STATISTICAL ANALYSIS PLAN

A multi-center, randomized, double-blind, placebo-controlled, parallel group-comparison trial to assess the efficacy and safety of brexpiprazole as adjunctive therapy in patients with major depressive disorder

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Otsuka Pharmaceutical Co., Ltd.

Investigational New Drug Brexpiprazole (OPC-34712)

Protocol No. 331-102-00058

A multi-center, randomized, double-blind, placebo-controlled, parallel group-comparison trial to assess the efficacy and safety of brexpiprazole as adjunctive therapy in patients with major depressive disorder

Statistical Analysis Plan

Version: 1.0
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List of Abbreviations and Definition of Terms

Abbreviation	Definition
ADT	Antidepressant therapy
AIMS	Abnormal Involuntary Movement Scale
ALT	Alanine aminotransferase
ANCOVA	Analysis of covariance
AST	Aspartate aminotransferase
BARS	Barnes Akathisia Rating Scale Barnes
BMI	Body mass index
BUN	Blood urea nitrogen
CGI	Clinical Global Impression
CGI-I	Clinical Global Impression - Improvement
CGI-S	Clinical Global Impression - Severity of Illness
CMH	Cochran-Mantel-Haenszel
C-SSRS	Columbia-Suicide Severity Rating Scale
CYP	Cytochrome P450
DIEPSS	Drug Induced Extra-Pyramidal Symptoms Scale
DSM-5	Diagnostic and statistical manual of mental disorders fifth edition
EM	Extensive metabolizer
GOT	Glutamic-oxaloacetic transaminase
GPT	Glutamic-pyruvic transaminase
FAS	Full analysis set
HAM-D	Hamilton Rating Scale for Depression
HDL	High-density lipoprotein
IM	Intermediate metabolizer
IMP	Investigational medicinal product
LDL	Low-density lipoprotein
LOCF	Last observation carried forward
MADRS	Montgomery Åsberg Depression Rating Scale
MADRS-S	The Montgomery Åsberg Depression Rating Scale Self-assessment
MAR	Missing At Random
MCMC	Monte Carlo Markov Chain
MedDRA	Medical Dictionary for Regulatory Activities ICH
MMRM	Mixed-model repeated measures
MNAR	Missing Not At Random
OC	Observed Cases
PM	Poor metabolizer
PT	Preferred Term
QTc	QT corrected for heart rate
QTcB	QT corrected for heart rate by Bazett's formula
QTcF	QT corrected for heart rate by Fridericia's formula
QTcN	QT corrected for heart rate by FDA Neuropharmacological Division formula
SDS	Sheehan Disability Scale

SNRI	Serotonin-noradrenaline reuptake inhibitor
SOC	System Organ Class
SSRI	Selective serotonin reuptake inhibitor
TEAE	Treatment-emergent adverse event
ULN	Upper limit of normal
WHODD	World Health Organization Drug Dictionary

1 Introduction

This statistical analysis plan documents in detail the statistical analysis methods planned for Trial 331-102-00058.

2 Trial Objectives

Primary endpoint: To assess the dosage and efficacy of brexpiprazole as adjunctive therapy vs placebo in combination with antidepressants (selective serotonin reuptake inhibitor [SSRI] or serotonin-noradrenaline reuptake inhibitor [SNRI]) in patients with major depressive disorder whose response to single-antidepressant therapy (SSRI or SNRI) was inadequate

Secondary endpoint: To assess the safety of brexpiprazole as adjunctive therapy vs placebo in combination with antidepressants (SSRI or SNRI) in patients with major depressive disorder whose response to single-antidepressant therapy (SSRI or SNRI) was inadequate

3 Trial Design

3.1 Type/Design of Trial

The trial is a multi-center, randomized, double-blind, placebo-controlled, parallel group-comparison trial to assess the efficacy and safety of brexpiprazole as adjunctive therapy in patients with major depressive disorder, who have received 1 to 3 adequate antidepressant drug treatments[a] for the current major depressive episode and have shown an inadequate response[b] to all of these treatments, and whose response during the antidepressant treatment period (Phase A) has also been inadequate.

The trial design is shown in Figure 3.1-1. The trial comprises a screening period, antidepressant treatment period (Phase A), double-blind period (Phase B) or antidepressant-responder treatment-continuation period (Phase A+), and post-treatment observation period.

[a]Definition of "adequate antidepressant drug treatment" is provided below.
Treatment with an antidepressant at an approved dose for at least 6 weeks (for combination therapy, treatment for at least 3 weeks)

[b]Definition of "inadequate response" is provided below.
With complete recovery from depressive symptoms and not the slightest improvement considered as 100% and 0%, respectively, patients carry out self-evaluations for improvement by antidepressant drug treatments used to date, from among 4 grades (< 25% Improvement, 25% to 49% Improvement, 50% to < 75% Improvement, and ≥ 75% Improvement), with the evaluations corresponding to < 25% Improvement or 25% to 49% Improvement classified as inadequate response.
Patients who, among 1 to 3 adequate antidepressant drug treatments, have received treatment for

≥ 6 weeks at least once (receiving only combination therapies for ≥ 3 weeks does not qualify) are eligible for selection.

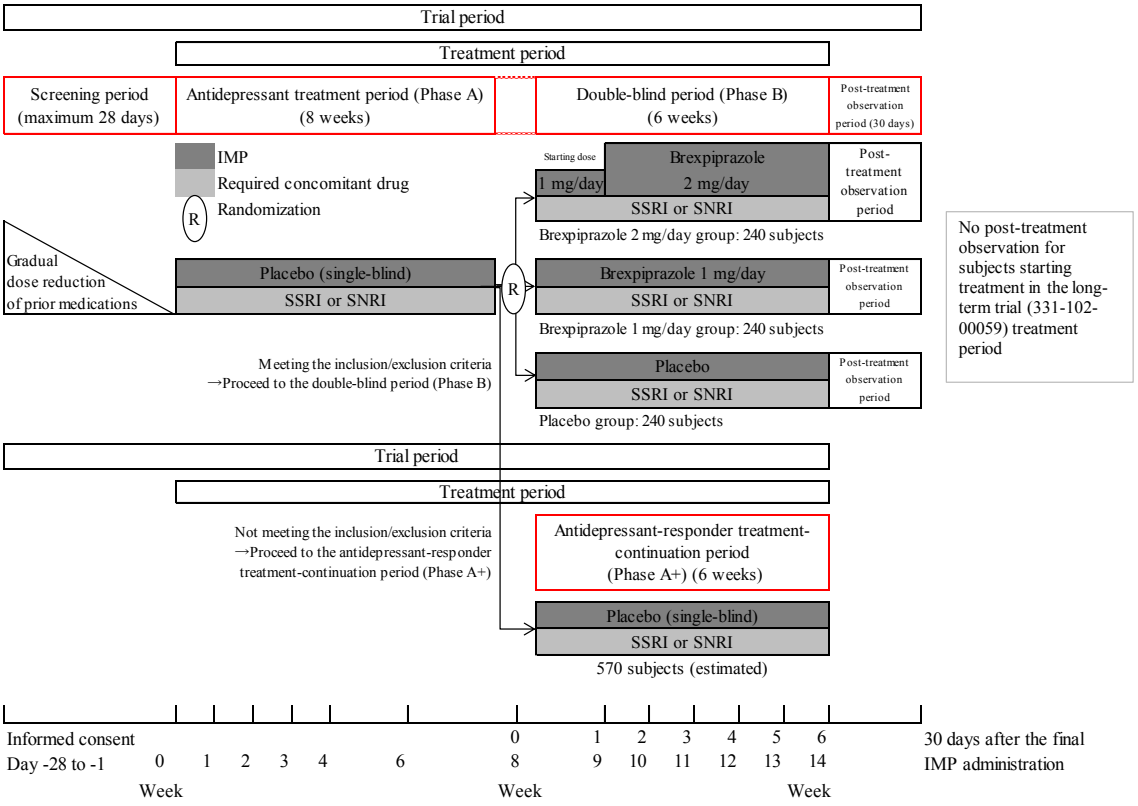

Figure 3.1-1 Trial Design

3.2 Trial Treatments

3.2.1 Antidepressant Treatment Period (Phase A)

1) Drugs

Among commercially available SSRIs (fluvoxamine maleate, paroxetine hydrochloride hydrate, sertraline hydrochloride, and escitalopram oxalate) and SNRIs (milnacipran hydrochloride, duloxetine hydrochloride, and venlafaxine hydrochloride), one antidepressant that is different from the prior medications of antidepressant*, plus the placebo tablet

*Antidepressant that meets the definition for "adequate antidepressant drug treatment" and has been taken at the time of informed consent.

2) Dose and regimen

In the antidepressant treatment period (Phase A), subjects will orally receive an antidepressant (SSRI or SNRI), which is different from the antidepressant prior

medications, plus a placebo tablet once daily in a single-blind manner. The antidepressant (SSRI or SNRI) will be administered at the dose and regimen specified in the package insert, and the dose of the antidepressant will be progressively increased, within the approved dose range, to the maximum dose, as far as possible, in accordance with subject status; for the last 2 weeks of the 8-week period, dose and regimen will be fixed. A placebo tablet will be orally administered once daily. When an antidepressant cannot be administered at a fixed dose and regimen for the last 2 weeks of the 8-week antidepressant treatment period (Phase A) for tolerability-related reasons, the subject will be withdrawn from the trial.

3) Treatment period

8 weeks

3.2.2 Double-blind Period (Phase B)

At Week 8 of the antidepressant treatment period (Phase A), subjects who meet the criteria for proceeding to the double-blind period (Phase B) will proceed to the double-blind period (Phase B).

1) Drugs

- One commercially available antidepressant (SSRI or SNRI) used in the antidepressant treatment period (Phase A)
- Investigational medicinal product (IMP):
  - 1 mg/day group: brexpiprazole 1 mg tablet
  - 2 mg/day group: brexpiprazole 1 mg tablet (until observations, examinations, and assessments at Week 1) and brexpiprazole 2 mg tablet (after observations, examinations, and assessments at Week 1)
  - Placebo group: placebo tablet

2) Dose and regimen

- Commercially available antidepressant (SSRI or SNRI):
  An antidepressant (SSRI or SNRI) used in the antidepressant treatment period (Phase A) will be continued with no changes from the final dose and regimen; no changes in dose, regimen, or drug will be allowed.
- IMP:
  - 1 mg/day group: One brexpiprazole 1 mg tablet will be orally administered once daily.
  - 2 mg/day group: Treatment will be started with brexpiprazole at 1 mg/day. One brexpiprazole 1 mg tablet will be orally administered once daily until observations, examinations, and assessments at Week 1. After the

observations, examinations, and assessments at Week 1, one brexpiprazole 2 mg tablet will be orally administered once daily.

– Placebo group: One placebo tablet will be orally administered once daily.

3) Treatment period

6 weeks

3.2.3 Antidepressant-responder Treatment-continuation Period (Phase A+)

Antidepressant responders who do not meet the criteria for proceeding to the double-blind period (Phase B) based on the assessment at Week 8 of the antidepressant treatment period (Phase A) will proceed to the antidepressant-responder treatment-continuation period (Phase A+).

1) Drugs

A commercially available antidepressant (SSRI or SNRI) used in the antidepressant treatment period (Phase A) plus the placebo tablet

2) Dose and regimen

Subjects will receive an antidepressant (SSRI or SNRI) used in the antidepressant treatment period (Phase A) with no changes from the final dose and regimen, plus oral placebo (1 tablet) once daily in a single-blind manner.

3) Treatment period

6 weeks

3.3 Trial Population

Adult patients with “major depressive disorder, single episode” or “major depressive disorder, recurrent episode” according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5).

3.3.1 Number of Subjects and Trial Population

The trial will be conducted in patients 20 to < 65 years of age who have major depressive disorder (major depressive disorder, single episode; major depressive disorder, recurrent episode) according to the DSM-5 classification. After provision of informed consent, subjects considered eligible at the screening examination and at the examination performed at the initiation of the antidepressant treatment period (Phase A) will commence the antidepressant treatment period (Phase A) in which they will receive antidepressants different from their prior antidepressant medications (SSRI or SNRI) and

placebo tablets for 8 weeks in a single-blind manner. Subjects showing no response to the antidepressants during the antidepressant treatment period (Phase A) who meet the criteria for proceeding will proceed to the double-blind period (Phase B) to receive the IMP (brexpiprazole at 1 or 2 mg/day, or placebo) for 6 weeks in combination with the antidepressants used in the antidepressant treatment period (Phase A). The planned number of subjects proceeding to the double-blind period (Phase B) is set as follows: brexpiprazole 1 mg/day group: 240; brexpiprazole 2 mg/day group: 240; placebo group: 240; total: 720.

Subjects responding to antidepressants during the antidepressant treatment period (Phase A) and not meeting the criteria for proceeding to the double-blind period (Phase B) will not proceed to the double-blind period (Phase B) and will instead proceed to the antidepressant-responder treatment-continuation period (Phase A+), to receive 6-week treatment with placebo tablets in addition to the antidepressants (SSRI or SNRI) used in the antidepressant treatment period (Phase A), in a single-blind manner.

3.4 Trial Visit Window

For all endpoints, acceptable windows for analysis are specified, and analysis should be based on the analysis time points regardless of time points recorded on the case report form.

Acceptable windows for analysis in the double-blind period (Phase B) are shown in Table 3.4-1. Day 1 is defined as the day when treatment with the IMP begins in the double-blind period. If multiple data exist within an acceptable window, the last data within the window will be used in analysis. Data obtained 7 days or later after the final dosing in the double-blind period will be excluded from the analysis.

Table 3.4-1 Acceptable Windows for Analysis in the Double-blind Period (Phase B)

Week	Target Day	Trial Day Interval
Baseline	1	- 1
Week 1 in the double-blind period	7	2 - 10
Week 2 in the double-blind period	14	11 - 17
Week 3 in the double-blind period	21	18 - 24
Week 4 in the double-blind period	28	25 - 31
Week 5 in the double-blind period	35	32 - 38
Week 6 in the double-blind period	42	39 - 49

Acceptable windows for analysis in the antidepressant treatment period (Phase A) are shown in Table 3.4-2. Day 1 is defined as the day when treatment with the IMP begins in the antidepressant treatment period (Phase A). If multiple data exist within an acceptable window, the last data within the window will be used in analysis. Data obtained after

initiation of IMP treatment in the double-blind period (Phase B) or in the antidepressant-responder treatment-continuation period (Phase A+) and data obtained 7 days or later after the final dosing in the antidepressant treatment period (Phase A) will be excluded from the analysis.

Table 3.4-2 Acceptable Windows for Analysis in the Antidepressant Treatment Period (Phase A)

Week	Target Day	Trial Day Interval
Baseline	1	- 1
Week 1 in the antidepressant treatment period	7	2 - 10
Week 2 in the antidepressant treatment period	14	11 - 17
Week 3 in the antidepressant treatment period	21	18 - 24
Week 4 in the antidepressant treatment period	28	25 - 31
Week 5 in the antidepressant treatment period	35	32 - 38
Week 6 in the antidepressant treatment period	42	39 - 45
Week 7 in the antidepressant treatment period	49	46 - 52
Week 8 in the antidepressant treatment period	56	53 - 63

Acceptable windows for analysis in the antidepressant-responder treatment-continuation period (Phase A+) are the same as for the double-blind period (Phase B) (Table 3.4-1).

3.5 Handling of Endpoints

3.5.1 Montgomery Åsberg Depression Rating Scale (MADRS)

The MADRS total score will be the sum of scores for MADRS Items 1 through 10.

3.5.2 Clinical Global Impression – Improvement (CGI-I)

"0. Not assessed" will be handled as missing data.

3.5.3 Clinical Global Impression - Severity of Illness (CGI-S)

"0. Not assessed" will be handled as missing data.

3.5.4 Hamilton Rating Scale for Depression (HAM-D)

The HAM-D 17-item total score will be the sum of scores for HAM-D Items 1 through 17.

3.5.5 Sheehan Disability Scale (SDS)

The mean SDS score will be the mean of scores for 3 SDS items (work/school, social life, and family life/home responsibilities). In the case of a missing score for work/school, the mean of scores for the other 2 items will be handled as the mean SDS score.

3.5.6 Montgomery Åsberg Depression Rating Scale Self-assessment (MADRS-S)

The MADRS-S total score will be the total score of MADRS-S Items 1 through 9.

3.5.7 Drug-induced Extrapyramidal Symptoms Scale (DIEPSS)

The DIEPSS total score will be the sum of scores for DIEPSS items 1 through 8.

3.5.8 Abnormal Involuntary Movement Scale (AIMS)

The AIMS total score will be the sum of scores for AIMS items 1 through 7.

4 Sample Size

In phase 3, double-blind, placebo-controlled, fixed dose trials of brexpiprazole (331-10-227, 331-10-228, and 331-13-214) conducted outside Japan, changes from baseline in MADRS total scores at Week 6 of the double-blind period (Phase B) have been analyzed by the Mixed-model Repeated Measure (MMRM) method (for 331-10-227 and 331-10-228, based on the results for efficacy from an analysis of subgroups meeting the inclusion criteria that had been revised in the middle of the trials), which demonstrated that the differences between the brexpiprazole groups (the 3 mg group in 331-10-227, and the 2 mg group in 331-10-228 and 331-13-214) and the placebo group were −1.9, −3.2, and −2.3, respectively, and that the standard deviations obtained from standard errors and numbers of subjects at Week 6 of the double-blind period (Phase B) were 7.2, 7.7, and 8.2, respectively. On the assumption that the difference in changes from baseline in MADRS total scores at Week 6 of the double-blind period (Phase B) is −2.4 for the brexpiprazole group compared with the placebo group with a standard deviation of 7.7, this trial will require 218 subjects per group to ensure a power of 90% in a two-sided test with a significance level of 0.05. We have decided that the planned number of subjects for randomization will be 240 per group, assuming that 7% of subjects will discontinue the trial during the double-blind period (Phase B) and some subjects will be excluded from analysis.

5 Statistical Analysis Datasets

5.1 Pharmacokinetic Analysis Set

The pharmacokinetic analysis set will comprise subjects who have been treated with brexpiprazole and for whom plasma brexpiprazole concentration data have been obtained.

5.2 Full Analysis Set

The full analysis set (FAS) will comprise subjects who, after randomization, have received at least 1 dose of the IMP in the double-blind period (Phase B), and from whom MADRS total scores have been obtained at baseline and at least 1 time point after initiation of the treatment.

5.3 Safety Analysis Set

The safety analysis set will comprise subjects who, after randomization, have received at least 1 dose of the IMP in the double-blind period (Phase B).

5.4 Antidepressant Therapy Set

The antidepressant therapy (ADT) set will comprise subjects who have received at least 1 dose of the IMP in the antidepressant treatment period (Phase A).

5.5 Phase A+ Set

The Phase A+ set will comprise subjects who have received at least 1 dose of the IMP in the antidepressant-responder treatment-continuation period (Phase A+).

5.6 Handling of Missing Data

The primary analysis of the primary endpoint will be performed in the observed cases (OC) dataset by MMRM without data imputation for missing data under the missing at random (MAR) assumption. As a sensitivity analysis for the handling of missing data, placebo multiple imputation and tipping point analysis will be performed under the missing not at random (MNAR) assumption. Details are described in Section 8.1.2.

For efficacy and safety analyses, the last observation carried forward (LOCF) method (in which missing post-dose data are imputed by the last observed data after initiation of IMP treatment in the double-blind period) will be used as needed.

For pharmacokinetic analysis, no imputation will be performed for missing data.

6 Primary and Secondary Outcome Variables:

6.1 Primary Outcome Variables

Mean changes from baseline (Week 8 of the antidepressant treatment period [Phase A]) in MADRS total scores at Week 6 of the double-blind period (Phase B)

6.2 Secondary Outcome Variables

- MADRS response rate at Week 6 of the double-blind period (Phase B)
  The proportion of subjects in whom MADRS total scores at Week 6 of the double-blind period (Phase B) have been reduced by at least 50% from baseline (Week 8 of the antidepressant treatment period [Phase A])
- MADRS remission rate at Week 6 of the double-blind period (Phase B)
  The proportion of subjects in whom MADRS total scores at Week 6 of the double-blind period (Phase B) have been reduced by at least 50% from baseline (Week 8 of the antidepressant treatment period [Phase A]), with their MADRS total scores, at Week 6 of the double-blind period (Phase B), being ≤ 10
- CGI-I improvement rate at Week 6 of the double-blind period (Phase B)
  The proportion of subjects who score 1 or 2 on the CGI-I scale at Week 6 of the double-blind period (Phase B)
- Mean changes in CGI-S at Week 6 of the double-blind period (Phase B)
  Mean changes from baseline (Week 8 of the antidepressant treatment period [Phase A]) in CGI-S at Week 6 of the double-blind period (Phase B)
- Mean changes in HAM-D 17-item total scores at Week 6 of the double-blind period (Phase B)
  Mean changes from baseline (Week 8 of the antidepressant treatment period [Phase A]) in HAM-D 17-item total scores at Week 6 of the double-blind period (Phase B)
- Mean changes in mean SDS scores at Week 6 of the double-blind period (Phase B)
  Mean changes from baseline (Week 8 of the antidepressant treatment period [Phase A]) in mean SDS scores at Week 6 of the double-blind period (Phase B)
- Mean changes in MADRS-S total scores at Week 6 of the double-blind period (Phase B)
  Mean changes from baseline (Week 8 of the antidepressant treatment period [Phase A]) in MADRS-S total scores at Week 6 of the double-blind period (Phase B)

7 Disposition and Demographic Analysis

7.1 Subject Disposition

Numbers and proportions of subjects from whom informed consent was obtained, those who received trial treatment in the antidepressant treatment period (Phase A), those who completed the antidepressant treatment period (Phase A), those who discontinued treatment in the antidepressant treatment period (Phase A), those who discontinued treatment in the antidepressant treatment period (Phase A) by reason, and those who were included in the ADT set will be summarized overall and for each requisite concomitant medication.

