The Safety and Efficacy of Psilocybin in Participants with Treatment Resistant Depression (P-TRD)

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The primary objective of this study is to evaluate the efficacy of psilocybin (25 mg or 10 mg) compared to 1 mg, administered under supportive conditions to adult participants with TRD, in improving depressive symptoms, as assessed by the change in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON55858

Source
ToetsingOnline

Brief title
Psilocybin in Participants with Treatment Resistant Depression (P-TRD)

Condition

- Mood disorders and disturbances NEC

Synonym
treatment resistant depression

Research involving
Human

Sponsors and support

Primary sponsor: COMPASS Pathfinder, Limited
Source(s) of monetary or material Support: COMPASS Pathways;Ltd

Intervention

Keyword: Psilocybin, P-TRD, Treatment Resistant Depression

Outcome measures

Primary outcome

The primary endpoint is the change in MADRS total score from Baseline (Day 1) to 3 weeks post psilocybin.

Secondary outcome

The secondary endpoints are:

* The proportion of participants with a response (defined as a * 50% improvement in MADRS total score from Baseline) at Week 3 post psilocybin.

* The proportion of participants with remission (defined as a MADRS total score * 10) at Week 3 post psilocybin.

* The proportion of participants who have a sustained response at Week 12. Sustained response is defined as the proportion of patients fulfilling response criteria at any visit up to and including Week 3, that also fulfills response criteria at all subsequent visits up to and including Week 12. Response is defined as * 50% decrease in MADRS total score from Baseline.

* Time to event measures: restart antidepressant medication for any reason, restart medication for continuing depressive symptoms, and relapse from a previously recovered state (clinical judgement, supported by the QIDS SR 16). Participants who withdraw from the study will be censored from the time to event analysis.

Study description

Background summary

A recent open label study of the effects of psilocybin in participants with treatment resistant depression (TRD) showed rapid significant decrease of depressive symptoms after treatment with psilocybin coupled with psychological support. Over 40% of participants sustained response at 3 months. In this study, the aim is to assess effectiveness of 3 different doses of psilocybin (1 mg, 10 mg, and 25 mg) in TRD, with the lowest dose assumed to be in effect a placebo.

