STATISTICAL ANALYSIS PLAN

A multicenter, randomized, double-blind, placebo-controlled, parallel-group comparison trial to evaluate the efficacy and safety of brexpiprazole (OPC-34712) in the treatment of patients with agitation associated with dementia of the Alzheimer's type

NCT Number: NCT03620981

Protocol No. 331-102-00088

Version Date: 01 Jun 2023 (Version 1.0)

Otsuka Pharmaceutical Co., Ltd.

Investigational New Drug Brexpiprazole (OPC-34712)

Protocol No. 331-102-00088

A multicenter, randomized, double-blind, placebo-controlled, parallel-group comparison trial to evaluate the efficacy and safety of brexpiprazole (OPC-34712) in the treatment of patients with agitation associated with dementia of the Alzheimer's type

Statistical Analysis Plan

Version: 1.0
Date: 01 Jun 2023
Protocol Version 6 Date: 24 Nov 2022

Confidential
May not be used, divulged, published, or otherwise disclosed without the prior written consent of Otsuka Pharmaceutical Co., Ltd

Table of Contents

Table	of Contents	2
List of	Appendices	5
List of	Contents 2 Appendices 5 Abbreviations and Definition of Terms 6 Introduction 8 Trial Objectives 8 Trial Design 8 Type/Design of Trial 8 Trial Treatments 9 Trial Population 10 Trial Visit Window 10 Handling of Endpoints 10 Cohen-Mansfield Agitation Inventory (CMAI) 10 Clinical Global Impression - Severity of Illness (CGI-S) 11 Clinical Global Impression - Improvement (CGI-I) 11 Drug Induced Extra-Pyramidal Symptoms Scale (DIEPSS) 11 Abnormal Involuntary Movement Scale (AIMS) 11 Sheehan Suicidality Tracking Scale (S-STS) 11 Alzheimer's Disease Cooperative Study - Activities of Daily Living (ADCS-ADL) 12 Mini-Mental State Examination (MMSE) 12 Sample Size 12 Statistical Analysis Datasets 13 Pharmacokinetic Analysis Set 13 Full Analysis Set 13 Safety Analysis Set 13	
1	Introduction	8
2	Trial Objectives	8
3	Trial Design	8
3.1	Type/Design of Trial	8
3.2	Trial Treatments	9
3.3	Trial Population	10
3.4	Trial Visit Window	10
3.5	Handling of Endpoints	10
3.5.1	Cohen-Mansfield Agitation Inventory (CMAI)	10
3.5.2	Clinical Global Impression - Severity of Illness (CGI-S)	.11
3.5.3	Clinical Global Impression - Improvement (CGI-I)	.11
3.5.4		
2.5.5		.11
3.5.5		
		.11
3.5.6	Drug Induced Extra-Pyramidal Symptoms Scale (DIEPSS)	11
3.5.7	Abnormal Involuntary Movement Scale (AIMS)	11
3.5.8	Sheehan Suicidality Tracking Scale (S-STS)	11
3.5.9		.12
3.5.10	Mini-Mental State Examination (MMSE)	.12
4	Sample Size	.12
5	Statistical Analysis Datasets	.13
5.1	Pharmacokinetic Analysis Set	.13
5.2	Full Analysis Set	.13
5.3	Safety Analysis Set	.13
5.4	Handling of Missing Data	.13
6	Primary and Secondary Outcome Variables	.13

6.1	Primary Endpoint	13
6.2	Secondary Endpoints	13
7	Disposition and Demographic Analysis	14
7.1	Subject Disposition	14
7.2	Demographic and Baseline Characteristics	14
7.3	Baseline Disease Evaluation	14
7.4	Treatment Compliance	14
7.5	Prior and Concomitant Medications	15
7.6	Protocol Deviations	15
8	Efficacy Analysis	15
8.1	Primary Efficacy Endpoint	15
8.1.1	Primary Efficacy Analysis	15
8.1.2	Sensitivity Analyses	16
8.1.2.1	Sensitivity Analysis for Handling of Missing Data	16
8.1.2.2	Sensitivity Analysis for Normality Assumption	17
8.1.3	Technical Computational Details for Primary Efficacy Analysis	17
8.2	Secondary Efficacy Analyses	18
8.3	Subgroup Analyses	18
8.4	Exploratory or Other Analyses	19
8.4.1	Exploratory Endpoint Analyses	19
8.4.2	Other Analyses	19
9	Safety Analyses	20
9.1	Extent of Exposure	20
9.2	Adverse Events	20
9.2.1	Adverse Events of Interest	21
9.2.2	Subgroup Analysis of Adverse Events	21
9.3	Clinical Laboratory Data	22
9.4	Vital Sign Data	23
9.5	Physical Examination Data	23
9.6	Electrocardiogram Data	23
9.7	Other Safety Data	24
9.7.1	Body Weight and Body Mass Index	24

Protocol 331-102-00088

9.7.2	DIEPSS, AIMS, and BARS	24
9.7.3	Sheehan Suicidality Tracking Scale	25
10	Pharmacokinetic Analyses	25
11	Pharmacodynamic Analyses	26
12	Pharmacogenomic Analyses	26
13	Analysis of Other Endpoints	26
14	Interim Analysis	26
15	Changes in the Planned Analyses	27
16	References	27

List of Appendices

Appendix 1	Criteria for Identifying Vital Signs and Weight of Potential Clinical Relevance	28
Appendix 2	Criteria for Identifying Laboratory Values of Potential Clinical Relevance	29
Appendix 3	Criteria for Identifying ECG Measurements of Potential Clinical Relevance	30
Appendix 4	Adverse Events of Interest	31
Appendix 5	List of Summary Tables	102
Appendix 6	List of Subject Data Listings	110

List of Abbreviations and Definition of Terms

Abbreviation	<u>Definition</u>
ADCS-ADL	Alzheimer's Disease Cooperative Study - Activities of Daily Living
AIMS	Abnormal Involuntary Movement Scale
ALT	Alanine aminotransferase
ANCOVA	Analysis of covariance
AST	Aspartate aminotransferase
BARS	Barnes Akathisia Rating Scale
BMI	Body mass index
BUN	Blood urea nitrogen
CGI-I	Clinical Global Impression - Global Improvement
CGI-S	Clinical Global Impression - Severity of Illness
CMAI	Cohen-Mansfield Agitation Inventory
CMH	Cochran Mantel Haenszel
CPK	Creatine phosphokinase
CYP	Cytochrome P450
DIEPSS	Drug Induced Extra-Pyramidal Symptoms Scale
EQ-5D-5L	EuroQol 5 dimension 5 level health questionnaire
FAS	Full analysis set
FCS	Fully Conditional Specification
HDL	High-density lipoprotein
IDMC	Independent data monitoring committee
IMP	Investigational medicinal product
LDH	Lactate (lactic acid) dehydrogenase
LDL	Low-density lipoprotein
LOCF	Last observation carried forward
MAR	Missing At Random
MedDRA	Medical Dictionary for Regulatory Activities
MMRM	Mixed models for repeated measures
MMSE	Mini-Mental State Examination
MNAR	Missing Not At Random
OC	Observed cases
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

Protocol 331-102-00088

S-STS	Sheehan Suicidality Tracking Scale
TEAE	Treatment-emergent adverse event
TITAL	TT 11 1. 0 1

ULN Upper limits of normal

1 Introduction

This statistical analysis plan documents in detail the statistical analysis methods planned for the clinical study report of Trial 331-102-00088.