Numbers and proportions of randomized subjects in the double-blind period (Phase B), those who received trial treatment in the double-blind period (Phase B), those who

completed the double-blind period (Phase B), those who discontinued treatment in the double-blind period (Phase B), those who discontinued treatment in the double-blind period (Phase B) by reason, and those who were included in each analysis set will be summarized overall, for each treatment group, and for the overall brexpiprazole group. Similar summarization will be performed for each requisite concomitant medication.

Numbers and proportions of subjects who received trial treatment in the antidepressant-responder treatment-continuation period (Phase A+), those who completed the antidepressant-responder treatment-continuation period (Phase A+), those who discontinued treatment in the antidepressant-responder treatment-continuation period (Phase A+), those who discontinued treatment in the antidepressant-responder treatment-continuation period (Phase A+) by reason, and those who were included in the Phase A+ set will be summarized overall and for each requisite concomitant medication.

Numbers and proportions of subjects who completed the double-blind period (Phase B) will be summarized by each period (days) (1-7, 8-14, 15-21, 22-28, 29-35, 36-42, and > 42) overall, for each treatment group, and for the overall brexpiprazole group.

7.2 Demographic and Baseline Characteristics

Descriptive statistics (mean, standard deviation, minimum, median, maximum; hereinafter the same applies) of age, height, body weight, waist circumference, and body mass index (BMI) and frequency distribution of age (< 55, ≥ 55), sex, race, ethnicity, country where trial is conducted, medical history, complications, and CYP2D6 phenotype will be determined overall, for each treatment group, and for the overall brexpiprazole group in each analysis set in the double-blind period (Phase B). Similar summarization will be performed for each requisite concomitant medication in the safety analysis set and the FAS.

Similar summarization (but not for CYP2D6 phenotype) will be performed overall and for each requisite concomitant medication in the ADT set and the Phase A+ set.

Baseline data in each period will be used for body weight, waist circumference, and BMI.

7.3 Baseline Disease Evaluation

Descriptive statistics of the duration (months) of the current major depressive episode, age at initial onset, duration (months) of major depressive episode from initial onset, MADRS total score, HAM-D 17 total score, and CGI-S and frequency distribution of DSM-5-based diagnosis (single, recurrent), severity (mild, moderate, severe), specific terms (“not applicable,” “applicable,” and disposition of each specific term), frequency of major depressive episodes (1, 2, 3, 4, ≥ 5), frequency of appropriate antidepressant drug

treatments of the current major depressive episode (1, 2, 3) will be determined overall, for each treatment group, and for the overall brexpiprazole group in the safety analysis set and the FAS. Similar summarization will be performed for each requisite concomitant medication.

Similar summarization will be performed overall and for each requisite concomitant medication in the ADT set and the Phase A+ set.

For the double-blind period (Phase B), values at baseline (8 weeks after the antidepressant treatment period [Phase A]) and at the start of the antidepressant treatment period (Phase A) will be used for MADRS total score, HAM-D 17 total score, and CGI-S. For the ADT set and the Phase A+ set, values at the start of the antidepressant treatment period (Phase A) will be used for those scores.

The duration of the current major depressive episode and the duration of major depressive episode from initial onset will be calculated using the following formula: duration (months) = (date of subject demographic evaluation – date of onset + 1) / 30. Any unknown month or day of onset will be replaced with June or 15, respectively.

7.4 Treatment Compliance

Treatment compliance (number of days when the subject actually received the IMP/number of days for which the IMP was prescribed) in the double-blind period (Phase B) will be grouped into < 70%, ≥ 70% to < 80%, ≥ 80% to < 90%, and ≥ 90%, and its frequency distribution will be determined overall, for each treatment group, and for the overall brexpiprazole group in the FAS.

7.5 Prior and Concomitant Medications

Numbers and proportions of subjects who used medications before the antidepressant treatment period (Phase A), during the antidepressant treatment period (Phase A) and the double-blind period (Phase B), and after the double-blind period (Phase B) will be determined by drug class and preferred term of the World Health Organization Drug Dictionary (WHODD) version Global B3 March 2018 overall, for each treatment group, and for the overall brexpiprazole group in the safety analysis set.

Medications used in the antidepressant treatment period (Phase A) will be similarly summarized overall and for each requisite concomitant medication in the ADT set. Medications used in the antidepressant-responder treatment-continuation period (Phase A+) will also be similarly summarized overall and for each requisite concomitant medication in the Phase A+ set.

Similar summarization will be performed for antipsychotics.

7.6 Protocol Deviations

In randomized subjects, numbers and proportions of subjects with major deviations from the protocol will be determined for each deviation category (treatment-related deviations, eligibility-related deviations, a failure to discontinue the trial when the subject meets the withdrawal criteria, procedure-related deviations that affect evaluation of the primary endpoint, use of prohibited medications, and overall) and each trial site, overall, for each treatment group, and for the overall brexpiprazole group.

In non-randomized subjects, similar summarization will be performed overall and for each requisite concomitant medication.

8 Efficacy Analysis

Efficacy analysis in the double-blind period (Phase B) will be performed using the FAS. Unless otherwise stated, the efficacy analysis described in this section relates only to the double-blind period (phase B).

8.1 Primary Efficacy Endpoint

The primary endpoint is mean changes from baseline (Week 8 of the antidepressant treatment period [Phase A]) in MADRS total scores at Week 6 of the double-blind period (Phase B).

8.1.1 Primary Efficacy Analysis

For the primary analysis, MMRM analysis will be performed using the OC data set in the FAS. The statistical hypotheses will be tested, based on differences in least square means between each brexpiprazole group and the placebo group, which are calculated by MMRM. To adjust for multiplicity of tests, due to there being 2 comparisons with the placebo group for each of the brexpiprazole groups, a fixed-sequence approach will be used to control overall type 1 error rates. Comparison between the brexpiprazole 2 mg/day group and placebo group will be performed first; only when significance is observed at a two-sided significance level of 5%, will comparison between the brexpiprazole 1 mg/day group and placebo group be performed at a two-sided significance level of 5%.

The MMRM will include treatment group (brexpiprazole 1 mg/day group, brexpiprazole 2 mg/day group, and placebo group), time point (double-blind period [Phase B] Weeks 1, 2, 3, 4, 5, and 6), and interaction between treatment group and time point as factors, and baseline and interaction between baseline and time point as covariates. Unstructured error variance-covariance structure will be assumed. For a degree-of-freedom approximation,

the Kenward-Roger method will be used. If any problems in convergence status arise in the estimation of variance components, heterogeneous Toeplitz, heterogeneous autoregressive of order 1, and heterogeneous compound symmetry, which are error variance-covariance structures, will be applied in this order, and the first structure that achieves convergence will be used in the primary analysis. If anything other than an unstructured variance-covariance structure is selected, a sandwich estimator for standard errors will be used.

For each time point, least square means of each treatment group and differences in least square means between each brexpiprazole group and the placebo group, as well as the two-sided 95% confidence intervals (CIs) will be determined.

8.1.2 Sensitivity Analyses

8.1.2.1 Sensitivity Analysis for Handling of Missing Data

As a sensitivity analysis for handling of missing data, placebo multiple imputation and tipping point analysis on MNAR assumption will be performed using a pattern-mixture model with multiple imputation.

Multiple imputation analysis will be performed according to the following procedure. The number of imputations will be 100.

1) The Markov Chain Monte Carlo (MCMC) method will be used to impute intermittent missing data to produce a monotone missing data pattern.
2) The monotone regression method will be used to impute monotone missing data.
3) The same MMRM as that of the primary efficacy analysis will be used to analyze the multiple-imputed datasets.
4) The MIANALYZE procedure will be used to integrate the analysis results of the multiple-imputed datasets, and the estimate of the difference between each brexpiprazole group and the placebo group at Week 6 in the double-blind period (Phase B) and its 95% CI and p-value will be determined.

In placebo multiple imputation, for discontinued subjects in each brexpiprazole group, MNAR will be assumed for missing data after discontinuation and an imputation model based on the placebo group will be used in imputation.

In tipping point analysis, for subjects in each brexpiprazole group who discontinued treatment for any of the following reasons, MNAR will be assumed for missing data after discontinuation.

- Withdrawal for any reason
- Withdrawal due to AEs, a lack of efficacy, or consent withdrawal
- Withdrawal due to AEs or a lack of efficacy

For subjects in each brexpiprazole group who discontinued treatment for reasons assumed as MNAR, the MAR assumption will be used to impute post-discontinuation missing data, add Δ (intergroup differences in MMRM of the primary efficacy analysis) × k% to the imputed value, and increase k until a statistically significant conclusion is reversed ($p > 0.05$).

8.1.2.2 Sensitivity Analysis for Normality Assumption

As a sensitivity analysis for normality assumption, multiple imputation under the MAR assumption will be performed, and the Wilcoxon rank sum test will be used to compare each brexpiprazole group and the placebo group for each time point, and the Hodges-Lehmann estimator of the intergroup difference will be determined. A robust regression analysis with treatment group as a factor and baseline as a covariate will also be performed for each time point. Similar analysis without multiple imputation will also be performed.

8.1.3 Technical Computational Details for Primary Efficacy Analysis

The SAS code for the MIXED procedure to perform the primary efficacy MMRM analysis is shown below.

```
proc mixed;
   class treatment visit subjid;
   model change=treatment visit baseline treatment*visit baseline*visit / ddfm=kr;
   repeated visit /type=un subject=subjid;
   lsmeans treament*visit / diff cl;
   ods output diffs=diffs lsmeans=lsmeans;
run;
```

8.2 Secondary Efficacy Analyses

- MADRS response rate at Week 6 of the double-blind period (Phase B)
- MADRS remission rate at Week 6 of the double-blind period (Phase B)
- CGI-I improvement rate at Week 6 of the double-blind period (Phase B)

For the MADRS response rate, a χ^2 test will be performed for between-treatment-group comparison using the LOCF data set. Differences in the response rates between each of the brexpiprazole groups and the placebo group, and the two-sided 95% CIs (Wald confidence interval) will be determined. For MADRS remission rate and CGI-I

improvement rate, the same analysis employed for the MADRS response rate will be used. The same analysis will be performed on the OC dataset.

- Mean changes from baseline (Week 8 of the antidepressant treatment period [Phase A]) in HAM-D 17-item total scores at Week 6 of the double-blind period (Phase B)

Using the LOCF data set, analysis will be performed by ANCOVA model with treatment group as a factor and baseline as a covariate. Least square means of each treatment group and differences in least square means between each brexpiprazole group and the placebo group, as well as the two-sided 95% CIs will be determined. The same analysis will be performed on the OC dataset.

- Mean changes from baseline (Week 8 of the antidepressant treatment period [Phase A]) in CGI-S at Week 6 of the double-blind period (Phase B)
- Mean changes from baseline (Week 8 of the antidepressant treatment period [Phase A]) in mean SDS scores at Week 6 of the double-blind period (Phase B)
- Mean changes from baseline (Week 8 of the antidepressant treatment period [Phase A]) in MADRS-S total scores at Week 6 of the double-blind period (Phase B)

As performed for the primary endpoint, MMRM analysis will be performed. Each item on the SDS (work/school, social life, and family life/home responsibilities) will also be analyzed in the same manner.

8.3 Subgroup Analyses

For the change from baseline (Week 8 of the antidepressant treatment period [Phase A]) in MADRS total score, the same MMRM analysis as that of the primary endpoint will be performed for each of the following subgroups.

For CYP2D6 phenotype, all subjects in the placebo group will be included in each subgroup.

- Requisite concomitant medication (duloxetine, escitalopram, fluvoxamine, milnacipran, paroxetine, sertraline, venlafaxine)
- Sex (male, female)
- Age (< 55, ≥ 55)
- Number of adequate antidepressant drug treatments (1, 2, 3)
- DSM-5 diagnosis (single episode, recurrent episode)
- Frequency of major depressive episodes (1, 2, ≥ 3)
- Duration (in months) of the current episode ($\leq$ median, $>$ median)
- Baseline MADRS total score ($\leq$ median, $>$ median)

- Concomitant use of ultrashort-acting sedative-hypnotic drugs in the double-blind period (Phase B) (yes or no)
- Body weight (≤ median, > median)
- BMI (≤ median, > median)
- CYP2D6 phenotype (IM, EM)
- Impact of COVID-19 pandemic (subjects from whom consent was obtained before 07 Apr 2020, those from whom consent was obtained on or after 07 Apr 2020)

8.4 Exploratory or Other Analyses

The Cochran Mantel Haenszel (CMH) Row Mean Scores test of CGI-I scores will be performed on the LOCF dataset to compare each brexpiprazole group and the placebo group. The mean in each treatment group and the mean difference between each brexpiprazole group and the placebo group with their two-sided 95% CIs will be determined. The same analysis will be performed on the OC dataset.

The MADRS total score, CGI-I, CGI-S, mean SDS score and the score of each item, and MADRS-S total score at each time point in the double-blind period (Phase B) will be analyzed in the FAS in the same manner as for the primary and secondary endpoints. Descriptive statistics or frequency distribution of actual measurements and changes from baseline at each time point will be calculated by treatment group.

For MADRS total score, HAM-D 17-item total score, CGI-S, mean SDS score and the score of each item, and MADRS-S total score in the antidepressant treatment period (Phase A), descriptive statistics of actual measurements and changes from baseline (before the start of the antidepressant treatment period [Phase A]) will be calculated overall and for each requisite concomitant medication in the ADT set.

For MADRS total score, HAM-D 17-item total score, CGI-S, mean SDS score and the score of each item, and MADRS-S total score in the antidepressant treatment period (Phase A) and the antidepressant-responder treatment-continuation period (Phase A+), descriptive statistics of actual measurements and changes from baseline (before the start of the antidepressant treatment period [Phase A]) will be calculated overall and for each requisite concomitant medication in the Phase A+ set.

9 Safety Analyses

Safety analysis for the double-blind period (Phase B) will be performed using the safety analysis set. Unless otherwise stated, the safety analysis described in this section relates only to the double-blind period (phase B).

9.1 Extent of Exposure

Frequency distribution of the duration (in days) of treatment with the IMP in the double-blind period (Phase B) (1-7, 8-14, 15-21, 22-28, 29-35, 36-42, and > 42) will be determined by treatment group and for the overall brexpiprazole group. Similar summarization will be performed for each requisite concomitant medication subgroup.

Frequency distribution of the duration (in days) of treatment with a requisite concomitant medication in the double-blind period (Phase B) (1-7, 8-14, 15-21, 22-28, 29-35, 36-42, and > 42) will be determined by treatment group and for the overall brexpiprazole group.

Descriptive statistics of the mean daily dose of each requisite concomitant medication in the double-blind period (Phase B) will be calculated by treatment group and for the overall brexpiprazole group.

Frequency distribution of the duration (in days) of treatment with a requisite concomitant medication in the antidepressant treatment period (Phase A) (1-7, 8-14, 15-21, 22-28, 29-35, 36-42, 43-49, 50-56, and > 56) will be determined overall and for each requisite concomitant medication in the ADT set.

Frequency distribution of the duration (in days) of treatment with a requisite concomitant medication in the antidepressant-responder treatment-continuation period (Phase A+) (1-7, 8-14, 15-21, 22-28, 29-35, 36-42, and > 42) will be determined overall and for each requisite concomitant medication in the Phase A+ set.

9.2 Adverse Events

All adverse events (AEs) will be coded by Medical Dictionary for Regulatory Activities (MedDRA) (Ver. 24.0) System Organ Class (SOC) and Preferred Term (PT). Numbers and proportions of subjects with the following AEs will be summarized by SOC and PT by treatment group and for the overall brexpiprazole group. If an AE occurs more than once in the same subject, the severest event will be used in summarization.

- Adverse events occurring after initiation of IMP administration in the double-blind period (Phase B) (treatment-emergent adverse events [TEAEs])
- TEAEs by severity
- TEAEs with an outcome of death
- Serious TEAEs
- TEAEs leading to discontinuation of the IMP
- TEAEs occurring in ≥ 2% of subjects in any brexpiprazole group and more frequently than in the placebo group

- TEAEs by date of initial onset (1-7, 8-14, 15-21, 22-28, 29-35, 36-42, > 42, post-trial treatment)

TEAEs potentially causally related to the IMP will also be summarized in the same manner.

9.2.1 Adverse Events of Interest

Each adverse event of interest is defined in Appendix 4. Numbers and proportions of subjects with the following AEs of interest will be summarized by SOC and PT by treatment group and for the overall brexpiprazole group.

- Extrapyramidal AEs
- Neuroleptic malignant syndrome-related AEs
- Rhabdomyolysis
- Seizure-related AEs
- Orthostatic disorder-related AEs
- Suicide/suicide attempt-related AEs
- Oversedation-related AEs
- Hypersensitive symptom-related AEs
- Venous thrombosis
- Blood disorder-related AEs
- Glucose metabolism-related AEs
- Lipid metabolism-related AEs
- Body weight-related AEs
- QT interval prolongation-related AEs
- Manic switch-related AEs
- Prolactin increase-related AEs

9.2.2 Subgroup Analysis of Adverse Events

Numbers and proportions of subjects with TEAEs will be summarized by SOC and PT by treatment group and for the overall brexpiprazole group in each of the following subgroups:

- Requisite concomitant medication (duloxetine, escitalopram, fluvoxamine, milnacipran, paroxetine, sertraline, venlafaxine)
- Sex (male, female)
- Age (< 55, ≥ 55)
- CYP2D6 phenotype (IM, EM, PM, Unknown)

- Impact of COVID-19 pandemic (subjects from whom consent was obtained before 07 Apr 2020, those from whom consent was obtained on or after 07 Apr 2020)

9.2.3 Adverse Events in the Antidepressant Treatment Period (Phase A) and the Antidepressant-responder Treatment-continuation Period (Phase A+)

Numbers and proportions of subjects who experienced AEs in the antidepressant treatment period (Phase A) will be summarized by SOC and PT overall and for each requisite concomitant medication in the ADT set.

Numbers and proportions of subjects who experienced AEs in the antidepressant-responder treatment-continuation period (Phase A+) will be summarized by SOC and PT overall and for each requisite concomitant medication in the Phase A+ set.

9.3 Clinical Laboratory Data

For each quantitative laboratory parameter, descriptive statistics of actual measurements and changes from baseline at each time point and the last time point will be calculated for each treatment group and for the overall brexpiprazole group.

For each quantitative laboratory parameter, actual measurements will be classified as "lower than the lower limit of the reference range," "within the reference range," and "higher than the upper limit of the reference range" using the reference range specified by the central laboratory, and a shift table from baseline will be produced for each treatment group and for the overall brexpiprazole group.

For each qualitative laboratory parameter, a shift table from baseline will be produced for each treatment group and for the overall brexpiprazole group.

Numbers and proportions of subjects with laboratory test values not meeting the criteria for potentially clinically significant laboratory test values (Appendix 2) at baseline and meeting the criteria after treatment will be determined for each treatment group and for the overall brexpiprazole group. A listing of these subjects will be provided.

Numbers and proportions of subjects with postdose values of alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total bilirubin (TBL) meeting Hy's Law criteria (ALT or AST $\geq 3 \times$ the upper limit of normal [ULN] and TBL $\geq 2 \times$ ULN) will be determined for each treatment group and for the overall brexpiprazole group. A listing of these subjects will be provided.

Numbers and proportions of subjects with a prolactin value not meeting the criteria of $> 1 \times$ ULN, $> 2 \times$ ULN, or $> 3 \times$ ULN at baseline and meeting the criteria after treatment

will be determined by sex for each treatment group and for the overall brexpiprazole group. A listing of these subjects will be provided.

Numbers and proportions of subjects with postdose values of fasting low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol, triglyceride, and blood glucose meeting the criteria for changes in glucose and lipid metabolism-related parameters (Table 9.3-1) will be determined by baseline value for each treatment group and for the overall brexpiprazole group. A listing of these subjects will be provided.

Table 9.3-1 Changes in Glucose and Lipid Metabolism-related Parameters

LAB PARAMETER	BASELINE	ANYTIME POST BASELINE
LDL Cholesterol, Fasting (mg/dL)	Borderline 100-<160 Normal/Borderline <160 Normal <100 Any Value	High >=160 High >=160 Borderline/High >=100 Increased >=30
HDL Cholesterol, Fasting (mg/dL)	Normal >=40 Any Value	Low <40 Decreased >=20
Triglycerides, Fasting (mg/dL)	Normal <150 Borderline 150-<200 Normal/Borderline <200 Normal <150 Normal/Borderline/high <500 Any Value	High 200-<500 High 200-<500 High 200-<500 Borderline/High/Very High >=150 Very High >=500 Increased >=50
Glucose Fasting, Serum (mg/dL)	Normal <100 Impaired 100-<126 Normal/Impaired <126 Any Value	High >=126 High >=126 High >=126 Increased >=10

Numbers and proportions of subjects not meeting the metabolic syndrome criteria (Table 9.3-2) at baseline and meeting the criteria after treatment will be determined for each treatment group and for the overall brexpiprazole group. A listing of these subjects will be provided.

Table 9.3-2 Metabolic Syndrome Criteria

Description	Metabolic Syndrome Criteria (Health, Labour and Welfare Ministry of Japan)
Central obesity	Waist Circumference ≥85 cm (Male), ≥90 cm (Female)
Dyslipidemia	Triglycerides, Fasting ≥150 mg/dL and/or HDL, Fasting <40 mg/dL
Supine blood pressure	Systolic ≥130 mmHg and/or Diastolic ≥85 mmHg
Glucose fasting, serum	≥110 mg/dL
Metabolic syndrome	met central obesity criteria and 2 of 3 other criteria at a visit

For each quantitative laboratory parameter in the antidepressant treatment period (Phase A), descriptive statistics of actual measurements and changes from baseline (before the

start of the antidepressant treatment period [Phase A]) at each time point and the last assessment time point will be calculated overall and for each requisite concomitant medication in the ADT set. A listing of subjects with laboratory test values meeting the criteria for potentially clinically significant laboratory test values (Appendix 2) will be provided.

For each quantitative laboratory parameter in the antidepressant treatment period (Phase A) and the antidepressant-responder treatment-continuation period (Phase A+), descriptive statistics of actual measurements and changes from baseline (before the start of the antidepressant treatment period [Phase A]) at each time point and the last assessment time point will be calculated overall and for each requisite concomitant medication in the Phase A+ set. A listing of subjects with laboratory test values meeting the criteria for potentially clinically significant laboratory test values (Appendix 2) will be provided.