Study objective

The primary objective of this study is to evaluate the efficacy of psilocybin (25 mg or 10 mg) compared to 1 mg, administered under supportive conditions to adult participants with TRD, in improving depressive symptoms, as assessed by the change in the Montgomery Asberg Depression Rating Scale (MADRS) total score from Baseline. Baseline is defined as the assessment score obtained on Day 1. The primary timepoint is Week 3; this variable will be analysed for the change from Baseline to Day 1, and Weeks 1, 3, 6, 9, and 12.
The secondary objectives are:
* To assess the efficacy of psilocybin compared to 1 mg psilocybin on:
o Proportion of participants with response defined as a * 50% decrease in MADRS total score from Baseline to Week 3. This will also be assessed at Day 1 and at Weeks 1, 6, 9, and 12.
o The proportion of participants who have a sustained response at Week 12. Sustained response is defined as the proportion of patients fulfilling response criteria at any visit up to and including Week 3, that also fulfills response criteria at all subsequent visits up to and including Week 12. Response is defined as * 50% decrease in MADRS total score from Baseline.
* To evaluate the safety and tolerability of psilocybin in participants with TRD based on adverse events (AEs), changes in vital signs, and suicidal ideation/behaviour (measured using the Columbia-Suicide Severity Rating Scale [C SSRS]) score at all visits.
The exploratory objectives are:
* To evaluate the effects of psilocybin on quality of life and wellbeing, functioning and associated disability, cognitive function, and anxiety compared to 1 mg psilocybin on:
outcomes as possible predictors of response.
The main purpose of this study is to allow COMPASS to determine the optimal dose of psilocybin, either 10 mg or 25 mg. The intent of the primary efficacy analysis is to demonstrate superiority of at least one therapeutic dose of psilocybin (10 mg or 25 mg) versus the 1 mg psilocybin via the following objectives.
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(25 mg or 10 mg) compared to 1 mg, administered under supportive conditions to adult participants with TRD, in improving depressive symptoms, as assessed by the change in the Montgomery Asberg Depression Rating Scale (MADRS) total score from Baseline. Baseline is defined as the assessment score obtained on Day 1. The primary timepoint is Week 3; this variable will be analysed for the change from Baseline to Day 1, and Weeks 1, 3, 6, 9, and 12.
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* To evaluate the safety and tolerability of psilocybin in participants with TRD based on adverse events (AEs), changes in vital signs, and suicidal ideation/behaviour (measured using the Columbia-Suicide Severity Rating Scale [C SSRS]) score at all visits.
The exploratory objectives are:
* To evaluate the effects of psilocybin on quality of life and wellbeing, functioning and associated disability, cognitive function, and anxiety compared to 1 mg psilocybin on:
o Quality of life in participant EuroQoL (EQ) 5 dimension 3 level scale (EQ 5D 3L) score change from Baseline to Week 3. This will also be assessed at Week 12.
o Quality of life in caregiver EQ 5D 3L score change from Baseline to Week 3. This will also be assessed at Week 12. This assessment is not mandatory.
o Functioning and associated disability in the Sheehan Disability Scale (SDS) score change from Baseline to Week 3. This will be also assessed at Week 12.
o Cognitive function as measured by the Digit Symbol Substitution Test (DSST) score change from Baseline to Week 3. This will also be assessed at Day 1 and Week 12.
o Level of anxiety as measured using the change in Generalised Anxiety Disorder 7 item Scale (GAD 7) total score change from Baseline to Week 3. This will also be assessed at Week 12.
o Participant determined level of depression as measured using the change in Quick Inventory of Depressive Symptomatology Self Rated (QIDS SR 16) total score from Baseline to Week 3. This will also be assessed at Day 1, and Weeks 1, 2, 6, 9, and 12.
o Psychosocial functioning and predictor of response duratbility as measured using the change in Work and Social Adjustment Scale (WSAS) from Baseline to Week 3. This will also be assessed at Week 12.
o To evaluate the impact of different psilocybin doses on real life functional activity estimated from passive data streams collected on a mobile

app on participants* mobile phones. The data collected from the participant*s phone will include:
* Number of and time of phone calls/e mails/texts (content will not be collected)
* Gestures used (taps, swipes, other)
* Gyroscope (orientation) of the phone (the way the phone is pointing)
* Acceleration of the phone (sudden movements of the phone)
* Keystroke patterns with characters redacted
* Location information from the GPS
* The app also maintains a histogram of daily words that the participant types on their phone. These words will be stripped from their context and syntax, thus preventing the content of any particular message from being deciphered.
o The Positive and Negative Affect Schedule, Five Dimension Altered States of Consciousness questionnaire, 2a receptor polymorphism test and the Scale to Assess Therapeutic Relationship (Clinician and Patient version, STAR C and STAR P, respectively) will be assessed for correlation with the primary and secondary outcomes as possible predictors of response.

Study design

This is a Phase 2, international multicentre, randomised, fixed dose, double blind trial. The study population will include adult men and women, 18 years of age and older, with TRD. Participants with TRD are defined as those who meet the Diagnostic and Statistical Manual of Mental Disorders (5th Edition; DSM 5) diagnostic criteria for single or recurrent episode of major depressive disorder (MDD) without psychotic features which have failed to respond to an adequate dose and duration of 2, 3, or 4 pharmacological treatments for the current episode; if single episode MDD, the duration of the current episode must be at least 3 months but not more than 2 years. Augmentation counts as a second treatment, provided it is approved for the adjunctive treatment of MDD in that country..
Participants will be outpatients and will be recruited primarily through referrals from general practitioners and specialised psychiatric services.
The majority of participants will have no prior exposure to psilocybin or so called magic mushrooms; however, to reflect the prevalence of experience in general population, we will allow up to 10% of participants with prior recreational experience with psilocybin or magic mushrooms. Past exposure to psilocybin has to be more than 12 months prior to Screening and not during the current depressive episode. This will be constrained by the centralised randomisation process, Interactive Web based Response System.
After signing the informed consent form (ICF), participants will be assessed for their eligibility with the Mini International Neuropsychiatric Interview (MINI), the Hamilton Depression Rating Scale (HAM D 17), the Massachusetts General Hospital Antidepressant Treatment History Response Questionnaire (MGH-ATRQ), the C SSRS, and McLean Screening Instrument for Borderline Personality Disorder. Those who meet the eligibility criteria will enter the screening period, which will last between 3 and 6 weeks. At the initial

