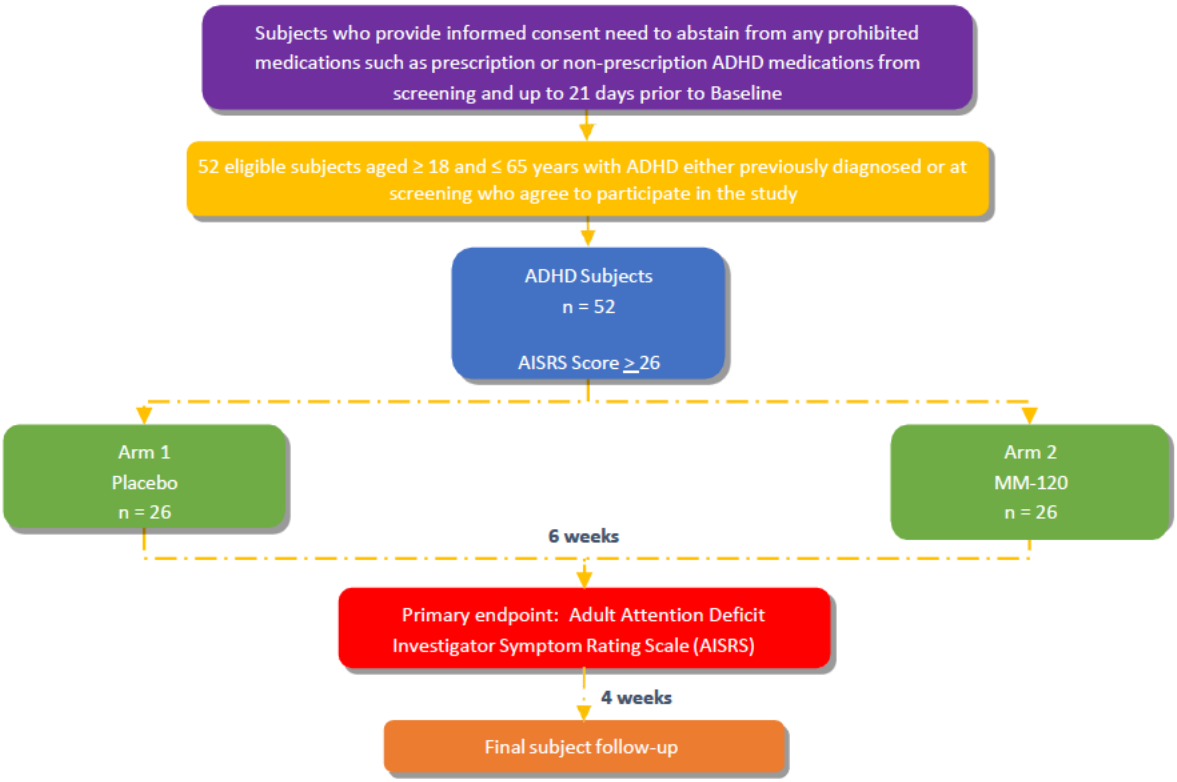
18. Women of childbearing potential (WOCBP) (i.e., physiologically capable of becoming pregnant) who are unwilling or unable to use a highly effective method of contraception, (see Protocol Appendix 2) for the duration of the study, OR Men physiologically capable of fathering a child who are sexually active with WOCBP but are unwilling or unable to use barrier contraception (e.g., condom with or without spermicidal cream or jelly) for the duration of the study. NOTE: See Protocol Appendix 2 for definitions of WOCBP and highly effective methods of contraception and for information about unacceptable methods of contraception.
19. Women who are currently pregnant or breastfeeding or plan to become pregnant or breastfeed during the study.
20. Men who plan to donate sperm during the study.
21. Use of weight loss drugs [redacted] of screening until the end of study.
22. Subjects who are either unable or unwilling to consume alcohol in any amount (including due to religious or personal reasons).
23. Subjects who have a change in AISRS score of ≥13-points between screening and baseline visits.

The baseline visit will occur on the clinic day before Day 1 and will confirm AISRS score. If there is a ≥ 13-point change in the AISRS between the screening visit assessment and the baseline assessment, or if the subject does not return for the baseline AISRS, the subject will not be randomized, and will be terminated from the study. Eligible subjects will be randomized at Day 1 to either 20 μg of MM-120 or to matching placebo and begin the double-blind treatment period on Day 1.

Double-blind treatment period:
The double-blind treatment period will last 6 weeks, with dosing twice weekly (every 3 to 4 days). Day 1 will be the first day of dosing. At the end of the 6 weeks-treatment period, subjects will be assessed by a study physician. All subjects and site staff will remain blinded to the treatment group.
Subjects will be provided with a diary in which the sleep quality/ duration rating data will be recorded.

Follow-up:
There will be a single follow-up visit 4 weeks after the last double-blind treatment visit (i.e., at Week 10).

Figure 1. Study Schedule Diagram



2.1.2 Schedule of assessments and visit windows

Table 1 reports full details on the schedule of assessments.

For all measurements, the actual date and time of assessment, including date of sampling, will be recorded in the eCRF.

Table 1: Schedule for study specific assessments.

Time in Weeks	**Screening**	**Baseline** [g]	**Dosing begins**	**Dosing Period (20 µg MM-120)** [h] **6-week Blinded Treatment**				**End of Study/ Early Termination** [h]
Arm 1 - placebo Arm 2 – MM-120	**Up to 4 weeks prior to Day -1**	**Day -1**	**Day 1**	**Week 2 (Pre-dose on 3rd dosing visit) Day 8 (+/- 1 day)**	**Twice weekly* Dosing (+/- 1 day) (Starts Day 1)**	**Every 2 weeks (first dose of the week) (Starts Day 15)**	**Week 6 (before final dose unless otherwise noted)**	**Week 10 follow-up or final visit if withdrawing from study**
Informed consent	X							
Demography	X							
Medical/surgical history	X							
Inclusion/exclusion criteria	X	X						
Pregnancy test (for women without documentation of sterilization)	X		X		X[8]			X
Physical examination	X						X	X
Weight and BMI [a]	X						X	X
Height	X						X	X
Vital signs [b]	X	X	X		X		X	X
Clinical Laboratory Tests [c]	X					X	X	X
Pharmacokinetics			X[7]					
[redacted]	[redacted]	[redacted]	[redacted]			[redacted]	[redacted]	
Pharmacodynamics (5D- ASC, & MEQ30) [d]			X				X[1, 5]	
12-lead ECG [e]	X		X[4]				X[4]	
Cognitive Performance Test		X					X	
CAARS [f]	X	X				X	X	X

Time in Weeks	**Screening**	**Baseline** [g]	**Dosing begins**	**Dosing Period (20 µg MM-120)** [h] **6-week Blinded Treatment**				**End of Study/ Early Termination** [h]
Arm 1 - placebo Arm 2 – MM-120	**Up to 4 weeks prior to Day -1**	**Day -1**	**Day 1**	**Week 2 (Pre-dose on 3rd dosing visit) Day 8 (+/- 1 day)**	**Twice weekly* Dosing (+/- 1 day) (Starts Day 1)**	**Every 2 weeks (first dose of the week) (Starts Day 15)**	**Week 6 (before final dose unless otherwise noted)**	**Week 10 follow-up or final visit if withdrawing from study**
ASRS (done prior to dosing)		X				X	X	X
AISRS, CGI-S	X	X		X			X	X
MINI	X							
C-SSRS screening/baseline	X							
C-SSRS since last visit (SLV)		X	X		X		X	X
VAS			X[6]					
Check daily diary	X	X	X		X		X	X
Randomization			X					
MM-120 or placebo administration			X		X[3]			
Adverse events	X	X	X		X		X	X
Concomitant medication	X	X	X		X		X	X
Blood sample collection for biobanking (PGX analysis)	X If the subject gives informed consent to provide a pharmacogenomic sample, collect a sample once during the study							

Abbreviations: 5D-ASC = 5 dimensions of altered states of consciousness scale; AISRS = Adult ADHD Investigator Symptom Rating Scale; ASRS = Adult ADHD Self-Report Scale; BMI = body mass index; BP = blood pressure; CAARS = Conners' Adult ADHD Rating Scale; CGI-S = Clinical Global Impression Scale; C-SSRS = Columbia-Suicide Severity Rating Scale; ECG = electrocardiogram; MEQ30 = Mystical Experience Questionnaire (30-item); PGX = pharmacogenomics; VAS = Visual Analog Scale.

*Twice weekly dosing will occur every 3 to 4 days (e.g., every Monday and Wednesday) with a ± 1 day window and will be coordinated to occur at the same time as the Week 2 visit and the every 2 weeks visits when possible.

a Body mass index will be calculated using body height at screening.

b Vital signs (pulse, BP, HR, RR, and body temperature) will be performed at every visit.

c Clinical laboratory samples for chemistry and hematology and urine samples for [redacted] and pregnancy testing will be collected pre-dose.

d Pharmacodynamic scales are completed at home up to 6 hours after dosing.

e Subject should be supine for 5 minutes prior to ECG collection.

f CAARS-S-OR conducted at screening. All other assessments will be with the CAARS-L-SR.

g Baseline visit is within 3 days of Day 1 (±1 day).

h Following day 1 dosing, all visits may be conducted remotely per Investigator decision as long as all activities can be conducted per protocol, e.g., calibrated blood pressure cuff, calibrated weight scale, ECG, computer cognitive scale. Any visit conducted remotely due to COVID-19 requires Sponsor Medical Monitor and operations team notification and conduct under urgent safety measures and all protocol deviations captured in EDC designated COVID-19 deviation.

X[1] subject fills out forms at home.

[redacted]

X[3] 6 weeks of blinded treatment on MM-120 / placebo; may be dosed at home per Investigator decision.

X[4] 2 hours after dosing.

X[5] 6 hours after dosing.

X[6] Collected repeatedly 0-6 hours after dosing.

X[7] PK samples will be collected at pre-dose, 0.5, 1, 2, 3, 4, and 6 hours post-dose.

X[8] During treatment period, pregnancy testing will occur predose at each dosing visit or a minimum of once weekly. All pregnancy test results are being recorded on the subject's source document (paper record). The pregnancy test results are not entered into the eCRF for weeks 3, 5, and 6.

2.1.3 Visit windows

As subjects do not always adhere to the protocol visit schedule, the following rules will be applied to assign actual visits to analysis visits for all parameters.

The visit windows and the target days for each visit (including unscheduled ones) are listed below in Table 2. The reference day is Day 1, the first day of dosing, as defined in Section 11.1.1. If a subject has two or more actual visits in the same visit window, the visit closest to the target day will be used for recording data from that visit in the EDC. The data collected scheduled and unscheduled visit(s) will be mapped to visits as follows: If two actual visits are equidistant from the target day within a visit window, the later visit will be used; if more than one value falls on the same day then the last sequential number in sdtm will be used.

All assessments corresponding to both scheduled and unscheduled visits will be included in subject listings.

Table 2 contains analysis visit windows and the target study days for the following selected visits: Baseline, Week 2, Week 4, Week 6 and Week 10; lower and upper limits associated with each visit will cover all possible days from randomization to end of study allowing mapping all the applicable assessments to the visits.

As vital signs and Columbia-Suicide Severity Rating Scale (C-SSRS) will be evaluated at each visit (twice weekly), a different time windowing will be applied to those variables only (see Table 3). Daily diary contains daily sleep quality/ duration rating assessments that will be computed at each week by the mean of values recorded between lower and upper limits (days) specified in Table 4, no target study day will be considered.

For parameters, where Time Interval Upper Limit for Baseline is equal to 1, please apply a rule of time defined in section 11.1.1.8 for Baseline.

Table 2: Scheduled Visit Window and Mapping of Assessments

Assessment	Scheduled Visit Number	Scheduled Time point	Label on output	Target Study Day*	Time Interval Lower Limit (Day*)	Time Interval Upper Limit (Day*)
[redacted] laboratory	Baseline	Baseline - Week 1D1	Baseline	1	No Lower limit	1
	Week 2	Week 1D5- Week 3D19	Week 2	15	2	21
	Week 4	Week 4 D22- Week 5 D33	Week 4	29	22	35
	Week 6	Week 6 D36 - Week 6 D40	Week 6	43	36	EOT
	Week 10 Follow-up/ Final visit for withdrawals	Week 10 Follow-up/ Final visit for withdrawals	Week 10 Follow-up/ Final visit for withdrawals	70	EOT+1	No Upper limit
Physical examination, ECG	Baseline	Baseline - Week 1D1	Baseline	1	No Lower limit	1
	Week 6	Week 6 D36 - Week 6 D40	Week 6	43	2	EOT
	Week 10 Follow-up/ Final visit for withdrawals	Week 10 Follow-up/ Final visit for withdrawals	Week 10 Follow-up/ Final visit for withdrawals	70	EOT+1	No Upper limit
Pregnancy test	Baseline	Baseline - Week 1D1	Baseline	1	-24	1
	Week 2	Week 1D5- Week 3D19	Week 2	15	2	21
	Week 4	Week 4 D22- Week 5 D33	Week 4	29	22	EOT
	Week 10 Follow-up/ Final visit for withdrawals	Week 10 Follow-up/ Final visit for withdrawals	Week 10 Follow-up/ Final visit for withdrawals	70	EOT+1	No Upper limit
Questionaries						
ASRS, CAARS-L-SR	Baseline	Baseline - Week 1D1	Baseline	-1	No Lower limit	-1
	Week 2	Week 1D5- Week 3D19	Week 2	15	2	21
	Week 4	Week 4 D22- Week 5 D33	Week 4	29	22	34

	Week 6	Week 6 D36	Week 6 D36	36	35	38
	Week 6	Week 6 D40	Week 6 D40	40	39	EOT
	Week 10 Follow-up/ Final visit for withdrawals	Week 10 Follow-up/Final visit for withdrawals	Week 10 Follow-up/ Final visit for withdrawals	70	EOT+1	No upper limit
AISRS, CGI	Baseline	Baseline	Baseline	1	No Lower limit	1
	Week 2	Week 2 D8	Week 2	8	2	21
	Week 6	Week 6 D40	Week 6	40	35	EOT
	Week 10 Follow-up/ Final visit for withdrawals	Week 10 Follow-up/Final visit for withdrawals	Week 10 Follow-up/ Final visit for withdrawals	70	EOT+1	No upper limit
Pharmacodynamics: 5D-ASC**, MEQ-30**, VAS**#	Week 1 D1	Week 1 D1	Week 1 D1	1	NA	5
	Week 6	Week 6 D40	Week 6	40	NA	No upper limit

* Relative to Study Day 1
**No baseline assessment, post-dose at Week 1 D1
#No assessment at Week 6, only at visit Week1 D1 post-dose

Table 3: Scheduled Visit Window and Mapping of Assessments for Vital Sign, C-SSRS

Scheduled Visit Number	**Scheduled Time point**	**Label on output**	**Target Study Day***	**Time Interval Lower Limit (Day*)**	**Time Interval Upper Limit (Day*)**
Baseline	**Baseline**	**Baseline -** Week 1 D1	**1**	No Lower limit	**1**
Week 1 D5	Week 1 D5	Week 1 D5	5	2	6
Week 2 D8	Week 2 D8	Week 2 D8	8	7	10
Week 2 D12	Week 2 D12	Week 2 D12	12	11	13
Week 3 D15	Week 3 D15	Week 3 D15	15	14	17

Scheduled Visit Number	Scheduled Time point	Label on output	Target Study Day*	Time Interval Lower Limit (Day*)	Time Interval Upper Limit (Day*)
Week 3 D19	Week 3 D19	Week 3 D19	19	18	20
Week 4 D22	Week 4 D22	Week 4 D22	22	21	24
Week 4 D26	Week 4 D26	Week 4 D26	26	25	27
Week 5 D29	Week 5 D29	Week 5 D29	29	28	31
Week 5 D33	Week 5 D33	Week 5 D33	33	32	34
Week 6 D36	Week 6 D36	Week 6 D36	36	35	38
Week 6 D40	Week 6 D40	Week 6 D40	40	39	EOT
Week 10 Follow-up/Final visit for withdrawals	Week 10 Follow-up/Final visit for withdrawals	Week 10 Follow-up/ Final visit for withdrawals	70	EOT+1	No upper limit

*Relative to Study Day 1

Table 4: Scheduled Visit Window and Mapping of Assessments for daily diary (Sleep Quality)

Scheduled Visit Number	Scheduled Time point	Label on output	Target Study Day*	Time Interval Lower Limit (Day*)	Time Interval Upper Limit (Day*)
Baseline	Baseline	Baseline	NA	No Lower limit	-1
Week 1	Day 1- Week 1 D5	Week 1	NA	1	6
Week 2	Week 2 D8- Week 2 D12	Week 2	NA	7	13
Week 3	Week 3 D15- Week 3 D19	Week 3	NA	14	20
Week 4	Week 4 D22- Week 4 D26	Week 4	NA	21	27
Week 5	Week 5 D29- Week 5 D33	Week 5	NA	28	34
Week 6	Week 6 D36- Week 6 D40	Week 6	NA	35	EOT
Week 10 Follow-up/Final visit for withdrawals	Week 10 Follow-up/Final visit for withdrawals	Week 10 Follow-up/ Final visit for withdrawals	NA	EOT+1	No upper limit

*Relative to Study Day 1; NA=Not Applicable

2.2 STUDY DOCUMENTS

The following study documents are used for the preparation of the SAP:

- MMED-007 Protocol, final version 5.0, 10 February, 2022;
- Annotated Case Report Form (CRF), version 5.0, 15 August, 2022 (MMED007 DMOP Attachment B Annotated CRF v5.0).

2.3 STUDY DATABASES

The following study databases are used in the study:

- CRF database is used in the study;
- Randomization list.
- Final list with concomitant medications, including flags for intake or change in prohibited medications/therapies which have potential confounding effects.

3 ASSIGNMENT OF PREFERRED TERMS TO ORIGINAL TERMINOLOGY

The original terms used by investigators to describe medical history and concomitant diseases, physical examination abnormalities, adverse events (AEs), indications for previous/concomitant medications will be associated with preferred terms for classification and tabulation.

The latest MedDRA dictionary will be used for assigning preferred terms. Previous and concomitant therapy will be coded according to ATC.

4 REQUIREMENTS FOR SAP EXECUTION

The SAP is executed after:

1. The investigator CRF database is locked;
2. Subject visits are completed and clean;
3. The protocol violation database is locked;
4. The coding database is completed and signed off.

5 RESPONSIBILITIES

The Project Statistician will be responsible for selection of the statistical methods. The Statistical Programmer will perform the statistical programming (selected listings, summary tables, analysis tables, figures, and exploratory investigations, as appropriate).

6 SOFTWARE FOR STATISTICAL ANALYSIS

The statistical analysis will be carried out by using SAS® version 9.4 – [redacted]

7 OBJECTIVES

7.1 PRIMARY OBJECTIVE

To assess the treatment efficacy vs placebo of repeated low doses (20 µg) of MM-120 for six weeks in adult subjects with ADHD measured by Adult Attention Deficit Investigator Symptom Rating Scale (AISRS).

7.2 SECONDARY OBJECTIVES

- To assess treatment efficacy vs placebo measured by change from baseline in AISRS after 1 week (2 doses) of treatment.

- To assess treatment efficacy vs placebo based on the proportion of subjects who experience at least a 1-point decrease in the Clinical Global Impression - Severity of Illness Scale (CGI-S).
- To assess treatment efficacy vs placebo measured by change from baseline in CGI-S.
- To assess other efficacy endpoints by the Adult ADHD Self-Report Scale (ASRS) and Connors' Adult ADHD Rating Scale
- To assess the pharmacokinetic (PK) profile of MM-120 in subjects with ADHD.
- To explore the pharmacokinetic/pharmacodynamic (PK/PD) relationship of single doses of MM-120 and psychological and physiological effects.
- To assess the safety and tolerability by AE and SAE assessment.

7.3 Exploratory Objective

To explore sleep quality/ duration as recorded in the daily diary.

For the purpose of future exploratory analysis (not covered in this SAP), for subjects who consent to provide a pharmacogenomics (PGX) sample, a single blood sample (2.5 mL) in a proprietary integrated standardized system for collection and stabilization of specimens (bio banking) will be collected during the study and stored.

8 VARIABLES/ENDPOINTS AND DEFINITIONS

8.1 SUBJECT CHARACTERISTICS

8.1.1 Demographic characteristics

Demographic characteristics of the subjects include age at acreening, sex at birth (male | female) at screening, profession, highest education level (less than primary, primary, secondary, tertiary [bachelor, master, doctoral degree]) and country. Demographics data are derived from "Demographic Characteristics" CRF section.

8.1.2 Baseline disease characteristics

Baseline disease characteristics of the subjects include baseline values for the Adult Attention Deficit Investigator Symptom Rating Scale (AISRS), Clinical Global Impression - Severity of Illness Scale (CGI-S), Adult ADHD Self-Report Scale (ASRS) and Connors' adult ADHD rating scale self-report long form (CAARS-L-SR).
These data are reported on the "AISRS", "CGI-S" and "Subject Reported Outcomes" CRF sections.
Baseline definition is available in section 11.1.1.

8.2 PHYSICAL EXAMINATION AT BASELINE

Physical examination at Baseline includes height (cm), weight (kg), body mass index (BMI, kg/m^2), blood pressure (mmHg), heart rate (bpm) and an assessment of the following: general appearance, skin, head and neck, lymph nodes, thyroid, abdomen, musculoskeletal, cardiovascular, respiratory, and neurological systems.