9.4 Vital Sign Data

For each vital sign parameter (by position for blood pressure and pulse rate), descriptive statistics of actual measurements and changes from baseline at each time point and the last assessment time point will be calculated for each treatment group and for the overall brexpiprazole group.

Numbers and proportions of subjects with vital signs meeting the criteria for potentially clinically significant vital signs (Appendix 1) will be determined for each treatment group and for the overall brexpiprazole group. A listing of these subjects will be provided.

For each vital sign parameter in the antidepressant treatment period (Phase A), descriptive statistics of actual measurements and changes from baseline (before the start of the antidepressant treatment period [Phase A]) at each time point and the last assessment time point will be calculated overall and for each requisite concomitant medication in the ADT set. A listing of subjects with vital signs meeting the criteria for potentially clinically significant vital signs (Appendix 1) will be provided.

For each vital sign parameter in the antidepressant treatment period (Phase A) and the antidepressant-responder treatment-continuation period (Phase A+), descriptive statistics of actual measurements and changes from baseline (before the start of the antidepressant treatment period [Phase A]) at each time point and the last assessment time point will be calculated overall and for each requisite concomitant medication in the Phase A+ set. A listing of subjects with vital signs meeting the criteria for potentially clinically significant vital signs (Appendix 1) will be provided.

9.5 Physical Examination Data

Physical examination data will be provided in a listing.

9.6 Electrocardiogram Data

For heart rate, PR interval, RR interval, QRS interval, QT interval, and QT corrected for heart rate (QTc), descriptive statistics of actual measurements and changes from baseline at each time point and the last time point will be calculated for each treatment group and for the overall brexpiprazole group.

A shift table from baseline for normal/abnormal 12-lead electrocardiogram (ECG) (evaluated at the trial site) will be produced for each treatment group and for the overall brexpiprazole group.

Numbers and proportions of subjects with actual measurements of QTc (QTcF, QTcB, QTcN) not meeting the criteria of > 450 msec, > 480 msec, and > 500 msec at baseline and meeting the criteria after treatment will be determined for each treatment group and for the overall brexpiprazole group. Numbers and proportions of subjects with actual measurements of > 450 msec with a % change from baseline of > 10% will be determined for each treatment group and for the overall brexpiprazole group.

Numbers and proportions of subjects with ECG results meeting the criteria for potentially clinically significant ECG data (Appendix 3) will be determined for each treatment group and for the overall brexpiprazole group. A listing of these subjects will be provided.

For each ECG parameter in the antidepressant treatment period (Phase A), descriptive statistics of actual measurements and changes from baseline (before the start of the antidepressant treatment period [Phase A]) at each time point and the last assessment time point will be calculated overall and for each requisite concomitant medication in the ADT set. A listing of subjects with ECG results meeting the criteria for potentially clinically significant ECG data (Appendix 3) will be provided.

For each ECG parameter in the antidepressant treatment period (Phase A) and the antidepressant-responder treatment-continuation period (Phase A+), descriptive statistics of actual measurements and changes from baseline (before the start of the antidepressant treatment period [Phase A]) at each time point and the last assessment time point will be calculated overall and for each requisite concomitant medication in the Phase A+ set. A listing of subjects with ECG results meeting the criteria for potentially clinically significant ECG data (Appendix 3) will be provided.

9.7 Other Safety Data

9.7.1 Body Weight, BMI, and Waist Circumference

For body weight, BMI, and waist circumference, descriptive statistics of actual measurements and changes from baseline at each time point and the last assessment time point will be calculated for each treatment group and for the overall brexpiprazole group.

In addition, analysis will be performed by the ANCOVA model with treatment group as a factor and baseline as a covariate. Least square means of each treatment group and differences in least square means between each brexpiprazole group and the placebo group, as well as the two-sided 95% CIs will be determined.

Numbers and proportions of subjects with results meeting the criteria for potentially clinically significant body weight gain or loss (Appendix 1) will be determined for each treatment group and for the overall brexpiprazole group. Body weight data will also be analyzed by baseline BMI category (< 18.5, ≥ 18.5 to < 25, ≥ 25 to < 30, ≥ 30) in a similar manner. A listing of subjects with results meeting the criteria for potentially clinically significant body weight gain or loss (Appendix 1) will be provided.

For body weight, BMI, and waist circumference in the antidepressant treatment period (Phase A), descriptive statistics of actual measurements and changes from baseline (before the start of the antidepressant treatment period [Phase A]) at each time point and the last assessment time point will be calculated overall and for each requisite concomitant medication in the ADT set. A listing of subjects with results meeting the criteria for potentially clinically significant body weight gain or loss (Appendix 1) will be provided.

For body weight, BMI, and waist circumference in the antidepressant treatment period (Phase A) and the antidepressant-responder treatment-continuation period (Phase A+), descriptive statistics of actual measurements and changes from baseline (before the start of the antidepressant treatment period [Phase A]) at each time point and the last assessment time point will be calculated overall and for each requisite concomitant medication in the Phase A+ set. A listing of subjects with results meeting the criteria for potentially clinically significant body weight gain or loss (Appendix 1) will be provided.

9.7.2 DIEPSS, AIMS, and Barnes Akathisia Rating Scale (BARS)

For DIEPSS total score (total of scores for items 1 through 8) and score for each DIEPSS item, AIMS total score (total of scores for items 1 through 7) and score for each of the items 8 through 10, and BARS, descriptive statistics of actual measurements and changes from baseline at each time point and the last assessment time point and the worst

postdose measurement and its change from baseline will be calculated for each treatment group and for the overall brexpiprazole group.

In addition, analysis will be performed by the ANCOVA model with treatment group as a factor and baseline as a covariate. Least square means of each treatment group and differences in least square means between each brexpiprazole group and the placebo group, as well as the two-sided 95% CIs will be determined.

For DIEPSS total score (total of scores for items 1 through 8) and score for each DIEPSS item, AIMS total score (total of scores for items 1 through 7) and score for each of the items 8 through 10, and BARS in the antidepressant-responder treatment-continuation period (Phase A+), descriptive statistics of actual measurements and changes from baseline (before the start of the antidepressant-responder treatment-continuation period [Phase A+]) at each time point and the last assessment time point will be calculated overall and for each requisite concomitant medication in the Phase A+ set.

9.7.3 Columbia-Suicide Severity Rating Scale (C-SSRS)

Numbers and proportions of subjects for each C-SSRS item (suicidality, suicidal ideation, suicidal behavior, completed suicide, emergence of suicidal ideation, emergence of serious suicidal ideation, worsening of suicidal ideation, and emergence of suicidal behavior) at each time point and in the overall period after initiation of IMP treatment in the double-blind period (including the post-treatment observation period, at discontinuation, and unscheduled visits) will be determined for each treatment group and for the overall brexpiprazole group. A listing of subjects with emergence of suicidal ideation, emergence of serious suicidal ideation, worsening of suicidal ideation, and emergence of suicidal behavior will be provided. Items of suicidal ideation and suicidal behavior will also be summarized in the same manner.

- Suicidality: “Yes” for any item of suicidal ideation or suicidal behavior
- Suicidal ideation: “Yes” for any item of suicidal ideation
- Suicidal behavior: “Yes” for any item of suicidal behavior
- Emergence of suicidal ideation: Change from “No” at baseline to “Yes” after baseline for suicidal ideation
- Emergence of serious suicidal ideation: Change from “No” at baseline to “Yes” with Grade 4 or 5 after baseline for suicidal ideation
- Worsening of suicidal ideation: Increase in the grade of suicidal ideation from baseline
- Emergence of suicidal behavior: Change from “No” at baseline to “Yes” after baseline for suicidal behavior

Items of suicidal ideation and suicidal behavior in the antidepressant treatment period (Phase A) will also be summarized in the ADT set.

Items of suicidal ideation and suicidal behavior in the antidepressant-responder treatment-continuation period (Phase A+) will also be summarized in the Phase A+ set.

10 Pharmacokinetic Analyses

Pharmacokinetic analysis will be performed on the pharmacokinetic analysis set.

Descriptive statistics of plasma brexpiprazole concentrations at time points (0-6, 6-12, 12-18, 18-24, 24-30, and > 30 hours) after the most recent dosing as well as trough brexpiprazole concentrations (20-28 hours after the most recent dosing) and plasma brexpiprazole concentrations at all time points will be calculated by treatment group. The descriptive statistics will also be calculated by CYP2D6 phenotype (EM, IM, PM, and Unknown) in each treatment group and by requisite concomitant medication in each treatment group in the same manner.

The mean plasma brexpiprazole concentration over time and individual values at each time point after the most recent dosing will be plotted by treatment group. Plotted diagrams by CYP2D6 phenotype in each treatment group and by requisite concomitant medication in each treatment group will also be provided in the same manner.

Scatter plots of plasma brexpiprazole concentrations over time will be provided by treatment group. Scatter plots by CYP2D6 phenotype in each treatment group and by requisite concomitant medication in each treatment group will also be provided in the same manner.

Plasma brexpiprazole concentrations below the lower limit of quantitation will be handled as 0 (ng/mL) when their descriptive statistics are calculated and when plotted diagrams and scatter plots are created.

11 Pharmacodynamic Analyses

Not applicable.

12 Pharmacogenomic Analyses

CYP2D6 genotype (phenotype) will be tabulated as specified in Section 7.2 Demographic and Baseline Characteristics. CYP2D6 phenotype will also be summarized in subgroup efficacy and safety analyses.

13 Interim Analysis

No interim analyses are planned.

14 Changes in the Planned Analyses

- The following changes were made to categorical analyses of QTc:
  Only subjects with postdose QTc meeting the criteria will be summarized, instead of summarization at all time points.

  Only subjects with QTc not meeting the criteria at baseline and meeting the criteria after baseline will be summarized.

- It has been decided that CYP2D6 phenotype will be tabulated as specified in Section 7.2 Demographic and Baseline Characteristics. CYP2D6 phenotype will also be summarized in subgroup efficacy and safety analyses.
- The original plan of using the LOCF dataset in ANCOVA of safety endpoints was changed as follows: Measurements at each time point and at the last assessment time point and, as necessary, the worst postdose measurement will be included in the analysis.
- The original plan of calculating descriptive statistics of plasma brexpiprazole concentrations by treatment group in pharmacokinetic analysis was changed as follows: Descriptive statistics of plasma brexpiprazole concentrations at each time point after the most recent dosing, trough concentrations, and plasma drug concentrations at all time points will be calculated by treatment group, by CYP2D6 phenotype in each treatment group, and by requisite concomitant medication in each treatment group.

15 References

Not applicable.

Appendix 1 Criteria for Identifying Vital Signs and Weight of Potential Clinical Relevance

Variable	Criterion Value[a]	Change Relative to Baseline[a]
Pulse Rate	> 120 bpm < 50 bpm	≥ 15 bpm increase ≥ 15 bpm decrease
Systolic Blood Pressure	> 180 mmHg < 90 mmHg	≥ 20 mmHg increase ≥ 20 mmHg decrease
Diastolic Blood Pressure	> 105 mmHg < 50 mmHg	≥ 15 mmHg increase ≥ 15 mmHg decrease
Orthostatic Hypotension	≥ 20 mmHg decrease in systolic blood pressure and a ≥ 25 bpm increase in pulse rate from supine to sitting/standing	Not Applicable
Weight	-	≥ 7% increase ≥ 7% decrease

[a]In order to be identified as potentially clinically relevant, an on-treatment value must meet the "Criterion Value" and also represent a change from the subject's baseline value of at least the magnitude shown in the "Change Relative to Baseline" column.

Appendix 2 Criteria for Identifying Laboratory Values of Potential Clinical Relevance

Laboratory Tests	Criteria
Chemistry	
AST (SGOT)	≥ 3 x upper limit of normal (ULN)
ALT (SGPT)	≥ 3 x ULN
Alkaline phosphatase	≥ 3 x ULN
LDH	≥ 3 x ULN
BUN	≥ 30 mg/dL
Creatinine	≥ 2.0 mg/dL
Uric Acid	
Men	≥ 10.5 mg/dL
Women	≥ 8.5 mg/dL
Bilirubin (total)	≥ 2.0 mg/dL
CPK	≥ 3 x ULN
Endocrinology	
Prolactin	> ULN
Hematology	
Hematocrit	
Men	≤ 37 % and decrease of ≥ 3 percentage points from Baseline
Women	≤ 32 % and decrease of ≥ 3 percentage points from Baseline
Hemoglobin	
Men	≤ 11.5 g/dL
Women	≤ 9.5 g/dL
White blood count	≤ 2,800/ mm^3 or ≥ 16,000/ mm^3
Eosinophils	≥ 10%
Neutrophils	≤ 15%
Absolute neutrophil count	≤ 1,000/ mm^3
Platelet count	≤ 75,000/ mm^3 or ≥ 700,000/ mm^3
Urinalysis	
Protein	Increase of ≥ 2 units
Glucose	Increase of ≥ 2 units
Additional Criteria	
Chloride	≤ 90 mEq/L or ≥ 118 mEq/L
Potassium	≤ 2.5 mEq/L or ≥ 6.5 mEq/L
Sodium	≤ 126 mEq/L or ≥ 156 mEq/L
Calcium	≤ 8.2 mg/dL or ≥ 12 mg/dL
Glucose	
Fasting	≥ 100 mg/dL
Non-Fasting	≥ 200 mg/dL
Total Cholesterol, Fasting	≥ 240 mg/dL
LDL Cholesterol, Fasting	≥ 160 mg/dL
HDL Cholesterol, Fasting	
Men	< 40 mg/dL
Women	< 50 mg/dL
Triglycerides, Fasting	≥ 150 mg/dL

Appendix 3 Criteria for Identifying ECG Measurements of Potential Clinical Relevance

Variable	Criterion Value[a]	Change Relative to Baseline[a]
Heart Rate	≥ 120 bpm ≤ 50 bpm	increase of ≥ 15 bpm decrease of ≥ 15 bpm
PR	≥ 200 msec	increase of ≥ 50 msec
QRS	≥ 120 msec	increase of ≥ 20 msec
QTcF	> 450 msec (males and females)	

[a]In order to be identified as potentially clinically relevant, an on-treatment value must meet the "Criterion Value" and also represent a change from the subject's baseline value of at least the magnitude shown in the "Change Relative to Baseline" column.

Appendix 4 Adverse Events of Interest

AE Category	Preferred Term
EFFECT ON GLUCOSE	Blood glucose abnormal
	Blood glucose increased
	Diabetes mellitus
	Diabetes mellitus inadequate control
	Diabetes with hyperosmolarity
	Diabetic coma
	Diabetic hyperglycaemic coma
	Diabetic hyperosmolar coma
	Diabetic ketoacidosis
	Diabetic ketoacidotic hyperglycaemic coma
	Glucose tolerance decreased
	Glucose tolerance impaired
	Glucose tolerance test abnormal
	Glucose urine present
	Glycosuria
	Glycosylated haemoglobin increased
	Hyperglycaemia
	Hyperglycaemic hyperosmolar nonketotic syndrome
	Impaired fasting glucose
	Increased insulin requirement
	Indeterminate glucose tolerance
	Insulin resistance
	Insulin resistant diabetes
	Insulin tolerance test abnormal
	Insulin-requiring type 2 diabetes mellitus
	Ketoacidosis
	Ketonuria
	Ketosis
	Metabolic syndrome
	Type 1 diabetes mellitus
	Type 2 diabetes mellitus
	Urine ketone body present
EFFECT ON LIPIDS	3-hydroxyacetyl-coenzyme A dehydrogenase deficiency
	Acquired mixed hyperlipidaemia
	Apolipoprotein
	Apolipoprotein A-I
	Apolipoprotein A-I abnormal
	Apolipoprotein A-I decreased
	Apolipoprotein A-I increased
	Apolipoprotein A-I normal
	Apolipoprotein A-II
	Apolipoprotein A-II abnormal
	Apolipoprotein A-II decreased
	Apolipoprotein A-II increased
	Apolipoprotein A-II normal
	Apolipoprotein B
	Apolipoprotein B abnormal
	Apolipoprotein B decreased
	Apolipoprotein B increased

Apolipoprotein B normal
Apolipoprotein B/Apolipoprotein A-1 ratio
Apolipoprotein B/Apolipoprotein A-1 ratio increased
Apolipoprotein C
Apolipoprotein C abnormal
Apolipoprotein E
Apolipoprotein E abnormal
Apolipoprotein E increased
Apolipoprotein abnormal
Apolipoprotein decreased
Apolipoprotein increased
Apolipoprotein normal
Autoimmune hyperlipidaemia
Barth syndrome
Blood cholesterol
Blood cholesterol abnormal
Blood cholesterol decreased
Blood cholesterol esterase increased
Blood cholesterol increased
Blood cholesterol normal
Blood triglycerides
Blood triglycerides abnormal
Blood triglycerides decreased
Blood triglycerides increased
Blood triglycerides normal
Body fat disorder
CANDLE syndrome
Cardiac steatosis
Carnitine
Carnitine abnormal
Carnitine decreased
Carnitine deficiency
Carnitine increased
Carnitine normal
Carnitine palmitoyltransferase deficiency
Carnitine-acylcarnitine translocase deficiency
Cholesterol absorption efficiency decreased
Cholesterosis
Chylomicron decreased
Chylomicron increased
Chylomicrons
Congenital carnitine deficiency
Dyslipidaemia
Epidural lipomatosis
Facial wasting
Familial high density lipoprotein deficiency
Familial hypertriglyceridaemia
Fat redistribution
Fatty acid deficiency
Fatty acid oxidation disorder
Fatty liver alcoholic
Free fatty acids
Free fatty acids abnormal

Free fatty acids decreased
Free fatty acids increased
Gastric xanthoma
HIV lipodystrophy
Hepatic steato-fibrosis
Hepatic steatosis
High density lipoprotein
High density lipoprotein abnormal
High density lipoprotein decreased
High density lipoprotein increased
High density lipoprotein normal
Hyper HDL cholesterolaemia
Hypercholesterolaemia
Hyperchylomicronaemia
Hyperlipidaemia
Hypertriglyceridaemia
Hypo HDL cholesterolaemia
Hypocarnitinaemia
Hypocholesterolaemia
Hypolipidaemia
Hypotriglyceridaemia
Inborn error of lipid metabolism
Intermediate density lipoprotein decreased
Intermediate density lipoprotein increased
Intestinal lipomatosis
Intestinal steatosis
LDL/HDL ratio
LDL/HDL ratio decreased
LDL/HDL ratio increased
Lecithin-cholesterol acyltransferase activity decreased
Lecithin-cholesterol acyltransferase activity increased
Lecithin-cholesterol acyltransferase deficiency
Lipaemia retinalis
Lipaemic index score
Lipid metabolism disorder
Lipid proteinosis
Lipids
Lipids abnormal
Lipids decreased
Lipids increased
Lipids normal
Lipoatrophy
Lipodystrophy acquired
Lipoedema
Lipohypertrophy
Lipomatosis
Lipoprotein (a)
Lipoprotein (a) abnormal
Lipoprotein (a) decreased
Lipoprotein (a) increased
Lipoprotein (a) normal
Lipoprotein abnormal
Lipoprotein deficiency

Lipoprotein increased
Long-chain acyl-coenzyme A dehydrogenase deficiency
Low density lipoprotein
Low density lipoprotein abnormal
Low density lipoprotein decreased
Low density lipoprotein increased
Low density lipoprotein normal
Medium-chain acyl-coenzyme A dehydrogenase deficiency
Mesangiolipidosis
Non-alcoholic steatohepatitis
Non-high-density lipoprotein cholesterol
Non-high-density lipoprotein cholesterol decreased
Non-high-density lipoprotein cholesterol increased
Nonalcoholic fatty liver disease
Pancreatic steatosis
Parotid lipomatosis
Partial lipodystrophy
Phospholipidosis
Phytanic acid increased
Phytosterol level
Phytosterol level increased
Phytosterolaemia
Primary hypercholesterolaemia
Remnant hyperlipidaemia
Remnant-like lipoprotein particles
Remnant-like lipoprotein particles increased
Renal lipomatosis
Renal phospholipidosis
Serum pristanic acid increased
Short-chain acyl-coenzyme A dehydrogenase deficiency
Steatohepatitis
Tangier disease
Thyroid steatosis
Total cholesterol/HDL ratio
Total cholesterol/HDL ratio abnormal
Total cholesterol/HDL ratio decreased
Total cholesterol/HDL ratio increased
Total cholesterol/HDL ratio normal
Trifunctional protein deficiency
Type I hyperlipidaemia
Type II hyperlipidaemia
Type III hyperlipidaemia
Type IIa hyperlipidaemia
Type IIb hyperlipidaemia
Type IV hyperlipidaemia
Type V hyperlipidaemia
Very long-chain acyl-coenzyme A dehydrogenase deficiency
Very low density lipoprotein
Very low density lipoprotein abnormal
Very low density lipoprotein decreased
Very low density lipoprotein increased
Very low density lipoprotein normal
Xanthelasma

	Xanthoma
	Xanthomatosis
	Zieve syndrome
EFFECTS ON WEIGHT	Abnormal weight gain
	Body mass index abnormal
	Body mass index increased
	Obesity
	Overweight
	Waist circumference increased
	Weight fluctuation
	Weight increased
EPS	Abnormal involuntary movement scale
	Action tremor
	Akathisia
	Akinesia
	Asterixis
	Athetosis
	Ballismus
	Blepharospasm
	Bradykinesia
	Bradyphrenia
	Buccoglossal syndrome
	Chorea
	Choreoathetosis
	Chronic tic disorder
	Clumsiness
	Cogwheel rigidity
	Complex tic
	Dopamine dysregulation syndrome
	Drooling
	Dysarthria
	Dyskinesia
	Dyskinesia neonatal
	Dyskinesia oesophageal
	Dyslalia
	Dysphonia
	Dystonia
	Dystonic tremor
	Emprosthotonus
	Essential tremor
	Excessive eye blinking
	Extrapyramidal disorder
	Facial spasm
	Fine motor skill dysfunction
	Freezing phenomenon
	Fumbling
	Gait disturbance
	Gait inability
	Gaze palsy
	Glabellar reflex abnormal
	Grimacing
	Head titubation
	Huntington's disease