2 Trial Objectives

The objective of the trial is to evaluate the superiority of brexpiprazole 1 or 2 mg over placebo after a 10-week treatment regimen for agitation associated with dementia of the Alzheimer's type in patients who require medication, to investigate the safety of brexpiprazole, and to identify the optimum dose.

3 Trial Design

3.1 Type/Design of Trial

This is a multicenter, randomized, double-blind, placebo-controlled, parallel-group comparison trial to evaluate the efficacy and safety of brexpiprazole in patients with agitation associated with dementia of the Alzheimer's type who require medication. The overview of the trial design is shown in Figure 3.1-1.

The trial consists of a screening period, a treatment period, and a follow-up period. The investigator or subinvestigator will explain the details of the trial to a prospective subject (if the investigator or subinvestigator judges that the subject is incapable of providing informed consent or if the subject is hospitalized for reasons related to medical protection, the subject's legally acceptable representative must provide written consent, and even when written consent is obtained from the legally acceptable representative, the subject should be given an explanation appropriate to his or her level of understanding and, if possible, should also provide written consent) and their caregivers using the explanatory materials and informed consent form (ICF) and obtain written consent for participation in the trial from the patient (or their legally acceptable representatives) and caregivers. The subject's clinical course will be followed in the same environment (see Section 3.4.2 Inclusion Criteria, 4 of the protocol) such as hospitalization in the same medical facility, institutionalization in the same care facility, and continued care at home from at least 3 weeks before baseline evaluation up to the completion of the examinations scheduled at the completion or discontinuation of investigational medicinal product (IMP) administration. After obtaining consent from the patient (or their legally acceptable representatives) and caregiver, the investigator or subinvestigator will perform the specified observations, tests, and investigations to confirm the subject's eligibility before IMP allocation. Subjects who are judged to be eligible in the screening examination and baseline evaluation will be randomized to the brexpiprazole 1 mg, brexpiprazole 2 mg, or

placebo group. The IMP allocation will be performed using a dynamic allocation method to minimize bias in background factors (medical care category, prior use of antipsychotics, Cohen-Mansfield Agitation Inventory (CMAI) total score in baseline assessment) among the treatment groups. Duration of IMP treatment is 10 weeks. The subject will receive brexpiprazole or placebo for 10 weeks according to Section 3.2 Trial Treatment, and undergo periodic observations, tests, and investigations to assess efficacy and safety. The subject will return to the trial site 28 days after the completion of IMP administration for follow-up observation. Discontinued subjects will also undergo follow-up observation.

For subjects who discontinued the trial during the treatment period, the examination at discontinuation will be performed.

The trial period of each subject is from the date of informed consent to the end date of follow-up observation. If subjects have transitioned to the extension trial and commenced IMP administration, follow-up observation will not be performed. In such a case, the trial period is until the end date of evaluation at Week 10 (Day 71).

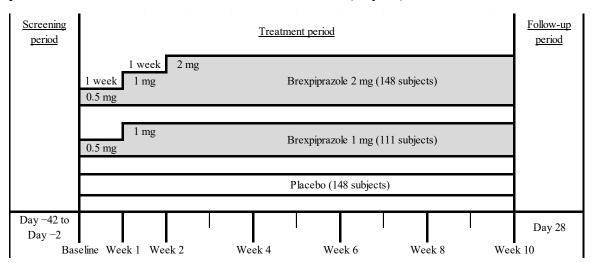


Figure 3.1-1 Trial Design

Follow-up observation will not be performed for subjects who have transitioned to the extension trial and commenced IMP administration.

3.2 Trial Treatments

The IMP will be administered orally as one tablet once a day for 10 weeks. The doses of brexpiprazole for each group are shown in Table 3.2-1. Although the temporal relationship between IMP administration and meals will not be considered, subjects should take the IMP at the specified time in so far as possible. Dose reduction is not

allowed during the trial, and if there are tolerability issues, administration of the IMP will be discontinued.

Table 3.2-1 Doses of IMPs			
Group	Day 1-7	Day 8-14	Day 15-70
Brexpiprazole 2 mg	0.5 mg	1 mg	2 mg
Brexpiprazole 1 mg	0.5 mg	1 mg	1 mg
Placebo	0 mg	0 mg	0 mg

The dose will be increased to 1 mg after evaluation at Week 1 (Day 8) and to 2 mg after evaluation at Week 2 (Day 15).

3.3 Trial Population

A total of 407 male and female patients (brexpiprazole 2 mg, 148 subjects; brexpiprazole 1 mg, 111 subjects; placebo 148 subjects) with agitation associated with dementia of the Alzheimer's type who require medication will be enrolled in the trial.

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 are shown in Table 3.4-1. Day 1 is defined as the day when treatment with the IMP begins. 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 will be excluded from the analysis.

Table 3.4-1 Acceptable Windows for Analysis		
Week	Target Day	Trial Day Interval
Baseline	1	- 1
Week 1	8	2 - 11
Week 2	15	12 - 22
Week 4	29	23 - 36
Week 6	43	37 - 50
Week 8	57	51 - 64
Week 10	71	65 - 78

3.5 Handling of Endpoints

3.5.1 Cohen-Mansfield Agitation Inventory (CMAI)

The CMAI total score will be the sum of scores for 29 CMAI items.

The CMAI Aggressive Behavior score will be the sum of scores for CMAI Items 3, 4, 7, 8, 9, 10, 11, 13, 14, 15, 21, and 25.

The CMAI Physically Non-aggressive Behavior score will be the sum of scores for CMAI Items 1, 2, 16, 22, 26, and 29.