8.3 MEDICAL HISTORY AND CONCOMITANT DISEASES

Medical history and concomitant diseases are collected in the "Prior Medical and Psychiatric Events" CRF section.

Subject medical history pertains to any previous Disease/Disorder/Surgery/Procedure (i.e. conditions in the form with the box 'ongoing' not ticked); concomitant diseases are any of the above condition with the box 'ongoing' ticked.

The original terms used by the investigators to describe Disease/ Disorder/ Surgery/ Procedure will be coded with the MedDRA v25.1.

Previous conditions will be reported separately from concomitant diseases.

8.3.1 ADHD Medical history

Attention-deficit/hyperactivity disorder (ADHD) medical history is available in the "ADHD Medical History" CRF section and the following characteristics are of interest:

- Time since ADHD diagnosis (in accordance with the rules, described in Section 11.2);
- Structured interview to assess diagnostic criteria according to DSMV [All criteria met (all criteria must be met for a diagnosis of ADHD in adults) | Not all criteria met];
- Complete CAARS-S-OR observer rating screening [(Yes|No). If Yes, then show: (A, B, C, D) scores];
- Current somatic disorder(s) [(Yes|No). If Yes, disease/disorder will be specified under specific SOC/PT of AEs summary;
- Previous hospitalisation(s), previous disorders, (somatic and psychiatric), previous surgery(s) [(Yes|No). If Yes, If Yes, disease/disorder will be specified under specific SOC of Medical History summary;
- Family History (psychiatric and somatic) [Yes|No];
- ADHD medication (prescription or non-prescription) [(Yes|No). If Yes, then show in separate summary table: (Name of medication/therapy, Indication, Total daily dose, Unit, Amount taken in the morning, Amount taken in the afternoon, Amount taken in the night time, Date of last dose)];
- Alcohol, caffeine, nicotine:
  - Current smoker [(Yes|No). If Yes, then show: (Cigarettes per day, Packs per year)];
  - Coffee [(Yes|No). If Yes, then show: (Coffee per day)];
  - Alcohol (Beer, wine, liquor etc. (standard drink)) [(Yes|No). If Yes, then show: (Per week)];
- MDMA/Ecstasy [(Yes|No). If Yes, then show: (Total lifetime use, Last use (dd.mm.yyyy))];
- Sedative, Narcotic (Benzos, Ketamine, Laughing gas (nitrous oxide)) [(Yes|No). If Yes, then show: (Total lifetime use, Last use (dd.mm.yyyy))];
- Hallucinogenic (LSD, Mescaline, Psilocybin) [(Yes|No). If Yes, then show: (Total lifetime use, Last use (dd.mm.yyyy))];
- Stimulants (Amphetamine, Cocaine, Methylphenidate (recreationally)) [(Yes|No). If Yes, then show: (Total lifetime use, Last use (dd.mm.yyyy))];
- Opioids (Morphine, Diacetylmorphin, Codeine, Methadone) [(Yes|No). If Yes, then show: (Total lifetime use, Last use (dd.mm.yyyy))];
- Cannabis, Marijuana, CBD [(Yes|No). If Yes, then show: (Total lifetime use, Last use (dd.mm.yyyy))];
- Others: (GHB, PCP, DXM, Spice) [(Yes|No). If Yes, then show: (Total lifetime use, Last use (dd.mm.yyyy))];

8.4 PREVIOUS AND CONCOMITANT MEDICATIONS

Previous and concomitant medications are collected in the "Concomitant Medications" CRF section. Medications for ADHD are those medications with the response "Yes" to the question 'Is this medication for ADHD?'.

Missing/Partial dates will be imputed according Section 11.3.3.

8.4.1 Previous medications

Any treatment with the stop date before the study treatment start date (see definition in Section 11.1.1).

8.4.2 Concomitant medications during treatment period

Any treatment taken during the treatment period (Section 11.1.1). This includes any treatment with:

- The start date on or after the treatment start date and before study treatment end date (included)

OR

- The start date before the treatment start date AND the stop date after or on the study treatment start date

Handling of missing dates is defined in section 11.3.3.

8.4.3 Prohibited concomitant medications.

Any treatment that may interfere with the IMP taken during the study. This includes treatment from Day -1/Baseline (Visit 2) until End of Study or Early Termination (except if needed for care and treatment of the subject during the study per Investigator discretion).

The **Error! Reference source not found.** in APPENDIX C provides a listing of prohibited m edications; however, it is not a comprehensive list of all restricted medications, supplements, and other therapeutics. Final list with prohibited medications will be identified on a case-by-case basis by a Sponsor medical review of the concomitant medications.

8.5 EXPOSURE TO INVESTIGATIONAL MEDICAL PRODUCT (IMP)

Exposure information will be expressed in terms of treatment duration (days) derived as the number of days from the date of first dose of randomized treatment received (Study treatment start date) to the date of the last dose received (Study treatment end date), inclusive (section 11.1.1) according to the formula:

Study treatment end date - Study treatment start date +1.

8.6 COMPLIANCE WITH STUDY TREATMENT

The IMP will be administered at the clinic under supervision of study personnel (i.e., the Investigator or delegate) and cannot be provided to the subjects to take home.
Compliance with treatment (%) will be always 100% if treatment is administered at each visit (12 in total), from Week 1 D1 to Week 6 D40.
Study treatment is considered administered if answered 'Yes' to the question "LSD / Placebo administered?" in the "Study Drug Administration" CRF section. Study drug administritation will be collected at each visit.

If Compliance with treatment (%) is different from 100%, it will be derived according to the following formula:

Total compliance (%) = (Total number of doses taken / Total number of expected doses) x 100*, *where*:

Total number of doses taken = Total number of expected doses – Total number of missed doses.

Total number of expected doses = 12 (number of doses to be administered at all 12 visits).

*Total number of missed doses = number of doses not administered (study treatment is considered **NOT** administered if answered 'No' to the question "LSD / Placebo administered?" in the "Study Drug Administration" CRF section).*

In case of “Special Situation” at any visit (answer to "Were there any special situation with the study drug?" is [Yes]), the compliance will be not calcultated, and the following information will be provided:

- Number of subjects with at least one Special Situation;
- Number of Special Situations;

and number of patients with ticked box 'Yes' to any of the following:

- Medication error or incorrect drug administration;
- Overdose (exceeds the protocol-specified maximum);
- Deliberate abuse;
- Deliberate misuse;
- Drug interaction;
- Occupational exposure.

8.7 TRIAL DISCONTINUATION

Subjects with premature trial termination are identified as those with answer 'No' to the question 'Did the subject complete the study?' in the “Termination Form” CRF section.

The reasons that can be associated with the trial discontinuation are:

- Lost to follow-up;
- Death;
- COVID-19 related;
- Other (to be specified).

8.8 EFFICACY ENDPOINTS

8.8.1 Primary endpoint

The primary endpoint is the mean change from baseline in ADHD symptoms, based on the evaluation of the AISRS change from baseline to Week 6.

The AISRS total score consists of 18 items from the original ADHD-RS, which were derived based on DSM-5 criteria for ADHD. The ADHD-RS includes 9 items that address symptoms of inattention and 9 items that address symptoms of impulsivity and hyperactivity. Each item will be rated from 0 to 3. The AISRS total score can range from 0 to 54. A higher score corresponds to a worse severity of ADHD.

8.9 SECONDARY ENDPOINTS

8.9.1 ADHD related endpoints

- Key secondary endpoint: change in AISRS from baseline to 1 week (Week 2, pre-dose, as per Schedule of assessments 2.1.2) after 2 doses of treatment;

- Occurrence of subjects who experience at least a 1-point decrease in the CGI-S (improvement). The change in CGI-S from baseline to Week 2 and Week 6 will be categorized as improved or worsened/ no change and will be evaluated as dichotomous variable:

$$CGI-S = \begin{cases} Improved\ if\ (Difference\ between\ week\ 2/6\ and\ baseline) < 0 \\ No\ change\ or\ Worsened\ if\ (Difference\ between\ week\ 2/6\ and\ baseline) \geq 0 \end{cases}$$

- Change from baseline in CGI-S after 1 week (Week 2-predose) and 6 weeks (Week 6) of treatment;

- Change from baseline to each timepoint (see Section 10.8.2.2) in subject self-assessment by the Adult ADHD Self-Report Scale (ASRS) and Connors' Adult ADHD Rating Scale (CAARS-L-SR).

  The CAARS-L-SR is a 66-item measure of ADHD symptoms. Responses are scored on a 4-point scale, where 0 = not at all, 1 = just a little, 2 = pretty much, and 3 = very much. Item scores are summed to three main scores which are then transformed using population-derived age- and sex-adjusted norm values to a T-score. A T- score < 60 indicates no ADHD. A T-score of 60-64 indicates borderline ADHD. A T-score of > 64 indicates ADHD.

  The ASRS has 18 questions, which address ADHD symptoms in adults. It uses a scale that ranges from 0-4 based on the individuals mark in either "never, rarely, sometimes, often, very often" column for a possible total score of 72. Each column is used to describe the severity of the individual's symptoms based on the question asked. If four or more answers are scored "positive" then a high consistency of ADHD will be indicated and further follow-up with a licensed clinician is necessary.

These data are derived from "AISRS", "CGI-S" and "Subject Reported Outcomes" CRF sections (see Section 2.1.2 for time points).

8.9.2 Pharmacokinetic endpoints

PK samples will be collected at pre-dose, hours 0.5, 1, 2, 3, 4, and 6 post-dose (at "Week 1 D1", first drug administration visit). The actual date and time of collection of each sample is recorded on the "Pharmacokinetics" CRF section.

- C_{max}, Maximum observed drug concentration
- t_{max}, Time to reach C_{max}
- AUC_{0-t}, Area under the concentration-time curve from time zero to the measurable concentration time t
- $t_{1/2}$, Terminal elimination half-life

AUC will be calculated using trapezoidal rule. Missing values will be imputed with linear interpolation of the non-missing values that precede and follow the missing one(s). For details of PK endpoints definition and analysis, refer to Section 10.9.

8.9.3 Acute effects (Pharmacodynamic) endpoints

- 5 Dimensions of Altered States of Consciousness scale (5D-ASC). The 5D-ASC scale is a visual analog scale consisting of 94 items. The instrument is constructed of five scales, and allows assessing mood, anxiety, derealization, depersonalization, changes in perception, auditory alterations, and reduced vigilance. Each item of the scale is scored on a 0-100 mm VAS;
- Mystical Experience Questionnaire (MEQ), drug effect Visual Analog Scale (VAS).

  The MEQ is a 30-item questionnaire rated on a six-point scale. Data on each domain scale is expressed as a percentage of the maximum possible score.

  A series of single item VAS is used: "any drug effect", "good drug effect", bad drug effect", "drug liking", "fear", nausea", "alteration of vision", "alteration of sense of time", and "the boundaries between myself and my surroundings seem to blur".

These data are derived from “5D-ASC”, “MEQ-30” and “VAS” CRF sections (see Section 2.1.2 for time points).

8.10 EXPLORATORY ENDPOINTS

Sleep quality/duration rating evaluated based on daily diary entries (“Sleep Quality” CRF section) and assessment is specified in Section 2.1.1.
The respondent marks, an integer score from 0 to 10, are defined according to the following five categories:

0 = terrible,
1–3 = poor,
4–6 = fair,
7–9 = good,
10 = excellent

8.11 SAFETY ENDPOINTS

The evaluation of safety of study drug will be done considering the following variables:

- Adverse events ('Adverse Event' CRF section);
- Safety laboratory evaluation and Urine pregnancy testing ('Blood sample' and '[redacted] sections of the CRF);
- Vital signs, i.e. supine blood pressure, body temperature, heart rate, respiratory rate ('Vital signs' CRF section);
- 12-lead safety ECG ('12-Lead ECG' CRF section);
- Columbia-Suicide Severity Rating Scale (C-SSRS, 'C-SSRS SLV' CRF section).

8.11.1 Adverse events (AEs)

Adverse events (AEs) data are collected in the "Adverse Events” CRF sub-section of the “Medical Events” section. An Adverse Event is any untoward medical occurrence in a clinical trial which does not necessarily have a causal relationship with this treatment.

As a general rule, the variable of interest will be the occurrence of at least one AE.

8.11.1.1 Treatment-emergent adverse events (TEAEs)

Treatment-emergent adverse events are any event with onset date/time between the study treatment start date and the study treatment end date, limits included.

8.11.1.2 Intensity of the adverse events

The intensity of an AE can be Mild (tolerable), Moderate (interferes with daily activates), Severe (daily activities impossible). If intensity is missing, it will be considered Severe for the analysis.

8.11.1.3 Adverse event leading to premature treatment discontinuation

An adverse event that led to the permanent discontinuation of study treatment is an AE with the 'Action taken with study drug' marked as 'Drug discontinued' in the CRF section “Adverse Event”.

8.11.1.4 AEs related to study drug

An AE is considered related to study drug if the tick box “Relationship to the study drug” is marked as “Definitely Related” or “Probably Related” or “Possibly Related” in the “Adverse Event” CRF section.

8.11.1.5 Unexpected Adverse Reaction (UAR)

When the outcome of an adverse reaction is not consistent with the applicable product information, this adverse reaction should be considered as an Unexpected Adverse Reaction (UAR). Information on UAR will not be included in the CRF but the sponsor will provide expectancy/unexpectancy details.

8.11.1.6 Suspected Unexpected Serious Adverse Reaction (SUSAR)

Suspected Unexpected Serious Adverse Reaction (SUSAR) is any suspected adverse reaction related to an IMP that is both unexpected and serious (expectancy/unexpectancy details will be provided by the Sponsor).

8.11.1.7 Serious Adverse Event (SAE)

An AE is considered serious if the question 'Is the event serious?' in the

CRF section “Adverse Event” is marked as 'Yes'.

8.11.1.8 Serious Adverse Reaction (SAR)

A Serious Adverse Reaction (SAR) is a SAE that is determined to be related to the study treatment. That is, SAEs that are determined to have a causal relationship of “Possibly Related”, “Probably Related” or “Definitely Related” on the 'Relationship to study drug' category of the 'Adverse Events' CRF secion will be considered SARs.

8.11.2 Death

The date and the cause of death occurred during the study are derived from “Adverse Event" section of the CRF.

8.11.3 Laboratory

A routine laboratory blood test will be performed at the screening examination, and similarly during follow-up visits: Week 2, Week 4, Week 6 and Week 10 (see Section 2.1.2).

In particular, the laboratory parameters are the ones listed below:

8.11.3.1 Hematology

- Hemoglobin;
- Hematocrit;
- MCV;
- MCH;
- Platelet count;
- Red blood cell count;
- White blood cell count (including Basophils, Eosinophils, Lymphocytes, Monocytes, Neutrophils).

8.11.3.2 Chemistry

- Albumin;
- Total protein;
- Alkaline phosphatase;
- ALT;
- AST;
- Bilirubin, total;
- Chloride;

- Creatinine;
- Creatinine clearance (CKD-EPI);
- FSH (follicle stimulating hormone;
- GGT (gamma-glutamyl transferase);
- C Reactive Protein;
- Glucose;
- Lactate dehydrogenase;
- Blood urea nitrogen or urea;
- Phosphate;
- Potassium;
- Calcium;
- Sodium.

In addition, a [redacted] and a urine pregnancy test, only in women, will be performed at selected time points (Baseline, Week 2, Week 4, Week 6, Week10) before IP dosing throughout the study (see Section 2.1.2).

The definitions of marked abnormalities in SI units are provided in Table 5 and Table 6 below.

The columns labelled "L", "LL", "H" and "HH" display the increasing grade (severity) of abnormally low ("L", "LL"), or high values ("H", and "HH") for each of the laboratory parameters listed in the first column, as appropriate.

Treatment-emergent MLAs are those occurring after the study treatment start and up to study treatment discontinuation, that were not present at baseline in the same or worse category (considering the direction of worsening). In other words, the MLAs are evaluated independently by direction of worsening (e.g., a post-baseline MLA of "HH" is considered treatment-emergent if the baseline is "L" or "LL" (where applicable) or "H", or within normal limits or missing. On the other hand, it is not considered as treatment-emergent if the baseline is "HH" when applicable).

Table 5. Abnormal laboratory values: Hematology (SI units)

Laboratory test name (CDISC Synonym[s])	L	LL	H	HH
Hemoglobin	<100 g/L	<80 g/L	>20 g/L above baseline	>40 g/L above baseline
Hematocrit; EVF; Erythrocyte Volume fraction; PCV; Packed Cell Volume *(male)*	<0.32 L/L	<0.20 L/L	>0.60 L/L	>0.65 L/L
Hematocrit; EVF; Erythrocyte Volume fraction; PCV; Packed Cell Volume *(female)*	<0.28 L/L	<0.20 L/L	>0.55 L/L	>0.65 L/L
MCV	< 82 fl	NA	> 98 fl	NA
MCH	< 27 pg	NA	> 33.2 pg	NA
Platelets *(assuming no platelet cluster)*	<75 x 10^9/L	<50 x 10^9/L	>600 x 10^9/L	>999 x 10^9/L

Red Bloodcell count (RBC)* / Erythrocytes (10^12/L) *Male* *Female*	 4.60/pl / 10^12/L 3.90/pl / 10^12/L	 4.1/pl / 10^12/L 3.5/pl / 10^12/L	 6.10/pl / 10^12/L 5.20/pl / 10^12/L	 6.3/pl / 10^12/L 5.5/pl / 10^12/L
Leukocytes; White Blood Cells	<3.0 x 10^9/L	<2.0 x 10^9/L	>20.0 x 10^9/L	>100.0 x 10^9/L
Granulocytes *PLUS* Neutrophils Band Form*	NA	NA	>90%	>95%
Monocytes Male Female	 < 5% < 5%	 NA NA	 > 12% > 13%	 NA NA
Basophils	NA	NA	≥ 1.5%	NA
Neutrophils (Abs)	<1.5 x 10^9/L	<1.0 x 10^9/L	NA	NA
Eosinophils (Abs)	NA	NA	>5.0 x 10^9/L	NA
Lymphocytes (Abs)	<0.8 x 10^9/L	<0.5 x 10^9/L	>4.0 x 10^9/L	>20 x 10^9/L

Red Bloodcell count (RBC) in pl should be used in all summaries and listings

Table 6. Abnormal laboratory values: Blood chemistry (SI units)

Laboratory test name (CDISC Synonym[s])	L	LL	H	HH
Alanine Aminotransferase; SGPT	NA	NA	> 3x ULN	> 5x ULN
Aspartate Aminotransferase; SGOT	NA	NA	> 3x ULN	> 5x ULN
Gamma Glutamyl Transferase	NA	NA	> 2.5x ULN	> 5x ULN
Alkaline Phosphatase	NA	NA	> 2.5x ULN	> 5x ULN
Bilirubin; Total Bilirubin	NA	NA	> 2x ULN	> 5x ULN
Creatinine	NA	NA	> 1.5x ULN	>3x ULN
Glucose *(Non-diabetic Fasting)*	<3.0 mmol/L	<2.2 mmol/L	>8.9 mmol/L	>13.9 mmol/L
Sodium	NA	<130 mmol/L	>150 mmol/L	>155 mmol/L
Potassium	<3.2 mmol/L	< 3.0 mmol/L	>5.5 mmol/L	>6.0 mmol/L
Creatine Kinase	NA	NA	>5x ULN	>10x ULN
Urate; Uric Acid	NA	NA	> 590 µmol/L	>720 µmol/L
Albumin	<30 g/L	<20 g/L	NA	NA
Total Protein	<66 g/L	NA	> 87 g/L	NA
Chloride	< 98 mmol/L	NA	>107 mmol/L	NA
Lactate dehydrogenase	NA	NA	≥ 250 U/L	NA
Creatinine Clearance	<60 ml/min	<30 ml/min	NA	NA
Blood Urea Nitrogen; Urea Nitrogen	NA	NA	>2.5x ULN	>5x ULN

8.11.4 Vital signs

Vital signs (supine blood pressure (mmHg), body temperature (°C), respiratory rate (breath/minute), heart rate (bpm)) will be measured at each visit (Section 2.1.2) and collected in the "Vital Signs" section of the CRF.

Refer to section 11.1.1.8 for definition of the Baseline. In case of missing time of the Vital Signs assessment on the date of fisrt dosing, please imput time 00:00 on the corresponding date.

8.11.5 Resting 12-lead ECG

A 12-lead ECG will be obtained after the subject has been resting in the supine position for at least 5 minutes, at time points outlined in the Section 2.1.2 (Baseline, Week 6). All ECGs will be documented by recording date, time of collection, all abnormal wave form noted, ventricular rate, all intervals including PR, RR, QRS, QT and QTcF (“12-Lead ECG” CRF section). ECG abnormalities are signed as 'Yes' on 'Clinically significant findings' field of the “12-Lead ECG” section.

8.11.6 Physical examination

A physical examination will be performed at Screening, Week 6 and Week 10 and collected in “Physical Examination” CRF section. Physical examination includes body weight, height, BMI, vital signs and an assessment of the following: general appearance, skin, head and neck, lymph nodes, thyroid, abdomen, musculoskeletal, cardiovascular, respiratory, and neurological systems.

8.11.7 Columbia-Suicide Severity Rating Scale

Columbia-Suicide Severity Rating Scale is collected at Screening (C-SSRS SCN CRF page) at Baseline, Week 2 D8, Week 2 D12, Week 3 D15, Week 3 D19, Week 4 D22, Week 4 D26, Week 5 D29, Week 5 D33, Week 6 D36, Week 6 D40, Week 10 Follow-up/Final visit for withdrawals (C-SSRS-SLV CRF page).