Hyperkinesia
Hyperkinesia neonatal
Hypertonia
Hypertonia neonatal
Hypokinesia
Hypokinesia neonatal
Hypokinetic dysarthria
Intention tremor
Laryngeal tremor
Laryngospasm
Meige's syndrome
Micrographia
Mobility decreased
Motor dysfunction
Movement disorder
Muscle contractions involuntary
Muscle contracture
Muscle rigidity
Muscle spasms
Muscle spasticity
Muscle tightness
Muscle tone disorder
Muscle twitching
Musculoskeletal stiffness
Myoclonus
Myotonia
Nuchal rigidity
Oculogyric crisis
Oesophageal spasm
On and off phenomenon
Opisthotonus
Oromandibular dystonia
Oropharyngeal spasm
Parkinson's disease
Parkinson's disease psychosis
Parkinsonian crisis
Parkinsonian gait
Parkinsonian rest tremor
Parkinsonism
Parkinsonism hyperpyrexia syndrome
Periodic limb movement disorder
Pharyngeal dyskinesia
Pharyngeal dystonia
Pleurothotonus
Postural reflex impairment
Postural tremor
Posture abnormal
Posturing
Propulsive gait
Protrusion tongue
Provisional tic disorder
Psychomotor hyperactivity
Rabbit syndrome

	Reduced facial expression
	Respiratory dyskinesia
	Resting tremor
	Restless legs syndrome
	Restlessness
	Risus sardonicus
	Saliva altered
	Salivary hypersecretion
	Secondary tic
	Spasmodic dysphonia
	Tardive dyskinesia
	Tic
	Tongue paralysis
	Tongue spasm
	Torticollis
	Torticollis psychogenic
	Tremor
	Tremor neonatal
	Trismus
	Uvular spasm
	Walking disability
	Writer's cramp
HAEMATOPOIETIC/LEUKOPENIA	5q minus syndrome
	ABO haemolytic disease of newborn
	ABO incompatibility
	ADAMTS13 activity abnormal
	ADAMTS13 activity assay
	ADAMTS13 activity decreased
	ADAMTS13 activity increased
	ADAMTS13 activity normal
	ADAMTS13 inhibitor screen assay
	Aase syndrome
	Abdominal lymphadenopathy
	Abnormal clotting factor
	Accessory spleen
	Acid haemolysin test
	Acid haemolysin test negative
	Acid haemolysin test positive
	Acquired Von Willebrand's disease
	Acquired amegakaryocytic thrombocytopenia
	Acquired antithrombin III deficiency
	Acquired asplenia
	Acquired complement deficiency disease
	Acquired dysfibrinogenaemia
	Acquired factor IX deficiency
	Acquired factor VIII deficiency
	Acquired factor XI deficiency
	Acquired haemoglobinopathy
	Acquired haemophilia
	Acquired protein S deficiency
	Acquired thalassaemia
	Acral angiokeratoma-like pseudolymphoma
	Activated partial thromboplastin time

Activated partial thromboplastin time abnormal
Activated partial thromboplastin time normal
Activated partial thromboplastin time prolonged
Activated partial thromboplastin time ratio
Activated partial thromboplastin time ratio abnormal
Activated partial thromboplastin time ratio decreased
Activated partial thromboplastin time ratio fluctuation
Activated partial thromboplastin time ratio increased
Activated partial thromboplastin time ratio normal
Activated partial thromboplastin time shortened
Activated protein C resistance
Activated protein C resistance test
Activated protein C resistance test positive
Acute bilineal leukaemia
Acute biphenotypic leukaemia
Acute chest syndrome
Acute erythroid leukaemia
Acute febrile neutrophilic dermatosis
Acute haemolytic transfusion reaction
Acute haemorrhagic oedema of infancy
Acute leukaemia
Acute leukaemia in remission
Acute lymphocytic leukaemia
Acute lymphocytic leukaemia (in remission)
Acute lymphocytic leukaemia recurrent
Acute lymphocytic leukaemia refractory
Acute megakaryocytic leukaemia
Acute megakaryocytic leukaemia (in remission)
Acute monocytic leukaemia
Acute monocytic leukaemia (in remission)
Acute myeloid leukaemia
Acute myeloid leukaemia (in remission)
Acute myeloid leukaemia recurrent
Acute myeloid leukaemia refractory
Acute myelomonocytic leukaemia
Acute promyelocytic leukaemia
Acute undifferentiated leukaemia
Adenoiditis
Administration site lymphadenopathy
Adult T-cell lymphoma/leukaemia
Adult T-cell lymphoma/leukaemia recurrent
Adult T-cell lymphoma/leukaemia refractory
Adult T-cell lymphoma/leukaemia stage I
Adult T-cell lymphoma/leukaemia stage II
Adult T-cell lymphoma/leukaemia stage III
Adult T-cell lymphoma/leukaemia stage IV
Agranulocytosis
Aleukaemic leukaemia
Allergic bronchopulmonary mycosis
Allergic eosinophilia
Alloimmunisation
Alpha-thalassaemia-intellectual deficit syndrome
Amegakaryocytic thrombocytopenia

Anaemia
Anaemia Heinz body
Anaemia folate deficiency
Anaemia macrocytic
Anaemia megaloblastic
Anaemia neonatal
Anaemia of chronic disease
Anaemia of malignant disease
Anaemia of pregnancy
Anaemia postoperative
Anaemia splenic
Anaemia vitamin B12 deficiency
Anaemia vitamin B6 deficiency
Anaemic hypoxia
Anaphylactoid syndrome of pregnancy
Anaplastic large cell lymphoma T- and null-cell types
Anaplastic large cell lymphoma T- and null-cell types recurrent
Anaplastic large cell lymphoma T- and null-cell types refractory
Anaplastic large cell lymphoma T- and null-cell types stage I
Anaplastic large cell lymphoma T- and null-cell types stage II
Anaplastic large cell lymphoma T- and null-cell types stage III
Anaplastic large cell lymphoma T- and null-cell types stage IV
Anaplastic large-cell lymphoma
Angiocentric lymphoma
Angiocentric lymphoma recurrent
Angiocentric lymphoma refractory
Angiocentric lymphoma stage I
Angiocentric lymphoma stage II
Angiocentric lymphoma stage III
Angiocentric lymphoma stage IV
Angioimmunoblastic T-cell lymphoma
Angioimmunoblastic T-cell lymphoma recurrent
Angioimmunoblastic T-cell lymphoma refractory
Angioimmunoblastic T-cell lymphoma stage I
Angioimmunoblastic T-cell lymphoma stage II
Angioimmunoblastic T-cell lymphoma stage III
Angioimmunoblastic T-cell lymphoma stage IV
Angiolymphoid hyperplasia with eosinophilia
Anisochromia
Anisocytosis
Anti A antibody
Anti A antibody positive
Anti B antibody
Anti B antibody positive
Anti Kell antibody test
Anti Kell antibody test negative
Anti Kell antibody test positive
Anti factor IX antibody
Anti factor IX antibody increased
Anti factor IX antibody negative
Anti factor IX antibody positive
Anti factor V antibody
Anti factor V antibody positive

Anti factor VII antibody positive
Anti factor VIII antibody increased
Anti factor VIII antibody negative
Anti factor VIII antibody positive
Anti factor VIII antibody test
Anti factor X activity
Anti factor X activity abnormal
Anti factor X activity decreased
Anti factor X activity increased
Anti factor X activity normal
Anti factor X antibody
Anti factor X antibody negative
Anti factor X antibody positive
Anti factor XI antibody positive
Anti factor XII antibody positive
Anti factor Xa activity decreased
Anti factor Xa assay normal
Anti-complement antibody
Anti-erythropoietin antibody
Anti-erythropoietin antibody negative
Anti-erythropoietin antibody positive
Anti-prothrombin antibody positive
Anti-thrombin antibody
Antiphospholipid syndrome
Antithrombin III
Antithrombin III abnormal
Antithrombin III decreased
Antithrombin III deficiency
Antithrombin III increased
Aplasia pure red cell
Aplastic anaemia
Application site lymphadenopathy
Aspiration bone marrow
Aspiration bone marrow abnormal
Aspiration bone marrow normal
Asplenia
Atypical haemolytic uraemic syndrome
Atypical lymphocytic lobular panniculitis
Atypical mycobacterial lymphadenitis
Autoimmune anaemia
Autoimmune aplastic anaemia
Autoimmune haemolytic anaemia
Autoimmune heparin-induced thrombocytopenia
Autoimmune lymphoproliferative syndrome
Autoimmune neutropenia
Autoimmune pancytopenia
Autosomal recessive megaloblastic anaemia
Axillary web syndrome
B precursor type acute leukaemia
B-cell aplasia
B-cell lymphoma
B-cell lymphoma recurrent
B-cell lymphoma refractory

B-cell lymphoma stage I
B-cell lymphoma stage II
B-cell lymphoma stage III
B-cell lymphoma stage IV
B-cell prolymphocytic leukaemia
B-cell small lymphocytic lymphoma
B-cell small lymphocytic lymphoma recurrent
B-cell small lymphocytic lymphoma refractory
B-cell small lymphocytic lymphoma stage I
B-cell small lymphocytic lymphoma stage II
B-cell small lymphocytic lymphoma stage III
B-cell small lymphocytic lymphoma stage IV
B-cell type acute leukaemia
B-cell unclassifiable lymphoma high grade
B-cell unclassifiable lymphoma low grade
B-lymphocyte abnormalities
B-lymphocyte count
B-lymphocyte count abnormal
B-lymphocyte count decreased
B-lymphocyte count increased
Babesiosis
Band neutrophil count
Band neutrophil count decreased
Band neutrophil count increased
Band neutrophil percentage
Band neutrophil percentage decreased
Band neutrophil percentage increased
Bandaemia
Banti's syndrome
Basophil count
Basophil count abnormal
Basophil count decreased
Basophil count increased
Basophil count normal
Basophil morphology
Basophil morphology abnormal
Basophil morphology normal
Basophil percentage
Basophil percentage decreased
Basophil percentage increased
Basophilia
Basophilopenia
Benign ethnic neutropenia
Benign lymph node neoplasm
Benign neoplasm of thymus
Benign spleen tumour
Benjamin syndrome
Bernard-Soulier syndrome
Beta globin abnormal
Bicytopenia
Bing-Neel syndrome
Biopsy bone marrow
Biopsy bone marrow abnormal

Biopsy bone marrow normal
Biopsy lymph gland
Biopsy lymph gland abnormal
Biopsy lymph gland normal
Biopsy spleen
Biopsy spleen abnormal
Biopsy spleen normal
Biopsy thymus gland
Biopsy thymus gland abnormal
Biopsy thymus gland normal
Blackwater fever
Blast cell count decreased
Blast cell count increased
Blast cell crisis
Blast cell proliferation
Blast cells
Blast cells absent
Blast cells present
Blast crisis in myelogenous leukaemia
Blastic plasmacytoid dendritic cell neoplasia
Bleeding time
Bleeding time abnormal
Bleeding time normal
Bleeding time prolonged
Bleeding time shortened
Blood count
Blood count abnormal
Blood count normal
Blood disorder
Blood erythropoietin
Blood erythropoietin abnormal
Blood erythropoietin decreased
Blood erythropoietin increased
Blood erythropoietin normal
Blood fibrinogen
Blood fibrinogen abnormal
Blood fibrinogen decreased
Blood fibrinogen increased
Blood fibrinogen normal
Blood group A
Blood group AB
Blood group B
Blood group O
Blood grouping
Blood incompatibility haemolytic anaemia of newborn
Blood loss anaemia
Blood loss anaemia neonatal
Blood loss assessment
Blood thrombin
Blood thrombin abnormal
Blood thrombin decreased
Blood thrombin increased
Blood thrombin normal

Blood thromboplastin
Blood thromboplastin abnormal
Blood thromboplastin decreased
Blood thromboplastin increased
Blood thromboplastin normal
Blood type incompatibility
Blood viscosity abnormal
Blood viscosity decreased
Blood viscosity increased
Bone marrow band neutrophil count increased
Bone marrow basophilic leukocyte count increased
Bone marrow disorder
Bone marrow eosinophilic leukocyte count increased
Bone marrow failure
Bone marrow granuloma
Bone marrow haemorrhage
Bone marrow infiltration
Bone marrow ischaemia
Bone marrow leukaemic cell infiltration
Bone marrow metamyelocyte count increased
Bone marrow myelogram
Bone marrow myelogram abnormal
Bone marrow myelogram normal
Bone marrow necrosis
Bone marrow oedema
Bone marrow oedema syndrome
Bone marrow plasmacyte count increased
Bone marrow polymorphonuclear leukocyte count increased
Bone marrow reticulin fibrosis
Bone marrow transplant rejection
Bone marrow tumour cell infiltration
Breakthrough haemolysis
Breast implant-associated anaplastic large cell lymphoma
Broncholithiasis
Bronchopulmonary aspergillosis allergic
Burkitt's leukaemia
Burkitt's lymphoma
Burkitt's lymphoma recurrent
Burkitt's lymphoma refractory
Burkitt's lymphoma stage I
Burkitt's lymphoma stage II
Burkitt's lymphoma stage III
Burkitt's lymphoma stage IV
CANDLE syndrome
CD4 lymphocyte percentage decreased
CD4 lymphocyte percentage increased
CD4 lymphocytes
CD4 lymphocytes abnormal
CD4 lymphocytes decreased
CD4 lymphocytes increased
CD4 lymphocytes normal
CD4/CD8 ratio
CD4/CD8 ratio decreased

CD4/CD8 ratio increased
CD8 lymphocyte percentage decreased
CD8 lymphocyte percentage increased
CD8 lymphocytes
CD8 lymphocytes abnormal
CD8 lymphocytes decreased
CD8 lymphocytes increased
Capillary fragility abnormal
Capillary fragility decreased
Capillary fragility increased
Capillary fragility normal
Capillary fragility test
Capillary permeability
Capillary permeability increased
Capillary permeability normal
Carboxyhaemoglobinaemia
Cardiac haemolytic anaemia
Cardiac lymphangioma
Castleman's disease
Central nervous system leukaemia
Central nervous system lymphoma
Chediak-Higashi syndrome
Chloroma
Chloroma (in remission)
Chorea-acanthocytosis
Chronic eosinophilic leukaemia
Chronic granulomatous disease
Chronic leukaemia
Chronic leukaemia in remission
Chronic lymphocytic leukaemia
Chronic lymphocytic leukaemia (in remission)
Chronic lymphocytic leukaemia recurrent
Chronic lymphocytic leukaemia refractory
Chronic lymphocytic leukaemia stage 0
Chronic lymphocytic leukaemia stage 1
Chronic lymphocytic leukaemia stage 2
Chronic lymphocytic leukaemia stage 3
Chronic lymphocytic leukaemia stage 4
Chronic lymphocytic leukaemia transformation
Chronic myeloid leukaemia
Chronic myeloid leukaemia (in remission)
Chronic myeloid leukaemia recurrent
Chronic myeloid leukaemia transformation
Chronic myelomonocytic leukaemia
Chronic myelomonocytic leukaemia (in remission)
Chronic myelomonocytic leukaemia with N-ras gene mutation
Chronic pigmented purpura
Circulating anticoagulant
Circulating anticoagulant positive
Clonal haematopoiesis
Clot retraction
Clot retraction abnormal
Clot retraction normal

Clot retraction time prolonged
Clot retraction time shortened
Coagulation disorder neonatal
Coagulation factor
Coagulation factor IX level
Coagulation factor IX level abnormal
Coagulation factor IX level decreased
Coagulation factor IX level increased
Coagulation factor IX level normal
Coagulation factor V level
Coagulation factor V level abnormal
Coagulation factor V level decreased
Coagulation factor V level increased
Coagulation factor V level normal
Coagulation factor VII level
Coagulation factor VII level abnormal
Coagulation factor VII level decreased
Coagulation factor VII level increased
Coagulation factor VII level normal
Coagulation factor VIII level
Coagulation factor VIII level abnormal
Coagulation factor VIII level decreased
Coagulation factor VIII level increased
Coagulation factor VIII level normal
Coagulation factor X level
Coagulation factor X level abnormal
Coagulation factor X level decreased
Coagulation factor X level increased
Coagulation factor X level normal
Coagulation factor XI level
Coagulation factor XI level abnormal
Coagulation factor XI level decreased
Coagulation factor XI level increased
Coagulation factor XI level normal
Coagulation factor XII level
Coagulation factor XII level abnormal
Coagulation factor XII level decreased
Coagulation factor XII level increased
Coagulation factor XII level normal
Coagulation factor XIII level
Coagulation factor XIII level abnormal
Coagulation factor XIII level decreased
Coagulation factor XIII level increased
Coagulation factor XIII level normal
Coagulation factor decreased
Coagulation factor deficiency
Coagulation factor increased
Coagulation factor inhibitor assay
Coagulation factor level normal
Coagulation factor mutation
Coagulation test
Coagulation test abnormal
Coagulation test normal

Coagulation time
Coagulation time abnormal
Coagulation time normal
Coagulation time prolonged
Coagulation time shortened
Coagulopathy
Cold type haemolytic anaemia
Complement deficiency disease
Composite lymphoma
Congenital anaemia
Congenital aplastic anaemia
Congenital coagulopathy
Congenital dyserythropoietic anaemia
Congenital dysfibrinogenaemia
Congenital dyskeratosis
Congenital haematological disorder
Congenital hypercoagulation
Congenital hypotransferrinaemia
Congenital lymphatic dysplasia
Congenital lymphoedema
Congenital malaria
Congenital methaemoglobinaemia
Congenital thrombocyte disorder
Congenital thrombocytopenia
Congenital thymus absence
Congenital white blood cell disorder
Conjunctival lymphangiectasia
Conjunctival pallor
Coombs direct test
Coombs direct test negative
Coombs direct test positive
Coombs indirect test
Coombs indirect test negative
Coombs indirect test positive
Coombs negative haemolytic anaemia
Coombs positive haemolytic anaemia
Coombs test
Coombs test negative
Coombs test positive
Crossmatch
Crossmatch compatible
Crossmatch incompatible
Cutaneous B-cell lymphoma
Cutaneous T-cell dyscrasia
Cutaneous T-cell lymphoma
Cutaneous T-cell lymphoma recurrent
Cutaneous T-cell lymphoma refractory
Cutaneous T-cell lymphoma stage I
Cutaneous T-cell lymphoma stage II
Cutaneous T-cell lymphoma stage III
Cutaneous T-cell lymphoma stage IV
Cutaneous extramedullary haemopoiesis
Cutaneous lymphoma

Cutaneovisceral angiomatosis with thrombocytopenia
Cyclic neutropenia
Cystic lymphangioma
Cytomegalovirus mononucleosis
Cytopenia
Cytophagic histiocytic panniculitis
Deficiency anaemia
Delayed haematopoietic reconstitution
Delayed haemolytic transfusion reaction
Delayed serologic transfusion reaction
Delta-beta thalassaemia
Dermatopathic lymphadenopathy
Differential white blood cell count
Differential white blood cell count abnormal
Differential white blood cell count normal
Diffuse large B-cell lymphoma
Diffuse large B-cell lymphoma recurrent
Diffuse large B-cell lymphoma refractory
Diffuse large B-cell lymphoma stage I
Diffuse large B-cell lymphoma stage II
Diffuse large B-cell lymphoma stage III
Diffuse large B-cell lymphoma stage IV
Dilutional coagulopathy
Disseminated intravascular coagulation
Disseminated intravascular coagulation in newborn
Disseminated large cell lymphoma
Double heterozygous sickling disorders
Double hit lymphoma
Dubowitz syndrome
Dysglobulinaemia
Ecchymosis
Elephantiasis
Elephantiasis nostras verrucosa
Elliptocytosis
Elliptocytosis hereditary
Endothelial protein C receptor polymorphism
Engraftment syndrome
Enteritis leukopenic
Enteropathy-associated T-cell lymphoma
Eosinopenia
Eosinophil count
Eosinophil count abnormal
Eosinophil count decreased
Eosinophil count increased
Eosinophil count normal
Eosinophil morphology
Eosinophil morphology abnormal
Eosinophil morphology normal
Eosinophil percentage
Eosinophil percentage abnormal
Eosinophil percentage decreased
Eosinophil percentage increased
Eosinophilia

Eosinophilia myalgia syndrome
Eosinophilic bronchitis
Eosinophilic cellulitis
Eosinophilic colitis
Eosinophilic cystitis
Eosinophilic fasciitis
Eosinophilic gastritis
Eosinophilic granulomatosis with polyangiitis
Eosinophilic leukaemia
Eosinophilic myocarditis
Eosinophilic oesophagitis
Eosinophilic otitis media
Eosinophilic panniculitis
Eosinophilic pleural effusion
Eosinophilic pneumonia
Eosinophilic pneumonia acute
Eosinophilic pneumonia chronic
Eosinophilic pustular folliculitis
Eosinophilic pustulosis
Eosinophilic rhinitis
Epstein Barr virus positive mucocutaneous ulcer
Epstein-Barr virus associated lymphoma
Epstein-Barr virus associated lymphoproliferative disorder
Erdheim-Chester disease
Erythraemic myelosis (in remission)
Erythroblast count
Erythroblast count abnormal
Erythroblast count decreased
Erythroblast count increased
Erythroblast count normal
Erythroblast morphology
Erythroblast morphology abnormal
Erythroblastosis
Erythroblastosis foetalis
Erythrocyte osmotic fragility test
Erythroid maturation arrest
Erythroid series abnormal
Erythropenia
Erythrophagocytosis
Erythropoiesis abnormal
Erythropoietin deficiency anaemia
Erythrosis
Essential thrombocythaemia
Ethanol gelation test
Ethanol gelation test negative
Ethanol gelation test positive
Evans syndrome
Extramedullary haemopoiesis
Extranodal marginal zone B-cell lymphoma (BALT type)
Extranodal marginal zone B-cell lymphoma (MALT type)
Extranodal marginal zone B-cell lymphoma (MALT type) recurrent
Extranodal marginal zone B-cell lymphoma (MALT type) refractory
Extranodal marginal zone B-cell lymphoma (MALT type) stage I