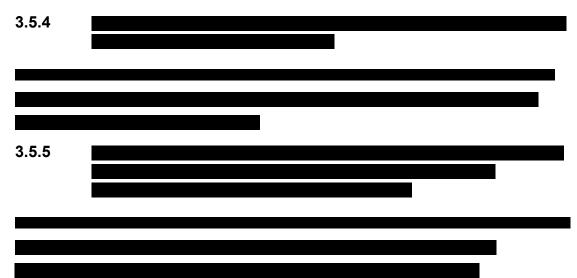
The CMAI Verbally Agitated Behavior score will be the sum of scores for CMAI Items 5, 6, 18, and 19.

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

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

3.5.3 Clinical Global Impression - Improvement (CGI-I)

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



3.5.6 Drug Induced Extra-Pyramidal Symptoms Scale (DIEPSS)

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

3.5.7 Abnormal Involuntary Movement Scale (AIMS)

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

3.5.8 Sheehan Suicidality Tracking Scale (S-STS)

The S-STS total score will be the sum of scores for Item 1a, Items 2 through 11, highest of Item 12 or any row of Item 16, highest of Item 14 or any row of Item 15, Item 17, and Item 20.

The S-STS suicidal ideation subscale score will be the sum of scores for Items 2 through 11.

The S-STS suicidal behavior subscale score will be the sum of scores for Item 1a, highest of Item 12 or any row of Item 16, highest of Item 14 or any row of Item 15, Item 17, and Item 20.

3.5.9 Alzheimer's Disease Cooperative Study - Activities of Daily Living (ADCS-ADL)

The ADCS-ADL total score will be the sum of scores for ADCS-ADL Items 1 through 19.

3.5.10 Mini-Mental State Examination (MMSE)

The MMSE total score will be the sum of scores for MMSE Items 1 through 30.

4 Sample Size

In Trial 331-12-283, which was performed outside Japan, the 2 mg fixed-dose group showed superiority over the placebo group in patients with aggression (patients with aggressive behavior at baseline), thus suggesting that it may also be the optimum dose for Japanese patients. Efficacy was not observed in the 1 mg fixed-dose group, but in Trial 331-12-284, the efficacy of a dose less than 2 mg was suggested by the results obtained in patients from the flexible-dose (0.5 to 2 mg) group, who had aggression.

In this trial, a power of detection $\geq 80\%$ will be achieved for comparison between the placebo group and the 1 mg group to allow evaluation of superiority over the placebo group if equivalent efficacy is demonstrated in the 1 and 2 mg groups. For comparison between the 2 mg group (possible optimum dose) and the placebo group, a more sufficient power of detection will be obtained by changing the randomization ratio. In this trial, it is assumed that the difference between the 2 mg group and the placebo group in the change in the CMAI total score from baseline to Week 10 is -5.35, and the standard deviation (calculated from the standard error of the difference between the 2 mg and placebo groups and the number of subjects at baseline) is 15.06 on the basis of the results of Trial 331-12-283. By setting the number of subjects in the 2 mg group, 1 mg group, and placebo group as 148, 111, and 148, respectively (randomization ratio of 4:3:4), the power of detection is 86.1% for the comparison between the 2 mg group and the placebo group and is 80.5% for the comparison between the 1 mg group and the placebo group in a test with a significance level of 5% (two sided).

On the basis of the above considerations, the number of subjects will be set at 148 in the 2 mg group, 111 in the 1 mg group, and 148 in the placebo group (randomization ratio of 4:3:4).

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 drug concentration data have been obtained, other than those deemed as "not analyzed" or "not determined."

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, and from whom CMAI 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.

5.4 Handling of Missing Data

The primary analysis of the primary endpoint will be performed in the observed cases (OC) dataset by mixed models for repeated measures (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 analyses of efficacy, safety, and other endpoints, 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) 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 Endpoint

The primary endpoint is change in CMAI total score from baseline to Week 10.

6.2 Secondary Endpoints

- Changes in CMAI subscales (Aggressive Behavior, Physically Non-aggressive Behavior, and Verbally Agitated Behavior) from baseline to Week 10
- Change in Clinical Global Impression—Severity of Illness (CGI-S) from baseline to Week 10

• Clinical Global Impression—Global Improvement (CGI-I) at Week 10

7 Disposition and Demographic Analysis

7.1 Subject Disposition

Numbers and proportions of subjects from whom informed consent was obtained, those who were randomized, those who received trial treatment, those who completed the trial, those who discontinued the trial, those who discontinued the trial by reason for discontinuation, and those included in each analysis set will be summarized overall, for each treatment group, and for the overall brexpiprazole group.

7.2 Demographic and Baseline Characteristics

Descriptive statistics (mean, standard deviation, minimum, median, and maximum; hereinafter the same applies) of age, height, baseline body weight, and baseline body mass index (BMI), and frequency distribution of age category ($< 80, \ge 80$) ($< 65, \ge 65$ to $< 75, \ge 75$), sex, race, ethnicity, country where trial is conducted, complications, medical history, and CYP2D6 phenotype will be determined in each analysis set, overall, for each treatment group, and for the overall brexpiprazole group.

7.3 Baseline Disease Evaluation

Descriptive statistics of the duration of dementia of the Alzheimer's type, duration of agitation associated with dementia of the Alzheimer's type, baseline CGI-S, CMAI (total score, subscale scores), MMSE total score, and ADCS-ADL total score, and frequency distribution of medical care category, type of caregiver, prior use of antipsychotics, prior medication other than antipsychotics (for agitation associated with dementia of the Alzheimer's type), and concomitant use of antidementia drugs (yes or no) will be determined overall, for each treatment group, and for the overall brexpiprazole group.

The duration of dementia of the Alzheimer's type and the duration of agitation associated with dementia of the Alzheimer's type 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) will be grouped into < 70%, $\ge 70\%$ to < 80%, $\ge 80\%$ to < 90%, and $\ge 90\%$, 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 (antipsychotics, antidementia drugs, other) before, during, and after the treatment period 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.

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, 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.

8 Efficacy Analysis

Efficacy analyses will be performed on the FAS. Baseline is defined as the last data obtained prior to initiation of IMP treatment.

8.1 Primary Efficacy Endpoint

8.1.1 Primary Efficacy Analysis

The primary analysis will be performed by MMRM using the OC dataset in the FAS. The model will include treatment group (brexpiprazole 1 mg group, brexpiprazole 2 mg group, or placebo group), time point (Week 2, 4, 6, 8, or 10), medical care category (inpatient or outpatient), prior use of antipsychotics (yes or no), 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.