9 ANALYSIS SETS, GROUPS AND SUBGROUPS

9.1 ANALYSIS SETS

Different analysis sets will be planned for the analyses and all will be identified and finalized before the database is locked. Subjects without valid written study informed consent will be excluded from all analysis sets.

The following analysis sets are defined for the statistical analysis:

- **Screened set (SCR)** - All subjects with signed written informed consent and a subject identification number;
- **Randomized set (RAN)** – All subjects who received a randomization number, regardless of receiving trial medication;
- **Safety set (SAF) –** All subjects who received the double-blind study drug. Subjects will be analyzed according to treatment received;
- **Full Analysis set (FAS) –** All subjects in RAN who were not mis-randomized (Mis-randomized subjects are those who have not been qualified for randomization or who have been inadvertently randomized into the study but have not received double-blind study drug). Following the intent-to-treat (ITT) principle, subjects will be analyzed according to the treatment they have been assigned to at the randomization;
- **Per Protocol set (PPS)** – All subjects in FAS who took the study medication and had no major protocol deviations;
- **Pharmacokinetic Analysis set (PKS)** – The PKS will include all subjects who receive a

dose of MM-120 and have at least 1 post-dose PK measurement without major protocol deviations or violations thought to significantly affect the PK of the drug. Data from subjects with deviations determined to affect PK will be excluded from the PKS. Subjects that receive placebo will not be part of the PK analysis set. Subjects will be analyzed according to the treatment they actually received.

9.2 GROUPS

Two randomized treatment groups will be used in all statistical analyses defined in this SAP (unless explicitly specified):

- MM-120 (D-lysergic acid diethylamide D-tartrate (LSD); refer to definition of the Arm 2-MM-120 in Section 2.1.1);
- Placebo (refer to definition of the Arm 1-Placebo in Section 2.1.1)

9.3 SUBGROUPS

Primary endpoint main analysis will be performed on the following subgroup populations:

1. Severe ADHD: Adult Attention Deficit Investigator Symptom Rating Scale (AISRS) score of ≥ 38 at baseline.

2. Moderate ADHD: Adult Attention Deficit Investigator Symptom Rating Scale (AISRS) score of < 38 at baseline.

10 STATISTICAL ANALYSIS

10.1 GENERAL STATISTICAL METHODOLOGY

Unless otherwise specified:

- Parameters will be shown in tables and listings according to the CRF order;
- In summary tables, all subjects will be grouped by treatment group; the 'LSD' treatment group will be displayed in the first column and 'Placebo' in the second; a ‘total’ column (including the two treatment groups) may be added in some tables as specified in TLF layouts section;
- Continuous numerical variables will be summarized using the following descriptive statistics: n, mean, standard deviation (SD), median, Q_1 (25^{th} percentile), Q_3 (75^{th} percentile), minimum, and maximum;
- Categorical including ordinal variables will be summarized by frequency and incidence;
- All statistical tests (unless explicitly specified) will be carried out at a significant level (α level) of 0.05, two-tailed 95% Confidence Interval (CI) will be reported.
- Listings include data from scheduled and unscheduled assessments;
- All listing will be ordered by Treatment, Subject ID, visit/date/time (where applicable).

10.2 SUBJECT DISPOSITION, PROTOCOL VIOLATIONS AND TRIAL TERMINATION

- Counts and percentages of subjects included and excluded from each analysis set will be provided.

- A summary of the subject disposition will be provided including the following variables, for the SCR:

- Subjects screened;
- Screen failures (screened, but not randomized);
- Subjects randomized;
- Subjects treated (who received at least one dose);
- Subjects who prematurely discontinued the study and reasons;
- Subjects who completed the study.

A listing of subjects' disposition will be provided, based on SCR set.

- Violations leading to exclusion from the PPS and PKS analysis sets will be listed.

10.3 SUBJECT CHARACTERISTICS

10.3.1 Demographic characteristics

Summary statistics (see Section 10.1) will be summarized by treatment group and overall for all the demographics characteristics (see Section 8.1.1); these summaries will be performed on the FAS.

Demographics will be listed on FAS.

10.3.2 Baseline disease characteristics

Baseline disease characteristics (Section 8.1.2) will be summarized by treatment group and overall, on the FAS, using descriptive statistics for continuous and categorical data.

10.3.3 Medical history and concomitant diseases

Medical history and concomitant diseases (section 8.3) will be summarized separately, displaying counts and percentages of subjects having experienced at least one prior or concomitant disease. Counts and percentages of subjects having experienced at least one prior or concomitant disease will be presented by system organ class (SOC) and individual preferred term within each SOC as well as by individual preferred term. The summary tables will be presented in descending order according to their incidence in the active treatment group (e.g., SOC and individual preferred term within each SOC with the highest number of occurrences appear first); ties will be sorted alphabetically.

The counting of the diseases is handled as follows:

- Subjects with two occurrences of the same disease (as qualified by its preferred term(s)) will be counted only once;
- In case the reported disease will be assigned to several preferred terms, subjects will be counted for each individual preferred term.

Previous conditions will be reported separately from concomitant ones.

Individual subjects' listings of previous and concomitant diseases will be provided separately on the FAS.

ADHD medical history will be summarized and listed separately on the FAS.

10.3.4 Previous and concomitant medications

Individual subject listing will be provided on the FAS.

Previous and concomitant medications (Section 8.4) will be summarized displaying counts and percentages of subjects having taken at least one treatment. A specific summary for previous and concomitant ADHD medication will be provided.
Counts and percentages of subjects having taken at least one treatment will be presented by Anatomic Therapeutic Chemical (ATC) class 3 and individual preferred term within each ATC as well as by individual preferred term. The summary tables will be presented in descending order according to their incidence in the active treatment group (e.g., ATC and individual preferred term within each ATC with the highest number of occurrences appear first) sorting ties alphabetically.

The counting of the medications will be handled as follows:

- Subjects who took more than once the same medication (as qualified by its preferred term(s)) will be counted only once;
- In case the reported medication is assigned to several preferred terms, subjects will be counted for each individual preferred term.

Prohibited medications will be flagged in the listing with the concomitant medications and will be summarized separately as defined for concomitant medications above. Final list with prohibited medications will be provided by the Sponsor.

10.3.5 Cognitive Performance Tests (Computer Test)

Tests are performed at Baseline and Week 6 (prior to last dose).

Frequency statistics will be provided for 'Stop Signal Task', 'Discounting Task', 'Psychomotor Vigilance Task', 'Time Production Task' and 'Time Reproduction Task' categories at Baseline and Week 6 for FAS population.

Additionally, the number (%) of completers and non-completers of the test will will be evaluated by the answer 'Yes|No' to the question Cognitive performance tests performed?' respectively and will be presented in the summary table. The data are collected in the 'Cognitive Performance Tests' sections at baseline and Week 6.

A listing with cognitive performance test results at each time point will be produced on FAS.

10.4 EXPOSURE TO STUDY TREATMENT

Treatment duration (days) as defined in section 8.5 will be listed and summarized on SAF using descriptive statistics for continuous variables, by treatment group

10.5 COMPLIANCE WITH STUDY TREATMENT

Compliance data will be summarized on SAF using descriptive statistics for categorical data as defined in Section 4.2.1.

A listing of compliance will be provided on SAF.

10.6 TRIAL DISCONTINUATION

A summary of reasons for premature trial discontinuation will be provided for the RAN. The summary table will be presented in descending order in the active treatment group (i.e., the reason with the highest number of occurrences appears first). A listing of subjects who did not complete the study (see section 8.7) will be provided.

10.7 PRIMARY EFFICACY ENDPOINT

The primary analysis will be performed according to the intent-to-treat (ITT) principle on the FAS.

10.7.1 Statistical model and hypotheses

The null hypothesis is that active MM-120 is not better than placebo; this will be rejected with a one-sided p-value < 0.10 with 80% power if the true efficacy of MM-120 reaches a standardized mean improvement over placebo of 0.60.

10.7.2 Main analysis

10.7.2.1 Estimand

The primary estimand quantifies the treatment effect of MM-120 at 6-weeks vs placebo after twice weekly administration while accounting for intercurrent events (IEs) with potential confounding effects and IEs leading to study discontinuation prior to the 6-week assessment.

The following attributes describe the primary estimand:

- Population: Subjects in the FAS
- Endpoint: Change from baseline to Week 6 in the AISRS Score
- Treatment of interest: the randomized treatment MM-120 or placebo as a twice weekly treatment.
- Handling of intercurrent events (IEs) prior to AISRS assessments.

  Depending on the IE causing the missing or potentially biased value, two sequential policy strategies will be applied:

  1. Policy strategy. Available data will be used; missing data will be imputed under a Missing At Random (MAR) assumption by borrowing information from subjects in the same treatment group in following cases:
     - IEs related to COVID-19 pandemic and other intercurrent missing data (see detals in Section 10.7.2.1.1).
  2. Policy strategy. Available data recorded after the IE will be set to missing; such missing data will be imputed/substituted under a Missing Not At Random (MNAR) assumption by borrowing information from the placebo arm subjects (reference-based imputation) in following cases:
     - Intake of prohibited medications/therapies with potential confounding effect (APPENDIX C) (see detals in Section 10.7.2.1.1).
     - Other IEs leading to treatment/study discontinuation (except those related to COVID- 19 pandemic (see detals in Section 10.7.2.1.1).

- Summary measure: Difference between MM-120 and placebo in mean change from baseline to Week 6 for AISRS Score.

10.7.2.1.1 Definition of intercurrent events (IEs)

1. IEs related to COVID-19 pandemic are confirmed if:

- AE term AEDECOD is 'SARS-CoV-2 test positive' in the sdtm database. The AE start date AESTDTC will be considered to assign missing values (as defined in bullet 1 of Section 10.7.2.2) to all assesments following this date and up to and including Week 6 D40.

2. Intake of prohibited medications/therapies defined in APPENDIX C will be finalized and flagged accordingly on a case-by-case basis by a Sponsor medical review of the concomitant medications as defined in Section 8.4.3. The CM start date will be considered to assign missing values (as defined in bullet 2 of Section 10.7.2.2) to all assesments following this date and up to and including Week 6 D40.

3. Other IEs leading to treatment/study discontinuation (except those related to COVID- 19 pandemic) are confirmed if:

   the action taken AEACNOTH of the corresponding adverse event is 'DRUG DISCONTINUED' or 'SUBJECT WITHDRAWAL' in the sdtm database and subject had study assesments after the AE onset date AESTDTC and up to and including Week 6 D40.

In all cases if the date of the assessment and the IE start date occur in the same date, this assessment values will be assigned to missing.

If the date of assessments following the IE start date are missing, these will be imputed based on the theoretical date the assessments should have been occurred:

- if the IE start date <= study day 9 then both Week 2 and 6 assessments have to be set to missing and imputed
- if the IE start date is between study day 10 and 44 then Week 6 assessment has to be set to missing and imputed

10.7.2.2 Analysis details

Primary endpoint, change in AISRS score from baseline to Week 6, will be analyzed applying Rubin's rule to a multiple imputations procedure to appropriate contrasts based on Mixed Model for Repeated Measures (MMRM) analysis of covariance with the change in the AISRS score from baseline to Week 2 and Week 6 visits as dependent variable, and treatment group, visit, visit-by-treatment group interaction, baseline score of AISRS, sex and age as fixed effects. An unstructured variance-covariance matrix will be used to model within-subject errors. Satterthwaite's method will be used to approximate the degrees of freedom. If convergence problems arise (even just in one imputed dataset) the following order of matrices will be applied: Heterogeneous TOEP (TOEPH), Toeplitz (TOEP), Autoregressive(1) (AR(1)). The same variance-covariance matrix will be used in sensitivity analyses.

The imputation model include the longitudinal sequence of AISRS Scores, and the covariates used in the model as defined above. As a general approach, imputations are performed on observed values specifying a minimum and a maximum threshold (zero and 54 respectively) for AISRS. The change from baseline in AISRS Scores will not be imputed to avoid imputation of nonsensical values. For the imputation of missing data of AISRS, one thousand (1000) data sets will be generated, and the random seed number will be 200208. MI will be implemented following the steps below:

1. Imputation assuming a MAR (policy strategy 1).
   MAR will be applied following the steps below:
   a)all assessments that took place after the IEs related to COVID-19 pandemic will be kept in the database;
   b)imputing all missing values already present in the data.

MI will be carried out based on fully conditional specification method (FCS, the details will be provided in the 'Programming standards and conventions' document). These datasets will be utilized in Step #2.

2. Imputation assuming MNAR (policy strategy 2).
   MNAR will be applied following the steps below:
   a)assigning missing values to all assessments that took place after the IEs specified in policy strategy 2 above;
   b)imputing missing values assigned at step (a).
   MNAR assumption based on copy reference approach (i.e. using the non-missing values of the placebo arm) will be used.
3. The MMRM model defined above will be run on each of the 1000 generated datasets with observed and imputed data. Rubin's rule will be used for combining results to draw inference.

In the evaluation of the primary endpoint will be included only subjects with NON missing baseline assessments.

The LS Means along with associated standard errors (SE) and 95%CIs will be displayed for each treatment group at each time point. For the comparison of MM-120 vs placebo treatment effect, the LS Mean, SE, 95%CI and one-sided p-value will be provided.

A listing of AISRS values overtime will be provided for the FAS population.

10.7.3 Sensitivity analyses

Sensitivity analyses will be implemented to assess the robustness of results on primary endpoint versus assumptions used in the statistical model for the main estimator.

The following sensitivity analyses will be performed:

- Tipping-point analysis: based on the assumption that subjects on active treatment who discontinue from the study perform worse by some amount than subjects of the same group remaining in the study (Section 10.7.3.1).
- Copy reference approach: based on the assumption that subjects on active treatment with any missing data follow the distribution of the ones in the placebo group (Section 10.7.3.2).
- Complete cases analysis (Section 10.7.3.3);
- Main analysis on the PPS.
- Main analysis stratified by ADHD severity at baseline.

10.7.3.1 Tipping point sensitivity analysis

For the imputation of missing data of AISRS, MI will be implemented assuming the MAR and imputing all missing data including missing data occurred/imputed after IEs as described in policy strategies 1 and 2. A delta-adjusted imputation method will be used applying progressive stress test to the MAR assumption of the main analysis. That is, a tipping-point analysis will be performed to see how severe departures from the MAR assumption should be to overturn the conclusions of the main analysis. It is assumed that study subjects from the MM-120 group with missing values would have, on average, their observed efficacy score worsened by some amount (delta) compared

with the efficacy score observed in study subjects of the same MM-120 group remaining in the study. A series of analysis models defiend above with progressively increasing deltas (δ= 0, 1, 2, 3…. ; from less conservative to more conservative, where a delta of zero, δ(0), corresponds to the reference) will be run until the model results to be not significant (p-value ≥ 0.05). The delta adjustment will only be applied to the multiple-imputed values (based on the MAR assumption) of the subjects in the MM-120 group. Same linear mixed effects model defined for the main analysis will be used.

The Tipping point analysis will be performed only in case the main analysis of the primary endpoint resulted significant.

10.7.3.2 Copy reference

A reference-based MI approach will be adopted considering a Missing Not at Random (MNAR) mechanism for all missing data of all IE events described in policy strategies 1 and 2: imputation of values in the MM-120 group will be done using the non-missing values of the placebo group (this approach will be referred as "Copy Reference"). This approach does not assume benefits for MM-120 in case of discontinuation and limits a post-discontinuation clinical effect to that of placebo.

10.7.3.3 Complete cases

The analysis of primary endpoint will be performed by fitting the MMRM on complete cases only (observed data) i.e., without implementing the MI and without the use of the "policy strategies".

10.7.3.4 Sensitivity analysis on the PPS population.

Main analysis defined in Section 10.7.2 will be performed on the PPS population.

10.7.3.5 Sensitivity analysis stratified by ADHD severity.

Main analysis defined in Section 10.7.2 will be stratified by ADHD severity at baseline (see definition of subgroup populations in Section 9.3) and analysed on FAS.

10.7.4 Other exploratory analyses

Exploratory factor analysis will be used as a statistical data reduction technique to determine the underlying constructs of the AISRS scale measures. The maximum-likelihood factor analysis with orthogonal transformation will be used for extracton of factors. Principal components analysis (PCA) with varimax rotation will be used to evaluate the factor structure of the AISRS.

As factor analysis requires complete cases, multiple imputation will be used in case of missing data as described in Section 10.7.2.2.

The analysis will be performed overall in two randomized treatment groups as described in Section 9.1 on FAS. The baseline AISRS scores will be used in current analysis.

A table with AISRS items and corresponding factor loadings after variamx rotation in pca will be produced for each factor exctracted in the analysis.

Distribution of the eigen values of the PCA will be reflected on Scree plot.

10.8 SECONDARY EFFICACY ENDPOINTS

Change from baseline to Week 1 and 6 in AISRS, CGI-S, ASRS, and CAARS-L-SR are analyzed descriptively reporting by visit: n, mean, standard deviation, Q1 (25th percentile), Q3 (75th percentile), minimum, and maximum, and 95% Confidence Interval for the mean and for the median. For the active doses similar statistics will be reported for the difference from placebo.

10.8.1 Key Secondary Endpoint

10.8.1.1 Change from baseline in AISRS at Week 2

The change from baseline (see Section 8.1.2) to Week 2 in AISRS Score will be analyzed using the same estimand and imputation process as the primary endpoint. The linear mixed effects model analysis of covariance (ANCOVA) with the change from baseline in the AISRS score at Week 2 following randomization as dependent variable, and treatment group, baseline score of AISRS, sex and age as fixed effects will be used in current analysis. The outcome will be considered confirmatory, if in agreement with the primary endpoint outcome and provided that the null hypothis is rejected for the primary outcome. This gatekeeping function of the primary outcome allows to avoid any adjustment for multiplicity of testing.

10.8.2 Other Secondary Endpoints

10.8.2.1 Change in CGI-S from baseline to Week 2 and Week 6

The change from baseline (see Section 11.2) to Week 2 and Week 6 will be summarized descriptively.

The proportion of subjects having improved or having worsened/being stable will be calculated at each post-baseline assessment by treatment group. The proportion difference and the relative risk (LSD over placebo) with 2-sided 95% CIs will be displayed. The proportion of subjects in each category will be calculated at each post-baseline assessment based on the number of subjects with non-missing CGI-S score.

A listing of CGI-S values over time will be provided for the FAS population.

10.8.2.2 Change from baseline in ASRS and CAARS-L-SR to Week 2, 4 and 6

The change in ASRS and CAARS-L-SR from baseline (see Section 11.2) to Week 2, 4 and 6 will be analyzed descriptively as indicated in section 8.9.1**Error! Reference source not found.** (in a ddition, the 95% confidence interval for the mean and median will be reported).

Separate listings of ASRS and CAARS-L-SR values overtime will be provided for the FAS.

10.9 PHARMACOKINETICS

The analyses of pharmacokinetic (PK) endpoints will be performed on the PKS (see definition in Section **Error! Reference source not found.**) population. The actual sampling time will be used f or PK parameter calculation and graphical presentation of individual data.

10.9.1 Pharmacokinetic Parameters

The following PK parameters will be determined by non-compartmental analysis using individual concentration-time profiles:

Table 7. Plasma Pharmacokinetic Parameters

Parameter, Units	Definition	Method of Determination

C_{max}, (ng/ml)	Maximum observed drug concentration	Observed value
t_{max}, (h)	Time to reach C_{max}	Actual elapsed time for observed C_{max} in each period
AUC_{0-t}, (ng·hr/ml)	Area under the concentration-time curve from time zero to the measurable concentration time t	AUC_{0-t} will be calculated using the linear-up log-down trapezoidal interpolation method
AUC_{0-inf},	Area under the concentration-time curve from time zero to infinity (extrapolated)	AUC_{0-inf} (extrapolation of the AUC_{0-t}) will be calculated as $AUC_{0-t} + \frac{C_t}{\lambda_t}$, where C_t is the last observed measurable concentration.
$AUC_{0\text{-}0.5h}$	Area under the drug concentration-time curve from time zero to time 0.5h	Calculated using linear-up log-down trapezoidal summation from time zero to 0.5 hour post MM-120 administration
$AUC_{0\text{-}1h}$	Area under the drug concentration-time curve from time zero to time 1h	Calculated using linear-up log-down trapezoidal summation from time zero to 1 hour post MM-120 administration
$AUC_{0\text{-}2h}$	Area under the drug concentration-time curve from time zero to time 3h	Calculated using linear-up log-down trapezoidal summation from time zero to 2 hours post MM-120 administration
$AUC_{0\text{-}3h}$	Area under the drug concentration-time curve from time zero to time 3h	Calculated using linear-up log-down trapezoidal summation from time zero to 3 hours post MM-120 administration
$AUC_{0\text{-}4h}$	Area under the drug concentration-time curve from time zero to time 4h	Calculated using linear-up log-down trapezoidal summation from time zero to 4 hours post MM-120 administration
$AUC_{0\text{-}6h}$	Area under the drug concentration-time curve from time zero to time 1h	Calculated using linear-up log-down trapezoidal summation from time zero to 6 hours post MM-120 administration
$t_{1/2}$, (hr)	Terminal elimination half-life	$\ln(2)/\lambda_z$, where λ_z is the first-order rate constant of drug associated with the terminal portion of the curve, see definition below.
λ_z	The observed elimination rate constant	Estimated by linear regression through at least three data points (not including t_{max}) in the terminal phase of the log concentration-time profile; see additional criteria below.