Extranodal marginal zone B-cell lymphoma (MALT type) stage II
Extranodal marginal zone B-cell lymphoma (MALT type) stage III
Extranodal marginal zone B-cell lymphoma (MALT type) stage IV
Extravascular haemolysis
Factor I deficiency
Factor II deficiency
Factor II inhibition
Factor II mutation
Factor III deficiency
Factor IX deficiency
Factor IX inhibition
Factor V Leiden mutation
Factor V deficiency
Factor V inhibition
Factor VII deficiency
Factor VII inhibition
Factor VIII deficiency
Factor VIII inhibition
Factor X deficiency
Factor X inhibition
Factor XI deficiency
Factor XII deficiency
Factor XIII Inhibition
Factor XIII deficiency
Factor Xa activity abnormal
Factor Xa activity decreased
Factor Xa activity increased
Factor Xa activity normal
Factor Xa activity test
Familial haemophagocytic lymphohistiocytosis
Familial polycythaemia
Febrile bone marrow aplasia
Febrile neutropenia
Felty's syndrome
Fibrin
Fibrin D dimer
Fibrin D dimer decreased
Fibrin D dimer increased
Fibrin D dimer normal
Fibrin abnormal
Fibrin decreased
Fibrin degradation products
Fibrin degradation products increased
Fibrin degradation products normal
Fibrin increased
Fibrin normal
Fibrinogen degradation products increased
Fibrinolysis
Fibrinolysis abnormal
Fibrinolysis decreased
Fibrinolysis increased
Fibrinolysis normal
Filariasis lymphatic

Foetal anaemia
Foetal haemoglobin
Foetal haemoglobin decreased
Foetal haemoglobin increased
Foetal haemoglobin normal
Follicle centre lymphoma diffuse small cell lymphoma
Follicle centre lymphoma diffuse small cell lymphoma recurrent
Follicle centre lymphoma diffuse small cell lymphoma refractory
Follicle centre lymphoma diffuse small cell lymphoma stage I
Follicle centre lymphoma diffuse small cell lymphoma stage II
Follicle centre lymphoma diffuse small cell lymphoma stage III
Follicle centre lymphoma diffuse small cell lymphoma stage IV
Follicle centre lymphoma, follicular grade I, II, III
Follicle centre lymphoma, follicular grade I, II, III recurrent
Follicle centre lymphoma, follicular grade I, II, III refractory
Follicle centre lymphoma, follicular grade I, II, III stage I
Follicle centre lymphoma, follicular grade I, II, III stage II
Follicle centre lymphoma, follicular grade I, II, III stage III
Follicle centre lymphoma, follicular grade I, II, III stage IV
Follicular dendritic cell sarcoma
Follicular lymphoma
Follicular lymphoma stage I
Follicular lymphoma stage II
Follicular lymphoma stage III
Follicular lymphoma stage IV
Free haemoglobin
Free haemoglobin absent
Free haemoglobin present
Full blood count
Full blood count abnormal
Full blood count decreased
Full blood count increased
Full blood count normal
Gammopathy
Gastroenteritis eosinophilic
Gastrointestinal lymphoma
Gastrosplenic fistula
Gelatinous transformation of the bone marrow
Glanzmann's disease
Gleich's syndrome
Glucose-6-phosphate dehydrogenase
Glucose-6-phosphate dehydrogenase abnormal
Glucose-6-phosphate dehydrogenase deficiency
Glucose-6-phosphate dehydrogenase normal
Glutathione decreased
Glutathione increased
Glutathione synthetase deficiency
Glutathione test
Good syndrome
Granulocyte count
Granulocyte count decreased
Granulocyte count increased
Granulocyte percentage

Granulocytes abnormal
Granulocytes maturation arrest
Granulocytopenia
Granulocytopenia neonatal
Granulocytosis
Granulomatous T-cell pseudolymphoma
Granulomatous lymphadenitis
Grey zone lymphoma
HELLP syndrome
Haemangioma of spleen
Haemangioma-thrombocytopenia syndrome
Haematocrit
Haematocrit abnormal
Haematocrit decreased
Haematocrit increased
Haematocrit normal
Haematological malignancy
Haematology test
Haematology test abnormal
Haematology test normal
Haematopoietic neoplasm
Haematotoxicity
Haemoconcentration
Haemodilution
Haemoglobin
Haemoglobin A absent
Haemoglobin A present
Haemoglobin A2
Haemoglobin Barts absent
Haemoglobin Barts present
Haemoglobin C
Haemoglobin C disease
Haemoglobin C present
Haemoglobin C trait
Haemoglobin D disease
Haemoglobin D trait
Haemoglobin E
Haemoglobin E absent
Haemoglobin E disease
Haemoglobin E present
Haemoglobin E trait
Haemoglobin E-thalassaemia disease
Haemoglobin Lepore trait
Haemoglobin S
Haemoglobin S decreased
Haemoglobin S increased
Haemoglobin S normal
Haemoglobin abnormal
Haemoglobin decreased
Haemoglobin distribution width
Haemoglobin distribution width decreased
Haemoglobin distribution width increased
Haemoglobin electrophoresis

Haemoglobin electrophoresis abnormal
Haemoglobin electrophoresis normal
Haemoglobin increased
Haemoglobin normal
Haemoglobinaemia
Haemoglobinopathy
Haemoglobinuria
Haemolysis
Haemolysis neonatal
Haemolytic anaemia
Haemolytic anaemia enzyme specific
Haemolytic icteroanaemia
Haemolytic transfusion reaction
Haemolytic uraemic syndrome
Haemophagocytic lymphohistiocytosis
Haemophilia
Haemophilia A with anti factor VIII
Haemophilia A without inhibitors
Haemophilia B with anti factor IX
Haemophilia B without inhibitors
Haemophilic pseudotumour
Haemorrhagic diathesis
Haemorrhagic disease of newborn
Haemorrhagic disorder
Haemorrhagic vasculitis
Haemosiderinuria
Hairy cell leukaemia
Hairy cell leukaemia recurrent
Hand and foot syndrome secondary to sickle cell anaemia
Heavy chain disease
Heinz bodies
Henoch-Schonlein purpura
Henoch-Schonlein purpura nephritis
Heparin resistance
Heparin-induced thrombocytopenia
Heparin-induced thrombocytopenia test
Heparin-induced thrombocytopenia test positive
Hepatic infiltration eosinophilic
Hepatic lymphocytic infiltration
Hepatosplenic T-cell lymphoma
Hepatosplenic abscess
Hepatosplenic candidiasis
Hepatosplenomegaly
Hepatosplenomegaly neonatal
Hereditary haemolytic anaemia
Hereditary sideroblastic anaemia
Hereditary spherocytosis
Hereditary stomatocytosis
Hermansky-Pudlak syndrome
Hexokinase deficiency anaemia
High grade B-cell lymphoma Burkitt-like lymphoma
High grade B-cell lymphoma Burkitt-like lymphoma recurrent
High grade B-cell lymphoma Burkitt-like lymphoma refractory

High grade B-cell lymphoma Burkitt-like lymphoma stage I
High grade B-cell lymphoma Burkitt-like lymphoma stage II
High grade B-cell lymphoma Burkitt-like lymphoma stage III
High grade B-cell lymphoma Burkitt-like lymphoma stage IV
High-grade B-cell lymphoma
Hilar lymphadenopathy
Histiocytic medullary reticulosis
Histiocytic necrotising lymphadenitis
Histiocytic sarcoma
Histiocytosis
Hodgkin's disease
Hodgkin's disease lymphocyte depletion stage I site unspecified
Hodgkin's disease lymphocyte depletion stage I subdiaphragm
Hodgkin's disease lymphocyte depletion stage I supradiaphragm
Hodgkin's disease lymphocyte depletion stage II site unspecified
Hodgkin's disease lymphocyte depletion stage II subdiaphragm
Hodgkin's disease lymphocyte depletion stage II supradiaphragm
Hodgkin's disease lymphocyte depletion type recurrent
Hodgkin's disease lymphocyte depletion type refractory
Hodgkin's disease lymphocyte depletion type stage III
Hodgkin's disease lymphocyte depletion type stage IV
Hodgkin's disease lymphocyte depletion type stage unspecified
Hodgkin's disease lymphocyte predominance stage I site unspec
Hodgkin's disease lymphocyte predominance stage I subdiaphragm
Hodgkin's disease lymphocyte predominance stage I supradiaphragm
Hodgkin's disease lymphocyte predominance stage II site unspec
Hodgkin's disease lymphocyte predominance stage II subdiaphragm
Hodgkin's disease lymphocyte predominance stage II supradiaphragm
Hodgkin's disease lymphocyte predominance type recurrent
Hodgkin's disease lymphocyte predominance type refractory
Hodgkin's disease lymphocyte predominance type stage III
Hodgkin's disease lymphocyte predominance type stage IV
Hodgkin's disease lymphocyte predominance type stage unspecified
Hodgkin's disease mixed cellularity recurrent
Hodgkin's disease mixed cellularity refractory
Hodgkin's disease mixed cellularity stage I site unspecified
Hodgkin's disease mixed cellularity stage I subdiaphragmatic
Hodgkin's disease mixed cellularity stage I supradiaphragmatic
Hodgkin's disease mixed cellularity stage II subdiaphragmatic
Hodgkin's disease mixed cellularity stage II supradiaphragmatic
Hodgkin's disease mixed cellularity stage III
Hodgkin's disease mixed cellularity stage IV
Hodgkin's disease mixed cellularity stage unspecified
Hodgkin's disease nodular sclerosis
Hodgkin's disease nodular sclerosis recurrent
Hodgkin's disease nodular sclerosis refractory
Hodgkin's disease nodular sclerosis stage I
Hodgkin's disease nodular sclerosis stage II
Hodgkin's disease nodular sclerosis stage III
Hodgkin's disease nodular sclerosis stage IV
Hodgkin's disease recurrent
Hodgkin's disease refractory
Hodgkin's disease stage I

Hodgkin's disease stage II
Hodgkin's disease stage III
Hodgkin's disease stage IV
Hodgkin's disease unclassifiable
Hyperbilirubinaemia
Hyperchromasia
Hyperchromic anaemia
Hypercoagulation
Hypereosinophilic syndrome
Hyperfibrinogenaemia
Hyperfibrinolysis
Hypergammaglobulinaemia
Hypergammaglobulinaemia benign monoclonal
Hyperglobulinaemia
Hyperhomocysteinaemia
Hyperleukocytosis
Hyperplasia of thymic epithelium
Hyperprothrombinaemia
Hypersensitivity vasculitis
Hypersplenism
Hypersplenism congenital
Hyperthrombinaemia
Hyperviscosity syndrome
Hypochromasia
Hypochromic anaemia
Hypocoagulable state
Hypocomplementaemia
Hypofibrinogenaemia
Hypoglobulinaemia
Hypoplastic anaemia
Hypoprothrombinaemia
Hyposplenism
Hypothrombinaemia
Hypothromboplastinaemia
Hypotransferrinaemia
ISTH score for disseminated intravascular coagulation
Idiopathic CD4 lymphocytopenia
Idiopathic neutropenia
Immature granulocyte count
Immature granulocyte count increased
Immature granulocyte percentage increased
Immune thrombocytopenia
Immune-mediated cytopenia
Immunoblastic lymphoma
Increased tendency to bruise
Indeterminable ABO blood type
Infantile genetic agranulocytosis
Infantile scurvy
Infected lymphocele
Infectious mononucleosis
Infusion site lymphadenopathy
Injection site lymphadenopathy
International normalised ratio

International normalised ratio abnormal
International normalised ratio decreased
International normalised ratio fluctuation
International normalised ratio increased
International normalised ratio normal
Intestinal T-cell lymphoma recurrent
Intestinal T-cell lymphoma refractory
Intestinal T-cell lymphoma stage I
Intestinal T-cell lymphoma stage II
Intestinal T-cell lymphoma stage III
Intestinal T-cell lymphoma stage IV
Intravascular haemolysis
Iron deficiency anaemia
Isoimmune haemolytic disease
Jaundice
Jaundice acholuric
Jaundice neonatal
Jessner's lymphocytic infiltration
Juvenile chronic myelomonocytic leukaemia
Kell blood group positive
Lactescent serum
Langerhans cell sarcoma
Langerhans' cell histiocytosis
Large granular lymphocytosis
Leptomeningeal myelomatosis
Leukaemia
Leukaemia basophilic
Leukaemia cutis
Leukaemia granulocytic
Leukaemia in remission
Leukaemia monocytic
Leukaemia recurrent
Leukaemic cardiac infiltration
Leukaemic infiltration
Leukaemic infiltration extramedullary
Leukaemic infiltration gingiva
Leukaemic infiltration hepatic
Leukaemic infiltration ovary
Leukaemic infiltration pulmonary
Leukaemic infiltration renal
Leukaemic lymphoma
Leukaemic retinopathy
Leukaemoid reaction
Leukocyte adhesion deficiency type I
Leukocyte vacuolisation
Leukocytosis
Leukoerythroblastic anaemia
Leukoerythroblastosis
Leukopenia
Leukopenia neonatal
Leukostasis syndrome
Light chain disease
Lineage switch leukaemia

Loeffler's syndrome
Loefgren syndrome
Loss of CAR T-cell persistence
Lupus anticoagulant hypoprothrombinaemia syndrome
Lymph gland infection
Lymph node abscess
Lymph node calcification
Lymph node fibrosis
Lymph node haemorrhage
Lymph node pain
Lymph node rupture
Lymph node tuberculosis
Lymph node ulcer
Lymph nodes scan abnormal
Lymph nodes scan normal
Lymphadenitis
Lymphadenitis bacterial
Lymphadenitis fungal
Lymphadenitis helminthic
Lymphadenitis viral
Lymphadenocyst
Lymphadenopathy
Lymphadenopathy mediastinal
Lymphangiectasia
Lymphangiectasia intestinal
Lymphangiectasia intestinal congenital
Lymphangioleiomyomatosis
Lymphangioma
Lymphangiopathy
Lymphangiosarcoma
Lymphangiosis carcinomatosa
Lymphangitis
Lymphatic disorder
Lymphatic duct injury
Lymphatic fistula
Lymphatic insufficiency
Lymphatic obstruction
Lymphatic sinus catarrh
Lymphatic system neoplasm
Lymphoblast count
Lymphoblast count increased
Lymphoblast morphology
Lymphoblast morphology abnormal
Lymphoblast morphology normal
Lymphoblastosis
Lymphocele
Lymphocyte count
Lymphocyte count abnormal
Lymphocyte count decreased
Lymphocyte count increased
Lymphocyte count normal
Lymphocyte morphology
Lymphocyte morphology abnormal

Lymphocyte morphology normal
Lymphocyte percentage
Lymphocyte percentage abnormal
Lymphocyte percentage decreased
Lymphocyte percentage increased
Lymphocyte stimulation test
Lymphocyte stimulation test negative
Lymphocyte stimulation test positive
Lymphocyte transformation test
Lymphocyte transformation test negative
Lymphocyte transformation test positive
Lymphocyte/monocyte ratio decreased
Lymphocytic infiltration
Lymphocytic leukaemia
Lymphocytic lymphoma
Lymphocytic oesophagitis
Lymphocytopenia neonatal
Lymphocytosis
Lymphoedema
Lymphogranuloma venereum
Lymphoid hyperplasia of intestine
Lymphoid leukaemia (in remission)
Lymphoid tissue hyperplasia
Lymphoid tissue hypoplasia
Lymphoma
Lymphoma AIDS related
Lymphoma transformation
Lymphopenia
Lymphoplasia
Lymphoplasmacytoid lymphoma/immunocytoma
Lymphoplasmacytoid lymphoma/immunocytoma recurrent
Lymphoplasmacytoid lymphoma/immunocytoma refractory
Lymphoplasmacytoid lymphoma/immunocytoma stage I
Lymphoplasmacytoid lymphoma/immunocytoma stage II
Lymphoplasmacytoid lymphoma/immunocytoma stage III
Lymphoplasmacytoid lymphoma/immunocytoma stage IV
Lymphoproliferative disorder
Lymphoproliferative disorder in remission
Lymphorrhoea
Lymphostasis
MLASA syndrome
MNS system antibodies positive
MYH9-related disease
Macrocytosis
Macrophage count
Macrophages decreased
Macrophages increased
Malaria
Malaria recrudescence
Malaria relapse
Malignant histiocytosis
Malignant lymphoid neoplasm
Malignant lymphoma unclassifiable high grade

Malignant lymphoma unclassifiable low grade
Malignant mast cell neoplasm
Malignant neoplasm of thymus
Malignant splenic neoplasm
Mantle cell lymphoma
Mantle cell lymphoma recurrent
Mantle cell lymphoma refractory
Mantle cell lymphoma stage I
Mantle cell lymphoma stage II
Mantle cell lymphoma stage III
Mantle cell lymphoma stage IV
March haemoglobinuria
Marginal zone lymphoma
Marginal zone lymphoma recurrent
Marginal zone lymphoma refractory
Marginal zone lymphoma stage I
Marginal zone lymphoma stage II
Marginal zone lymphoma stage III
Marginal zone lymphoma stage IV
Marrow hyperplasia
Mast cell activation syndrome
Mastocytic leukaemia
Mastocytosis
Mature B-cell type acute leukaemia
McLeod neuroacanthocytosis syndrome
Mean cell haemoglobin
Mean cell haemoglobin concentration
Mean cell haemoglobin concentration abnormal
Mean cell haemoglobin concentration decreased
Mean cell haemoglobin concentration increased
Mean cell haemoglobin concentration normal
Mean cell haemoglobin decreased
Mean cell haemoglobin increased
Mean cell haemoglobin normal
Mean cell volume
Mean cell volume abnormal
Mean cell volume decreased
Mean cell volume increased
Mean cell volume normal
Mean platelet volume
Mean platelet volume abnormal
Mean platelet volume decreased
Mean platelet volume increased
Mean platelet volume normal
Medical device site lymphadenopathy
Megakaryocyte destruction increased
Megakaryocytes
Megakaryocytes abnormal
Megakaryocytes decreased
Megakaryocytes increased
Megakaryocytes normal
Megaloblasts increased
Melanaemia

Meningitis eosinophilic
Metamyelocyte count
Metamyelocyte count decreased
Metamyelocyte count increased
Metamyelocyte percentage
Metamyelocyte percentage increased
Metastases to bone marrow
Metastases to lymph nodes
Metastases to spleen
Metastatic lymphoma
Methaemoglobinaemia
Methaemoglobinuria
Methylenetetrahydrofolate reductase deficiency
Methylenetetrahydrofolate reductase polymorphism
Microangiopathic haemolytic anaemia
Microcytic anaemia
Microcytosis
Minimal residual disease
Mitogen stimulation test
Mitogen stimulation test abnormal
Mitogen stimulation test normal
Monoblast count
Monoblast count decreased
Monoblast count increased
Monoclonal B-cell lymphocytosis
Monoclonal gammopathy
Monocyte count
Monocyte count abnormal
Monocyte count decreased
Monocyte count increased
Monocyte count normal
Monocyte morphology
Monocyte morphology abnormal
Monocyte percentage
Monocyte percentage abnormal
Monocyte percentage decreased
Monocyte percentage increased
Monocytic leukaemia in remission
Monocytopenia
Monocytosis
Mononuclear cell count
Mononuclear cell count abnormal
Mononuclear cell count decreased
Mononuclear cell count increased
Mononuclear cell percentage
Mononucleosis syndrome
Multicentric reticulohistiocytosis
Myeloblast count
Myeloblast count decreased
Myeloblast count increased
Myeloblast percentage
Myeloblast percentage decreased
Myeloblast percentage increased

Myeloblast present
Myeloblastoma
Myelocyte count
Myelocyte count decreased
Myelocyte count increased
Myelocyte percentage
Myelocyte percentage decreased
Myelocyte percentage increased
Myelocyte present
Myelocytosis
Myelodysplastic syndrome
Myelodysplastic syndrome transformation
Myelodysplastic syndrome unclassifiable
Myelofibrosis
Myeloid leukaemia
Myeloid leukaemia in remission
Myeloid maturation arrest
Myeloid metaplasia
Myelolipoma
Myeloperoxidase deficiency
Myeloproliferative neoplasm
Myelosuppression
Natural killer T cell count
Natural killer T cell count decreased
Natural killer T cell count increased
Natural killer cell count
Natural killer cell count decreased
Natural killer cell count increased
Natural killer-cell leukaemia
Natural killer-cell lymphoblastic lymphoma
Necrotic lymphadenopathy
Neonatal alloimmune thrombocytopenia
Neonatal leukaemia
Neoplasm of thymus
Nephrogenic anaemia
Neuroacanthocytosis
Neutropenia
Neutropenia neonatal
Neutropenic colitis
Neutropenic infection
Neutropenic sepsis
Neutrophil Fc gamma RIIIb deficiency
Neutrophil Pelger-Huet anomaly present
Neutrophil chemotaxis
Neutrophil chemotaxis abnormal
Neutrophil chemotaxis normal
Neutrophil count
Neutrophil count abnormal
Neutrophil count decreased
Neutrophil count increased
Neutrophil count normal
Neutrophil function disorder
Neutrophil function test