Between-group comparison will be performed by calculating the difference of the least squares mean between each of the brexpiprazole groups and the placebo group at Week 10. The fixed sequence procedure will be used to adjust the multiplicity of testing due to the performance of two comparisons (ie, the brexpiprazole 1 mg group versus the placebo group and the brexpiprazole 2 mg group versus the placebo group) to control the

overall type I error rate. Initially, the brexpiprazole 2 mg group will be compared with the placebo group. Only if the difference is statistically significant at a significance level of 5% (two sided), the brexpiprazole 1 mg group will be compared with the placebo group at a significance level of 5% (two sided).

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.

If any problems in convergence status arise in the estimation of variance components of MMRM, 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.

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 Fully Conditional Specification (FCS) method will be used to impute missing data. The imputation model for each period will include the medical care category (inpatient or outpatient) and prior use of antipsychotics (yes or no), as well as the CMAI total score for the preceding periods.
- 2) The same MMRM as that of the primary efficacy analysis will be used to analyze the multiple-imputed datasets.
- 3) 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 10 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 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 adverse events (AEs), a lack of efficacy, or consent withdrawal (by subject, legally acceptable representative, or caregiver)
- 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 missing data, add Δ (intergroup differences in MMRM of the primary efficacy analysis) \times k% to the imputed value after withdrawal, and increase k (with 200 as the upper limit) 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 Van Elteren test with medical care category (inpatient or outpatient) and prior use of antipsychotics (yes or no) as strata 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, medical care category (inpatient or outpatient), and prior use of antipsychotics (yes or no) as factors 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 hoterm beformed;
```

model change=treatment visit baseline treatment*visit baseline*visit hoterm beformed / ddfm=kr;

repeated visit /type=un subject=subjid;

lsmeans treament*visit / diff cl;

ods output diffs=diffs lsmeans=lsmeans;

run;

*hoterm: medical care category

*beformed: prior use of antipsychotics

8.2 Secondary Efficacy Analyses

- Changes in CMAI subscales (Aggressive Behavior, Physically Non-aggressive Behavior, and Verbally Agitated Behavior) from baseline at Week 10
- Change in CGI-S related to agitation from baseline to Week 10
 The same MMRM analysis as that for the primary endpoint will be performed using the OC dataset.

• CGI-I at Week 10

Each brexpiprazole group will be compared with the placebo group by the Cochran Mantel Haenszel (CMH) Row Mean Scores test with medical care category (inpatient or outpatient) and prior use of antipsychotics (yes or no) as strata using the LOCF dataset. Mean values in each treatment group, differences in mean values between each brexpiprazole group and the placebo group based on CMH Row Mean Scores test, and their two-sided 95% CIs will be calculated. The same analysis will be performed on the OC dataset.

8.3 Subgroup Analyses

The same MMRM analysis as that for the primary endpoint will be performed on the change in CMAI total score from baseline for each of the subgroup categories within each of the following items using the OC dataset (in the subgroup analyses of medical care category and prior use of antipsychotics, those particular factors will be excluded from the respective analysis models). For CYP2D6 phenotype, all subjects in the placebo group will be included in each subgroup.

- Medical care category (inpatient, outpatient)
- Prior use of antipsychotics (yes or no)
- Type of caregiver (hospital staff, care facility staff, family)
- Sex (male, female)
- Age $(< 80, \ge 80)$ $(< 65, \ge 65 \text{ to } < 75, \ge 75)$
- CMAI total score at baseline (≤ median or > median)
- Body weight (\leq median, > median)
- BMI (\leq median, > median)
- CYP2D6 phenotype (IM, EM)

- Impact of COVID-19 pandemic (subjects who completed/discontinued the trial before 07 Apr 2020, subjects who completed/discontinued the trial on or after 07 Apr 2020)
- Concomitant use of antidementia drugs (yes or no)

8.4 Exploratory or Other Analyses

8.4.1 Exploratory Endpoint Analyses

•	
•	
•	
•	
•	
•	
•	
•	
•	
•	
•	
•	
•	
•	
•	

8.4.2 Other Analyses

The CMAI total score, CMAI subscales (Aggressive Behavior, Physically Nonaggressive Behavior, and Verbally Agitated Behavior), CGI-S, CGI-I,

at

each time point will be analyzed in the same manner as for the primary and secondary efficacy endpoints and the exploratory endpoints. Descriptive statistics or frequency distribution of actual measurements and changes from baseline at each time point will be calculated by treatment group.

9 Safety Analyses

Safety analysis will be performed using the safety analysis set. Baseline is defined as the last data obtained prior to initiation of IMP treatment.

9.1 Extent of Exposure

Descriptive statistics and frequency distribution (1-7, 8-14, 15-21, 22-28, 29-35, 36-42, 43-49, 50-56, 57-63, 64-70, > 70 and ≥ 7 , ≥ 14 , ≥ 28 , ≥ 42 , ≥ 56 , ≥ 70) of the duration (days) of treatment with the IMP will be determined for each treatment group and for the overall brexpiprazole group.

9.2 Adverse Events

Adverse events will be coded using Medical Dictionary for Regulatory Activities (MedDRA) (Ver. 25.0). The incidences of the following events will be summarized according to System Organ Class (SOC) and Preferred Term (PT) for each 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 (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 $\geq 2\%$ of subjects in any brexpiprazole group and more frequently than in the placebo group
- TEAEs by days of initial onset (1-7, 8-14, 15-21, 22-28, 29-35, 36-42, 43-49, 50-56, 57-63, 64-70, > 70, 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 AE 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 for each treatment group and for the overall brexpiprazole group.

- Extrapyramidal AEs
- Accident- and injury-related AEs