10.9.1.1 Additional criteria for the observed elimination rate constant (λ_z) determination.

This parameter will be the negative of the estimated slope of the linear regression of the ln-transformed concentration versus time profile in the terminal elimination phase (log-linear regression after semilogarithmic transformation of the data using at least the last 3 data points of the terminal linear phase of the concentration-time curve.). Best fit method will be used to calculate the $\boldsymbol{\lambda_z}$ from at least 3 concentration data points including only data points after C_{max} (t_{max}). Rsq adjusted, the goodness of fit statistic for the terminal elimination phase, adjusted for the number of points used in the estimation of $\boldsymbol{\lambda_z}$ must be ≥ 0.8. If the $\boldsymbol{\lambda_z}$ cannot be measured (e.g.: fewer than 3 non-zero concentrations in the terminal elimination phase or Rsq adjusted < 0.8), the PK parameters derived from $\boldsymbol{\lambda_z}$ will not be reported for that individual PK profile (AUC_{0-inf}, and $t_{1/2}$). The timepoint where ln-linear $\boldsymbol{\lambda_z}$ calculation begins ($\boldsymbol{\lambda_z}$ Lower) and the actual sampling time of the last measurable concentration used to estimate the $\boldsymbol{\lambda_z}$ ($\boldsymbol{\lambda_z}$ Upper), as well as the Rsq adjusted for the ln-linear regression for the calculation of the elimination rate constant will be reported.

10.9.2 Handling of Below Lower Limit of Quantification (BLOQ) values

Concentration BLOQ will be imputed by 0 for the calculation of descriptive statistics, PK analyses and graphical presentation except for the geometric mean and the geometric CV, where it will be imputed as Lower Limit of Quantification (LLOQ)/2.
If the concentrations before the first quantifiable concentration time point is BLOQ, the concentration will be set to 0.
If the concentrations after the last quantifiable concentration time point is BLOQ, the concentration will be set to missing.
If there are embedded BLOQ values between quantifiable concentrations, these BLOQ values will be set to missing.
If there is a quantifiable concentration after 2 consecutive BLOQ values at the end of the profile, this quantifiable concentration and any further quantifiable concentration will be set to missing.

Handling of other potential anomalies in the serum PK profiles will be discussed with the sponsor before PK parameter derivation.

10.9.3 Summary Statistics

Summary statistics include n, arithmetic mean, standard deviation (SD), geometric mean, coefficient of variation (CV), median, minimum and maximum. The CV will be expressed as a percentage and calculated as follows:

CV of the arithmetic mean (%): $\frac{\text{SD}}{\text{mean}} \times 100$

CV of the geometric mean (%): $\sqrt{\exp(\text{variance for log transformed data}) - 1} \times 100$

A table with summaries on PKS at “Week 1 D1” (first drug administration visit) will be presented with the following information:

- MM-120 plasma concentrations;

A table with summaries on PKS and in accordans with the definitions in Table 7 will be presented with the following information:

- Terminal elimination half-life $t_{1/2}$(hours)
- C_{max};
- t_{max};

- AUC;

Individual plots of MM-120 concentrations over actual sample time with all subjects on the same plot and separately per each subject's PK profile will be generated using linear and semi-logarithmic scales (i.e. log y-axis) on PKS and sampling time (pre- and post-dose).

Listings of individual MM-120 plasma concentrations and all parameters defined in Table 7 will be produced on PKS.

10.10 PHARMACODYNAMICS

Pharmacodynamic analysis (unless explicitly specified) will be performed on FAS population, in each treatment group.
Pharmacodynamic descriptive statistics will include: n, mean, standard deviation, Q1 (25th percentile), Q3 (75th percentile), minimum, maximum, and 95% Confidence Interval for the mean and for the median.

10.10.15 Dimensions of Altered States of Consciousness scale (5D-ASC).

5D-ASC will be assessed at Week 1 Day 1 and Week 6, 6 hours after dosing (see Section 2.1.2). The scale consists of 94 items (questions) and is scored on a 0-100 mm VAS extrapolated to 100% scale for quantitative evaluation. Each item of the scale corresponds to one of the 5 dimensions defined below. The descriptice statistics, as defined above, will be shown for 5 5D-ASC dimensions:

1) Oceanic boundlessness – summation of questions 1, 3, 9, 12, 16, 18, 26, 34, 35, 36, 40, 41, 42, 45, 50, 52, 57, 62, 63, 69, 71, 73, 81, 86, 87, 91, and 94. Maximum value = 2700.
2) Anxious ego dissolution – summation of questions 6, 8, 21, 27, 32, 38, 43, 44, 46, 47, 53, 56, 60, 64, 67, 78, 79, 80, 85, 88, and 89. Maximum value = 2100.
3) Visionary destructuralization – summation of questions 7, 14, 20, 22, 23, 28, 31, 33, 39, 54, 58, 70, 72, 75, 77, 82, 83, and 90. Maximum value = 1800.
4) Auditory alterations – summation of questions 4, 5, 11, 13, 19, 25, 30, 48, 49, 55, 65, 66, 74, 76, 92 and 93. Maximum value = 1600.
5) Vigilance reduction – summation of questions 2, 10, 15, 17, 24, 29, 37, 51, 59, 61, 68, and 84. Maximum value = 1200.

The 5D-ASC Total Score will be calculated as the sum of all the questions. The maximum value for the Total Score is 9400.

Additionally, the number (%) of completers and non-completers of the questionarie will be evaluated by the answer 'Yes|No' to the question 'Was the 5D-ASC questionnaire completed by the subject? ' respectively and will be presented in the summary table. The data are collected in the '5D-ASC' CRF section.

A spider-plot will be produced for graphical representation of 5 5D-ASC dimensions described above. The mean of the scores in 5 dimensions defined above standardized to 0-100 scale (eg, ' Vigilance reduction' mean/1200*100) will be displayed on the spider plot.

A listing of the 5D-ASC subscales and Total Score will be provided.

10.10.2 Mystical Experience Questionnaire (MEQ), drug effect Visual Analog Scale (VAS).

Mystical Experience Questionnaire (MEQ) will be assessed at Week 1 Day 1 and Week 6, 6 hours after dosing (see Section 1.2.2). The descriptice statistics, as defined above, will be shown for 4 MEQ scores and Total score (expressed on 100% scale):

1) Transcendence;
2) Positive mood;
3) Ineffability;
4) Mystical;
5) Total score.

Additionally, the number (%) of completers and non-completers of the questionarie will will be evaluated by the answer 'Yes|No' to the question 'Was the MEQ 30 questionnaire completed by the subject?' respectively and will be presented in the summary table. The data are collected in the ' MEQ-30' CRF section.

Box plot showing the distribution of MEQ scores in each treatment group will be produced.

Visual Analog Scale (VAS) will be assessed at Baseline, at 0, 0.5, 1, 2, 3, 4 and 6 hours after dosing (see Section 2.1.2). The following 9 items will be used in VAS (0-100 mm) assessment of the score:

1) Any drug effect;
2) Good drug effect;
3) Bad drug effect;
4) Drug liking;
5) Fear;
6) Nausea;
7) Alteration of vision;
8) Alteration of sense of time;
9) The boundaries between myself and my surroundings seem to blur.

The descriptive statistics of scores (extrapolated to 100% scale) will be presented for each time point of assessment in each treatment group and overall.

Additionally, the number (%) of completers and non-completers of the questionarie will will be evaluated by the answer 'Yes|No' to the question 'Was the VAS questionnaire completed by the subject?' respectively and will be presented in the summary table. The data are collected in the ' VAS' CRF section.

10.11 EXPLORATORY ENDPOINTS

Sleep quality/duration data are collected in the “Sleep Quality” CRF section and will be analyzed on FAS as continuous and categorical variable by treatment and visit as described in Section 8.10.

10.12 SAFETY ENDPOINTS

The AEs (adverse events) will be tabulated according to their System Organ Class (SOC) and Preferred Term (PT), in accordance with the Medical Dictionary for Regulatory Activities (MedDRA) coding.

10.12.1 Adverse events

Adverse events (AEs) will be summarized for treatment emergent adverse events (TEAEs). TEAEs are defined as AEs that occur on or after the day of the first dose. MedDRA terminology will be used to classify all AEs with respect to system organ class (SOC) and preferred term (PT).

A summary of subjects with TEAEs will be presented for each treatment group. The summary will include counts and percentages for subjects who experience at least one AE, overall and by SOC and PT. This will be repeated for severe TEAEs, related TEAEs and serious TEAEs. Severity will be captured as Grade 1 through Grade 5 with Grades 3-5 categorized as severe. Related will be captured

as: none, unlikely, possibly or probably, with related = possibly or probably. Serious will be captured with the standard serious adverse event (SAE) criteria.

The summary tables will be presented in descending order according to the incidence in the 'All' group (e.g., SOC and PT within each SOC with the highest number of occurrences will appear first). Equal frequency of different SOC/PTs will be sorted in alphabetical order of the SOC/PT.

Subjects who report the same PT on multiple occasions will be counted once for the preferred term under the highest severity when summarizing by severity, under the closest relationship to the drug when summarizing by relationship, under most serious when summarizing by seriousness.

Separate summary tables by SOC and PT will be provided for: TR-TEAEs, SAEs, and AEs leading to premature treatment discontinuation.

Individual subject listings will be provided on SAF.

10.12.1.1 Subgroup analysis

TEAEs, SAEs, AEs related to the study drug and AEs leading to premature treatment discontinuation will be tabulated on SAF by preferred term (PT) by treatment phase as follows:

- **Days of dosing**: all AEs occurred on same date/visit of treatment but only during or after administration of study drug (with time on or after treatment administration). Week 1 D1 (Dose 1), Week 1 D5 (Dose 2), Week 2 D8 (Dose 3), Week 2 D12 (Dose 4), Week 3 D15 (Dose 5), Week 3 D19 (Dose 6), Week 4 D22 (Dose 7), Week 4 D26 (Dose 8), Week 5 D29 (Dose 9), Week 5 D33 (Dose 10), Week 6 D36 (Dose 11), Week 6 D40 (Last dose 12);

  This information will be pooled in summary table, i.e. all AEs occurred on/after all doses: first, second etc. until last dose; as well as will be summarized separately, i.e. AEs occurred on/after each dose: on/after first dose, on/after second dose etc. and until on/after last dose.

- **Non-dosing days**: (a) all AEs with the date different from treatment administration date/visit defined above and until Week 10 Follow-up visit. (b) all AEs which occurred prior to study drug adminiatration (with time before administered dose) on dosing days.

  This information will be pooled in summary table, i.e. all AEs occurred between doses: first and second, second and third etc. until Week 10 Follow-up visit (EOS) or until Early Termination (ET) whatever comes earlier, as well as will be summarized separately, i.e. split by periods between doses: Dose 1 - Dose 2, Dose 2 - Dose 3, Dose 3 - Dose 4, Dose 4 - Dose 5, Dose 5 - Dose 6, Dose 6 - Dose 7, Dose 7 - Dose 8, Dose 8 - Dose 9, Dose 9 - Dose 10, Dose 10 - Dose 11, Dose 11 - Dose 12, Dose 12 | last administered Dose - EOS | ET.

In case of missing dates, the rules defined in Section 11.3.3 will be applied. In case of missing time of the AE or the treatment administration on the same day, the AE will be considered as occurred after the treatment administration, meaning will be summarized in 'Days of dosing' category.

Frequency statistics will be presented by treatment group. The summary tables will be presented in descending order according to their incidence in the active treatment group of 'Days of dosing' treatment phase (e.g., individual preferred term with the highest number of occurrences appear first) sorting ties alphabetically.

10.12.2 Vital signs

Vital signs (defined in section 8.11.4), including changes from baseline (defined in section 11.1.1), will be listed and summarized on the SAF for each parameter separately, using descriptive statistics

for continuous data. In the evaluation of the absolute changes from baseline, only subjects with both the baseline and specific time point assessment will be included.

10.12.3 Resting 12-lead ECG

12-lead ECG parameters (defined in section 8.11.5) will be separately listed and summarized on SAF, using descriptive statistics for continuous data, absolute values and corresponding change from baseline at each time point.

Treatment emergent ECG abnormalities (see definition in Section 8.11.5) will be summarized.

10.12.4Laboratory

Clinical laboratory data, abnormalities (defined in section 8.11.3) will be summarized on SAF.

The percentage of subjects with values beyond clinically important limits will be summarized by frequency tables and shift tables (Normal, Abnormal not clinically significant, Abnormal clinically significant), as well as the abnormalities in general. Data will be also summarized for the absolute value and corresponding change from baseline at each scheduled assessment, using respective SI units.

Individual listings will be produced for all parameters reporting flags of abnormal or out-of-range values.

Listings of pregnancy test results will be presented.

10.12.5 Physical examination

All physical examination data will be listed on SAF by visits (Baseline, Week 6 and Week 10), with associated general assessment. If an abnormality is found, further details describing the signs and symptoms related to the abnormality will be specified.

10.12.6 Columbia-Suicide Severity Rating Scale

Columbia-Suicide Severity Rating Scale will be listed at Baseline, Week 2 D8, Week 2 D12, Week 3 D15, Week 3 D19, Week 4 D22, Week 4 D26, Week 5 D29, Week 5 D33, Week 6 D36, Week 6 D40, Week 10 Follow-up/Final visit for withdrawals on SAF.

11 STUDY DEFINITIONS AND CONVENTIONS

11.1 DEFINITIONS

11.1.1 General definition of terms

11.1.1.1 Screening date

The screening date is the “Date of visit” in the "Demographics" CRF section.

11.1.1.2 Study treatment start date (Day 1)

Study treatment start date is the date of Week 1 D1 as collected in the “Date of visit” field in the section “Medical Events checks” when “LSD / Placebo administered” is ticked “Yes” in “Study Drug Administration” section.

11.1.1.3 Study treatment end date (EOT)

This is the last day of study drug intake, which is the date reported in "Date of visit" field in section "Medical Events checks" (for each Visit form) when "LSD / Placebo administered" is ticked "Yes" in "Study Drug Administration" section.

11.1.1.4 End-of-study (EOS) date

The date of the Visit Week 10 Follow-up as reported on "Week 10 Follow-up" section, "Medical Events checks" CRF section. If no Week 10 Follow-up visit has been done, then the date reported in "Early termination date" included in the "Termination Form" CRF section for premature withdrawals is used.

11.1.1.5 Treatment period

It is the period from the start date to the end date (limits included) of study treatment administration.

11.1.1.6 Study Day

The study day is the day of the event/assessment relative to the treatment start date.
The study day is defined as:

- The date of the event (visit date, onset date of an event, assessment date, etc.) – treatment start date + 1, if the event is on or after the treatment start date;
- The date of the event (visit date, onset date of an event, assessment date, etc.) – treatment start date, if the event precedes the treatment start date.

For dates prior to the treatment start, study day is the negative number of days elapsed between the date under consideration and the day of study treatment start. Therefore, the study day is always different from 0.

11.1.1.7 Study-completer subject

Refers to a subject who completed the study, i.e. subjects with answer "Yes" to the question 'Did the subject complete the study?' in the "Termination Form" CRF section.

11.1.1.8 Baseline value

Except where otherwise specified, baseline is defined as the last value measured or assessed before or on the date of the first dose of investigational drug administration at Visit 1. If the baseline visit takes place on the date of the first dose of investigational drug, then time should be considered, i.e. baseline date/time < first dose date/time.

11.2 Derivation, algorithm and conversion rules

11.2.1 Time since diagnosis

Time since diagnosis (days) is defined as = Screening date – Date of diagnosis +1 (date of diagnosis from "ADHD Medical History" CRF section).
Missing/Partial diagnosis dates will be imputed according Section 11.3.3.

11.2.2 Change from baseline

Each change from baseline will be defined as difference between the value at each post-baseline assessment and the baseline value:
Change from baseline= value at post-baseline visit-value at Baseline visit.

11.3 CONVENTIONS

11.3.1 Missing data

No substitution of missing data will be performed except for efficacy analysis (see section 10.7).

11.3.2 Handling of missing data

For primary and key secondary endpoints, missing/potentially biased data will be imputed using a multiple imputation approach assuming that the missingness mechanism can be retrieved from observed data (Section 10.7.2).

For all other endpoints, no imputation for missing values will be performed.

11.3.3 Handling of missing date and time fields

All dates and times used in the analysis are supposed to be complete, apart from the types included in the table below.

The dates in these types that are missing or incomplete will be derived as follows:

- Dates will be split into 3 parts: year, month and day. Year will be the top-level, month will be medium level and day will be lower level. If a part expected to be numeric value will be outside a valid range, the complete date will be handled as missing. For example, if date = 44Nov2000 the whole date will be considered to be missing.
- If a part expected to be numeric value is not numeric, i.e. contains values like for example ND, NA, --, ??, 2?, it will be considered as missing.
- If a part will be missing, all other parts of a lower level will be considered missing. This means that a ddmmyy date '21ND99' will be considered as '----99'.
- Missing parts will be changed into acceptable non-missing values in a way depending on the type of date to be replaced.

In the following, 'lower limit' and 'upper limit' refer to the minimum or maximum, respectively, of a possible date. For example, if the day is missing, the lowest limit will be the first day of the given month and the upper limit will be the last day of the given month. If the day and month are missing, the lower limit refers to the first day of the given year and the upper limit to the last day of the given year. The earliest and the latest of different dates refer to the first or last date, respectively, when ordered in sequence.

Table 8. Handling of missing date and time fields

Type of Date	*Date is incomplete*	*Date is missing*
Treatment administration date	If the question 'LSD / Placebo administered' is ticked as 'Yes', then impute the date of the corresponding planned visit date	If the question 'LSD / Placebo administered' is ticked as 'Yes', then impute the date of the corresponding planned visit date. Otherwise, no replacement should be done and the dosing is considered not done.
Date of diagnosis	Day missing: 15th of the month Day and month missing: June, 30th.	No replacement

Type of Date	*Date is incomplete*	*Date is missing*
AE stop date	The earliest between: -The upper limit and -date of DB extraction if it follows in the range of possible dates	No approximation, the AE is considered as ongoing in the analysis.
AE start date	If the stop date of the AE is not before the study treatment start date, and if the study treatment start date falls in the range of possible dates, it will be the study treatment start date. In all the other cases, it will be the lower limit.	The earlier of the stop date of the AE and the study treatment start date.
Previous and concomitant medication stop date	Upper limit	the subject will be considered having a concomitant medication and the date is not replaced.
Previous and concomitant medication start date	Lower limit	Impute with the of treatment start date if the treatment start date is earlier than the end date of concomitant medication. If the treatment start date is later or equal to the previous medication end date then impute with the screening date
ASRS, CAARS-L-SR, AISRS, CGI 5D-ASC, MEQ-30, VAS, C-SSRS SLV date	If the question ' Was the XXX questionnaire completed by the patient or investigator? ' is ticked as 'Yes', then impute the date of the corresponding actual visit date	If the question ' Was the XXX questionnaire completed by the patient or investigator? ' is ticked as 'Yes', then impute the date of the corresponding actual visit date. If the box is not ticked 'Yes', no imputation should be done.