Neutrophil function test abnormal
Neutrophil function test normal
Neutrophil hypersegmented morphology present
Neutrophil morphology
Neutrophil morphology abnormal
Neutrophil morphology normal
Neutrophil percentage
Neutrophil percentage abnormal
Neutrophil percentage decreased
Neutrophil percentage increased
Neutrophil toxic granulation present
Neutrophil/lymphocyte ratio
Neutrophil/lymphocyte ratio decreased
Neutrophil/lymphocyte ratio increased
Neutrophilia
Neutrophilic dermatosis
Nodal marginal zone B-cell lymphoma
Nodal marginal zone B-cell lymphoma recurrent
Nodal marginal zone B-cell lymphoma refractory
Nodal marginal zone B-cell lymphoma stage I
Nodal marginal zone B-cell lymphoma stage II
Nodal marginal zone B-cell lymphoma stage III
Nodal marginal zone B-cell lymphoma stage IV
Nodular lymphocyte predominant Hodgkin lymphoma
Non-Hodgkin's lymphoma
Non-Hodgkin's lymphoma metastatic
Non-Hodgkin's lymphoma recurrent
Non-Hodgkin's lymphoma refractory
Non-Hodgkin's lymphoma stage I
Non-Hodgkin's lymphoma stage II
Non-Hodgkin's lymphoma stage III
Non-Hodgkin's lymphoma stage IV
Non-Hodgkin's lymphoma transformed recurrent
Non-Hodgkin's lymphoma unspecified histology aggressive
Non-Hodgkin's lymphoma unspecified histology aggressive recurrent
Non-Hodgkin's lymphoma unspecified histology aggressive refractory
Non-Hodgkin's lymphoma unspecified histology aggressive stage I
Non-Hodgkin's lymphoma unspecified histology aggressive stage II
Non-Hodgkin's lymphoma unspecified histology aggressive stage III
Non-Hodgkin's lymphoma unspecified histology aggressive stage IV
Non-Hodgkin's lymphoma unspecified histology indolent
Non-Hodgkin's lymphoma unspecified histology indolent stage I
Non-Hodgkin's lymphoma unspecified histology indolent stage II
Non-Hodgkin's lymphoma unspecified histology indolent stage III
Non-Hodgkin's lymphoma unspecified histology indolent stage IV
Non-immune heparin associated thrombocytopenia
Nontherapeutic agent blood negative
Nontherapeutic agent blood positive
Normochromic anaemia
Normochromic normocytic anaemia
Normocytic anaemia
Nucleated red cells
Ocular icterus

Ocular lymphoma
Oculoglandular syndrome
Omenn syndrome
Oral purpura
Oropharyngeal lymphoid hyperplasia
PFAPA syndrome
POEMS syndrome
PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome
Pancytopenia
Panmyelopathy
Paraproteinaemia
Paratracheal lymphadenopathy
Paroxysmal nocturnal haemoglobinuria
Passenger lymphocyte syndrome
Pearson's syndrome
Peripheral T-cell lymphoma unspecified
Peripheral T-cell lymphoma unspecified recurrent
Peripheral T-cell lymphoma unspecified refractory
Peripheral T-cell lymphoma unspecified stage I
Peripheral T-cell lymphoma unspecified stage II
Peripheral T-cell lymphoma unspecified stage III
Peripheral T-cell lymphoma unspecified stage IV
Perisplenitis
Pernicious anaemia
Persistent generalised lymphadenopathy
Petechiae
Philadelphia positive acute lymphocytic leukaemia
Philadelphia positive chronic myeloid leukaemia
Pickwickian syndrome
Pigment nephropathy
Placental transfusion syndrome
Plasma cell count
Plasma cell disorder
Plasma cell leukaemia
Plasma cell leukaemia in remission
Plasma cell myeloma
Plasma cell myeloma in remission
Plasma cell myeloma recurrent
Plasma cell myeloma refractory
Plasma cells absent
Plasma cells decreased
Plasma cells increased
Plasma cells present
Plasma viscosity
Plasma viscosity abnormal
Plasma viscosity decreased
Plasma viscosity normal
Plasmablast count
Plasmablast count decreased
Plasmablast count increased
Plasmablastic lymphoma
Plasmacytoma
Plasmacytosis

Plasmin decreased
Plasmin increased
Plasmin inhibitor
Plasmin inhibitor decreased
Plasmin inhibitor increased
Plasminogen
Plasminogen activator inhibitor
Plasminogen activator inhibitor decreased
Plasminogen activator inhibitor increased
Plasminogen activator inhibitor polymorphism
Plasminogen activator inhibitor type 1 deficiency
Plasminogen decreased
Plasminogen increased
Plasminogen normal
Plasmodium falciparum infection
Plasmodium knowlesi infection
Plasmodium malariae infection
Plasmodium ovale infection
Plasmodium vivax infection
Platelet adhesiveness
Platelet adhesiveness abnormal
Platelet adhesiveness decreased
Platelet adhesiveness increased
Platelet adhesiveness normal
Platelet aggregation abnormal
Platelet aggregation decreased
Platelet aggregation increased
Platelet aggregation inhibition
Platelet aggregation normal
Platelet aggregation test
Platelet anisocytosis
Platelet count
Platelet count abnormal
Platelet count decreased
Platelet count increased
Platelet count normal
Platelet destruction increased
Platelet disorder
Platelet distribution width
Platelet distribution width abnormal
Platelet distribution width decreased
Platelet distribution width increased
Platelet dysfunction
Platelet factor 4
Platelet factor 4 decreased
Platelet factor 4 increased
Platelet function test
Platelet function test abnormal
Platelet function test normal
Platelet glycoprotein gene mutation
Platelet maturation arrest
Platelet morphology
Platelet morphology abnormal

Platelet morphology normal
Platelet production decreased
Platelet storage pool deficiency
Platelet toxicity
Platelet-large cell ratio
Platelet-large cell ratio decreased
Platelet-large cell ratio increased
Plateletcrit
Plateletcrit abnormal
Plateletcrit decreased
Plateletcrit increased
Plateletcrit normal
Poikilocytosis
Polychromasia
Polychromic red blood cells present
Polyclonal B-cell lymphocytosis
Polycythaemia
Polycythaemia neonatorum
Polycythaemia vera
Polymorphonuclear chromatin clumping
Post transfusion purpura
Post transplant distal limb syndrome
Post transplant lymphoproliferative disorder
Post-anaphylaxis mast cell anergy
Post-depletion B-cell recovery
Postmastectomy lymphoedema syndrome
Postoperative lymphocele
Postsplenectomy syndrome
Precursor B-lymphoblastic lymphoma
Precursor B-lymphoblastic lymphoma recurrent
Precursor B-lymphoblastic lymphoma refractory
Precursor B-lymphoblastic lymphoma stage I
Precursor B-lymphoblastic lymphoma stage II
Precursor B-lymphoblastic lymphoma stage III
Precursor B-lymphoblastic lymphoma stage IV
Precursor T-lymphoblastic leukaemia acute
Precursor T-lymphoblastic lymphoma/leukaemia
Precursor T-lymphoblastic lymphoma/leukaemia recurrent
Precursor T-lymphoblastic lymphoma/leukaemia refractory
Precursor T-lymphoblastic lymphoma/leukaemia stage I
Precursor T-lymphoblastic lymphoma/leukaemia stage II
Precursor T-lymphoblastic lymphoma/leukaemia stage III
Precursor T-lymphoblastic lymphoma/leukaemia stage IV
Prekallikrein decreased
Prekallikrein increased
Prekallikrein test
Prekallikrein test abnormal
Prekallikrein test normal
Primary breast lymphoma
Primary cardiac lymphoma
Primary effusion lymphoma
Primary gastrointestinal follicular lymphoma
Primary mediastinal large B-cell lymphoma

Primary mediastinal large B-cell lymphoma recurrent
Primary mediastinal large B-cell lymphoma refractory
Primary mediastinal large B-cell lymphoma stage I
Primary mediastinal large B-cell lymphoma stage II
Primary mediastinal large B-cell lymphoma stage III
Primary mediastinal large B-cell lymphoma stage IV
Primary myelofibrosis
Proerythroblast count
Proerythroblast count abnormal
Proerythroblast count decreased
Proerythroblast count increased
Proerythroblast count normal
Prolymphocytic leukaemia
Promyelocyte count
Promyelocyte count decreased
Promyelocyte count increased
Protein C
Protein C decreased
Protein C deficiency
Protein C increased
Protein S
Protein S abnormal
Protein S decreased
Protein S deficiency
Protein S increased
Protein S normal
Protein deficiency anaemia
Prothrombin consumption time prolonged
Prothrombin consumption time shortened
Prothrombin fragment 1.2
Prothrombin fragment 1.2 increased
Prothrombin index
Prothrombin level
Prothrombin level abnormal
Prothrombin level decreased
Prothrombin level increased
Prothrombin level normal
Prothrombin time
Prothrombin time abnormal
Prothrombin time normal
Prothrombin time prolonged
Prothrombin time ratio
Prothrombin time ratio abnormal
Prothrombin time ratio decreased
Prothrombin time ratio increased
Prothrombin time shortened
Pseudolymphoma
Pseudomononucleosis
Pulmonary eosinophilia
Pulmonary lymphangiectasia
Pulmonary nodular lymphoid hyperplasia
Punctate basophilia
Pure white cell aplasia

Purpura
Purpura fulminans
Purpura neonatal
Purpura non-thrombocytopenic
Purpura senile
Pyruvate kinase deficiency anaemia
Radiation leukopenia
Radiation-induced lymphocyte apoptosis
Red blood cell Heinz bodies present
Red blood cell abnormality
Red blood cell acanthocytes present
Red blood cell agglutination
Red blood cell agglutination present
Red blood cell analysis
Red blood cell analysis abnormal
Red blood cell analysis normal
Red blood cell anisocytes
Red blood cell anisocytes present
Red blood cell burr cells present
Red blood cell count
Red blood cell count abnormal
Red blood cell count decreased
Red blood cell count increased
Red blood cell count normal
Red blood cell elliptocytes present
Red blood cell enzymes abnormal
Red blood cell hyperchromic morphology
Red blood cell hyperchromic morphology present
Red blood cell hypochromic morphology present
Red blood cell macrocytes present
Red blood cell microcytes
Red blood cell microcytes absent
Red blood cell microcytes present
Red blood cell morphology
Red blood cell morphology abnormal
Red blood cell morphology normal
Red blood cell nucleated morphology
Red blood cell nucleated morphology present
Red blood cell poikilocytes
Red blood cell poikilocytes present
Red blood cell punctate basophilia present
Red blood cell rouleaux formation present
Red blood cell schistocytes
Red blood cell schistocytes present
Red blood cell sedimentation rate
Red blood cell sedimentation rate abnormal
Red blood cell sedimentation rate decreased
Red blood cell sedimentation rate increased
Red blood cell sedimentation rate normal
Red blood cell sickled cells present
Red blood cell siderocytes present
Red blood cell spherocytes
Red blood cell spherocytes present

Red blood cell target cells present
Red blood cell vacuolisation
Red cell distribution width
Red cell distribution width abnormal
Red cell distribution width decreased
Red cell distribution width increased
Red cell distribution width normal
Red cell fragmentation syndrome
Refractory anaemia with an excess of blasts
Refractory anaemia with ringed sideroblasts
Refractory cytopenia with multilineage dysplasia
Refractory cytopenia with unilineage dysplasia
Renal lymphocele
Renal-limited thrombotic microangiopathy
Reticular cell count
Reticulocyte count
Reticulocyte count abnormal
Reticulocyte count decreased
Reticulocyte count increased
Reticulocyte count normal
Reticulocyte haemoglobin equivalent
Reticulocyte percentage
Reticulocyte percentage abnormal
Reticulocyte percentage decreased
Reticulocyte percentage increased
Reticulocyte percentage normal
Reticulocytopenia
Reticulocytosis
Reticuloendothelial dysfunction
Reticuloendothelial system stimulated
Retinopathy sickle cell
Retroperitoneal lymphadenopathy
Rhesus antibodies
Rhesus antibodies negative
Rhesus antibodies positive
Rhesus antigen
Rhesus antigen negative
Rhesus antigen positive
Rhesus haemolytic disease of newborn
Rhesus incompatibility
Richter's syndrome
Rosai-Dorfman syndrome
Rouleaux formation
Russell's viper venom time
Russell's viper venom time abnormal
Russell's viper venom time normal
Scan bone marrow
Scan bone marrow abnormal
Scan bone marrow normal
Scan lymph nodes
Scan spleen
Schistocytosis
Schumm's test

Schumm's test negative
Schumm's test positive
Secondary thrombocytosis
Septic coagulopathy
Serum colour abnormal
Severe fever with thrombocytopenia syndrome
Sezary cell count
Sezary cells increased
Shift to the left
Shift to the right
Shwachman-Diamond syndrome
Sickle cell anaemia
Sickle cell anaemia with crisis
Sickle cell disease
Sickle cell nephropathy
Sickle cell trait
Sideroblastic anaemia
Solitary epithelioid histiocytoma
Soluble fibrin monomer complex
Soluble fibrin monomer complex increased
Spherocytic anaemia
Spleen atrophy
Spleen congestion
Spleen contusion
Spleen disorder
Spleen follicular hyperplasia
Spleen ischaemia
Spleen malformation
Spleen procedural complication
Spleen scan abnormal
Spleen scan normal
Spleen tuberculosis
Splenic abscess
Splenic artery perforation
Splenic artery stenosis
Splenic artery thrombosis
Splenic calcification
Splenic candidiasis
Splenic cyst
Splenic embolism
Splenic fibrosis
Splenic granuloma
Splenic haematoma
Splenic haemorrhage
Splenic hamartoma
Splenic induration
Splenic infarction
Splenic infection
Splenic infection bacterial
Splenic infection fungal
Splenic infection helminthic
Splenic infection viral
Splenic injury

Splenic lesion
Splenic marginal zone lymphoma
Splenic marginal zone lymphoma recurrent
Splenic marginal zone lymphoma refractory
Splenic marginal zone lymphoma stage I
Splenic marginal zone lymphoma stage II
Splenic marginal zone lymphoma stage III
Splenic marginal zone lymphoma stage IV
Splenic necrosis
Splenic neoplasm malignancy unspecified
Splenic peliosis
Splenic rupture
Splenic thrombosis
Splenic varices
Splenic varices haemorrhage
Splenic vein occlusion
Splenic vein thrombosis
Splenitis
Splenomegaly
Splenorenal shunt
Splenosis
Spontaneous haematoma
Spontaneous haemorrhage
Spontaneous heparin-induced thrombocytopenia syndrome
Spur cell anaemia
Sticky platelet syndrome
Stomatocytes present
Stress polycythaemia
Subacute combined cord degeneration
Subcapsular splenic haematoma
Sulphaemoglobinaemia
Systemic mastocytosis
T-cell chronic lymphocytic leukaemia
T-cell lymphoma
T-cell lymphoma recurrent
T-cell lymphoma refractory
T-cell lymphoma stage I
T-cell lymphoma stage II
T-cell lymphoma stage III
T-cell lymphoma stage IV
T-cell prolymphocytic leukaemia
T-cell type acute leukaemia
T-cell unclassifiable lymphoma high grade
T-cell unclassifiable lymphoma low grade
T-lymphocyte count
T-lymphocyte count abnormal
T-lymphocyte count decreased
T-lymphocyte count increased
T-lymphocyte count normal
TEMPI syndrome
Thalassaemia
Thalassaemia alpha
Thalassaemia beta

Thalassaemia minor
Thalassaemia sickle cell
Thrombasthenia
Thrombin time
Thrombin time abnormal
Thrombin time normal
Thrombin time prolonged
Thrombin time shortened
Thrombin-antithrombin III complex
Thrombin-antithrombin III complex abnormal
Thrombin-antithrombin III complex decreased
Thrombin-antithrombin III complex increased
Thrombin-antithrombin III complex normal
Thrombocytopenia
Thrombocytopenia neonatal
Thrombocytopenia-absent radius syndrome
Thrombocytopenic purpura
Thrombocytosis
Thromboelastogram
Thrombopoietin level abnormal
Thrombotic microangiopathy
Thrombotic thrombocytopenic purpura
Thromboxane decreased
Thromboxane increased
Thymic cancer metastatic
Thymic cyst
Thymoma
Thymoma benign
Thymoma malignant
Thymoma malignant recurrent
Thymus abscess
Thymus disorder
Thymus enlargement
Thymus hypoplasia
Thyroid B-cell lymphoma
Transcobalamin deficiency
Transformation to acute myeloid leukaemia
Transfusion reaction
Transfusion-related alloimmune neutropenia
Traumatic ulcerative granuloma with stromal eosinophilia
Triple hit lymphoma
Trisomy 12
Tropical eosinophilia
Tropical sprue
Tuberculosis of intrathoracic lymph nodes
Tuberculosis of peripheral lymph nodes
Ultrasound spleen
Vaccination site lymphadenopathy
Vascular purpura
Venolymphatic malformation
Vitamin C deficiency
Von Willebrand's disease
Von Willebrand's factor activity abnormal

	Von Willebrand's factor activity decreased
	Von Willebrand's factor activity increased
	Von Willebrand's factor activity normal
	Von Willebrand's factor activity test
	Von Willebrand's factor antibody
	Von Willebrand's factor antibody positive
	Von Willebrand's factor antigen abnormal
	Von Willebrand's factor antigen decreased
	Von Willebrand's factor antigen increased
	Von Willebrand's factor antigen normal
	Von Willebrand's factor antigen test
	Von Willebrand's factor inhibition
	Von Willebrand's factor multimers abnormal
	Von Willebrand's factor multimers normal
	Von Willebrand's factor multimers test
	Waldenstrom's macroglobulinaemia
	Waldenstrom's macroglobulinaemia recurrent
	Waldenstrom's macroglobulinaemia refractory
	Waldenstrom's macroglobulinaemia stage I
	Waldenstrom's macroglobulinaemia stage II
	Waldenstrom's macroglobulinaemia stage III
	Waldenstrom's macroglobulinaemia stage IV
	Warm type haemolytic anaemia
	White blood cell agglutination present
	White blood cell analysis
	White blood cell analysis abnormal
	White blood cell analysis normal
	White blood cell count
	White blood cell count abnormal
	White blood cell count decreased
	White blood cell count increased
	White blood cell count normal
	White blood cell disorder
	White blood cell morphology
	White blood cell morphology abnormal
	White blood cell morphology normal
	White clot in blood present
	Wiskott-Aldrich syndrome
	X-linked lymphoproliferative syndrome
HYPERSENSITIVITY	Acquired C1 inhibitor deficiency
	Acute generalised exanthematous pustulosis
	Acute respiratory failure
	Administration related reaction
	Administration site dermatitis
	Administration site eczema
	Administration site hypersensitivity
	Administration site photosensitivity reaction
	Administration site rash
	Administration site recall reaction
	Administration site urticaria
	Administration site vasculitis
	Airway remodelling
	Allergic bronchitis

Allergic colitis
Allergic cough
Allergic cystitis
Allergic eosinophilia
Allergic gastroenteritis
Allergic hepatitis
Allergic keratitis
Allergic oedema
Allergic otitis externa
Allergic otitis media
Allergic pharyngitis
Allergic reaction to excipient
Allergic respiratory disease
Allergic respiratory symptom
Allergic sinusitis
Allergic stomatitis
Allergic transfusion reaction
Allergy alert test positive
Allergy test positive
Allergy to chemicals
Allergy to fermented products
Allergy to immunoglobulin therapy
Allergy to surgical sutures
Allergy to vaccine
Alpha tumour necrosis factor increased
Alveolitis
Anal eczema
Anaphylactic reaction
Anaphylactic shock
Anaphylactic transfusion reaction
Anaphylactoid reaction
Anaphylactoid shock
Anaphylaxis treatment
Angioedema
Anti-insulin antibody increased
Anti-insulin antibody positive
Anti-insulin receptor antibody increased
Anti-insulin receptor antibody positive
Anti-neutrophil cytoplasmic antibody positive vasculitis
Antiallergic therapy
Antibody test abnormal
Antibody test positive
Antiendomysial antibody positive
Application site dermatitis
Application site eczema
Application site hypersensitivity
Application site photosensitivity reaction
Application site rash
Application site recall reaction
Application site urticaria
Application site vasculitis
Arthritis allergic
Aspirin-exacerbated respiratory disease

Asthma
Asthma late onset
Asthma-chronic obstructive pulmonary disease overlap syndrome
Asthmatic crisis
Atopic cough
Atopy
Auricular swelling
Blepharitis allergic
Blister
Blister rupture
Blood immunoglobulin A abnormal
Blood immunoglobulin A increased
Blood immunoglobulin D increased
Blood immunoglobulin E abnormal
Blood immunoglobulin E increased
Blood immunoglobulin G abnormal
Blood immunoglobulin G increased
Blood immunoglobulin M abnormal
Blood immunoglobulin M increased
Bromoderma
Bronchial hyperreactivity
Bronchial oedema
Bronchospasm
Bullous haemorrhagic dermatosis
Bullous impetigo
Caffeine allergy
Capillaritis
Catheter site dermatitis
Catheter site eczema
Catheter site hypersensitivity
Catheter site rash
Catheter site urticaria
Catheter site vasculitis
Charcot-Leyden crystals
Cheilitis
Childhood asthma
Choking
Choking sensation
Chronic eosinophilic rhinosinusitis
Chronic hyperplastic eosinophilic sinusitis
Circulatory collapse
Circumoral oedema
Circumoral swelling
Complement factor C1 decreased
Complement factor C2 decreased
Complement factor C3 decreased
Complement factor C4 decreased
Complement factor decreased
Conjunctival oedema
Conjunctivitis
Conjunctivitis allergic
Contact stomatitis
Contrast media allergy

Contrast media reaction
Corneal exfoliation
Corneal oedema
Cough variant asthma
Cross sensitivity reaction
Cutaneous vasculitis
Cytokine increased
Cytokine release syndrome
Cytokine storm
Dennie-Morgan fold
Dermatitis
Dermatitis acneiform
Dermatitis allergic
Dermatitis atopic
Dermatitis bullous
Dermatitis contact
Dermatitis exfoliative
Dermatitis exfoliative generalised
Dermatitis herpetiformis
Dermatitis infected
Dermatitis psoriasiform
Device allergy
Dialysis membrane reaction
Distributive shock
Documented hypersensitivity to administered product
Drug eruption
Drug hypersensitivity
Drug provocation test
Drug reaction with eosinophilia and systemic symptoms
Ear swelling
Eczema
Eczema infantile
Eczema nummular
Eczema vaccinatum
Eczema vesicular
Eczema weeping
Encephalitis allergic
Encephalopathy allergic
Eosinophil count abnormal
Eosinophil count increased
Eosinophil percentage abnormal
Eosinophil percentage increased
Eosinophilia
Eosinophilia myalgia syndrome
Eosinophilic bronchitis
Eosinophilic granulomatosis with polyangiitis
Eosinophilic oesophagitis
Eosinophilic pneumonia
Eosinophilic pneumonia acute
Eosinophilic pneumonia chronic
Epidermal necrosis
Epidermolysis
Epidermolysis bullosa