- Cerebrovascular AEs
- Cardiovascular AEs
- Glucose metabolism-related AEs
- Lipid metabolism-related AEs
- Body weight-related AEs
- Blood disorder-related AEs
- Hypersensitive symptom-related AEs
- Neuroleptic malignant syndrome-related AEs
- Orthostatic disorder-related AEs
- Prolactin increase-related AEs
- QT interval prolongation-related AEs
- Rhabdomyolysis
- Seizure-related AEs
- Oversedation-related AEs
- Suicide/suicide attempt-related AEs
- Venous thrombosis
- Pneumonia-related AEs

9.2.2 Subgroup Analysis of Adverse Events

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

- Medical care category (inpatient, outpatient)
- Prior use of antipsychotics (yes or no)
- Type of caregiver (hospital staff, care facility staff, family, or other)
- Sex (male, female)
- Age $(< 80, \ge 80)$ $(< 65, \ge 65 \text{ to } < 75, \ge 75)$
- Body weight (\leq median, > median)
- BMI (\leq median, > median)

- CYP2D6 phenotype (IM, EM, PM, Unknown)
- Impact of COVID-19 pandemic (subjects who completed/discontinued the trial before 07 Apr 2020, subjects who completed/discontinued the trial on or after 07 Apr 2020)
- Concomitant use of antidementia drugs (yes or no)

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 × the upper limit of normal [ULN] and TBL \geq 2 × 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 C	hanges in Glucose and Lipi	d Metabolism-related
Parameters		
LAB PARAMETER	BASELINE	ANYTIME POST BASELINE
Cholesterol, Fasting	Normal <200	High >=240
(mg/dL)	Borderline 200-<240	High >=240
	Normal/Borderline <240	High >=240
	Normal <200	Borderline/High >=200
	Any Value	Increased >=40
LDL Cholesterol, Fasting	Normal <100	High >=160
(mg/dL)	Borderline 100-<160	High >=160
	Normal/Borderline < 160	High >=160
	Normal <100	Borderline/High >=100
	Any Value	Increased >=30
HDL Cholesterol, Fasting	Normal >=40	Low <40
(mg/dL)	Any Value	Decreased >=20
Triglycerides, Fasting	Normal <150	High 200-<500
(mg/dL)	Normal <150	Very High >=500
	Borderline 150-<200	High 200-<500
	Normal/Borderline < 200	High 200-<500
	Normal/Borderline < 200	Very High >=500
	Normal <150	Borderline/High/Very High >=150
	Normal/Borderline/high <500	Very High >=500
	Any Value	Increased >=50
Glucose Fasting, Serum	Normal <100	High >=126
(mg/dL)	Impaired 100-<126	High >=126
	Normal/Impaired <126	High >=126
	Any Value	Increased >=10

9.4 Vital Sign Data

For each vital sign parameter (in the sitting position), 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.

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 = QT interval/[RR interval]^{0.37}) not meeting the criteria of > 450 msec, > 480 msec, and > 500 msec at baseline and meeting the criteria after treatment and numbers and proportions of subjects with changes from baseline of > 30 msec and > 60 msec 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.

9.7 Other Safety Data

9.7.1 Body Weight and Body Mass Index

For body weight and BMI, 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 analysis of covariance (ANCOVA) model with treatment group, medical care category (inpatient or outpatient), and prior use of antipsychotics (yes or no) as factors 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 ($< 18.5, \ge 18.5$ to $< 25, \ge 25$ to $< 30, \ge 30$) 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.

9.7.2 DIEPSS, AIMS, and 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 3

global judgment items (items 8 through 10), and BARS, descriptive statistics of actual measurements and changes from baseline at each time point, at the last assessment time point, and for the worst postdose measurement, 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, medical care category (hospitalized or outpatient), and prior use of antipsychotics (yes or no) as factors 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.

9.7.3 Sheehan Suicidality Tracking Scale

For the score for each S-STS item (2 through 14), total score, suicidal ideation subscale score, and suicidal behavior subscale score, 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, medical care category (hospitalized or outpatient), and prior use of antipsychotics (yes or no) as factors 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.

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 hours 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 in the same manner.

The mean plasma brexpiprazole concentration over time will be plotted by treatment group. Plotted diagrams by CYP2D6 phenotype in each treatment group will also be provided in the same manner.

Scatter plots of plasma brexpiprazole concentrations will be provided by treatment group. Scatter plots by CYP2D6 phenotype 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. CYP2D6 phenotype will also be summarized in subgroup efficacy and safety analyses.

13 Analysis of Other Endpoints

Analysis of other endpoints will be performed using the safety analysis set. Baseline is defined as the last data obtained prior to initiation of IMP treatment.

- ADCS-ADL
- MMSE
- EQ-5D-5L

For ADCS-ADL total score, MMSE total score and each item of EQ-5D-5L (subject evaluation [proxy version] and caregiver evaluation), 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, medical care category (hospitalized or outpatient), and prior use of antipsychotics (yes or no) as factors 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.

14 Interim Analysis

Safety will be evaluated by the IDMC when approximately 25%, 50%, and 75% of the target number of subjects have completed or discontinued the trial.

A statistical analysis plan for interim analysis is described in a separate interim analysis plan.

15 Changes in the Planned Analyses



- In the subgroup efficacy analysis, "other" was excluded from the type of caregiver. The CMAI total score category at baseline was changed from "< 56 or ≥ 56 " to "< median or > median."
- The following changes were made to categorical analyses of QTc:
 Only subjects with postdose QTc meeting the criteria were summarized, instead of summarization at all time points.
 - Only subjects with QTc not meeting the criteria at baseline and meeting the criteria after baseline were summarized.
- It was decided that CYP2D6 phenotype would be tabulated as specified in Section 7.2. CYP2D6 phenotype were also summarized in subgroup efficacy and safety analyses.