12 LIST OF SUMMARY TABLES, LISTINGS AND FIGURES (TLFs)

12.1 Subject disposition

Output Name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
ANA	S	Overview of analysis sets	SCR	Yes	Layout T1	10.2
DISP	S	Subjects disposition	SCR	Yes	Layout T2	
LDISP	L	Listing of subject disposition	SCR		Layout L1	
PDEV	L	Subject listing of violations leading to exclusion from the PPS or PKS analysis set	FAS		Layout L2	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.2 Subject characteristics

12.2.1 Demographics

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
SDEM	S	Summary of demographic characteristics	FAS	Yes	Layout T3	10.3.1
LDEM	L	Subject listing of demographic characteristics	FAS		Layout L3	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.2.2 Baseline disease characteristics

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
SBDC	S	Summary of Baseline disease characteristics	FAS	Yes	Layout T3	10.3.2
LBDC	L	Subject listing of Baseline disease characteristics	FAS		Layout L4	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.2.3 Medical history and concomitant diseases

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
MHCDS	S	Summary of medical history and concomitant diseases by system organ class (SOC) and individual preferred term (PT)	FAS		Layout T4	10.3.3
MHADHD	S	Summary of ADHD medical history	FAS		Layout T14	
MHADHDSP	S	Summary of ADHD medical history by system organ class (SOC) and individual preferred term (PT)	FAS		Layout T4	
MDADHD	S	Summary of ADHD medication	FAS		Layout T24	
LMHCDS	L	Subject listing of medical history and concomitant diseases	FAS		Layout L5	
LMHADHD	L	Subject listing of ADHD medical history	FAS		Layout L17	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.2.4 Previous and concomitant medication

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
PM	S	Summary of previous medications by ATC class and preferred term	FAS		Layout T5	10.3.4
PMADHD	S	Summary of previous ADHD medications by ATC class and preferred term	FAS		Layout T5	
CM	S	Summary of concomitant medications by ATC class and preferred term	FAS		Layout T5	
CMADHD	S	Summary of concomitant ADHD medications by ATC class and preferred term	FAS		Layout T5	
PT	S	Summary of concomitant prohibited medications by ATC class and preferred term	FAS		Layout T5	

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
LM	L	Subject listing of previous and concomitant medications	FAS		Layout L6	
LPADHD	L	Subject listing of previous and concomitant ADHD medications	FAS		Layout L6a	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.2.5 Cognitive Performance Tests (Computer Test)

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
SCPT	S	Summary of cognitive performance test at Baseline and Week 6	FAS		Layout T15	10.3.5
LCPT	L	Subject listing of cognitive performance test at Baseline and Week 6	FAS		Layout L15	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.3 Study treatment exposure and compliance

12.3.1 Exposure to study treatment

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
EXP	S	Summary of treatment duration (days) by treatment group	SAF	Yes	Layout T6	10.4
LEXP	L	Subject listing of treatment duration (days)	SAF		Layout L7	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.3.2 Compliance with study treatment

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
COMPLSP	S	Summary of compliance (includes special situation and subjects with compliance not calculated due to special situations)	SAF		Layout T11	10.5
LCOMPLSP	L	Subject listing of compliance (includes special situation and subjects with compliance not calculated due to special situations)	SAF		Layout L8	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.3.3 Trial discontinuation

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
DISC	S	Summary of reasons for premature trial discontinuation	RAN, FAS	Yes	Layout T7	10.6
LDISC	L	Subject listing of subjects who did not complete the study	RAN		Layout L9	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.4Primary and secondary efficacy endpoint(s)

12.4.1 Primary efficacy endpoint

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
MMRMAISRS	S	MMRM for change from Baseline up to Week 6 in AISRS Score	FAS	Yes	Layout T16	10.7.2.2
LAISRS	L	Listing of AISRS values over time	FAS		Layout L18	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.4.2 Sensitivity analysis

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
MMRMMAR	S	Sensitivity analysis: MMRM for change from Baseline up to Week 6 in AISRS Score – MAR assumption	FAS	Yes	Layout T16	10.7.3
TIPP	S	Sensitivity analysis: Tipping point analysis	FAS	Yes	Layout T17	
MMRMMNAR	S	Sensitivity analysis: MMRM for change from Baseline up to Week 6 in AISRS Score – MNAR assumption	FAS	Yes	Layout T16	
MMRMCP	S	Sensitivity analysis: MMRM for change from Baseline up to Week 6 in AISRS Score – Completed cases	FAS	Yes	Layout T16	
MMRMAISRS	S	Sensitivity analysis: MMRM for change from Baseline up to Week 6 in AISRS Score	PPS	Yes	Layout T16	
MMRMAISRSSEV	S	Sensitivity analysis: MMRM for change from Baseline up to Week 6 in AISRS Score by ADHD severity at baseline	FAS	Yes	Layout T16	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.4.3 Other exploratory analyses

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
FAAISRS	S	Factor Analysis of the AISRS Scores at Baseline	FAS		Layout T30	10.7.4
FAISRS	F	Distribution of the eigen values of the PCA	FAS		Figure F5	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.4.4 Secondary endpoint(s)

12.4.4.1 Key Secondary Endpoint

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
ANCOVA AISRS	S	ANCOVA for change from Baseline to Week 2 in AISRS Score	FAS	Yes	Layout T12	10.8.1.1

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.4.4.2 Other Secondary Endpoint

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
CAISRS	S	Summary of change from Baseline to Week 2 and 6 of AISRS	FAS		Layout T10	10.8, 10.8.2
CCGI-S	S	Summary of change from Baseline to Week 2 and 6 of CGI-S	FAS		Layout T10	
PCGI-S	S	Summary of proportion of improved subjects in CGI-S by visit	FAS		Layout T13	
CASRS	S	Summary of change from Baseline to Weeks 2, 4 and 6 of ASRS	FAS		Layout T10	
CCAARS	S	Summary of change from Baseline to Week 2, 4 and 6 of CAARS	FAS		Layout T10	
LCGIS	L	Listing of CGI-S values overtime	FAS		Layout L19	
LASRS	L	Listing of ASRS values overtime	FAS		Layout L20	
LCAARS	L	Listing of CAARS values overtime	FAS		Layout L21	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.5PHARMACOKINETICS

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
PCMM-120	S	Summary table of MM-120 plasma concentration at Week 1 D1	PKS		Layout T25	10.9
SPK	S	Summary table of C_{max}, T_{max}, $t_{1/2}$, AUC_{0-inf}, $AUC_{0-0.5h}$, AUC_{0-1h}, AUC_{0-2h}, AUC_{0-3h} AUC_{0-4h}, AUC_{0-6h}	PKS		Layout T26	
PMM-120-ALL	F	Plot of all MM-120 concentrations on linear scale	PKS		Figure F1	
PMM-120-IDL	F	Individual plots of MM-120 concentrations on linear scale	PKS		Figure F1	
PMML-120-ALL	F	Plot of all MM-120 concentrations on semi-logarithmic scale	PKS		Figure F2	
PMML-120-IDL	F	Individual plots of MM-120 concentrations on semi-logarithmic scale	PKS		Figure F2	
LPC	L	Listing of MM-120 plasma concentration	PKS		Layout L26	
LPK	L	Listing of C_{max}, T_{max}, $t_{1/2}$, AUC_{0-inf}, $AUC_{0-0.5h}$, AUC_{0-1h}, AUC_{0-2h}, AUC_{0-3h} AUC_{0-4h}, AUC_{0-6h}	PKS		Layout L27	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.6PHARMACODYNAMICS

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
S5DASC	S	Summary of 5D-ASC Score at Week 1 Day 1 and Week 6	FAS		Layout T18	10.10.15, 10.10.2
MEQ	S	Summary of MEQ at Week 1 Day 1 and Week 6	FAS		Layout T19	

VAS	S	Summary of VAS Score at hours 0, 0.5, 1, 2, 3, 4 and 6 after the first dose	FAS		Layout T20	
SP5DASC	F	Spider-plot of 5D-ASC Score at Week 1 Day 1 and Week 6	FAS		Figure F3	
GMEQ	F	Box plot of MEQ Score at Week 1 Day 1 and Week 6	FAS		Figure F4	
L5DASC	L	Listing of 5D-ASC Score at Week 1 Day 1 and Week 6	FAS		Layout L22	
LMEQ	L	Listing of MEQ Score at Week 1 Day 1 and Week 6	FAS		Layout L23	
LVAS	L	Listing of VAS Score	FAS		Layout L16	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.7 Exploratory and other efficacy endpoints

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
SQD	S	Summary of sleep quality/duration data overtime	FAS		Layout T21	10.11

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.8 Safety endpoints

12.8.1 Adverse events

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
AESOC	S	Summary of adverse events (AE) by system organ class (SOC) and individual preferred term (PT)	SAF		Layout T4	10.12.1
AEPT	S	Summary of adverse events (AE) by individual preferred term (PT)	SAF		Layout T8	

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
TEAESOC	S	Summary of treatment-emergent adverse events (TEAE) by system organ class (SOC) and individual preferred term (PT)	SAF	Yes	Layout T4	
TEAEPT	S	Summary of treatment-emergent adverse events (TEAE) by individual preferred term (PT)	SAF		Layout T8	
SAESOC	S	Summary of serious adverse events (SAE) by system organ class (SOC) and individual preferred term (PT)	SAF	Yes	Layout T4	
SAEPT	S	Summary of serious adverse events (SAE) by individual preferred term (PT)	SAF		Layout T8	
SARSOC	S	Summary of serious adverse reaction (SAR) by system organ class (SOC) and individual preferred term (PT)	SAF		Layout T4	
SARPT	S	Summary of serious adverse reaction (SAR) by individual preferred term (PT)	SAF		Layout T8	
AEPDSOC	S	Summary of adverse events leading to premature discontinuation of study drug by system organ class (SOC) and individual preferred term (PT)	SAF		Layout T4	
AEPDPT	S	Summary of adverse events leading to premature discontinuation of study drug by individual preferred term (PT)	SAF		Layout T8	
AESRSOC	S	Summary of adverse events related to the study drug by system organ class (SOC) and individual preferred term (PT)	SAF		Layout T4	

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
AESRPT	S	Summary of adverse events related to the study drug by individual preferred term (PT)	SAF		Layout T8	
DEATH	S	Summary of deaths and causes of death	SAF		Layout T9	
LAE	L	Subject listing of adverse events	SAF		Layout L10	
LUAR	L	Subject listing of Unexpected Adverse Reaction (UAR) and Suspected Unexpected Serious Adverse Reaction (SUSAR)	SAF		Layout L10	
LSAE	L	Subject listing of serious adverse events (SAE)	SAF		Layout L10	
LSAR	L	Subject listing of serious adverse reaction (SAR)	SAF		Layout L10	
LAEPD	L	Subject listing of adverse events leading to premature discontinuation of study drug	SAF		Layout L10	
LDEATH	L	Subject listing of deaths	SAF		Layout L24	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.8.1.1. Subgroup analysis

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
TEAEPTTP	S	Summary of treatment-emergent adverse events (TEAE) by individual preferred terms (PT) by treatment phase.	SAF	Yes	Layout T27	
SAEPTTP	S	Summary of serious adverse events (SAE) by individual preferred terms (PT) by treatment phase.	SAF	Yes	Layout T27	10.12.1.1

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
AEPDPTTP	S	Summary of adverse events leading to premature discontinuation of study drug by individual preferred terms (PT) by treatment phase.	SAF		Layout T27	
AESRPTTP	S	Summary of adverse events related to the study drug by individual preferred terms (PT) by treatment phase.	SAF		Layout T27	

12.8.2 Vital signs

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
VIT	S	Summary of vital signs values and change from Baseline	SAF		Layout T22	10.12.2
LVIT	L	Listing of vital signs values	SAF		Layout L11	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.8.3 Resting 12-lead ECG

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
ECG	S	Summary of 12-lead ECG and change from Baseline by parameters	SAF		Layout T22	10.12.3
ECGTEA	S	Summary of treatment emergent 12-lead ECG abnormalities	SAF		Layout T23	
LECG	L	Listing of 12-lead ECG parameters and related abnormalities	SAF		Layout L25	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.8.4 Columbia-Suicide Severity Rating Scale

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
LCSSRS	L	Subject listing of Columbia-Suicide Severity Rating Scale	SAF		Layout L28	10.12.6

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.8.5 Laboratory

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
LAB	S	Change from Baseline over time by laboratory parameters (SI unit)	SAF		Layout T22	10.12.4
LABABN	S	Summary of clinical laboratory abnormalities (beyond clinically important limits) by visit	SAF		Layout T28	
SHIFTLABABN	S	Shift table of clinical laboratory abnormalities by visit	SAF		Layout T29	
LAB	L	Listing of laboratory parameters, with abnormal or out-of-range values flagged	SAF		Layout L12	
LPT	L	Listing of pregnancy test results	SAF		Layout L13	

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

12.8.6 Physical examination

Output name	Display*	Title (Description)	Analysis set(s)**	Key deliverable	Mock layout	SAP section
PHYPS	L	Subject listing of physical examination data by visit (Baseline, Week 6 and Week 10)	SAF		Layout L14	10.12.5

* S=Summary table, L= Listing, F=Figure, ** SCR=Screened set, FAS=Full Analysis set, SAF=Safety set, RAN=Randomized set, PPS=Per protocol set, PKS=Pharmacokinetic analysis set

13 APPENDICES

APPENDIX A - TABLE, FIGURE AND LISTING LAYOUTS

13.1 TABLE LAYOUTS

13.1.1 Layout T1

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>

	MM-120 N=xx	Placebo N=xx	All N=xx N (%)
Screened Set (SCR)			
Subjects Included			xx (100%)
Randomized Set (RAN)*			
Subjects Included	xx	xx	xx (yy.y)
Subjects Excluded			xx (yy.y)
Safety Set (SAF)**			
Subjects Included	xx	xx	xx (yy.y)
Subjects Excluded	xx	xx	xx (yy.y)
Full Analysis Set (FAS)**			
Subjects Included	xx	xx	xx (yy.y)
Subjects Excluded	xx	xx	xx (yy.y)
Per Protocol Set (PPS)***			
Subjects Included	xx	xx	xx (yy.y)
Subjects Excluded	xx	xx	xx (yy.y)
Pharmacokinetic Analysis Set (PKS)^			
Subjects Included	xx		xx (yy.y)
Subjects Excluded	xx		xx (yy.y)

*Percentages are calculated on the SCR
**Percentages are performed on the RAN
***Percentages are performed on the FAS
^ Percentages are performed on the SAF
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

13.1.2 Layout T2

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>

	MM-120 N=xx	Placebo N=xx	All N=xx N (%)
Subjects screened	xx	xx	xx (100%)
Screen failures			xx (yy.y)
Subjects randomized	xx	xx	xx (yy.y)
Subjects treated	xx	xx	xx (yy.y)
Subjects who completed the study	xx	xx	xx (yy.y)
Subjects who prematurely discontinued the study, reasons:			
Lost to follow-up	xx	xx	xx (yy.y)
Death	xx	xx	xx (yy.y)
COVID-19 related	xx	xx	xx (yy.y)
Other	xx	xx	xx (yy.y)

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

13.1.3 Layout T3

Study MMED007 – Deliverables: <Deliverables>

Table <Number of table>
<Title>
Analysis set: <analysis set>

	MM-120 N=xx N (%)	Placebo N=xx N (%)	All N=xx N (%)
<categorical parameter> [n (%)]			
<category 1>	xx (yy.y)	xx (yy.y)	xx (yy.y)
.			
.			
<category n>	xx (yy.y)	xx (yy.y)	xx (yy.y)
<continous parameter> *(unit)*			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard deviation	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

Note for programmer:

- *For table "SDEM" use: sex at birth (male | female) at screening, profession, highest education level (less than primary, primary, secondary, tertiary [bachelor, master, doctoral degree]) and country as categorical; age at screening as continuous.*
- *For table "SBDC" use: Baseline values for the Adult Attention Deficit Investigator Symptom Rating Scale (AISRS), Clinical Global Impression - Severity of Illness Scale (CGI-S), Adult ADHD Self-Report Scale (ASRS) and Connors' adult ADHD rating scale self-report long form (CAARS-L-SR) as continuous. <A/B/C/D/E/F/G/H> refer to scores on baseline 'Patient Reported Outcomes' eCRF page to be summarized in the table. In the table scores <A/B/C/D/E/F/G/H> should be reported as: A=Inattention/Memory Problems; B=Hyperactivity/Restlessness; C=Impulsivity/Emotional Lability; D=Problems with Self-Concept; E=DSM-IV Inattentive Symptoms; F=DSM-IV Hyperactive-Impulsive Symptoms; G=DSM-IV ADHD Symptoms Total; H=ADHD Index.*
- *For table "SCPT" use: 'Stop Signal Task', 'Discounting Task', 'Psychomotor Vigilance Task', 'Time Production Task' and 'Time Reproduction Task' categories at Baseline and Week 6; the number (%) of completers and non-completers of the test by the answer 'Yes|No' to the question Cognitive performance tests performed?.*

13.1.4 Layout T4

Study MMED007 - Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>

<Medical history/Concomitant diseases>

System Organ Class / Preferred Term	MM-120 N=xx N (%)	Placebo N=xx N (%)	All N=xx N (%)
ALL SYSTEM ORGAN CLASSES			
Total number of subjects with at least one *<medical and psychiatric events | AE>*	xx (yy.y)	xx (yy.y)	xx (yy.y)
System Organ Class 1	xx (yy.y)	xx (yy.y)	xx (yy.y)
<preferred term1>	xx (yy.y)	xx (yy.y)	xx (yy.y)
<preferred term2>	xx (yy.y)	xx (yy.y)	xx (yy.y)
System Organ Class n	xx (yy.y)	xx (yy.y)	xx (yy.y)
<preferred term1>	xx (yy.y)	xx (yy.y)	xx (yy.y)
<preferred term2>	xx (yy.y)	xx (yy.y)	xx (yy.y)

System Organ Class and Preferred terms are based on MedDRA 25.1 dictionary.
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

Note for programmer: display medical history and concomitant diseases in separate pages.
Please use 'System Organ Class and' only in tables by SOC and PT and not in those only by PT.
Please add footnote 'Treatment-emergent adverse events are events with onset date/time between the study treatment start date and the study treatment end date, limits included.' In the tables with treatment-emergent AEs.
Please add footnote 'A Serious Adverse Reaction (SAR) is a serious adverse event that is determined to be related to the study treatment' to the table with Summary of serious adverse reaction (SAR) by system organ class (SOC) and individual preferred term (PT).

13.1.5 Layout T5

Study MMED007 - Deliverables: <Deliverables>
Table <Number of table>

<Title>
Analysis set: <analysis set>

Anatomical Therapeutic Chemical Class / Preferred Term	MM-120 N=xx N (%)	Placebo N=xx N (%)	All N=xx N (%)
ALL THERAPEUTIC CLASSES			
Total number of subjects with at least one medication	xx (yy.y)	xx (yy.y)	xx (yy.y)
Total number of medication	xx	xx	xx
ATC class 1			
Total number of subjects with at least one medication	xx (yy.y)	xx (yy.y)	xx (yy.y)
Total number of medication	xx	xx	xx
<preferred term1>	xx (yy.y)	xx (yy.y)	xx (yy.y)
<preferred term2>	xx (yy.y)	xx (yy.y)	xx (yy.y)
ATC class n			
Total number of subjects with at least one medication	xx (yy.y)	xx (yy.y)	xx (yy.y)
Total number of medication	xx	xx	xx
<preferred term1>	xx (yy.y)	xx (yy.y)	xx (yy.y)
<preferred term2>	xx (yy.y)	xx (yy.y)	xx (yy.y)

ATC= Anatomical Therapeutic Chemical Class
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

13.1.6 Layout T6

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>

	MM-120 N=xx	Placebo N=xx
Exposure (days)	xx	xx
n	xx.x	xx.x
Mean	xx.x	xx.x
Standard Deviation	xx.x	xx.x
Standard Error	xx.x	xx.x
Median	xx.x	xx.x
Q1 , Q3	xx.x, xx.x	xx.x, xx.x
Min , Max	xx.x, xx.x	xx.x, xx.x

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

13.1.7 Layout T7

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>

	MM-120 N=xx N (%)	Placebo N=xx N (%)
Subjects who did not complete the trial	xx (yy.y)	xx (yy.y)
Reason for premature trial discontinuation		
Lost to follow-up	xx (yy.y)	xx (yy.y)
Death	xx (yy.y)	xx (yy.y)
COVID-19 related	xx (yy.y)	xx (yy.y)
Other	xx (yy.y)	xx (yy.y)
xxx	xx (yy.y)	xx (yy.y)

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

13.1.8 Layout T8

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>
Visit

	MM-120	Placebo	All

Preferred Term	N=xx N (%)	N=xx N (%)	N=xx N (%)
ALL SYSTEM ORGAN CLASSES Total number of subjects with at least one AE	xx (yy.y)	xx (yy.y)	xx (yy.y)
<preferred term1>	xx (yy.y)	xx (yy.y)	xx (yy.y)
<preferred term2>	xx (yy.y)	xx (yy.y)	xx (yy.y)

Preferred terms are based on MedDRA 25.1 dictionary.

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

13.1.9 Layout T9

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>

System organ class Preferred term	MM-120 N=xx N (%)	Placebo N=xx N (%)	All N=xx N (%)
All deaths	xx (yy.y)	xx (yy.y)	xx (yy.y)
System organ class 1	xx (yy.y)	xx (yy.y)	xx (yy.y)
<preferred term1>	xx (yy.y)	xx (yy.y)	xx (yy.y)
<preferred term2>	xx (yy.y)	xx (yy.y)	xx (yy.y)
	xx (yy.y)	xx (yy.y)	xx (yy.y)
System organ class n			
<preferred term1>	xx (yy.y)	xx (yy.y)	xx (yy.y)
<preferred term2>	xx (yy.y)	xx (yy.y)	xx (yy.y)

System Organ Class and Preferred terms are based on MedDRA 25.1 dictionary.

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

13.1.10 Layout T10

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>
Score: <A/B/C/D/E/F/G/H>
Visit

	MM-120 N=xx*	Placebo N=xx*
Baseline		
n	xx	xx
Mean	xx.x	xx.x
Standard deviation	xx.x	xx.x
Median	xx.x	xx.x
Q_1, Q_3	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x
Week <n>		
n	xx	xx
Mean	xx.x	xx.x
Standard deviation	xx.x	xx.x
Median	xx.x	xx.x
Q_1, Q_3	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x
Change from Baseline to Week <n>		
n	xx	xx
Mean	xx.x	xx.x
Standard deviation	xx.x	xx.x
Median	xx.x	xx.x
Q_1, Q_3	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

Note for programmer: Table will be presented by week: only subjects with both the baseline and specific time point assessment will be included. <A/B/C/D/E/F/G/H> refer to scores on 'Patient Reported Outcomes' eCRF page to be summarized in the table. In the table scores <A/B/C/D/E/F/G/H> should be reported as: A=Inattention/Memory Problems; B=Hyperactivity/Restlessness;

C=Impulsivity/Emotional Lability; D=Problems with Self-Concept; E=DSM-IV Inattentive Symptoms; F=DSM-IV Hyperactive-Impulsive Symptoms; G=DSM-IV ADHD Symptoms Total; H=ADHD Index.
Visit:
For scores ASRS and CAARS-L-SR: Week 2, Week 4, Week 6.
For scores AISRS and CGI-S: Week 2, Week 6.