Epiglottic oedema
Erythema
Erythema multiforme
Erythema nodosum
Exfoliative rash
Eye allergy
Eye oedema
Eye swelling
Eyelid oedema
Face oedema
Fixed eruption
Flushing
Gastrointestinal oedema
Generalised bullous fixed drug eruption
Generalised oedema
Genital rash
Genital swelling
Giant papillary conjunctivitis
Gingival oedema
Gingival swelling
Gleich's syndrome
HLA marker study positive
Haemolytic transfusion reaction
Haemorrhagic urticaria
Hand dermatitis
Henoch-Schonlein purpura
Henoch-Schonlein purpura nephritis
Heparin-induced thrombocytopenia
Human anti-hamster antibody increased
Human anti-hamster antibody positive
Hypersensitivity
Hypersensitivity myocarditis
Hypersensitivity pneumonitis
Hypersensitivity vasculitis
Idiopathic urticaria
Immediate post-injection reaction
Immune complex level increased
Immune thrombocytopenia
Immune tolerance induction
Immunoglobulins abnormal
Immunoglobulins increased
Immunology test abnormal
Implant site dermatitis
Implant site hypersensitivity
Implant site photosensitivity
Implant site rash
Implant site urticaria
Incision site dermatitis
Incision site rash
Infusion related hypersensitivity reaction
Infusion related reaction
Infusion site dermatitis
Infusion site eczema

Infusion site hypersensitivity
Infusion site photosensitivity reaction
Infusion site rash
Infusion site recall reaction
Infusion site urticaria
Infusion site vasculitis
Injection related reaction
Injection site dermatitis
Injection site eczema
Injection site hypersensitivity
Injection site panniculitis
Injection site photosensitivity reaction
Injection site rash
Injection site recall reaction
Injection site urticaria
Injection site vasculitis
Instillation site hypersensitivity
Instillation site rash
Instillation site urticaria
Interstitial granulomatous dermatitis
Interstitial lung disease
Intestinal angioedema
Iodine allergy
Kounis syndrome
Laryngeal dyspnoea
Laryngeal obstruction
Laryngeal oedema
Laryngitis allergic
Laryngospasm
Laryngotracheal oedema
Leukotriene increased
Limbal swelling
Lip exfoliation
Lip oedema
Lip swelling
Localised oedema
Macrophage inflammatory protein-1 alpha increased
Mast cell activation syndrome
Mast cell degranulation present
Mechanical urticaria
Medical device site dermatitis
Medical device site eczema
Medical device site hypersensitivity
Medical device site photosensitivity reaction
Medical device site rash
Medical device site recall reaction
Medical device site urticaria
Mesenteric panniculitis
Monocyte chemotactic protein-2 increased
Mouth swelling
Mouth ulceration
Mucocutaneous rash
Mucocutaneous ulceration

Mucosa vesicle
Mucosal erosion
Mucosal exfoliation
Mucosal necrosis
Mucosal ulceration
Multiple allergies
Nasal crease
Necrotising panniculitis
Nephritis allergic
Neurodermatitis
Neutralising antibodies positive
Nikolsky's sign
Nodular rash
Non-neutralising antibodies positive
Noninfective conjunctivitis
Nutritional supplement allergy
Occupational asthma
Occupational dermatitis
Oculomucocutaneous syndrome
Oculorespiratory syndrome
Oedema mouth
Oedema mucosal
Oral allergy syndrome
Oral mucosal exfoliation
Orbital oedema
Oropharyngeal blistering
Oropharyngeal oedema
Oropharyngeal spasm
Oropharyngeal swelling
Palatal oedema
Palatal swelling
Palisaded neutrophilic granulomatous dermatitis
Palpable purpura
Panniculitis
Pathergy reaction
Penile exfoliation
Penile oedema
Penile rash
Penile swelling
Perineal rash
Perioral dermatitis
Periorbital oedema
Periorbital swelling
Perivascular dermatitis
Pharyngeal oedema
Pharyngeal swelling
Photosensitivity reaction
Pneumonitis
Procedural shock
Prurigo
Pruritus
Pruritus allergic
Pulmonary eosinophilia

Radioallergosorbent test positive
Rash
Rash erythematous
Rash follicular
Rash macular
Rash maculo-papular
Rash maculovesicular
Rash morbilliform
Rash neonatal
Rash papulosquamous
Rash pruritic
Rash pustular
Rash rubelliform
Rash scarlatiniform
Rash vesicular
Reaction to azo-dyes
Reaction to colouring
Reaction to excipient
Reaction to food additive
Reaction to preservatives
Reactive airways dysfunction syndrome
Red man syndrome
Respiratory arrest
Respiratory distress
Respiratory failure
Respiratory tract oedema
Reversible airways obstruction
Rhinitis allergic
Rhinitis perennial
SJS-TEN overlap
Scleral oedema
Scleritis allergic
Scrotal dermatitis
Scrotal exfoliation
Scrotal oedema
Scrotal swelling
Seasonal allergy
Septal panniculitis
Serum sickness
Serum sickness-like reaction
Shock
Shock symptom
Skin erosion
Skin exfoliation
Skin necrosis
Skin oedema
Skin reaction
Skin swelling
Skin test positive
Sneezing
Solar urticaria
Solvent sensitivity
Status asthmaticus

Stevens-Johnson syndrome
Stoma site hypersensitivity
Stoma site rash
Stomatitis
Streptokinase antibody increased
Stridor
Suffocation feeling
Sunscreen sensitivity
Swelling face
Swelling of eyelid
Swollen tongue
Symmetrical drug-related intertriginous and flexural exanthema
Throat tightness
Tongue exfoliation
Tongue oedema
Toxic epidermal necrolysis
Toxic skin eruption
Tracheal obstruction
Tracheal oedema
Tracheostomy
Transplantation associated food allergy
Type I hypersensitivity
Type II hypersensitivity
Type III immune complex mediated reaction
Type IV hypersensitivity reaction
Upper airway obstruction
Urticaria
Urticaria cholinergic
Urticaria chronic
Urticaria contact
Urticaria papular
Urticaria physical
Urticaria pigmentosa
Urticaria vesiculosa
Urticarial dermatitis
Urticarial vasculitis
Vaccination site dermatitis
Vaccination site eczema
Vaccination site exfoliation
Vaccination site hypersensitivity
Vaccination site photosensitivity reaction
Vaccination site rash
Vaccination site recall reaction
Vaccination site urticaria
Vaccination site vasculitis
Vaccination site vesicles
Vaccine associated enhanced disease
Vaccine associated enhanced respiratory disease
Vaginal oedema
Vaginal ulceration
Vasculitic rash
Vernal keratoconjunctivitis
Vessel puncture site rash

	Vessel puncture site vesicles
	Visceral oedema
	Vulval eczema
	Vulval oedema
	Vulval ulceration
	Vulvovaginal exfoliation
	Vulvovaginal rash
	Vulvovaginal swelling
	Vulvovaginal ulceration
	Vulvovaginitis allergic
	Wheezing
MANIC SWITCH	Hypomania
	Mania
	Manic symptom
NEUROLEPTIC MALIGNANT SYNDROME	Altered state of consciousness
	Autonomic nervous system imbalance
	Blood creatine phosphokinase MM increased
	Blood creatine phosphokinase abnormal
	Blood creatine phosphokinase increased
	Blood pressure abnormal
	Blood pressure decreased
	Blood pressure fluctuation
	Blood pressure increased
	Body temperature increased
	Cardiovascular insufficiency
	Catatonia
	Coma
	Confusional state
	Consciousness fluctuating
	Delirium
	Depressed level of consciousness
	Disorientation
	Dyskinesia
	Dyslalia
	Dysphagia
	Dystonia
	Dystonic tremor
	Extrapyramidal disorder
	Fatigue
	Freezing phenomenon
	Heart rate abnormal
	Heart rate increased
	Hyperhidrosis
	Hyperkinesia
	Hyperpyrexia
	Hypertension
	Hyperthermia malignant
	Hypertonia
	Hyporesponsive to stimuli
	Hypotension
	Labile blood pressure
	Labile hypertension
	Leukocytosis

	Loss of consciousness
	Malignant catatonia
	Muscle enzyme increased
	Muscle necrosis
	Muscle rigidity
	Muscular weakness
	Myalgia
	Myoclonus
	Myoglobin blood increased
	Myoglobin blood present
	Myoglobin urine present
	Myoglobinaemia
	Myoglobinuria
	Necrotising myositis
	Neuroleptic malignant syndrome
	Oculogyric crisis
	Opisthotonus
	Palpitations
	Parkinson's disease
	Parkinsonian crisis
	Parkinsonian rest tremor
	Parkinsonism
	Pyrexia
	Respiratory failure
	Resting tremor
	Rhabdomyolysis
	Salivary hypersecretion
	Serotonin syndrome
	Slow response to stimuli
	Stupor
	Tachycardia
	Tremor
	Unresponsive to stimuli
	Urinary retention
	White blood cell count abnormal
	White blood cell count increased
	Withdrawal catatonia
ORTHOSTATIC HYPOTENSION, DIZZINESS, AND SYNCOPE	Dizziness
	Dizziness postural
	Hypotension
	Orthostatic hypotension
	Presyncope
	Syncope
PROLACTIN	Amenorrhoea
	Amenorrhoea-galactorrhoea syndrome
	Anorgasmia
	Blood prolactin
	Blood prolactin abnormal
	Blood prolactin increased
	Breast discharge
	Breast enlargement
	Breast swelling
	Ejaculation disorder

	Erectile dysfunction
	Female orgasmic disorder
	Female sexual dysfunction
	Galactorrhoea
	Gynaecomastia
	Hirsutism
	Hyperprolactinaemia
	Hypomenorrhoea
	Lactation disorder
	Libido decreased
	Loss of libido
	Male sexual dysfunction
	Menstrual disorder
	Menstruation delayed
	Menstruation irregular
	Oligomenorrhoea
	Orgasm abnormal
	Orgasmic sensation decreased
	Prolactin-producing pituitary tumour
	Sexual dysfunction
QT PROLONGATION	Cardiac arrest
	Cardiac death
	Cardiac fibrillation
	Cardio-respiratory arrest
	Electrocardiogram QT interval abnormal
	Electrocardiogram QT prolonged
	Electrocardiogram U wave inversion
	Electrocardiogram U wave present
	Electrocardiogram U-wave abnormality
	Electrocardiogram repolarisation abnormality
	Long QT syndrome
	Long QT syndrome congenital
	Loss of consciousness
	Sudden cardiac death
	Sudden death
	Syncope
	Torsade de pointes
	Ventricular arrhythmia
	Ventricular fibrillation
	Ventricular flutter
	Ventricular tachyarrhythmia
	Ventricular tachycardia
RHABDOMYOLYSIS AND CPK ELEVATION	Acute kidney injury
	Anuria
	Biopsy muscle abnormal
	Blood calcium decreased
	Blood creatine phosphokinase MM increased
	Blood creatine phosphokinase abnormal
	Blood creatine phosphokinase increased
	Blood creatinine abnormal
	Blood creatinine increased
	Chromaturia
	Chronic kidney disease

	Compartment syndrome
	Creatinine renal clearance abnormal
	Creatinine renal clearance decreased
	Diaphragm muscle weakness
	Electromyogram abnormal
	End stage renal disease
	Glomerular filtration rate abnormal
	Glomerular filtration rate decreased
	Haematoma muscle
	Hypercreatininaemia
	Hypocalcaemia
	Muscle discomfort
	Muscle disorder
	Muscle enzyme increased
	Muscle fatigue
	Muscle haemorrhage
	Muscle necrosis
	Muscle rupture
	Muscle strength abnormal
	Muscular weakness
	Musculoskeletal discomfort
	Musculoskeletal disorder
	Musculoskeletal pain
	Musculoskeletal toxicity
	Myalgia
	Myalgia intercostal
	Myoglobin blood increased
	Myoglobin blood present
	Myoglobin urine present
	Myoglobinaemia
	Myoglobinuria
	Myopathy
	Myopathy toxic
	Myositis
	Necrotising myositis
	Oliguria
	Renal failure
	Renal impairment
	Renal tubular necrosis
	Rhabdomyolysis
	Subacute kidney injury
	Tendon discomfort
	Thyrotoxic myopathy
SEIZURES	1p36 deletion syndrome
	2-Hydroxyglutaric aciduria
	Acquired epileptic aphasia
	Acute encephalitis with refractory, repetitive partial seizures
	Alcoholic seizure
	Alpers disease
	Amygdalohippocampectomy
	Aspartate-glutamate-transporter deficiency
	Atonic seizures
	Atypical benign partial epilepsy

Aura
Automatism epileptic
Autonomic seizure
Baltic myoclonic epilepsy
Benign familial neonatal convulsions
Benign rolandic epilepsy
Biotinidase deficiency
CDKL5 deficiency disorder
CEC syndrome
CSWS syndrome
Change in seizure presentation
Clonic convulsion
Congenital bilateral perisylvian syndrome
Convulsion in childhood
Convulsions local
Convulsive threshold lowered
Corpus callosotomy
Deja vu
Double cortex syndrome
Dreamy state
Drop attacks
Drug withdrawal convulsions
Early infantile epileptic encephalopathy with burst-suppression
Eclampsia
Epilepsy
Epilepsy surgery
Epilepsy with myoclonic-atonic seizures
Epileptic aura
Epileptic psychosis
Faciobrachial dystonic seizure
Febrile convulsion
Febrile infection-related epilepsy syndrome
Foaming at mouth
Focal cortical resection
Focal dyscognitive seizures
Frontal lobe epilepsy
GM2 gangliosidosis
Gelastic seizure
Generalised onset non-motor seizure
Generalised tonic-clonic seizure
Glucose transporter type 1 deficiency syndrome
Grey matter heterotopia
Hemiconvulsion-hemiplegia-epilepsy syndrome
Hemimegalencephaly
Hyperglycaemic seizure
Hypocalcaemic seizure
Hypoglycaemic seizure
Hyponatraemic seizure
Idiopathic generalised epilepsy
Infantile spasms
Jeavons syndrome
Juvenile absence epilepsy
Juvenile myoclonic epilepsy

	Lafora's myoclonic epilepsy
	Lennox-Gastaut syndrome
	Migraine-triggered seizure
	Molybdenum cofactor deficiency
	Multiple subpial transection
	Myoclonic epilepsy
	Myoclonic epilepsy and ragged-red fibres
	Narcolepsy
	Neonatal epileptic seizure
	Neonatal seizure
	Parietal lobe epilepsy
	Partial seizures
	Partial seizures with secondary generalisation
	Petit mal epilepsy
	Polymicrogyria
	Post stroke epilepsy
	Post stroke seizure
	Post-traumatic epilepsy
	Postictal headache
	Postictal paralysis
	Postictal psychosis
	Postictal state
	Preictal state
	Schizencephaly
	Seizure
	Seizure anoxic
	Seizure cluster
	Seizure like phenomena
	Seizure prophylaxis
	Severe myoclonic epilepsy of infancy
	Simple partial seizures
	Status epilepticus
	Sudden unexplained death in epilepsy
	Temporal lobe epilepsy
	Tongue biting
	Tonic clonic movements
	Tonic convulsion
	Tonic posturing
	Topectomy
	Transient epileptic amnesia
	Tuberous sclerosis complex
	Uncinate fits
SOMNOLENCE	Fatigue
	Hypersomnia
	Malaise
	Sedation
	Sedation complication
	Somnolence
SUICIDALITY	Assisted suicide
	Columbia suicide severity rating scale abnormal
	Completed suicide
	Depression suicidal
	Intentional overdose

	Intentional self-injury
	Poisoning deliberate
	Self-injurious ideation
	Suicidal behaviour
	Suicidal ideation
	Suicide attempt
	Suicide threat
	Suspected suicide
	Suspected suicide attempt
VTE (THROMBOTIC AND EMBOLIC EVENTS)	Aseptic cavernous sinus thrombosis
	Axillary vein thrombosis
	Brachiocephalic vein occlusion
	Brachiocephalic vein thrombosis
	Budd-Chiari syndrome
	Catheter management
	Catheterisation venous
	Cavernous sinus thrombosis
	Central venous catheterisation
	Cerebral venous sinus thrombosis
	Cerebral venous thrombosis
	Compression garment application
	Deep vein thrombosis
	Deep vein thrombosis postoperative
	Embolism venous
	Hepatic vein embolism
	Hepatic vein occlusion
	Hepatic vein thrombosis
	Homans' sign positive
	Iliac vein occlusion
	Inferior vena cava syndrome
	Inferior vena caval occlusion
	Jugular vein embolism
	Jugular vein occlusion
	Jugular vein thrombosis
	Mahler sign
	May-Thurner syndrome
	Mesenteric vein thrombosis
	Mesenteric venous occlusion
	Obstetrical pulmonary embolism
	Obstructive shock
	Ophthalmic vein thrombosis
	Ovarian vein thrombosis
	Paget-Schroetter syndrome
	Pelvic venous thrombosis
	Penile vein thrombosis
	Peripheral vein occlusion
	Peripheral vein thrombus extension
	Phlebectomy
	Portal vein cavernous transformation
	Portal vein embolism
	Portal vein occlusion
	Portal vein thrombosis
	Portosplenomesenteric venous thrombosis

Post procedural pulmonary embolism
Post thrombotic syndrome
Postoperative thrombosis
Postpartum venous thrombosis
Pulmonary embolism
Pulmonary infarction
Pulmonary microemboli
Pulmonary oil microembolism
Pulmonary thrombosis
Pulmonary vein occlusion
Pulmonary veno-occlusive disease
Pulmonary venous thrombosis
Renal vein embolism
Renal vein occlusion
Renal vein thrombosis
Retinal vein occlusion
Retinal vein thrombosis
SI QIII TIII pattern
Septic pulmonary embolism
Splenic vein occlusion
Splenic vein thrombosis
Subclavian vein occlusion
Subclavian vein thrombosis
Superior sagittal sinus thrombosis
Superior vena cava occlusion
Superior vena cava syndrome
Thrombophlebitis
Thrombophlebitis migrans
Thrombophlebitis neonatal
Thrombophlebitis superficial
Thrombosed varicose vein
Thrombosis corpora cavernosa
Transverse sinus thrombosis
Vascular graft
Vena cava embolism
Vena cava filter insertion
Vena cava filter removal
Vena cava thrombosis
Venogram abnormal
Venoocclusive disease
Venoocclusive liver disease
Venous angioplasty
Venous occlusion
Venous operation
Venous recanalisation
Venous repair
Venous stent insertion
Venous thrombosis
Venous thrombosis in pregnancy
Venous thrombosis limb
Venous thrombosis neonatal
Visceral venous thrombosis

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CT-5.6.2	Summary of Mean Change From Baseline to Phase A by Study Week in CGI-S (ADT Sample)
CT-5.6.3	Summary of Mean Change From Baseline to Phase A and Phase A+ by Study Week in CGI-S (Phase A Plus Sample)
CT-5.7.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B in HAM-D 17 Total Score - LOCF (Full Analysis Set)
CT-5.7.2	Summary of Mean Change From Baseline (End of Phase A) to Phase B in HAM-D 17 Total Score - OC (Full Analysis Set)

CT-5.7.3	Summary of Mean Change From Baseline to Phase A in HAM-D 17 Total Score (ADT Sample)
CT-5.7.4	Summary of Mean Change From Baseline to Phase A and Phase A+ in HAM-D 17 Total Score (Phase A Plus Sample)
CT-5.8.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in SDS Scores - MMRM (Full Analysis Set)
CT-5.8.2	Summary of Mean Change From Baseline to Phase A by Study Week in SDS Scores (ADT Sample)
CT-5.8.3	Summary of Mean Change From Baseline to Phase A and Phase A+ by Study Week in SDS Scores (Phase A Plus Sample)
CT-5.9.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS-S Total Score - MMRM (Full Analysis Set)
CT-5.9.2	Summary of Mean Change From Baseline to Phase A by Study Week in MADRS-S Total Score (ADT Sample)
CT-5.9.3	Summary of Mean Change From Baseline to Phase A and Phase A+ by Study Week in MADRS-S Total Score (Phase A Plus Sample)
CT-5.10.1	Summary of Mean CGI-I Score by Study Week in Phase B Relative to Baseline (End of Phase A) - LOCF (Full Analysis Set)
CT-5.10.2	Summary of Mean CGI-I Score by Study Week in Phase B Relative to Baseline (End of Phase A) - OC (Full Analysis Set)
CT-5.11.1	Sensitivity Analysis of MNAR Using Tipping Point Analysis in MADRS Total Score Assume All Dropouts as MNAR (Full Analysis Set)
CT-5.11.2	Sensitivity Analysis of MNAR Using Tipping Point Analysis in MADRS Total Score Dropout due to AE or LOE or Withdrew Consent as MNAR (Full Analysis Set)
CT-5.11.3	Sensitivity Analysis of MNAR Using Tipping Point Analysis in MADRS Total Score Dropout due to AE or LOE as MNAR (Full Analysis Set)
CT-5.11.4	Sensitivity Analysis of MNAR Using Placebo Based Imputation in MADRS Total Score (Full Analysis Set)
CT-5.11.5	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score - MI Wilcoxon Rank Sum Test, MI Robust Regression (Full Analysis Set)
CT-5.11.6	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score - OC Wilcoxon Rank Sum Test, OC Robust Regression (Full Analysis Set)
CT-6.1.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by ADT: Duloxetine - MMRM (Full Analysis Set)
CT-6.1.2	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by ADT: Escitalopram - MMRM (Full Analysis Set)
CT-6.1.3	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by ADT: Fluvoxamine - MMRM (Full Analysis Set)
CT-6.1.4	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by ADT: Milnacipran - MMRM (Full Analysis Set)
CT-6.1.5	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by ADT: Paroxetine - MMRM (Full Analysis Set)
CT-6.1.6	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by ADT: Sertraline - MMRM (Full Analysis Set)
CT-6.1.7	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by ADT: Venlafaxine - MMRM (Full Analysis Set)
CT-6.2.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Gender: Male - MMRM (Full Analysis Set)
CT-6.2.2	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Gender: Female - MMRM (Full Analysis Set)
CT-6.3.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Age: <55 Years - MMRM (Full Analysis Set)