- The original plan of using the LOCF dataset in ANCOVA of safety endpoints and other endpoints was changed as follows: Measurements at each time point and at the last assessment time point and, as necessary, the worst postdose measurement were 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 were calculated by treatment group and by CYP2D6 phenotype in each treatment group. Additionally, the mean plasma brexpiprazole concentration over time and scatter plots of plasma brexpiprazole concentrations were provided by treatment group and by CYP2D6 phenotype in each treatment group.

16 References

C.S. Davis, Y. Chung. Randomization model methods for evaluating treatment efficacy in multicenter clinical trials. Biometrics. 1995; 51(3): 1163-1174.

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	≥ 15 bpm increase
Pulse Rate	< 50 bpm	≥ 15 bpm decrease
Systolic Blood Pressure	> 180 mmHg	≥ 20 mmHg increase
Systolic Blood Flessure	< 90 mmHg	≥ 20 mmHg decrease
Diastolic Blood Pressure	> 105 mmHg	≥ 15 mmHg increase
Diastolic Blood Pressure	< 50 mmHg	≥ 15 mmHg decrease
Waight		≥ 7% increase
Weight	-	≥ 7% decrease

^aIn 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)	$\geq 2.0 \text{ mg/dL}$
СРК	≥3 x ULN
Endocrinology	
Prolactin	> ULN
Hematology	
Hematocrit	
Men	\leq 37 % and decrease of \geq 3 percentage points from Baseline
Women	\leq 32 % and decrease of \geq 3 percentage points from Baseline
Hemoglobin	
Men	≤ 11.5 g/dL
Women	≤ 9.5 g/dL
White blood count	$\leq 2,800/ \text{ mm}^3 \text{ or } \geq 16,000/ \text{ mm}^3$
Eosinophils	≥ 10%
Neutrophils	≤ 15%
Absolute neutrophil count ≤ 1,000/ mm ³	
Platelet count	\leq 75,000/ mm ³ or \geq 700,000/ mm ³
Urinalysis	
Protein	Increase of ≥ 2 units
Glucose	Increase of ≥ 2 units
Additional Criteria	
Chloride	\leq 90 mEq/L or \geq 118 mEq/L
Potassium	\leq 2.5 mEq/L or \geq 6.5 mEq/L
Sodium	$\leq 126 \text{ mEq/L or} \geq 156 \text{ mEq/L}$
Calcium	$\leq 8.2 \text{ mg/dL or} \geq 12 \text{ mg/dL}$
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	$\geq 150 \text{ mg/dL}$

Appendix 3 Criteria for Identifying ECG Measurements of Potential Clinical Relevance

Variable	Criterion Value ^a	Change Relative to Baseline ^a
Heart Rate	≥ 120 bpm	increase of ≥ 15 bpm
	≤ 50 bpm	decrease of ≥ 15 bpm
PR	≥ 200 msec	increase of ≥ 50 msec
QRS	≥ 120 msec	increase of ≥ 20 msec
QTcF	> 450 msec	
	(males)	
	> 470 msec	
	(females)	

^aIn 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

Category

ACCIDENTS AND INJURIES INCLUDING FALL

Preferred Term

Abdomen crushing

Abdominal injury

Abdominal wall wound

Accident

Accident at home

Accident at work

Accidental death

Acetabulum fracture

Acoustic shock

Acquired asplenia

Acquired cerebral palsy

Acquired encephalocele

Acrotrophodynia

Adrenal gland injury

Anal injury

Animal attack

Animal bite

Ankle fracture

Anterior capsular rupture

Anterior cord syndrome

Anterior labroligamentous periosteal sleeve avulsion lesion

Aortic annulus rupture

Aortic injury

Aortic rupture

Aponeurosis contusion

Application site wound

Arterial injury

Arterial rupture

Atrial rupture

Atypical femur fracture

Atypical fracture

Avulsion fracture

Axillary nerve injury

Back injury

Bankart lesion

Battle's sign

Bile duct stenosis traumatic

Bladder injury

Bladder perforation

Blast injury

Blindness traumatic

Bone contusion

Bone fissure

Bone fragmentation

Bowman's membrane injury

Brachial plexus injury

Brain contusion

Breast injury

Burn oral cavity

Burns first degree

Burns fourth degree

Burns second degree

Burns third degree

Bursa injury

Buttock injury

Cardiac contusion

Cartilage injury

Cataract traumatic

Central cord syndrome

Central nervous system injury

Cervical vertebral fracture

Cervix injury

Chance fracture

Chemical burn

Chemical burn of genitalia

Chemical burn of oral cavity

Chemical burn of respiratory tract

Chemical burn of skin

Chemical burns of eye

Chest crushing

Chest injury

Chillblains

Clavicle fracture

Closed globe injury

Cochlear injury

Cold burn

Cold exposure injury

Cold shock response

Colon injury

Comminuted fracture

Commotio retinae

Complicated fracture

Compression fracture

Concussion

Conjunctival abrasion

Conjunctival laceration

Contusion

Corneal abrasion

Corneal laceration

Corneal perforation

Costal cartilage fracture

Costochondral separation

Cranial nerve injury

Craniocerebral injury

Craniocervical dislocation

Craniofacial fracture

Craniofacial injury

Crush injury

Crush syndrome

Crushing injury of trunk

Cuboid syndrome

Deafness traumatic

Decapitation

Deep dissecting haematoma

Depressed fracture

Diaphragmatic injury

Diaphragmatic rupture

Diffuse axonal injury

Dislocation of sternum

Dislocation of vertebra

Drowning

Duodenal rupture

Dural tear

Ear canal abrasion

Ear canal injury

Ear canal stenosis traumatic

Version: 1.0 Date: 01/06/2023

Ear injury

Electric injury

Electric shock

Electrocution

Enophthalmos traumatic

Epidural haemorrhage

Epiphyseal fracture

Epiphyseal injury

Epiphysiolysis

External genitalia crushing

Extradural haematoma

Extrahepatic biliary tree injury

Eye abrasion

Eye contusion

Eye injury

Eye luxation

Eyeball avulsion

Eyelash injury

Eyelid contusion

Eyelid haematoma

Eyelid injury

Face crushing

Face injury

Facial bones fracture

Facial nerve injury due to birth trauma

Fall

Femoral neck fracture

Femoral nerve injury

Femur fracture

Fibula fracture

First degree chemical burn of skin

Flail chest

Foot fracture

Forearm fracture

Foreign body aspiration

Foreign body in eye

Foreign body in gastrointestinal tract

Foreign body in mouth

Foreign body in reproductive tract

Foreign body in respiratory tract

Foreign body in skin or subcutaneous tissue

Foreign body in throat

Foreign body in urogenital tract

Foreign body ingestion

Fourth degree chemical burn of skin

Fracture

Fracture displacement

Fracture of clavicle due to birth trauma

Fracture of penis

Fracture pain

Fractured coccyx

Fractured sacrum

Fractured skull depressed

Frostbite

Gallbladder injury

Gallbladder rupture

Gastrointestinal injury

Gastrointestinal organ contusion

Version: 1.0 Date: 01/06/2023

Genital contusion

Genital injury

Gingival injury

Glaucoma traumatic

Greenstick fracture

Gun shot wound

Haematuria traumatic

Haemothorax

Hand fracture

Hanging

Head crushing injury

Head injury

Heat cramps

Heat exhaustion

Heat stroke

Hepatic rupture

Hernia perforation

High-energy trauma

Hip fracture

Human bite

Humerus fracture

Hyperthermia

Hyphaema

Hypothermia

IIIrd nerve injury