13.1.11Layout T11

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>

	MM-120 N=xx N (%)	Placebo N=xx N (%)
Compliance (%) categories		
100% (12/12)	xx (yy.y)	xx (yy.y)
91.7% (11/12)	xx (yy.y)	xx (yy.y)
83.3% (10/12)	xx (yy.y)	xx (yy.y)
etc.	xx (yy.y)	xx (yy.y)
Number of subjects with at least one Special Situation	xx (yy.y)	xx (yy.y)
Number of Special Situations	xx	xx
Special situation*:		
Medication error or incorrect drug administration	xx (yy.y)	xx (yy.y)
Overdose	xx (yy.y)	xx (yy.y)
Deliberate abuse	xx (yy.y)	xx (yy.y)
Deliberate misuse	xx (yy.y)	xx (yy.y)
Drug interaction	xx (yy.y)	xx (yy.y)
Occupational exposure	xx (yy.y)	xx (yy.y)

*Percentages are computed on "Number of Special Situations"
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.1.12Layout T12

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>

	MM-120 N=xx	Placebo N=xx
Baseline		
n	xx	xx
Mean	xx.x	xx.x
Standard deviation	xx.x	xx.x
Median	xx.x	xx.x
Q_1, Q_3	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x
Week 2		
n	xx	xx
Mean	xx.x	xx.x
Standard deviation	xx.x	xx.x
Median	xx.x	xx.x
Q_1, Q_3	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x
Change from Baseline to Week 2		
n	xx	xx
Mean	xx.x	xx.x
Standard deviation	xx.x	xx.x
Median	xx.x	xx.x
Q_1, Q_3	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x
Absolute Change (from ANCOVA model)		
LS Mean	xx.x	xx.x
95% CL of LS Mean	xx.x, xx.x	xx.x, xx.x
TREATMENT EFFECT (MM-120 vs Placebo)		
p-value (based on ANCOVA model)	x.xxxx	

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.1.13Layout T13

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>
Visit

Category/Statistic		Baseline				
		0	1	2	…	6
<**MM-120rm/Placebo** > (N=xxx)						
Timepoint #1	0	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	1	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	…	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	6	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Missing	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Improved	## (##.#)				
	95% CIs	(##.#, ##.#)				
Timepoint #2	0	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	1	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	…	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	6	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Missing	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
	Improved	## (##.#)				
	95% CIs	(##.#, ##.#)				
Etc…		## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)

Percentages are based on N (number of patients in the analysis set)
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.1.14Layout T14

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>

	MM-120 N=xx N (%)	Placebo N=xx N (%)	All N=xx N (%)
Time since ADHD diagnosis, days			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard deviation	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Diagnostic criteria assessment according to DSMV			

All criteria met	xx (yy.y)	xx (yy.y)	xx (yy.y)
Not all criteria met	xx (yy.y)	xx (yy.y)	xx (yy.y)
Complete CAARS-S-OR at screening			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	xx (yy.y)	xx (yy.y)	xx (yy.y)
If 'Yes':			
A Score			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard deviation	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
B Score			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard deviation	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
C Score			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard deviation	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
D Score			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard deviation	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Current somatic disorder			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	xx (yy.y)	xx (yy.y)	xx (yy.y)
Previous hospitalization(s), previous disorders, (somatic and psychiatric), previous surgery(s)			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	xx (yy.y)	xx (yy.y)	xx (yy.y)
Family history (psychiatric and somatic)			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	xx (yy.y)	xx (yy.y)	xx (yy.y)
ADHD medication (prescription or non-prescription)			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	xx (yy.y)	xx (yy.y)	xx (yy.y)
Alcohol, caffeine, nicotine:			
Current Smoker			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	xx (yy.y)	xx (yy.y)	xx (yy.y)
Cigarettes per day			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard deviation	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Packs per year			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard deviation	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Coffee			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	xx (yy.y)	xx (yy.y)	xx (yy.y)
Coffee per day			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard deviation	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Alcohol (Beer, wine, liquor, ect.)			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	xx (yy.y)	xx (yy.y)	xx (yy.y)
Alcohol per week			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard deviation	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
MDMA/Ecstasy			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	xx (yy.y)	xx (yy.y)	xx (yy.y)
Sedative, Narcotic (Benzos, Ketamine, Laughing gas (nitrous oxide))			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	xx (yy.y)	xx (yy.y)	xx (yy.y)
Hallucinogenic (LSD, Mescaline, Psilocybin)			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	xx (yy.y)	xx (yy.y)	xx (yy.y)
Stimulants (Amphetamine, Cocaine, Methylphenidate (recreationally))			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	xx (yy.y)	xx (yy.y)	xx (yy.y)
Opioids (Morphine, Diacetylmorphin, Codeine, Methadone)			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	xx (yy.y)	xx (yy.y)	xx (yy.y)
Cannabis, Marijuana, CBD			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	xx (yy.y)	xx (yy.y)	xx (yy.y)
Others: (GHB, PCP, DXM, Spice)			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	xx (yy.y)	xx (yy.y)	xx (yy.y)

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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Note for Programmer: CAARS-S-OR scores should be reported in the table as: A-Score=DSM-IV Inattentive Symptoms; B-Score=DSM-IV Hyperactive/Impulsive Symptoms; C-Score=DSM-IV ADHD Symptoms Total; D-Score=ADHD Index.

13.1.15Layout T15

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>
Visit

	MM-120 N=xx N (%)	Placebo N=xx N (%)	All N=xx N (%)
Test performed			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	*xx (yy.y)*	*xx (yy.y)*	*xx (yy.y)*
Missing	*xx (yy.y)*	*xx (yy.y)*	*xx (yy.y)*
Stop signal task			
Done	xx (yy.y)	xx (yy.y)	xx (yy.y)
Not done	*xx (yy.y)*	*xx (yy.y)*	*xx (yy.y)*
Missing	*xx (yy.y)*	*xx (yy.y)*	*xx (yy.y)*
Discounting task			
Done	xx (yy.y)	xx (yy.y)	xx (yy.y)
Not done	*xx (yy.y)*	*xx (yy.y)*	*xx (yy.y)*
missing	*xx (yy.y)*	*xx (yy.y)*	*xx (yy.y)*
Psychomotor Vigilance Task			
Done	xx (yy.y)	xx (yy.y)	xx (yy.y)
Not done	*xx (yy.y)*	*xx (yy.y)*	*xx (yy.y)*
Missing	*xx (yy.y)*	*xx (yy.y)*	*xx (yy.y)*

Time Production Task			
Done	xx (yy.y)	xx (yy.y)	xx (yy.y)
Not done	*xx (yy.y)*	*xx (yy.y)*	*xx (yy.y)*
Missing	*xx (yy.y)*	*xx (yy.y)*	*xx (yy.y)*
Time Reproduction Task			
Done	xx (yy.y)	xx (yy.y)	xx (yy.y)
Not done	*xx (yy.y)*	*xx (yy.y)*	*xx (yy.y)*
Missing	*xx (yy.y)*	*xx (yy.y)*	*xx (yy.y)*

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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Note for Programmer: Visit = Baseline, Week 6. Please report No/Note done only if such data is available in the data. If it is not available, report Yes/Done values and missing for subjects where no data is available in the data set. All percentages should be calculated on the N.

13.1.16Layout T16

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>
Severe ADHD (AISRS score at baseline ≥ 38) | Moderate ADHD (AISRS score at baseline < 38)

Visit Treatment group	n	LS Mean	SE	95% CL	Difference to placebo LSMean	SE	95% CL	p-value*
Change from Baseline to Week 6								
MM-120	xx	xx.x	xx.x	[xx.x, xx.x]	xx.x	xx.x	[xx.x, xx.x]	0.xxx
Placebo	xx	xx.x	xx.x	[xx.x, xx.x]	-	-	-	-

*p-value is one-sided
**MMRM=Mixed Model for Repeated Measures
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

Note for programmer:
-for "MMRMAISRS" dependent variable is AISRS Score (analysis performed on FAS);
*-for "MMRMMAR" dependent variable is AISRS Score, with MAR assumption (analysis performed on FAS); add Footnote: *** MAR= Missing At Random.*
*-for "MMRMMNAR" dependent variable is AISRS Score, with MNAR assumption (analysis performed on FAS); add Footnote: *** MNAR= Missing Not At Random.*
-for "MMRMCP" dependent variable is AISRS Score, completed cases (analysis performed on FAS)
-for "MMRMAISRS" dependent variable is AISRS Score (analysis performed on PPS)

Please use subgroups 'Severe ADHD (AISRS score at baseline ≥ 38) | Moderate ADHD (AISRS score at baseline < 38)' in the sensitivity analysis of the MMRMAISRSSEV

13.1.17Layout T17

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>

Number of Subjects considered in the model	
MM-120	xx
Placebo	xx

Shift values	Difference to placebo LSMean	SE	95% CL	p-value
0	xx.x	xx.x	[xx.x, xx.x]	0.xxx
1	xx.x	xx.x	[xx.x, xx.x]	0.xxx
2	xx.x	xx.x	[xx.x, xx.x]	0.xxx
3	xx.x	xx.x	[xx.x, xx.x]	0.xxx
…	xx.x	xx.x	[xx.x, xx.x]	0.xxx

Note 1: Analysis is based on a Tipping Point analysis for primary endpoint
Note 2: Tipping point is performed until the MMRM model results to be not significant (p-value ≥ 0.05).
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

Note for programmer:

The Tipping point analysis will be performed only in case the main analysis of the primary endpoint (MMRMAISRS) resulted significant, p-value < 0.05.
The vector of shift values will include the values: (δ= 0, 1, 2, 3…) until the first value when MMRM model results to be not significant (p-value ≥ 0.05).

13.1.18Layout T18

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>
Visit

	MM-120 N=xx N (%)	Placebo N=xx N (%)	All N=xx N (%)
Completers			
n	xx	xx	xx
Oceanic boundlessness			
n	xx	xx	xx
Mean, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Standard deviation	xx.x	xx.x	xx.x
Median, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Anxious ego dissolution			
n	xx	xx	xx
Mean, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Standard deviation	xx.x	xx.x	xx.x
Median, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Visionary destructuralization			
n	xx	xx	xx
Mean, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Standard deviation	xx.x	xx.x	xx.x
Median, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Auditory alterations			
n	xx	xx	xx
Mean, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Standard deviation	xx.x	xx.x	xx.x
Median, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Vigilance reduction			
n	xx	xx	xx
Mean, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Standard deviation	xx.x	xx.x	xx.x
Median, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Total Score			
n	xx	xx	xx
Mean, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Standard deviation	xx.x	xx.x	xx.x
Median, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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Note for Programmer: Visit = Week 1 Day 1, Week 6

13.1.19Layout T19

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>
Visit

	MM-120 N=xx N (%)	Placebo N=xx N (%)	All N=xx N (%)
n	xx	xx	xx

Transcendence			
n	xx	xx	xx
Mean, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Standard deviation	xx.x	xx.x	xx.x
Median, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Positive mood			
n	xx	xx	xx
Mean, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Standard deviation	xx.x	xx.x	xx.x
Median, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Ineffability			
n	xx	xx	xx
Mean, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Standard deviation	xx.x	xx.x	xx.x
Median, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Mystical			
n	xx	xx	xx
Mean, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Standard deviation	xx.x	xx.x	xx.x
Median, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Total Score	xx	xx	xx
n	xx	xx	xx
Mean, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Standard deviation	xx.x	xx.x	xx.x
Median, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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Note for Programmer: Visit = Week 1 D1, Week 6

13.1.20Layout T20

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>
Timepoint x.xh (hours)*

	MM-120 N=xx N (%)	Placebo N=xx N (%)	All N=xx N (%)
Completers			
n	xx	xx	xx
Item n			
n	xx	xx	xx
Mean, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Standard deviation	xx.x	xx.x	xx.x
Median, 95% CL	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]	xx.x [xx.x, xx.x]
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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Note for programmer:
-Item 1: Any drug effect;
-Item 2: Good drug effect;
-Item 3: Bad drug effect;
-Item 4: Drug liking;
-Item 5: Fear;
-Item 6: Nausea;
-Item 7: Alteration of vision;
-Item 8: Alteration of sense of time;
-Item 9: The boundaries between myself and my surroundings seem to blur;
Timepoint x.xh: Week 1 Day 1, hours 0, 0.5, 1, 2, 3, 4, 6.*

13.1.21Layout T21

Study MMED007 – Deliverables: <Deliverables>

Table <Number of table>
<Title>
Analysis set: <analysis set>

	MM-120 N=xx N (%)	Placebo N=xx N (%)	All N=xx N (%)
Week <n>			
Sleep quality, continuous scale			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard deviation	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Sleep quality, categorical scale			
terrible	xx (yy.y)	xx (yy.y)	xx (yy.y)
poor	xx (yy.y)	xx (yy.y)	xx (yy.y)
fair	xx (yy.y)	xx (yy.y)	xx (yy.y)
good	xx (yy.y)	xx (yy.y)	xx (yy.y)
excellent	xx (yy.y)	xx (yy.y)	xx (yy.y)
Missing	xx (yy.y)	xx (yy.y)	xx (yy.y)
Sleep duration, hours			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard deviation	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

The respondent marks, an integer score from 0 to 10, are defined according to the following five categories: 0 = terrible, 1-3 = poor, 4-6 = fair, 7-9 = good, 10 = excellent.

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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Note for programmer: Sleep quality corresponds to the question 'How well did the patient sleep that night?' and duration to the question 'How many hours did the patient *approximately sleep that night?' on the 'Sleep Quality' eCRF page.*
"Missing" category is shown only if there are missing sleep quality values.

13.1.22Layout T22

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>
<*parameter (unit)*>

	MM-120 N=xx	Placebo N=xx
Visit		
Baseline		
n	xx	xx
Mean	xx.x	xx.x
Standard deviation	xx.x	xx.x
Median	xx.x	xx.x
Q_1, Q_3	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x
Week <n>		
n	xx	xx
Mean	xx.x	xx.x
Standard deviation	xx.x	xx.x
Median	xx.x	xx.x
Q_1, Q_3	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x
Change from Baseline to Week <n>		
n	xx	xx
Mean	xx.x	xx.x
Standard deviation	xx.x	xx.x
Median	xx.x	xx.x
Q_1, Q_3	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

Note for programmer:
-for "LAB", table will be presented by week: only subjects with both the baseline and specific time point assessment will be included;

-For "Vital Sign", table will be presented by week: only subjects with both the baseline and specific time point assessment will be included.

13.1.23Layout T23

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>
Visit

Abnormality category finding	MM-120 N=xx N (%)	Placebo N=xx N (%)
Subjects with at least one finding	xx (yy.y)	xx (yy.y)
<Category 1>	xx (yy.y)	xx (yy.y)
Finding 1	xx (yy.y)	xx (yy.y)
…	xx (yy.y)	xx (yy.y)
Finding n	xx (yy.y)	xx (yy.y)
<Category n>	xx (yy.y)	xx (yy.y)
Finding 1	xx (yy.y)	xx (yy.y)
…	xx (yy.y)	xx (yy.y)
Finding n	xx (yy.y)	xx (yy.y)

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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Note for Programmer: Visit = Baseline, Week 6

13.1.24Layout T24

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>

	MM-120 N=xx N (%)	Placebo N=xx N (%)	All N=xx N (%)
ADHD medication (prescription or non-prescription)			
Yes	xx (yy.y)	xx (yy.y)	xx (yy.y)
No	xx (yy.y)	xx (yy.y)	xx (yy.y)
If 'Yes':			
Name of medication/therapy			
Indication	xx (yy.y)	xx (yy.y)	xx (yy.y)
Total daily dose (*Unit*)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard deviation	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Amount taken in the morning			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard deviation	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Amount taken in the afternoon			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard deviation	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Amount taken in the night time			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
Standard deviation	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.1.25Layout T25

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>

	MM-120 N=xx
MM-120 plasma concentration at Week 1 Day 1, ng/ml	
Pre-dose: 0 hours	
n	xx (xx.x)
Mean (StD)	xx.x
CV of mean	xx.x
Geometric mean (CV)	xx.x (xx.x)
Median	xx.x
Min , Max	xx.x, xx.x
Time after dose: xx hours	
n	xx (xx.x)
Mean (StD)	xx.x
CV of mean	xx.x
Geometric mean (CV)	xx.x (xx.x)
Median	xx.x
Min , Max	xx.x, xx.x

StD=Standard Deviation; CV=Coefficient of Variation
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.1.26Layout T26

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>

	MM-120 N=xx
Parameter n, units	
n	xx (xx.x)
Mean (StD)	xx.x
CV of mean	xx.x
Geometric mean (CV)	xx.x (xx.x)
Median	xx.x
Min , Max	xx.x, xx.x

StD=Standard Deviation;
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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Note for Programmer: Parameter n1=Cmax, ng/ml; n2=Tmax, h; n3=t1/2, h; n4=AUC0-inf, ng·h/ml; n5=AUC0-0.5h, ng·h/ml; n6=AUC0-1h, ng·h/ml; n7=AUC0-2h, ng·h/ml; n8=AUC0-3h, ng·h/ml; n9=AUC0-4h, ng·h/ml; n10=AUC0-6h, ng·h/ml.

13.1.27Layout T27

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>

	Treatment Phase			
	Days of dosing*		Non-dosing days**	
Preferred Term	MM-120, N=xx N (%)	Placebo N=xx N (%)	MM-120, N=xx N (%)	Placebo N=xx N (%)
ALL Preferred Terms Total number of subjects with at least one AE	xx (yy.y)	xx (yy.y)	xx (yy.y)	xx (yy.y)
Dose 1 for Days of dosing | Period between Dose 1 and Dose 2 for Non-dosing days				
<preferred term1>	xx (yy.y)	xx (yy.y)	xx (yy.y)	xx (yy.y)
<preferred term2>	xx (yy.y)	xx (yy.y)	xx (yy.y)	xx (yy.y)
…				
Dose n for Days of dosing | Period between Dose m and Dose n for Non-dosing days				
<preferred term1>	xx (yy.y)	xx (yy.y)	xx (yy.y)	xx (yy.y)
<preferred term2>	xx (yy.y)	xx (yy.y)	xx (yy.y)	xx (yy.y)

…

*Days of dosing: all adverse events (AEs) occurred on same date/visit of treatment but only during or after administration of study drug;
**Non-dosing days:(a) all AEs with the date different from treatment administration date/visit until Week 10 Follow-up visit; (b) all AEs which occurred prior to study drug adminiatration on dosing days.
***Period between last administered Dose and end of treatment (ET): in this category reported all patients who discontinued study treatment preliminary
Preferred terms are based on MedDRA 25.1 dictionary.

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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Note for programmer:
1)for Treatment Phase 'Days of dosing': the AEs should be polled for all doses taken and should be split by dose n: Dose 1 correspond to dose administered at visit Week 1 D1, Dose 2 at visit Week 1 D5, Dose 3 at visit Week 2 D8, Dose 4 at visit Week 2 D12, Dose 5 at visit Week 3 D15, Dose 6 at visit Week 3 D19, Dose 7 at visit Week 4 D22, Dose 8 at visit Week 4 D26, Dose 9 at visit Week 5 D29, Dose 10 at visit Week 5 D33, Dose 11 at visit Week 6 D36, Dose 12 at visit Week 6 D40 (Last dose);
2)for Treatment Phase 'Non-dosing days': all AEs should be pooled for all doses taken and should be split by periods between doses m and n: Dose 1 - Dose 2, Dose 2 - Dose 3, Dose 3 - Dose 4, Dose 4 - Dose 5, Dose 5 - Dose 6, Dose 6 - Dose 7, Dose 7 - Dose 8, Dose 8 - Dose 9, Dose 9 - Dose 10, Dose 10 - Dose 11, Dose 11 - Dose 12, Dose 12|last dose - EOS|ET. Non dosing AEs correspond to (a)all AEs occurred on same date/visit of treatment administration as defined above, but with time before administered dose; (b)all AEs with the date different from treatment administration date/visit defined above and until Week 10 Follow-up.

Please report this footnote if such category has appeared in the table***Period between last administered Dose and end of treatment (ET): in this category reported all patients who discontinued study treatment preliminary

13.1.28Layout T28

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>
<Hematology/Chemistry>
Visit

Category/Statistic	MM-120 N=xx N(%)	Placebo N=xx N(%)	All N=xx N(%)
<Parameter>(Unit)			
n	##	##	##
L	##.#	##.#	##.#
LL	##.#	##.#	##.#
H			
HH			

Labels "L", "LL", "H" and "HH" display the increasing grade (severity) of abnormally low ("L", "LL"), or high values ("H", and "HH") for each of the laboratory parameters

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.1.29Layout T29

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>

Category/Statistic		Baseline				
		Normal	Abnormal NCS	Abnormal CS	Total non-missing	Missing
<**MM-120rm/Placebo** > (N=xxx)	n=xxx					
Timepoint #1 – n (%)	Normal	## (##.#)	## (##.#)	## (##.#)	## (##.#)	##

	Abnormal NCS	## (##.#)	## (##.#)	## (##.#)	## (##.#)	##
	Abnormal CS	## (##.#)	## (##.#)	## (##.#)	## (##.#)	##
	Total non-missing	## (##.#)	## (##.#)	## (##.#)	##	##
	Missing	##	##	##	##	##
	n=xxx					
Timepoint #2 – n (%)	Normal	## (##.#)	## (##.#)	## (##.#)	## (##.#)	##
	Abnormal NCS	## (##.#)	## (##.#)	## (##.#)	## (##.#)	##
	Abnormal CS	## (##.#)	## (##.#)	## (##.#)	## (##.#)	##
	Total non-missing	## (##.#)	## (##.#)	## (##.#)	##	##
	Missing	##	##	##	##	##
Etc…	n=xxx	## (##.#)	## (##.#)	## (##.#)	## (##.#)	##

CS= Clinically Significant.
n is the number of subjects with non-missing assessment.
Percentages are based on the number of subjects with non-missing assessment (n) in each treatment/visit
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.1.30Layout T30

Study MMED007 – Deliverables: <Deliverables>
Table <Number of table>
<Title>
Analysis set: <analysis set>

Item Number	Wording	Factor 1	…	Factor *m*
Sabscale 1				
Item 1	XXX	xx.x	*xx.x*	xx.x
…	…	…	…	…
Item *n*	XXX	xx.x	*xx.x*	xx.x
…				
Subscale 2				
Item 1	XXX	xx.x	*xx.x*	xx.x
…	…	…	…	…
Item n	XXX	xx.x	*xx.x*	xx.x

The maximum-likelihood factor analysis with orthogonal transformation was used for extracton of factors. Principal components analysis (PCA) with varimax rotation was used to evaluate the factor structure of the AISRS. Only itmes with loading factor ≥|0.4| are reported.