Screening visit (V1), the participant will also be evaluated with the QIDS SR 16, and the Adult Self Report Scale. Additionally, a medical history, an electrocardiogram (ECG), blood tests, and vital signs will be obtained.
During the screening period, participants who are on antidepressant medications will be expected to complete the taper at least 2 weeks prior to Baseline (V2). Participants will be given a choice of the tapering rate. During the tapering period all participants will be supported by the study clinician.
Once a patient completes all V1 assessments and all screening data is entered into the Electronic Data Capture (EDC), the Medical Monitor (MM) and Clinical Assessment Technologies Team (CAT) will review data entered and issue approval, if the patient is eligible. Once approval is issued, the patient should then be invited for a screening V1a visit. The V1a visit is the point at which the patient begins tapering off their antidepressant and/or antipsychotic medications, if appropriate. The patient must complete the taper within the first 4 weeks of this period, prior to 2 weeks completely off antidepressant and/or antipsychotic medications, before Baseline V2. The tapering period used in the study is set at the industry standard for depression trials.
The designated study team member will be in frequent contact with the participants to monitor for withdrawal and worsening of depression symptoms. Participants will be assessed for suicidality with the C SSRS at each contact/visit.
The participant will meet with a therapist for a minimum of 3 visits during screening. These are safety sessions and will cover what to expect during the psilocybin session. The therapist and the participant will review psychoeducational materials provided at the time of enrolment.
All participants will be evaluated for safety at the clinic weekly for a minimum of 3 weeks prior to psilocybin administration to ensure safe discontinuation of current antidepressant therapy required by the protocol.
Participants* companions (friends or family members) will be educated about the signs of worsening of depression and suicidality, and instructed on ways to contact the study team in case of significant worsening of depression. Any safety assessment visits during the screening period will be called V1a, V1b, etc. During these visits, the C SSRS and any changes in medications since the previous visit will be obtained in addition to other assessments at the study clinician*s discretion.
The day before psilocybin session, the participants will undergo a baseline assessment (3 to 6 weeks after initial Screening [V1]) that will consist of the HAM D 17, MADRS, QIDS SR 16, C SSRS, SDS, GAD 7, DSST, EQ 5D 3L (administered to both participant and caregiver [the latter is not mandatory]), WSAS, vital signs, urinalysis, urine drug screen, and urine pregnancy test (only for women of childbearing potential). Both the therapist and the participant will be asked to fill out a therapeutic alliance evaluation questionnaire, STAR C and STAR P, respectively. After baseline data is entered into EDC, the CAT team will complete a final review to ensure the participant*s continued eligilblilty. Participants cannot be progressed to V3 until this approval is received.
The psilocybin administration session (V3, Day 0) will last approximately 6

hours and will be supported by a trained therapist. Psilocybin session may be video recorded for training and adherence monitoring. A full description of the activities of the psilocybin administration session is found in the Therapist Manual. After the acute effects of the psilocybin pass, participants will be evaluated for safety and accompanied home. On Day 1 (V4), the day following psilocybin administration, participants will be seen in person for a safety check, assessment of suicidality, and to discuss their experience during the psilocybin session. All sessions between the therapist and the participant may be audio recorded for adherence monitoring and quality assurance. Audio and video recording of the sessions are subject to participant consent. Participants who do not consent to either or all recordings will not be excluded from the study.
All participants will be asked to remain off their antidepressant medications for at least 3 weeks following the psilocybin session until the primary endpoint assessment, or longer. Rescue medications are allowed as noted in the protocol. Participants who restart their antidepressant medications during the first 3 weeks after the psilocybin treatment administration will be assessed for reasons of resuming their medications and followed until 12 weeks post psilocybin administration.
The treatment period will determine the optimal therapeutic dose; 216 participants will be randomised in a 1:1:1 ratio to receive 1 mg psilocybin, 10 mg psilocybin, or 25 mg psilocybin.
Participants will be seen at the clinic for Screening (V1 plus a minimum of 3 safety visits), Baseline (V2, Day 1), Day 0 (V3, Dosing), Day 1 (V4), Week 1 (V5), Week 2 (V6), Week 3 (V7), and Week 12 (V10). Participants will also be contacted for follow up at Week 6 (V8) and Week 9 (V9). The MADRS will be done by telephone and the other assessments will be done electronically. Participants are seen at the clinic for safety visits between the initial Screening (V1) and the Baseline (V2) visit, and the visits will be labelled V1a, V1b, V1c, etc.