IVth nerve injury

Ilium fracture

Impacted fracture

Implant site injury

Inguinal hernia perforation

Injury

Injury corneal

Injury of conjunctiva

Injury to brachial plexus due to birth trauma

Internal injury

Intervertebral disc injury

Intra-abdominal organ avulsion

Intra-abdominal vascular injury

Iris injury

Iris tear

Jaw fracture

Joint dislocation

Joint hyperextension

Joint injury

Keratorhexis

Keraunoparalysis

Kidney contusion

Kidney rupture

Laryngeal injury

Lens dislocation

Lenticular injury

Ligament injury

Ligament rupture

Ligament sprain

Limb crushing injury Limb fracture

Limb injury

Limb reattachment surgery

Limb traumatic amputation

Lip injury

Lisfranc fracture

Liver contusion

Liver injury

Loose body removal

Lower limb fracture

Lumbar vertebral fracture

Lumbosacral plexus injury

Lung perforation

Lymphatic duct injury

Macular detachment

Maisonneuve fracture

Median nerve injury

Meniscus cyst

Meniscus injury

Metallosis of globe

Metaphyseal corner fracture

Mouth injury

Multiple fractures

Multiple injuries

Muscle contusion

Muscle injury

Muscle reattachment

Muscle rupture

Muscle strain

Musculocutaneous nerve injury

Musculoskeletal foreign body

Musculoskeletal injury

Myocardial rupture

Nail avulsion

Nail injury

Nasal injury

Near drowning

Neck crushing

Neck injury

Nerve compression

Nerve injury

Nerve root injury

Nerve root injury cervical

Nerve root injury lumbar

Nerve root injury sacral

Nerve root injury thoracic

Oesophageal injury

Oesophageal rupture

Open fracture

Open globe injury

Optic nerve injury

Optic pathway injury

Oral contusion

Orbital compartment syndrome

Osteo-meningeal breaches

Osteochondral fracture

Osteophyte fracture

Ovarian injury

Palate injury

Pancreatic contusion

Pancreatic duct rupture

Pancreatic injury

Paranasal sinus injury

Parasympathetic nerve injury

Patella fracture

Pellegrini Stieda disease

Pelvic bone injury

Pelvic fracture

Pelvic organ injury

Penetrating abdominal trauma

Version: 1.0 Date: 01/06/2023

Penetrating eye injury repair

Penile contusion

Penis injury

Penis reattachment

Perforation bile duct

Perineal injury

Peripheral nerve injury

Peritoneal perforation

Pernio-like erythema

Peroneal nerve injury

Pharyngeal contusion

Pharyngeal injury

Photoelectric conjunctivitis

Phrenic nerve injury

Pleural injury

Pneumothorax traumatic

Post concussion syndrome

Post-traumatic headache

Post-traumatic neck syndrome

Post-traumatic osteoporosis

Post-traumatic pain

Posterior capsule rupture

Posterior tibial nerve injury

Prevertebral soft tissue swelling of cervical space

Product package associated injury

Pulmonary contusion

Puncture site injury

Radial head dislocation

Radial nerve injury

Radius fracture

Rectal injury

Renal injury

Repair of diaphragm injury

Retinal detachment

Retinal injury

Retinal tear

Rhegmatogenous retinal detachment

Rib fracture

Road traffic accident

Sacroiliac fracture

Scapula fracture

Scapulothoracic dissociation

Sciatic nerve injury

Scratch

Scrotal injury

Second degree chemical burn of skin

Second impact syndrome

Serous retinal detachment

Shrapnel wound

Sinus tarsi syndrome

Skeletal injury

Skin abrasion

Skin injury

Skin laceration

Skin pressure mark

Skull fracture

Skull fracture treatment

Skull fractured base

Snake bite

Soft tissue foreign body

Soft tissue injury

Spinal column injury

Spinal compression fracture

Spinal cord injury

Spinal cord injury cauda equina

Spinal cord injury cervical

Spinal cord injury lumbar

Spinal cord injury sacral

Spinal cord injury thoracic

Spinal epidural haematoma

Spinal epidural haemorrhage

Spinal fracture

Spinal fracture treatment

Spinal fusion fracture

Spinal shock

Spinal subarachnoid haemorrhage

Spinal subdural haematoma

Spleen contusion

Splenic injury

Splenic rupture

Splenosis

Splinter

Spondylopathy traumatic

Sports injury

Stab wound

Stapes fracture

Sternal fracture

Sternal injury

Stress fracture

Struck by lightning

Subcapsular hepatic haematoma

Subchondral insufficiency fracture

Subdural haematoma

Subdural haematoma evacuation

Subdural haemorrhage

Subendocardial haemorrhage

Subretinal fluid

Sunburn

Superficial injury of eye

Sympathetic nerve injury

Synovial rupture

Tendon dislocation

Tendon injury

Tendon rupture

Testicular injury

Testicular rupture

Thermal burn

Thermal burns of eye

Third degree chemical burn of skin

Thoracic vertebral fracture

Thyroid gland injury

Tibia fracture

Tissue injury

Tissue rupture

Tongue injury

Tooth avulsion

Tooth dislocation

Tooth fracture

Tooth injury

Torus fracture

Tracheal injury

Tractional retinal detachment

Version: 1.0 Date: 01/06/2023

Traumatic amputation

Traumatic anuria

Traumatic arthritis

Traumatic arthropathy

Traumatic arthrosis

Traumatic coma

Traumatic ear amputation

Traumatic fracture

Traumatic haematoma

Traumatic haemorrhage

Traumatic haemothorax

Traumatic heart injury

Traumatic intracranial haematoma

Traumatic intracranial haemorrhage

Traumatic iritis

Traumatic liver injury

Traumatic lung injury

Traumatic pancreatitis

Traumatic renal injury

Traumatic shock

Traumatic spinal cord compression

Traumatic torticollis

Traumatic ulcer

Traumatic ulcerative granuloma with stromal eosinophilia

Trench foot

Trunk injury

Tympanic membrane perforation

Ulna fracture

Ulnar nerve injury

Upper limb fracture

Ureteric injury

Ureteric perforation

Ureteric rupture

Urethral injury

Urethral perforation

Urethral stricture traumatic

Urinary bladder explosion

Urinary bladder haematoma

Urinary bladder rupture

Urinary tract injury

Uveal prolapse

VIIIth nerve injury

VIIth nerve injury VIth nerve injury

Vaginal perforation

Vascular injury

Vascular rupture

Vena cava injury

Venous injury

Ventricle rupture

Vessel puncture site injury

Vitreous detachment

Vitreous injury

Vitreous loss

Vitreous prolapse

Vth nerve injury

Vulvovaginal injury

Wound

Wrist fracture

XIIth nerve injury

XIth nerve injury

Accelerated idioventricular rhythm

Version: 1.0 Date: 01/06/2023

Accessory cardiac pathway

Acute cardiac event

Acute cardiac event

Acute coronary syndrome

Acute left ventricular failure

Acute myocardial infarction

Acute pulmonary oedema

Acute right ventricular failure

Adams-Stokes syndrome

Agonal rhythm

Andersen-Tawil syndrome

Angina pectoris

Angina unstable

Angina unstable

Anginal equivalent