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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Note for programmer: number of factors to be presented in the table depends on the results (see SAP for details). Wording (XXX) corresponds to item on the 'AISRS' eCRF page. Item number can take values from 1 to 18 corresponding to eeach particular wording. Values to be presented in columns Factor 1 – Factor m are factor loadings after variamx rotation in pca.

13.2 LISTING LAYOUTS

13.2.1 Layout L1

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Screened	Failure	Randomized	Treated	Prematurely discontinued the study (reasons)	Completed study Reason
xxx	Yes/No	Yes/No	Yes/No	Yes/No	Yes(xxxxx)/No	Yes/No: xxxxxx

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.2.2 Layout L2

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	Date / time	Protocol Violation	Violations leading to exclusion from PPS	Violations leading to exclusion from PKS
xxx	xxx	ddmmyyyy/hh:mm	xxxxxxxxx	Yes/No	Yes/No
		ddmmyyyy/hh:mm	xxxxxxxxx	Yes/No	Yes/No
		…	…	…	…

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

13.2.3 Layout L3

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	Sex	Age (years)	Profession	Highest education level	Country
xxx	xxxxxxx	xx	xx	xxxxxx	xxxxxx	xxxxx

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.2.4 Layout L4

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	AISRS	CGI-S	ASRS	CAARS-L-SR (*A/B/C/D/E/F/G/H*)
xxx	xxxxxxx	xx	xx	xx	xx

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

Note for programmer: <A/B/C/D/E/F/G/H> refer to Connors' adult ADHD rating scale self-report long form (CAARS-L-SR) scores on baseline 'Patient Reported Outcomes' eCRF page. In the listing scores <A/B/C/D/E/F/G/H> should be reported as: A=Inattention/Memory Problems; B=Hyperactivity/Restlessness; C=Impulsivity/Emotional Lability; D=Problems with Self-Concept; E=DSM-IV Inattentive Symptoms; F=DSM-IV Hyperactive-Impulsive Symptoms; G=DSM-IV ADHD Symptoms Total; H=ADHD Index.

13.2.5 Layout L5

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	System Organ Class	Preferred Term	Reported Term	Start date	End date	Ongoing
xxx	xxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxx	ddmmyyyyy	ddmmyyy	Yes/No

Medical or surgical History is coded using Medical Dictionary for regulatory activities (MedDRA 25.1) dictionary latest version.
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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Note for programmer: display medical history and concomitant diseases in separate pages

13.2.6 Layout L6

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	ATC Class/ Preferred Term/ Medication name	Start date	Ongoing Stop date	Prohibited therapy	Reason for admistration Specification* Medication for ADHD**/ Dose (Unit)/ Frequency^/ Route^^	Medication given for the treatment of an AE/Medical History If yes: AE/ Medical History Reference(Report term and start date)
xxx	xxxxxxx	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	ddmmyyyy	Yes/No: ddmmyyyy	Yes/No	Adverse Event, Prophylaxis, Medical History, Other: xxxxxxxxx Yes/No / xx.x (Unit+) / xxxxx++ xxxxxxx^/ xxxxx+++ xxxxxxx^^	No/Yes: xxxxxxxx (xxxx, ddmmyyyy)

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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Note for programmer:
Don't show the following symbol in the listing. They are specified for a better programming understanding.
**If answer to "Reason for administration" is "Other"*
***If answer to "Reason for administration" is "Medical History" or "Other"*
+Unit can be "mg", "mcg", "g", "mL", "Tab", "IU", "Capsule", "Puff", if answer to "Unit" is "Other" include the text specified
++Frequency can be "QD", "QOD", "QID", "BID", "TID", "PRN", "Once per week", "Monthly", "As needed", if answer to "Unit" is "Other" include the text specified
+++Route can be "P.O. ", "SC", "IM", "IV", "Rectal", "Topical", "Nasal", "Inhaled", "Sublingual", "Transdermal", "Intraocular", if answer to "Unit" is "Other" include the text specified

13.2.7 Layout L6a

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	ATC Class/ Preferred Term/ Medication name	Date of Last Dose	Total Daily Dose (Unit)	Amount taken in the:		
					Morning	Afternoon	Night Time
xxx	xxxxxxx	xxxxxxxxx/ xxxxxxxxx/ xxxxxxxxx	ddmmyyyy	xx.x (Unit+)	x	x	x

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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Note for programmer:
Don't show the following symbol in the listing. They are specified for a better programming understanding.

+Unit can be "mg", "mcg", "g", "mL", "Tab", "IU", "Capsule", "Puff", if answer to "Unit" is "Other" include the text specified

13.2.8 Layout L7

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	Active treatment	Treatment---------- Start	---- End	Treatment duration (days)
xxx	xxxxxxx	xxxxxxx	ddmmyyyy	ddmmyyyy	xx

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.2.9 Layout L8

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	Total number of doses taken	Compliance(%) Category	Special situation Category
xxx	xxx	xxx	xxxxx	No/Yes: xxxxxxx

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.2.10Layout L9

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	Treatment Start	Treatment End	Day	Study completed Reason
xxx	xxx	ddmmyyyy	ddmmyyyy	xx	Yes/No: xxxxx

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.2.11Layout L10

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Active Treatment	System organ class/ Preferred term/ Reported term	Start date/ Time/ Study Day*	End date/ Time/ Duration (days)	Treatment Emergent**	Serious	Severity	Relation. to study drug	Action Taken With Study drug	Outcome
xxx	xxx	xxxxxxx/ xxxxxxxx/ xxxxxxx	ddmmy yyy/ Hh:mm	ddmmyyyy / Hh:mm	Yes/No	No/Yes: xxxxx	xxxxx	xxxxx	xxxxx	xxxxx

*Study day is the day of the event relative to the treatment start date.
**Treatment-emergent adverse event is any event with onset date/time between the study treatment start date and the study treatment end date, limits included.
System Organ Class and Preferred terms are based on MedDRA 25.1 dictionary.
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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Note for Programmer: Severity = Intensity of AE.

13.2.12Layout L11

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Active Treatment	Visit	Parametr (unit)	Assessment date/time	Study day	Result	Change from baseline	Report any clinically significant findings during the vital signs assessment
xxx	xxx	xxxxxxx	Xxxxxxxx (xx)	ddmmyyyy/ Hh:mm	xx	xx.x	xx.x	xxxxxxx

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.2.13Layout L12

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>

Analysis set: <analysis set>

Subject ID / Active Treatment	Visit	Parameter (unit)	Test	Assessment date/time	Study Day	Result	Change from Baseline	Test performed	Value category	Value
xxx / xxxxx	xxxx x	xxxxx (xx)	Hematology | Chemistry | Urine	ddmmyyyy/hh :mm	xx	xx.x	xx.x	No/Yes	Normal/Abnormal not clinically significant/Abnormal clinically significant	xx.x

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.2.14Layout L13

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Active Treatment	Visit	Pregnancy test performed	Result*	Serum pregnancy test performed as confirmation
xxx	xxxxx	xxxxx	No/Yes	Negative/Positive	Yes/No

*If pregnancy test is positive, subject must be withdrawn from study
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.2.15Layout L14

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Active Treatment	Visit	Physical examination And Blood pressure		Physical examination finding (clinically significant)	
xxx	xxxxxxx	xxxxxxx	Body Weight (kg)	xx.x	General appearance	Yes/No
			Height (cm)	xx.x	Skin	Yes/No
			BMI (kg/m2)	xx.x	Head / neck / thyroid	Yes/No
			Temperature (C°)	xx.x	Lymph nodes	Yes/No

Respiratory Rate (Breaths/minute)	xx.x	Musculosceletal system	Yes/No
Systolic (mmHg)	xx.x	Cardiovascular system	Yes/No
Diastolic (mmHg)	xx.x	Respiratory system	Yes/No
Heart rate (beats/min)	xx.x	Abdomen	Yes/No
		Neurological system	Yes/No
		Other(specify):	
		xxxxxxx	Yes/No
		xxxxxxx	Yes/No

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

Note to Programmer: parameters in column 'Physical examination And Blood pressure' are reported for Baseline vivst only

13.2.16Layout L15

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	Test performed	Visit	Date(Time)	Stop signal task	Discounting task	Psychomotor Vigilance Task	Time Production Task	Time Reproduction Task
xxx	xxxxxxx	Yes/No	xxx	Ddmmyyyy(Time)	Done/Not done	Done/Not done	Done/Not done	Done/Not done	Done/Not done

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.2.17Layout L16

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	Date of completion/ Time of completion	Time Expected	VAS questionnaire completed by the subject	VAS (mm)								
					Any drug effect	Good drug effect	Bad drug effect	Drug liking	Fear	Nausea	Alteration of vision	Alteration of sense of time	The boundaries between myself and my surroundings seem to blur
xxx	xxxxxx	ddmmyyyy / hh:mm	0/ 0.5/ 1/ 2/ 3/ 4/ 6	No/Yes	xx	xx	xx	xx	xx	xx	xx	xx	xx

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.2.18 Layout L17

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	Date of ADHD diagnosis	Attention deficit (hyperactivity) disorder confirmed	ADHD medication Name of medication/ Indication/ Total daily dose(Unit)/ Amount taken in the morning/ Amount taken in the afternoon/ Amount taken in the night	Alcohol, caffeine, nicotine	Substance use

					time/ Date of last dose				
xxx	xxxxx	ddmmyyyy	Criteria according to DSMV	All Criteria Met/No Met	No/Yes: xxxxx / xxxxx /xx.x (Unit)/ xxxxx/ xxxxx/ xxxxx/ ddmmyyyy	Current smoker	No/Yes(Cigarettes per day: xx/ Packs per year: xx)	MDMA/Ecstasy	No/Yes(Total lifetime use: xx.x/ Last use: ddmmyyyy)
			Complete CAARS-S-OR screening	No/Yes(*A/B/C/D*)		Coffee	No/Yes(Per day xx)	Sedative, Narcotic (Benzos, Ketamine, Laughing gas (nitrous oxide))	No/Yes(Total lifetime use: xx.x/ Last use: ddmmyyyy)
			Current somatic disorder	No/Yes		Alcohol (Beer, wine, liquor etc. (standard drink))	No/Yes(Per week xx)	Hallucinogenic (LSD, Mescaline, Psilocybin)	No/Yes(Total lifetime use: xx.x/ Last use: ddmmyyyy)
			Previous hospitalisation(s), previous disorders, (somatic and psychiatric), previous surgery(s)	No/Yes				Stimulants (Amphetamine, Cocaine, Methylphenidate (recreationally))	No/Yes(Total lifetime use: xx.x/ Last use: ddmmyyyy)
			Family History (psychiatric and somatic)	Yes/No				Opioids (Morphine, Diacetylmorphin, Codeine, Methadone)	No/Yes(Total lifetime use: xx.x/ Last use: ddmmyyyy)
								Cannabis, Marijuana, CBD	No/Yes(Total lifetime use: xx.x/ Last use: ddmmyyyy)
								Others: (GHB, PCP, DXM, Spice)	No/Yes(Total lifetime use: xx.x/ Last use: ddmmyyyy)

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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Note for Programmer: CAARS-S-OR scores A,B,C,D correspond to: A-Score=DSM-IV Inattentive Symptoms; B-Score=DSM-IV Hyperactive/Impulsive Symptoms; C-Score=DSM-IV ADHD Symptoms Total; D-Score=ADHD Index on the screening 'ADHD Medical History' eCRF form.

13.2.19Layout L18

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	Visit	Date of completion/ Time of completion	Study day	AISRS completed by investigator	Score	Adult ADHD investigator symptom rating scale (AISRS)	
xxx	xxxxxxx		xx.x/ ddmmyyyy/ hh:mm		No/Yes	xx.x	Do you make careless mistakes when working on a boring or difficult project?	0 None/ 1 Mild/ 2 Moderate/ 3 Severe
							Do you fidget or squirm with your	0 None/ 1 Mild/ 2 Moderate/

	hands or feet when you have to sit down for a long time?	3 Severe
	Do you have difficulty keeping your attention when you are doing boring or repetitive work?	0 None/ 1 Mild/ 2 Moderate/ 3 Severe
	Do you leave your seat in meetings or other situations in which you are expected to remain seated?	0 None/ 1 Mild/ 2 Moderate/ 3 Severe
	Do you have difficulty concentrating on what people say to you, even when they are speaking to you directly?	0 None/ 1 Mild/ 2 Moderate/ 3 Severe
	Do you feel restless or fidgety?	0 None/ 1 Mild/ 2 Moderate/ 3 Severe
	Do you have trouble wrapping up the final details of a project, once the challenging parts have been done?	0 None/ 1 Mild/ 2 Moderate/ 3 Severe
	Do you have difficulty unwinding and relaxing when you have time to yourself?	0 None/ 1 Mild/ 2 Moderate/ 3 Severe
	Do you feel overly active and compelled to do things, like you were driven by a motor?	0 None/ 1 Mild/ 2 Moderate/ 3 Severe
	Do you avoid or delay getting started on a task that requires a lot of thought?	0 None/ 1 Mild/ 2 Moderate/ 3 Severe
	Do you find yourself talking too much when you are in social situations?	0 None/ 1 Mild/ 2 Moderate/ 3 Severe
	Do you misplace or have difficulty finding things at home or at work?	0 None/ 1 Mild/ 2 Moderate/ 3 Severe
	When you're in a conversation, do you find yourself finishing the sentences of the people you that talking to, before they can finish them themselves?	0 None/ 1 Mild/ 2 Moderate/ 3 Severe

Do you find yourself being distracted by activity or noise around you?	0 None/ 1 Mild/ 2 Moderate/ 3 Severe
Do you have difficulty waiting your turn in situations when turn taking is required?	0 None/ 1 Mild/ 2 Moderate/ 3 Severe
Do your have problems remembering appointments or obligations?	0 None/ 1 Mild/ 2 Moderate/ 3 Severe
Do you interrupt others when they are busy?	0 None/ 1 Mild/ 2 Moderate/ 3 Severe

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.2.20Layout L19

Study MMED007 - Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	Date of completion/ Time of completion	CGI-S completed by investigator	Considering your total clinical experience with this particular population, how mentally ill is the subject at this time?
xxx	xxxxxxx	ddmmyyyy/ hh:mm	No/Yes:	1. Normal, not at all ill/ 2. Borderline mentally ill/ 3. Mildly ill/ 4. Moderately ill/ 5. Markedly ill/ 6. Severely ill/ 7. Among the most extreme ill subjects

Clinical Global Impression - Severity of Illness Scale (CGI-S)
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

13.2.21Layout L20

Study MMED007 - Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	Date of completion/ Time of completion	ASRS completed by subject	Score/
xxx	xxxxxxx	ddmmyyyy/ hh:mm	No/Yes:	xx.x

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.2.22 Layout L21

Study MMED007 - Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	Date of completion/ Time of completion	CAARS completed by the subject	Score
xxx	xxxxxxx	ddmmyyyy/ hh:mm	No/Yes	

A:xx/*B*:xx /*C*:xx /*D*:xx
/*E*:xx /*F*:xx /*G*:xx
/*H*:xx

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

Note for Programmer: <A/B/C/D/E/F/G/H> refer to scores on 'Patient Reported Outcomes' eCRF page. In the listing scores <A/B/C/D/E/F/G/H> should be reported as: A=Inattention/Memory Problems; B=Hyperactivity/Restlessness; C=Impulsivity/Emotional Lability; D=Problems with Self-Concept; E=DSM-IV Inattentive Symptoms; F=DSM-IV Hyperactive-Impulsive Symptoms; G=DSM-IV ADHD Symptoms Total; H=ADHD Index.

13.2.23 Layout L22

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	Date of completion/ Time of completion	5D-ASC completed by the subject	If yes:
xxx	xxxxxxx	ddmmyyyy/ hh:mm	No/Yes	1.Oceanic boundlessness: xx 2.Anxious ego dissolution: xx 3.Visionary destructuralization: xx 4.Auditory alterations: xx 5.Vigilance reduction: xx Total score: xx

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

13.2.24 Layout L23

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Randomized Treatment	Date of completion/ Time of completion	MEQ completed by the subject	If yes;
xxx	xxxxxx	ddmmyyyy/ hh:mm	No/Yes:	Transcendence: xx.x% Positive mood: xx.x% Ineffability: xx.x% Mystical: xx.x% Total score: xx.x%

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.2.25Layout L24

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Active Treatment	Date of death	Study Day of death*	Treatment Emergent**	Cause of death (Preferred term)
xxx	xxxxxx	ddmmyyyy	xx	Yes/No	xxxxxxxx

*Study day is the day of death relative to the treatment start date.
**Treatment-emergent date/time of death occured between the study treatment start date and the study treatment end date, limits included.
Preferred terms are based on MedDRA 25.1 dictionary.

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

13.2.26Layout L25

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Active Treatment	Visit	Parameter (unit)	Assessment date/time	Day	Result	Change from Baseline	Abnormalities found	Abnormalities Explanation
xxx	xxxxxx	xxxxxx	xxxxxx (xx)	ddmmyyyy/ hh:mm	xx	xx.x	xx.x	No/Yes	xxxxxxxxx

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

13.2.27Layout L26

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Sex	Age (years)	Visit	Assessment date/time	Planned Time Point	MM-120 plasma concentration (ng/ml)	Systolic (mmHg)	Diastolic (mmHg)	Heart rate (bpm])	Other Information
xxx	xx	xx	Week 1 Day 1	ddmmyyyy						
				hh:mm	pre-dose	xx.x	xx.x	xx.x	xx.x	xxxxxx
				hh:mm	after dose	xx.x	xx.x	xx.x	xx.x	xxxxxx
				hh:mm	after dose	xx.x	xx.x	xx.x	xx.x	xxxxxx
				…	…	…	…	…	…	…

Lower Limit of Quantitation = xx.x; Upper Limit of Quantitation = *xx.x*.
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

Note for programmer: Other Information: fill in with free text if it is available in the provided data, if not ignore and do not report this column in the table.