Intervention

216 patients will be randomized in a 1:1:1 ratio to 25 mg, 10 mg, or 1 mg of psilocybin.

Study burden and risks

Side effects associated with psilocybin:
Over 1000 psilocybin sessions have conducted in modern scientific studies in patients and healthy volunteers. Hundreds of patients were treated with psilocybin in the 1950s and 60s and millions of people have taken psilocybin in the form of magic mushrooms in recreational settings.
The most common acute side-effects associated with psilocybin are anxiety and nausea. In addition, psilocybin can raise blood pressure and heart rate but not to dangerous levels.

It is not uncommon to feel anxious after being given the drug but with proper support and guidance, these effects are short-lived. Developing a relationship of trust in the patients* therapist and feeling safe and relaxed in the surroundings can minimise the feeling of being anxious in psilocybin sessions. The participants will receive psilocybin in a calm environment, have eye-shades and listen to relaxing music playing quietly for most of the drug experience. The participants will be fully supported by a psychiatrist and psychologist/therapist and other members of the research team, who will be specially trained and competent in dealing with any problems that might arise.

So-called *flashbacks* or a sense of re-experiencing psychedelic drug effects when no drug has been taken, have been described in scientific literature but have not been reported in modern research studies with psilocybin.

It is possible that the participants* depression may fail to respond to the study medication they receive in this trial and even deteriorate further. The site will be in frequent contact with the participants throughout the study to record their mood.

Below is a summary of the frequency of effects with psilocybin:

Common (over 50%):
1) Visual and other sensory distortions, feeling of unreality & changed sense of time
2) Anxiety at the onset of the drug effects
3) Increased heart rate and blood pressure

Less common (about 10-40%):
1) Nausea
2) Dizziness, blurred vision, drowsiness & sleepiness
3) Headache
5) Temporary suspiciousness

Rare (< 10%):
1) *Flashbacks*, or hallucinogen-induced persistent perceptual disorder (HIPPD). This adverse effect is seen rarely following recreational use and has not been reported in scientific studies done under supportive clinical conditions
2) Worsening of mental state after the drug experience (very rare and was not seen in similar studies).

Possible risks from Blood Sampling
The risks of taking blood include fainting and pain, bruising, swelling, or tenderness where the needle was inserted. These discomforts are generally brief and temporary.
Very rarely there can be some inflammation of the vein, infection, formation of

blood clots (thrombosis) or permanent nerve injury.

Possible risks from Electrocardiogram (ECG)
Skin irritation from the ECG electrode pads or pain when removing the pads are possible side effects.

Contacts

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Scientific
COMPASS Pathfinder, Limited

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GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Participants meeting all the following inclusion criteria at Screening (V1) should be considered for admission into the study
1. Signed ICF.
2. 18 years of age or older at Screening (V1).
3. At least moderate MDD (single or recurrent episode as informed by DSM 5; if

single episode, duration of * 3 months and * 2 years) based on medical records, clinical assessment and documented completion of the version 7.0.2 MINI.
4. HAM D 17 (17 item) score * 18 at Screening (V1) and at Baseline (V2).
5. Failure to respond to an adequate dose and duration of 2, 3, or 4 pharmacological treatment for the current episode as determined through the MGH ATRQ and using the supplementary advice on additional antidepressants not included in MGH ATRQ (Appendix III). Augmentation with an add on treatment counts as a second treatment, provided it is approved for the adjunctive treatment of MDD in that country.
6. McLean Screening Instrument for Borderline Personality Disorder < 7 at Screening (V1).
7. Have successfully discontinued all antidepressant medications at least 2 weeks prior to Baseline (V2).
8. Ability to complete all protocol required assessment tools without any assistance or alteration to the copyrighted assessments, and to comply with all study visits.