CT-6.3.2	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Age: >=55 Years - MMRM (Full Analysis Set)
CT-6.4.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Number of Previous Adequate Antidepressant Treatments: 1 Treatment - MMRM (Full Analysis Set)
CT-6.4.2	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Number of Previous Adequate Antidepressant Treatments: 2 Treatments - MMRM (Full Analysis Set)
CT-6.4.3	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Number of Previous Adequate Antidepressant Treatments: 3 Treatments - MMRM (Full Analysis Set)
CT-6.5.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by DSM-5 Diagnosis: Single Episode - MMRM (Full Analysis Set)
CT-6.5.2	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by DSM-5 Diagnosis: Recurrent Episode - MMRM (Full Analysis Set)
CT-6.6.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Number of Previous Depressive Episodes: 1 Episode - MMRM (Full Analysis Set)
CT-6.6.2	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Number of Previous Depressive Episodes: 2 Episodes - MMRM (Full Analysis Set)
CT-6.6.3	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Number of Previous Depressive Episodes: 3 or more Episodes- MMRM (Full Analysis Set)
CT-6.7.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Duration of Current Episode: <=Median - MMRM (Full Analysis Set)
CT-6.7.2	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Duration of Current Episode: >Median - MMRM (Full Analysis Set)
CT-6.8.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Baseline MADRS Total Score: <=Median - MMRM (Full Analysis Set)
CT-6.8.2	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Baseline MADRS Total Score: >Median - MMRM (Full Analysis Set)
CT-6.9.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Ultrashort-acting Sedative-hypnotic Drugs: Present - MMRM (Full Analysis Set)
CT-6.9.2	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Ultrashort-acting Sedative-hypnotic Drugs: Absent - MMRM (Full Analysis Set)
CT-6.10.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Baseline Weight: <=Median - MMRM (Full Analysis Set)
CT-6.10.2	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Baseline Weight: >Median - MMRM (Full Analysis Set)
CT-6.11.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Baseline BMI: <=Median - MMRM (Full Analysis Set)
CT-6.11.2	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Baseline BMI: >Median - MMRM (Full Analysis Set)
CT-6.12.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by CYP2D6 Metabolism Status: IM - MMRM (Full Analysis Set)

CT-6.12.2	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by CYP2D6 Metabolism Status: EM - MMRM (Full Analysis Set)
CT-6.13.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Impact of COVID-19 Pandemic: Subjects Completed/Discontinued before 07APR2020 - MMRM (Full Analysis Set)
CT-6.13.2	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score by Impact of COVID-19 Pandemic: Subjects Completed/Discontinued on or after 07APR2020 - MMRM (Full Analysis Set)
CF-1	Mean Change From Baseline (End of Phase A) to Phase B by Study Week in MADRS Total Score - MMRM (Full Analysis Set)
CT-7.1.1	Extent of Exposure to Study Medication During Phase B (Safety Analysis Set)
CT-7.1.2	Extent of Exposure to ADT During Phase B (Safety Analysis Set)
CT-7.1.3	Extent of Exposure to ADT During Phase A (ADT Sample)
CT-7.1.4	Extent of Exposure to ADT During Phase A Plus (Phase A Plus Sample)
CT-7.1.5	Average Daily Dose ADT During Phase B (Safety Analysis Set)
CT-7.2	Summary of Treatment Compliance (Full Analysis Set)
CT-8.1	Adverse Events During Phase B (All Causalities) (Safety Analysis Set)
CT-8.2.1	Incidence of TEAEs During Phase B by MedDRA System Organ Class and Preferred Term (Safety Analysis Set)
CT-8.2.2	Incidence of Drug-related TEAEs During Phase B by MedDRA System Organ Class and Preferred Term (Safety Analysis Set)
CT-8.3.1	Incidence of TEAEs During Phase B by MedDRA System Organ Class, Preferred Term and Severity (Safety Analysis Set)
CT-8.3.2	Incidence of Drug-related TEAEs During Phase B by MedDRA System Organ Class, Preferred Term and Severity (Safety Analysis Set)
CT-8.4.1	Incidence of Deaths due to TEAEs During Phase B by MedDRA System Organ Class and Preferred Term (Safety Analysis Set)
CT-8.4.2	Incidence of Deaths due to Drug-related TEAEs During Phase B by MedDRA System Organ Class and Preferred Term (Safety Analysis Set)
CT-8.5.1	Incidence of Serious TEAEs During Phase B by MedDRA System Organ Class and Preferred Term (Safety Analysis Set)
CT-8.5.2	Incidence of Serious Drug-related TEAEs During Phase B by MedDRA System Organ Class and Preferred Term (Safety Analysis Set)
CT-8.6.1	Incidence of TEAEs Resulting in Discontinuation of IMP During Phase B by MedDRA System Organ Class and Preferred Term (Safety Analysis Set)
CT-8.6.2	Incidence of Drug-related TEAEs Resulting in Discontinuation of IMP During Phase B by MedDRA System Organ Class and Preferred Term (Safety Analysis Set)
CT-8.7.1	Incidence of TEAEs During Phase B of at Least 2% in Any Brexpiprazole Group and Greater Than Placebo by MedDRA System Organ Class and Preferred Term (Safety Analysis Set)
CT-8.7.2	Incidence of Drug-related TEAEs During Phase B of at Least 2% in Any Brexpiprazole Group and Greater Than Placebo by MedDRA System Organ Class and Preferred Term (Safety Analysis Set)
CT-8.8.1	Incidence of TEAEs During Phase B by MedDRA System Organ Class, Preferred Term and Time to First Onset (Safety Analysis Set)
CT-8.8.2	Incidence of Drug-related TEAEs During Phase B by MedDRA System Organ Class, Preferred Term and Time to First Onset (Safety Analysis Set)
CT-8.9.1	Incidence of TEAEs for EPS (Safety Analysis Set)
CT-8.9.2	Incidence of TEAEs During Phase B for Neuroleptic Malignant Syndrome (Safety Analysis Set)
CT-8.9.3	Incidence of TEAEs During Phase B for Rhabdomyolysis and CPK Elevation (Safety Analysis Set)
CT-8.9.4	Incidence of TEAEs During Phase B for Seizures (Safety Analysis Set)

CT-8.9.5	Incidence of TEAEs During Phase B for Orthostatic Hypotension, Dizziness, and Syncope (Safety Analysis Set)
CT-8.9.6	Incidence of TEAEs During Phase B for Suicidality (Safety Analysis Set)
CT-8.9.7	Incidence of TEAEs During Phase B for Somnolence (Safety Analysis Set)
CT-8.9.8	Incidence of TEAEs During Phase B for Hypersensitivity (Safety Analysis Set)
CT-8.9.9	Incidence of TEAEs During Phase B for VTE (Thrombotic and Embolic Events) (Safety Analysis Set)
CT-8.9.10	Incidence of TEAEs During Phase B for Haematopoietic/Leukopenia (Safety Analysis Set)
CT-8.9.11	Incidence of TEAEs During Phase B for Effect on Glucose (Safety Analysis Set)
CT-8.9.12	Incidence of TEAEs During Phase B for Effect on Lipids (Safety Analysis Set)
CT-8.9.13	Incidence of TEAEs During Phase B for Effect on Weight (Safety Analysis Set)
CT-8.9.14	Incidence of TEAEs During Phase B for QT Prolongation (Safety Analysis Set)
CT-8.9.15	Incidence of TEAEs During Phase B for Manic Switch (Safety Analysis Set)
CT-8.9.16	Incidence of TEAEs During Phase B for Effect on Prolactin (Safety Analysis Set)
CT-8.10.1	Incidence of TEAEs During Phase B by MedDRA System Organ Class and Preferred Term, by ADT (Safety Analysis Set)
CT-8.10.2	Incidence of TEAEs During Phase B by MedDRA System Organ Class and Preferred Term, by Gender (Safety Analysis Set)
CT-8.10.3	Incidence of TEAEs During Phase B by MedDRA System Organ Class and Preferred Term, by Age (Safety Analysis Set)
CT-8.10.4	Incidence of TEAEs During Phase B by MedDRA System Organ Class and Preferred Term, by CYP2D6 Metabolism Status (Safety Analysis Set)
CT-8.10.5	Incidence of TEAEs During Phase B by MedDRA System Organ Class and Preferred Term, by Impact of COVID-19 Pandemic (Safety Analysis Set)
CT-8.11.1	Incidence of TEAEs During Phase A by MedDRA System Organ Class and Preferred Term (ADT Sample)
CT-8.11.2	Incidence of TEAEs During Phase A Plus by MedDRA System Organ Class and Preferred Term (Phase A Plus Sample)
CT-9.1.1	Listing of Deaths During Phase B
CT-9.1.2	Listing of Deaths During Phase A and Phase A Plus
CT-9.2.1	Listing of Serious Adverse Events During Phase B
CT-9.2.2	Listing of Serious Adverse Events During Phase A and Phase A Plus
CT-9.3.1	Listing of Discontinuation of IMP due to Adverse Events During Phase B
CT-9.3.2	Listing of Discontinuation of IMP due to Adverse Events During Phase A and Phase A Plus
CT-10.1.1	Mean Change From Baseline (End of Phase A) in Clinical Laboratory Test Results - Serum Chemistry (Safety Analysis Set)
CT-10.1.2	Mean Change From Baseline (End of Phase A) in Clinical Laboratory Test Results - Hematology (Safety Analysis Set)
CT-10.1.3	Mean Change From Baseline (End of Phase A) in Clinical Laboratory Test Results - Urinalysis (Safety Analysis Set)
CT-10.1.4	Mean Change From Baseline (End of Phase A) in Clinical Laboratory Test Results - Prolactin, by Gender (Safety Analysis Set)
CT-10.1.5	Mean Change From Baseline (End of Phase A) in Clinical Laboratory Test Results - Other Tests (Safety Analysis Set)
CT-10.2.1	Shift Tables of Clinical Laboratory Test Results - Serum Chemistry (Safety Analysis Set)
CT-10.2.2	Shift Tables of Clinical Laboratory Test Results - Hematology (Safety Analysis Set)
CT-10.2.3	Shift Tables of Clinical Laboratory Test Results - Urinalysis1 (Safety Analysis Set)
CT-10.2.4	Shift Tables of Clinical Laboratory Test Results - Urinalysis2 (Safety Analysis Set)

CT-10.2.5	Shift Tables of Clinical Laboratory Test Results - Prolactin, by Gender (Safety Analysis Set)
CT-10.2.6	Shift Tables of Clinical Laboratory Test Results - Other Tests (Safety Analysis Set)
CT-10.3.1	Incidence of Laboratory Test Values With Potential Clinical Relevance During Phase B (Safety Analysis Set)
CT-10.3.2	Listing of Laboratory Test Values With Potential Clinical Relevance During Phase B by Subject (Safety Analysis Set)
CT-10.4.1	Incidence of Potential Hy's Law Cases During Phase B (Safety Analysis Set)
CT-10.4.2	Listing of Potential Hy's Law Cases During Phase B (Safety Analysis Set)
CT-10.5.1	Incidence of Laboratory Test Values With Potential Clinical Relevance During Phase B - Prolactin (Safety Analysis Set)
CT-10.5.2	Listing of Laboratory Test Values With Potential Clinical Relevance During Phase B - Prolactin (Safety Analysis Set)
CT-10.6.1	Incidence of Treatment-emergent Significant Change in Lipids During Phase B (Safety Analysis Set)
CT-10.6.2	Listing of Treatment-emergent Significant Change in Lipids During Phase B (Safety Analysis Set)
CT-10.7.1	Incidence of Treatment-emergent Significant Change in Glucose During Phase B (Safety Analysis Set)
CT-10.7.2	Listing of Treatment-emergent Significant Change in Glucose During Phase B (Safety Analysis Set)
CT-10.8.1	Incidence of Treatment-emergent Metabolic Syndrome During Phase B (Safety Analysis Set)
CT-10.8.2	Listing of Treatment-emergent Metabolic Syndrome During Phase B (Safety Analysis Set)
CT-10.9.1	Mean Change From Baseline in Clinical Laboratory Test Results During Phase A - Serum Chemistry (ADT Sample)
CT-10.9.2	Mean Change From Baseline in Clinical Laboratory Test Results During Phase A - Hematology (ADT Sample)
CT-10.9.3	Mean Change From Baseline in Clinical Laboratory Test Results During Phase A - Urinalysis (ADT Sample)
CT-10.9.4	Mean Change From Baseline in Clinical Laboratory Test Results During Phase A - Prolactin, by Gender (ADT Sample)
CT-10.9.5	Mean Change From Baseline in Clinical Laboratory Test Results During Phase A - Other Tests (ADT Sample)
CT-10.10.1	Mean Change From Baseline in Clinical Laboratory Test Results During Phase A and Phase A+ - Serum Chemistry (Phase A Plus Sample)
CT-10.10.2	Mean Change From Baseline in Clinical Laboratory Test Results During Phase A and Phase A+ - Hematology (Phase A Plus Sample)
CT-10.10.3	Mean Change From Baseline in Clinical Laboratory Test Results During Phase A and Phase A+ - Urinalysis (Phase A Plus Sample)
CT-10.10.4	Mean Change From Baseline in Clinical Laboratory Test Results During Phase A and Phase A+ - Prolactin, by Gender (Phase A Plus Sample)
CT-10.10.5	Mean Change From Baseline in Clinical Laboratory Test Results During Phase A and Phase A+ - Other Tests (Phase A Plus Sample)
CT-10.11.1	Listing of Laboratory Test Values With Potential Clinical Relevance During Phase A by Subject (ADT Sample)
CT-10.11.2	Listing of Laboratory Test Values With Potential Clinical Relevance During Phase A and Phase A+ (Phase A Plus Sample)
CT-11.1	Mean Change From Baseline (End of Phase A) in Vital Signs During Phase B (Safety Analysis Set)
CT-11.2	Incidence of Potentially Clinically Relevant Abnormalities in Vital Signs During Phase B (Safety Analysis Set)
CT-11.3	Listing of Potentially Clinically Relevant Abnormalities in Vital Signs During Phase B (Safety Analysis Set)

CT-11.4	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in Body Weight (kg) (Safety Analysis Set)
CT-11.5	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in Waist Circumference (cm) (Safety Analysis Set)
CT-11.6	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in BMI (kg/m^2) (Safety Analysis Set)
CT-11.7	Incidence of Potentially Clinically Relevant Weight Gain or Loss by Baseline BMI (Safety Analysis Set)
CT-11.8	Mean Change From Baseline in Vital Signs During Phase A (ADT Sample)
CT-11.9	Mean Change From Baseline in Vital Signs During Phase A and Phase A+ (Phase A Plus Sample)
CT-11.10	Listing of Potentially Clinically Relevant Abnormalities in Vital Signs During Phase A (ADT Sample)
CT-11.11	Listing of Potentially Clinically Relevant Abnormalities in Vital Signs During Phase A and Phase A+ (Phase A Plus Sample)
CT-12.1	Mean Change From Baseline (End of Phase A) in ECG Results During Phase B (Safety Analysis Set)
CT-12.2	Shift Tables of ECG (Safety Analysis Set)
CT-12.3	Incidence of Categorical Changes in QT/QTc During Phase B (Safety Analysis Set)
CT-12.4	Incidence of Potentially Clinically Relevant Abnormalities in ECG Evaluations During Phase B (Safety Analysis Set)
CT-12.5	Listing of Potentially Clinically Relevant Abnormalities in ECG Evaluations During Phase B (Safety Analysis Set)
CT-12.6	Mean Change From Baseline in ECG Results During Phase A (ADT Sample)
CT-12.7	Mean Change From Baseline in ECG Results During Phase A and Phase A+ (Phase A Plus Sample)
CT-12.8	Listing of Potentially Clinically Relevant Abnormalities in ECG Evaluations During Phase A (ADT Sample)
CT-12.9	Listing of Potentially Clinically Relevant Abnormalities in ECG Evaluations During Phase A and Phase A+ (Phase A Plus Sample)
CT-13.1	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in DIEPSS (Safety Analysis Set)
CT-13.2	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in AIMS Total Score and Item Scores 8, 9 and 10 (Safety Analysis Set)
CT-13.3	Summary of Mean Change From Baseline (End of Phase A) to Phase B by Study Week in BARS, Global Clinical Assessment of Akathisia (Safety Analysis Set)
CT-13.4	Summary of Mean Change From Baseline (End of Phase A) to Phase A+ by Study Week in DIEPSS (Phase A Plus Sample)
CT-13.5	Summary of Mean Change From Baseline (End of Phase A) to Phase A+ by Study Week in AIMS Total Score and Item Scores 8, 9 and 10 (Phase A Plus Sample)
CT-13.6	Summary of Mean Change From Baseline (End of Phase A) to Phase A+ by Study Week in BARS, Global Clinical Assessment of Akathisia (Phase A Plus Sample)
CT-14.1	C-SSRS During Phase B, Suicidality (Safety Analysis Set)
CT-14.2	C-SSRS During Phase B, Suicidal Behavior by Type (Safety Analysis Set)
CT-14.3	C-SSRS During Phase B, Suicidal Ideation by Type (Safety Analysis Set)
CT-14.4	C-SSRS During Phase B, Treatment Emergent Suicidal Behavior and Ideation (Safety Analysis Set)
CT-14.5	C-SSRS - Listing of Treatment-emergent Suicidal Ideation During Phase B (Safety Analysis Set)
CT-14.6	C-SSRS - Listing of Treatment-emergent Suicidal Behavior During Phase B (Safety Analysis Set)
CT-14.7	C-SSRS - Listing of Treatment-emergent Serious Ideation During Phase B (Safety Analysis Set)
CT-14.8	C-SSRS - Listing of Worsening Suicidal Ideation During Phase B (Safety Analysis Set)

CT-14.9	C-SSRS During Phase A, Suicidal Behavior by Type (ADT Sample)
CT-14.10	C-SSRS During Phase A, Suicidal Ideation by Type (ADT Sample)
CT-14.11	C-SSRS During Phase A+, Suicidal Behavior by Type (Phase A Plus Sample)
CT-14.12	C-SSRS During Phase A+, Suicidal Ideation by Type (Phase A Plus Sample)
PKT-1	Individual Subject and Summary of Brexpiprazole Plasma Concentrations Following 1 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)
PKT-2	Individual Subject and Summary of Brexpiprazole Plasma Concentrations Following 2 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)
PKT-3	Summary of Brexpiprazole Plasma Concentrations for Each CYP2D6 Phenotype Following 1 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)
PKT-4	Summary of Brexpiprazole Plasma Concentrations for Each CYP2D6 Phenotype Following 2 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)
PKT-5	Summary of Brexpiprazole Plasma Concentrations for Each Requisite Concomitant Medication Following 1 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)
PKT-6	Summary of Brexpiprazole Plasma Concentrations for Each Requisite Concomitant Medication Following 2 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)
PKF-1	Mean (SD) and Scatter Plots of Brexpiprazole Plasma Concentrations Following 1 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)
PKF-2	Mean (SD) and Scatter Plots of Brexpiprazole Plasma Concentrations Following 2 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)
PKF-3	Mean (SD) and Scatter Plots of Brexpiprazole Plasma Concentrations for Each CYP2D6 Phenotype Following 1 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)
PKF-4	Mean (SD) and Scatter Plots of Brexpiprazole Plasma Concentrations for Each CYP2D6 Phenotype Following 2 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)
PKF-5	Mean (SD) and Scatter Plots of Brexpiprazole Plasma Concentrations for Each Requisite Concomitant Medication Following 1 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)
PKF-6	Mean (SD) and Scatter Plots of Brexpiprazole Plasma Concentrations for Each Requisite Concomitant Medication Following 2 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)
PKF-7	Scatter Plot of Brexpiprazole Plasma Concentrations Following 1 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)
PKF-8	Scatter Plot of Brexpiprazole Plasma Concentrations Following 2 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)
PKF-9	Scatter Plot of Brexpiprazole Plasma Concentrations for Each CYP2D6 Phenotype Following 1 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)
PKF-10	Scatter Plot of Brexpiprazole Plasma Concentrations for Each CYP2D6 Phenotype Following 2 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)
PKF-11	Scatter Plot of Brexpiprazole Plasma Concentrations for Each Requisite Concomitant Medication Following 1 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)

PKF-12	Scatter Plot of Brexpiprazole Plasma Concentrations for Each Requisite Concomitant Medication Following 2 mg/day Doses of Brexpiprazole at Week 3 During Phase B (Pharmacokinetic Analysis Set)

Appendix 6 List of Subject Data Listings

AE-1.1	Adverse Events (Randomized Subjects)
AE-1.2	Adverse Events (Non-randomized Subjects)
DEMOG-1.1	Demographic Characteristics (Randomized Subjects)
DEMOG-1.2	Demographic Characteristics (Non-randomized Subjects)
DREAS-1.1	Discontinued Subjects and Reason for Discontinuation (Randomized Subjects)
DREAS-1.2	Discontinued Subjects and Reason for Discontinuation (Non-randomized Subjects)
LAB-1.1	Laboratory Test Results: Serum Chemistry (Randomized Subjects)
LAB-1.2	Laboratory Test Results: Serum Chemistry (Non-randomized Subjects)
LAB-2.1	Laboratory Test Results: Hematology (Randomized Subjects)
LAB-2.2	Laboratory Test Results: Hematology (Non-randomized Subjects)
LAB-3.1	Laboratory Test Results: Urinalysis (Randomized Subjects)
LAB-3.2	Laboratory Test Results: Urinalysis (Non-randomized Subjects)
LAB-4.1	Laboratory Test Results: Other Laboratory Tests (Randomized Subjects)
LAB-4.2	Laboratory Test Results: Other Laboratory Tests (Non-randomized Subjects)
LAB-5.1	Pregnancy Test (Randomized Subjects)
LAB-5.2	Pregnancy Test (Non-randomized Subjects)
EFF-1.1	Montgomery Asberg Depression Rating Scale (MADRS) (Randomized Subjects)
EFF-1.2	Montgomery Asberg Depression Rating Scale (MADRS) (Non-randomized Subjects)
EFF-2.1	Clinical Global Impression - Severity of Illness (CGI-S) (Randomized Subjects)
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