13.2.28Layout L27

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Sex	Age (years)	Parameter (unit)	Value
xxx	xx	xx	xxxxxx (xx)	xx.x

Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
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13.2.29 Layout L28

Study MMED007 – Deliverables: <Deliverables>
Listing <Number of listing>
<Title>
Analysis set: <analysis set>

Subject ID	Active Treatment	Was the C-SSRS completed by the investigator?	Visit	Date/ time of completion	Suicidal ideation since last visit (SLV)	Description if Yes for Suicidal ideation SLV	Intensity of ideation since last visit	Description of intensity of ideation SLV	Suicidal behavior since last visit	Description of suicidal behavior SLV	Answer for actual attempts only
xxx	xxx	Yes/No	Baseline …	ddmmyyyy/ hh:mm	1. Wish to be dead? *[Yes | No]* …	1. xxxxx …	Most severe ideation …	*[1 | 2 | 3 | 4 | 5] + description* …	Actual Attempt/ *[Yes | No]* …	*Total number of attempts | NA* …	Most lethal attempt date / *dd.mm.yyyy* Actual lethality / Medical damage /

[0 | 1 | 2 | 3 | 4 | 5]

Potential Lethality / *[0 | 1 | 2]*

| NA

NA = Not available
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

Note for programmer:
Visits: Baseline, Week 2 D8, Week 2 D12, Week 3 D15, Week 3 D19, Week 4 D22, Week 4 D26, Week 5 D29, Week 5 D33, Week 6 D36, Week 6 D40, Week 10 Follow-up/Final visit for withdrawals
Suicidal ideation since last visit (SLV) / Description if Yes for Suicidal ideation SLV

1. *Wish to be dead? [Yes | No] / Description*
2. *Non-specific active suicidal thoughts [Yes | No] / Description*
3. *Active suicidal ideation with any methods (not plan) without intent to act [Yes | No] / Description*
4. *Active suicidal ideation with some intent to act, without specific plan [Yes | No] / Description*
5. *Active Suicidal Ideation with Specific Plan and Intent [Yes | No] / Description*

Intensity of ideation since last visit / Description of intensity of ideation SLV

- *Most severe ideation / [1 | 2 | 3 | 4 | 5] + Description*
- *Frequency / [Less than once a week | Once a week | 2-5 times in a week | Daily or almost daily | Many times each day]*
- *Duration / [Fleeting - few seconds or minutes | Less than 1 hour / some of the time | 1-4 hours / a lot of time | 4-8 hours / most of the day | More than 8 hours / persistent or continuous]*
- *Controllability / [Easily able to control thoughts | Can control thoughts with little difficulty | Can control thoughts with some difficulty | Can control thoughts with a lot of difficulty | Unable to control thoughts | Does not attempt to control thoughts]*
- *Deterrents / [Deterrents definitely stopped you from attempting suicide | Deterrents probably stopped you | Uncertain that deterrents stopped you | Deterrents most likely did not stop you | Deterrents definitely did not stop you | Does not apply]*
- *Reasons for ideation / [Completely to get attention | Mostly to get attention | Equally to get attention, revenge or a reaction from others and to end / stop the pain | Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling) | Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling) | Does not apply]*

Suicidal behavior since last visit / Description of suicidal behavior SLV

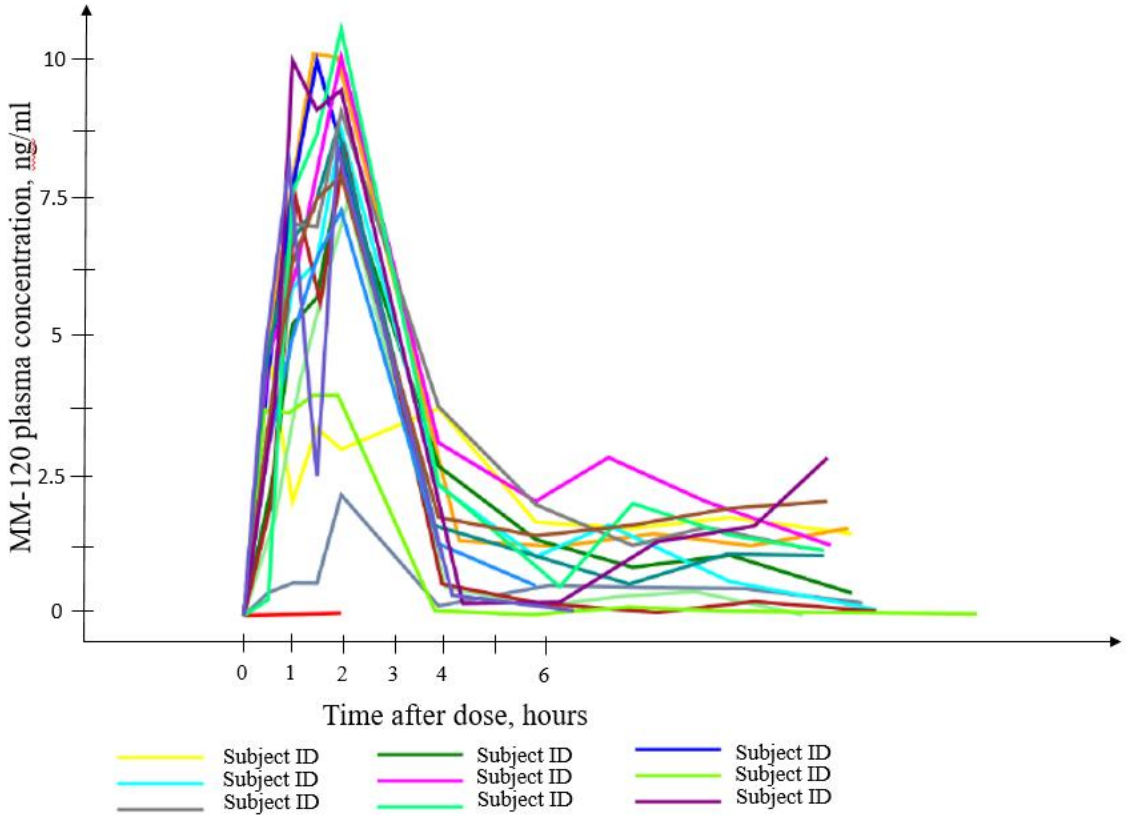
- *Actual Attempt [Yes | No] / Total number of attempts*
- *Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)? [Yes | No] / Description*
- *Has subject engaged in Non-Suicidal Self-Injurious Behaviour? [Yes | No] / --*
- *Interrupted Attempt [Yes | No] /Total number of interrupted attempts + Description*
- *Aborted Attempt [Yes | No] / Total number of interrupted attempts + Description*
- *Preparatory Acts or Behavior [Yes | No] / Description*
- *Suicidal behavior was present during the assessment period? [Yes | No] / --*
- *Suicide [Yes | No] / --*

If there are no data to report, e.g. no patients with suicide attempts, please put in those columns 'NA'. For example in last three columns, 'Description of suicidal behavior SLV', 'Answer for actual attempts only'.

13.3 FIGURE LAYOUTS

13.3.1 Figure F1

Study MMED007 – Deliverables: <Deliverables>
Figure <Number of figure>
<Title>
Analysis set: <analysis set>

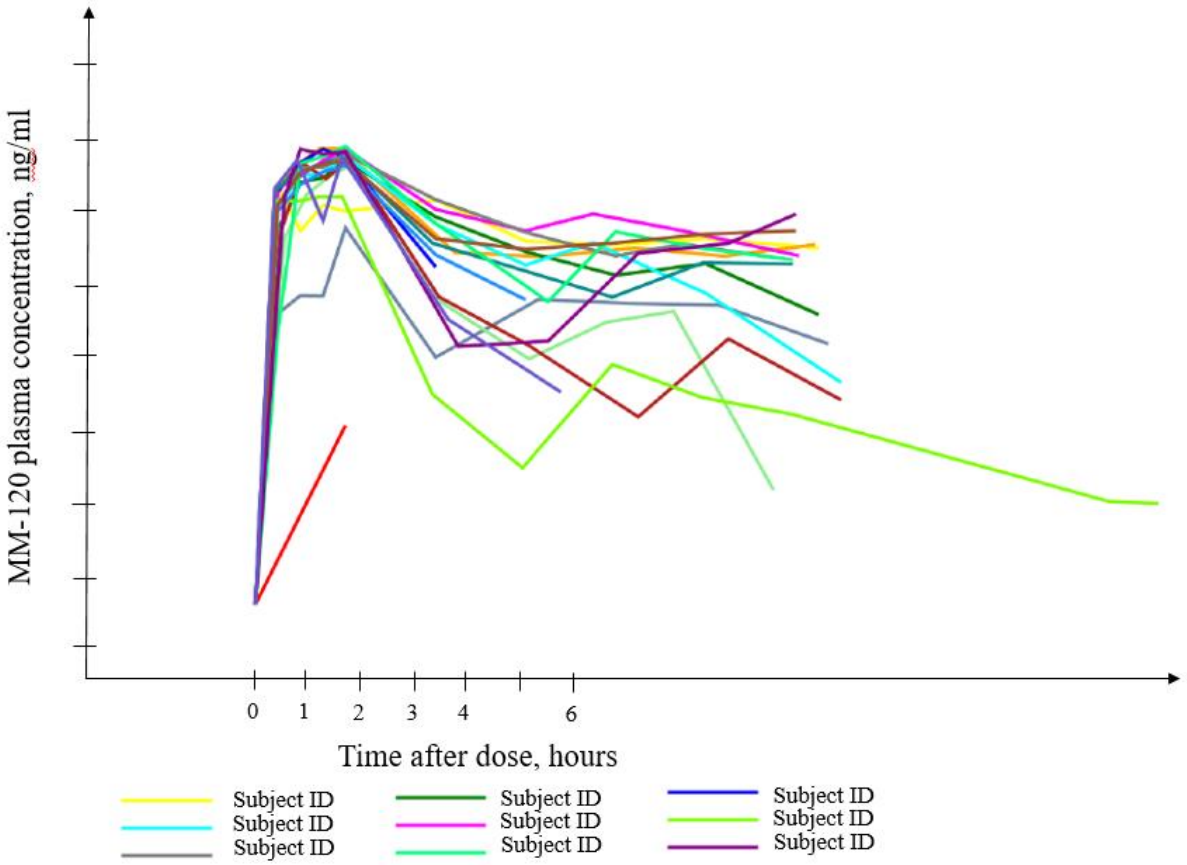


Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

Note for Programmer: Please use this template both for all PK profiles on same plot and for individual PK profiles (for each patient) on separate plots

13.3.2 Figure F2

Study MMED007 – Deliverables: <Deliverables>
Figure <Number of figure>
<Title>
Analysis set: <analysis set>

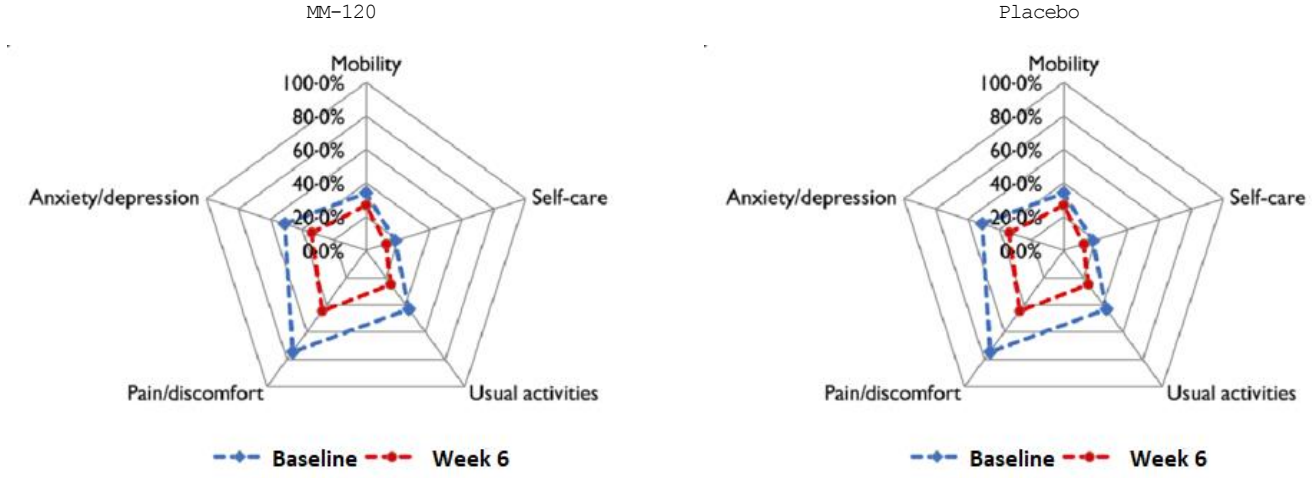


Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

Note for Programmer: Please use this template both for all PK profiles on same plot and for individual PK profiles (for each patient) on separate plots

13.3.3 Figure F3

Study MMED007 – Deliverables: <Deliverables>
Figure <Number of figure>
<Title>
Analysis set: <analysis set>

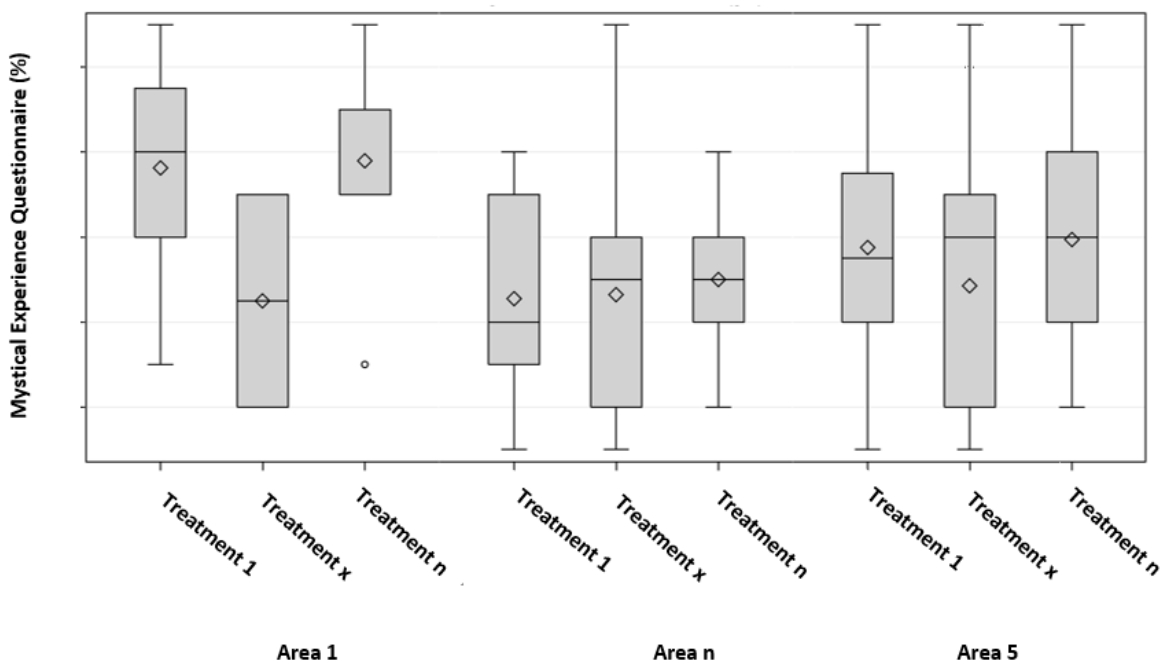


The scale is expressed in percentages
Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

Note for programmer: Change Area text in "Oceanic boundlessness", "Anxious ego dissolution", "Visionary destructuralization", "Auditory alterations", "Vigilance reduction". The baseline on the plot should be substituted by the Week 1 Day 1
Change legend including treatment (Not Visit that is already shown above the graph)

13.3.4 Figure F4

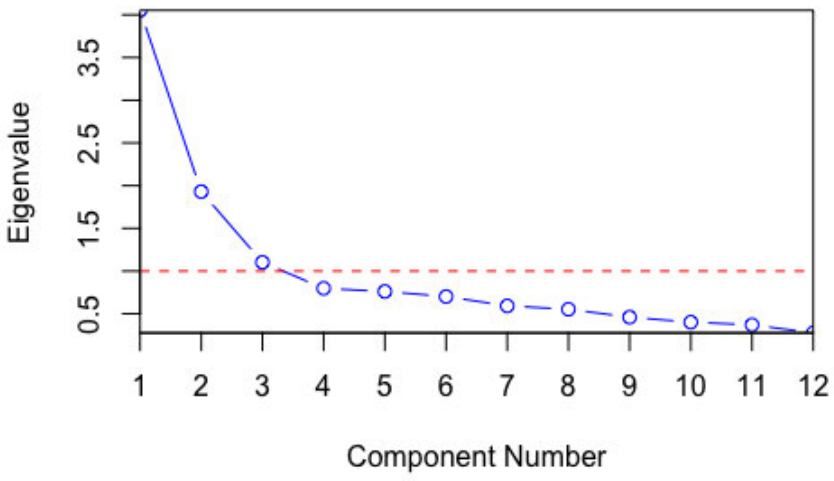
Study MMED007 – Deliverables: <Deliverables>
Figure <Number of figure>
<Title>
Analysis set: <analysis set>
< Week 1 Day 1 /Week 6>



Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final
Page x of x

13.3.5 Figure F5

Study MMED007 – Deliverables: <Deliverables>
Figure <Number of figure>
<Title>
Analysis set: <analysis set>
<Baseline>



Program: program_name.sas, Produced on yyyy-mm-dd hh:mm (CET),
Snapshot date: yyyy-mm-dd, Draft/final

Page x of x

Note for Programmer: Component=Factor

APPENDIX B – DOCUMENT HISTORY

Table 9. Version History

Version	Effective Date	Reason
Final 1.0	31.03.2023	First Final Version
Final 2.0	19.12.2023	Implementation of the CSR. The following updates took place since the version 1.0: 1)Visit windows - if more than one value falls on the same day then the last sequential number in sdtm will be used; 2)Visit windows - for parameters, where Time Interval Upper Limit for Baseline is equal to 1, please apply a rule of time defined in section 11.1.1.8 for Baseline; 3)Visit windows - updatedupper and lower limits for time intervals; 4)Visit windows - added visit windows for AISRS, CGI and Pharmacodynamics endpoints. 5)Study databases - final list with concomitant prohibited medications, including flags for intake or change in prohibited concomitant medications/therapies which have potential confounding effects will be provided by the Sponsor; 6)Safety endpoints - treatment-emergent MLAs definition added; 7)Abnormal laboratory values - Red Bloodcell count (RBC) in pl should be used in all summaries and listings; 8)Vital signs - in case of missing time of the Vital Signs assessment on the date of fisrt dosing, time 00:00 will be imputed on the corresponding date; 9)Columbia-Suicide Severity Rating Scale definition was added; 10)Primary efficacy endpoint analysis (handling the IEs) - intake or change in concomitant medications/therapies which have potential confounding effects will be treated as prohibited medications in the analyses as have the same definition.

		11)Primary efficacy endpoint analysis (handling the IEs) - definition of intercurrent events (IEs) is added; 12)Primary efficacy endpoint analysis - all assessments that took place after the IEs related to COVID-19 pandemic will be kept in the database; 13)Primary efficacy endpoint analysis - in the evaluation of the primary endpoint will be included only subjects with NON missing baseline assessments; 14)Dimensions of Altered States of Consciousness scale - baseline is not available for this endpoint, thus was substituted by the Week 1 Day 1; mean instead of median of the scores in 5 dimensions will be displayed on the spider plot as quite all the medians are zero; 15)Adverse events analysis - added clarification: the summary tables will be presented in descending order according to the incidence in the 'All' group (e.g., SOC and PT within each SOC with the highest number of occurrences will appear first). Equal frequency of different SOC/PTs will be sorted in alphabetical order of the SOC/PT; 16)Columbia-Suicide Severity Rating Scale analysis is added; 17)Baseline definition is clarified - if the baseline visit takes place on the date of the first dose of investigational drug, then time should be considered, i.e. baseline date/time < first dose date/time; 18)Handling of missing date and time fields is updated; 19)Topline results endpoints were defined in section 12; 20)Some update of shells; 21)Text editings throughout the document.

APPENDIX C – PROHIBITED MEDICATIONS

Drug Class or Drug Name	Washout Conditions/ Prohibition Period [a]	Allowable Conditions for use during study
Benzodiazepines	Last dose must have been taken at least 5 half-lives prior to Day -1 /baseline	To treat anxiety during study at Investigator's discretion [b]
Lithium	Last dose must have been taken at least 7 days prior to Day -1 /baseline	None
Monoamine oxidase inhibitors (MAOIs)[c]	Last dose must have been taken at least 3 weeks prior to Day-1 /baseline	None
Antipsychotics – traditional Antipsychotics – atypical Atypical agents (e.g., bupropion, mirtazapine) Barbiturates Selective serotonin reuptake inhibitors (SSRIs). For fluoxetine and its active metabolite, norfluoxetine, half-life (T1/2) of metabolite is more extended than other SSRIs and T1/2 of 7 to 15 days should be allowed. Serotonin-norepinephrine reuptake inhibitors (SNRIs) Serotonin–norepinephrine–dopamine reuptake inhibitors (SNDRIs) Serotonin modulators (e.g., vortioxetine, trazodone) Tricyclic antidepressants (TCAs) Stimulants to treat AHD (e.g., methylphenidate hydrochloride, amphetamines) Non-stimulants to treat ADHD	Last dose must have been taken at least 5 half-lives prior to Day -1/baseline	None
Other medications, e.g., efavirenz, supplements, herbal treatments, or therapeutics that affect serotonergic function (e.g., ginkgo biloba, St. John's Wort, 5- hydroxytryptophan [5- HTP], ayahuasca, dimethyltryptamine [DMT], and opioids, in particular, tramadol, ketamine, dextromethorphan, meperidine, methadone, and other agents that inhibit the reuptake of serotonin)	Last dose must have been taken at least 5 half-lives prior to Day -1/Baseline	None

a. Subjects on prohibited medications, supplements, or other therapeutics at the time of Screening may taper off that substance(s) prior to Day -1/Baseline (Visit 2) and will be eligible to participate in the study if the required washout conditions have been met.

b. Benzodiazepines should only be offered and administered if non-pharmacological interventions (e.g., reassurance, verbal communication) do not adequately address severe anxiety symptoms.

c. Although the half-life of MAOIs is typically 1.5-4 hours (eliminated quickly), the irreversible inhibition of monoamine oxidase may persist for 2-3 weeks due to the requirement for de novo synthesis of new enzyme, which is a relatively slow process. Therefore, washout for any MAOI should be conservatively 3 weeks.

APPENDIX D – CHANGES TO THE ANALYSES PLANNED IN THE STUDY PROTOCOL

1. A summary of ADHD Medical History was provided in Section 8.3.

2. The definition of the Screened analysis set missing in the Protocol, was added in section **Error! Reference source not found.** of the SAP to include data from subject screening f ailures in analyses.

3. For data completeness, the "Complete cases" sensitivity analysis on primary endpoint was added in Section 10.7.3.3.

4. Main analysis of the primary endpoint will be produced also on the PPS as a sensitivity analysis.

5. The definition of the secondary pharmacokinetic objective missing in the Protocol, was provided in Section 7.2 of the SAP.

6. The definition of the secondary pharmacodynamic objective missing in the Protocol, was provided in Section 7.2 of the SAP.

7. The exploratory objective was modified as pharmacogenomic data analysis will not be covered in this SAP.

8. Trial discontinuation analysis is adapted to the data provided in the "Termination Form" CRF section (section 4.2.2 of the SAP) and is different from what is planned in the Protocol section 3.1.

9. Factor analysis was added in this SAP (see Section 10.7.4) as an exploratory analysis aimed at understanding the relative contributions of individual AISRS items to overall observed efficacy.

10. The pregnancy test results will be not analyzed at weeks 3, 5, and 6 as will be not recorded in the eCRF. All pregnancy test results are being recorded on the subject's source document (paper record). See corresponding changes done in the footnote of the Table 2Table 1 in Section 2.1.2

11. Categorical presentation of the Quality Sleep results was added with the exploratory purpose, see changes in Sections 8.10, 10.11 and 13.1.21.

12. Intake or change in concomitant medications/therapies which have potential confounding effects will be treated as prohibited medications in the analyses as have the same definition.