Exclusion criteria

Participants meeting any of the following exclusion criteria at Screening (V1) will not be enrolled in the study.
Psychiatric Exclusion Criteria:
1. Current or past history of schizophrenia, psychotic disorder (unless substance induced or due to a medical condition), bipolar disorder, delusional disorder, paranoid personality disorder, schizoaffective disorder, borderline personality disorder, or any serious psychiatric comorbidity as assessed by medical history and a structured clinical interview (version 7.0.2 MINI).
2. Prior electroconvulsive therapy and/or ketamine for current episode.
3. Current cognitive behavioural therapy (CBT) that will not remain stable for the duration of the study. CBT cannot be initiated within 21 days of baseline.
4. Current (within the last year) alcohol or substance abuse as informed by DSM 5 at Screening (V1).
5. Significant suicide risk as defined by (1) suicidal ideation as endorsed on items 4 or 5 on the C-SSRS within the past year, at Screening or at Baseline, or; (2) suicidal behaviors within the past year, or; (3) clinical assessment of significant suicidal risk during subject interview.
6. Depression secondary to other severe medical conditions.
7. Other personal circumstances and behaviour judged to be incompatible with establishment of rapport or safe exposure to psilocybin, including exposure to psilocybin within the past year and use of psychedelics, such as ayahuasca, during the current depressive episode.
General Medical Exclusion Criteria:
8. Women who are pregnant, nursing, or planning a pregnancy. Participants who are sexually active must agree to use a highly effective contraceptive method throughout their participation in the study. Women of child bearing potential

must have a negative urine pregnancy test at Screening (V1) and Baseline (V2).
9. Cardiovascular conditions: recent stroke (< 1 year from signing of ICF), recent myocardial infarction (< 1 year from signing of ICF), hypertension (blood pressure > 140/90 mmHg) or clinically significant arrhythmia within 1 year of signing the ICF.
10. Uncontrolled insulin dependent diabetes.
11. Seizure disorder.
12. Positive urine drug screen for illicit drugs or drugs of abuse at V1 and/or V2. Any positive urine drug test will be reviewed with participants to determine the pattern of use and eligibility will be determined at the investigator*s discretion in conjunction with the medical monitor.
13. Current enrolment in any investigational drug or device study or participation in such within 30 days of Screening (V1).
14. Current enrolment in an interventional study for depression or participation in such within 30 days of Screening (V1).
15. Abnormal and clinically significant results on the physical examination, vital signs, ECG, or laboratory tests at Screening (V1).
16. Any other clinically significant cardiovascular, pulmonary, gastrointestinal, hepatic, renal or any other major concurrent illness that, in the opinion of the investigator, may interfere with the interpretation of the study results or constitute a health risk for the participant if he/she takes part in the study.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-04-2019

Enrollment:	53
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Placebo for Psilocybin 1 mg and 5 mg
Generic name:	Placebo for Psilocybin 1 mg and 5 mg
Product type:	Medicine
Brand name:	Psilocybin 1 mg
Generic name:	Psilocybin 1 mg
Product type:	Medicine
Brand name:	Psilocybin 5 mg
Generic name:	Psilocybin 5 mg

Ethics review

Approved WMO Date:	09-02-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-06-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-06-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-08-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-10-2018
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-10-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-11-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-11-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-12-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-01-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-02-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-02-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-03-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-04-2019
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-04-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-08-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-08-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-08-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-08-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-08-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-01-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-03-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-04-2020
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-05-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-07-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-07-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-10-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-11-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-02-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-04-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2017-003288-36-NL
CCMO	NL64161.042.18