Anomalous atrioventricular excitation

Arrhythmia

Arrhythmia neonatal

Arrhythmia supraventricular

Arrhythmic storm

Arrhythmogenic right ventricular dysplasia

Arteriosclerosis coronary artery

Arteriospasm coronary

Atrial conduction time prolongation

Atrial escape rhythm

Atrial escape rhythm

Atrial fibrillation

Atrial flutter

Atrial parasystole

Atrial standstill

Atrial tachycardia

Atrioventricular block

Atrioventricular block complete

Atrioventricular block first degree

Atrioventricular block second degree

Atrioventricular conduction time shortened

Atrioventricular dissociation

Atrioventricular node dispersion

Atrioventricular node dysfunction

BRASH syndrome

Bifascicular block

Blood creatine phosphokinase MB abnormal

Blood creatine phosphokinase MB increased

Blood creatine phosphokinase abnormal

Blood creatine phosphokinase increased

Bradyarrhythmia

Brugada syndrome

Brugada syndrome

Bundle branch block

Bundle branch block bilateral

Bundle branch block left

Bundle branch block right

Cardiac asthma

Cardiac failure

Cardiac failure acute

Cardiac failure chronic

Cardiac failure congestive

Cardiac failure high output

Cardiac fibrillation

Cardiac fibrillation

Cardiac flutter

Cardiac perfusion defect

Cardiac ventricular scarring

Version: 1.0 Date: 01/06/2023

Cardiogenic shock

Cardiohepatic syndrome

Cardiopulmonary failure

Cardiorenal syndrome

Chronic atrial and intestinal dysrhythmia syndrome

Chronic coronary syndrome

Chronic left ventricular failure

Chronic right ventricular failure

Chronotropic incompetence

Conduction disorder

Congenital supraventricular tachycardia

Congestive hepatopathy

Cor pulmonale

Cor pulmonale acute

Cor pulmonale chronic

Coronary angioplasty

Coronary arterial stent insertion

Coronary artery bypass

Coronary artery compression

Coronary artery disease

Coronary artery dissection

Coronary artery embolism

Coronary artery insufficiency

Coronary artery occlusion

Coronary artery reocclusion

Coronary artery restenosis

Coronary artery stenosis

Coronary artery surgery

Coronary artery thrombosis

Coronary brachytherapy

Coronary bypass stenosis

Coronary bypass thrombosis

Coronary endarterectomy

Coronary no-reflow phenomenon

Coronary ostial stenosis

Coronary revascularisation

Coronary steal syndrome

Coronary vascular graft occlusion

Coronary vascular graft stenosis

Defect conduction intraventricular

Diabetic coronary microangiopathy

ECG electrically inactive area

ECG signs of myocardial infarction

ECG signs of myocardial ischaemia

Early repolarisation syndrome

Early repolarisation syndrome

Ejection fraction decreased

Electrocardiogram PR prolongation

Electrocardiogram PR shortened

Electrocardiogram Q wave abnormal

Electrocardiogram QRS complex prolonged

Electrocardiogram QT prolonged

Electrocardiogram RR interval prolonged

Electrocardiogram ST segment abnormal

Electrocardiogram ST segment elevation

Electrocardiogram ST-T segment elevation

Electrocardiogram U wave inversion

Electrocardiogram U wave inversion

Electrocardiogram U wave present

Electrocardiogram U-wave abnormality

Electrocardiogram delta waves abnormal

Version: 1.0 Date: 01/06/2023

Electrocardiogram repolarisation abnormality

Electrocardiogram repolarisation abnormality

External counterpulsation

Extrasystoles

Fascicular block

Foetal arrhythmia

Foetal heart rate disorder

Foetal tachyarrhythmia

Frederick's syndrome

Haemorrhage coronary artery

Heart alternation

Heart block congenital

Heart rate irregular

Hepatojugular reflux

Holiday heart syndrome

Infarction

Ischaemic cardiomyopathy

Ischaemic mitral regurgitation

Junctional ectopic tachycardia

Junctional ectopic tachycardia

Kounis syndrome

Left ventricular failure

Lenegre's disease

Long QT syndrome

Long QT syndrome congenital

Low cardiac output syndrome

Lown-Ganong-Levine syndrome

Microvascular coronary artery disease

Myocardial hypoperfusion

Myocardial hypoxia

Myocardial infarction

Myocardial ischaemia

Myocardial necrosis

Myocardial necrosis marker increased

Myocardial reperfusion injury

Myocardial stunning

Neonatal bradyarrhythmia

Neonatal cardiac failure

Neonatal tachyarrhythmia

Nodal arrhythmia

Nodal rhythm

Obstructive shock

Pacemaker generated arrhythmia

Pacemaker syndrome

Papillary muscle infarction

Parasystole

Paroxysmal arrhythmia

Paroxysmal atrioventricular block

Percutaneous coronary intervention

Periprocedural myocardial infarction

Post procedural myocardial infarction

Postinfarction angina

Prinzmetal angina

Pulmonary oedema

Pulmonary oedema neonatal

Pulseless electrical activity

Radiation associated cardiac failure

Reperfusion arrhythmia

Rhythm idioventricular

Right ventricular ejection fraction decreased

Right ventricular failure

Scan myocardial perfusion abnormal

Silent myocardial infarction

Sinoatrial block

Sinus arrest

Sinus arrhythmia

Sinus bradycardia

Sinus node dysfunction

Sinus tachycardia

Stress cardiomyopathy

Subclavian coronary steal syndrome

Subendocardial ischaemia

Sudden cardiac death

Supraventricular extrasystoles

Supraventricular tachyarrhythmia

Supraventricular tachycardia

Tachyarrhythmia

Torsade de pointes

Trifascicular block

Troponin I increased

Troponin T increased

Troponin increased

Vascular graft occlusion

Vascular stent occlusion

Vascular stent thrombosis

Ventricular arrhythmia

Ventricular asystole

Ventricular dyssynchrony

Ventricular extrasystoles

Ventricular failure

Ventricular fibrillation

Ventricular flutter

Ventricular parasystole

Ventricular pre-excitation

Ventricular tachyarrhythmia

Ventricular tachycardia

Wandering pacemaker

Wellens' syndrome Withdrawal arrhythmia

Wolff-Parkinson-White syndrome

Wolff-Parkinson-White syndrome congenital

Amaurosis fugax

Balint's syndrome

Basal ganglia haematoma

Basal ganglia haemorrhage

Basal ganglia infarction

Basal ganglia stroke

Basal ganglia stroke

Basilar artery aneurysm

Basilar artery occlusion

Basilar artery perforation

Basilar artery stenosis

Basilar artery thrombosis

Benedikt's syndrome

Brachiocephalic arteriosclerosis

Brachiocephalic artery occlusion

Brachiocephalic artery stenosis

Brain hypoxia

Brain stem embolism

Brain stem haematoma

Brain stem haemorrhage

Brain stem infarction

CEREBROVASCULAR EVENT

Brain stem ischaemia

Brain stem microhaemorrhage

Brain stem stroke

Brain stem stroke

Brain stem thrombosis

Brain stent insertion

CADASIL

CARASIL syndrome

CSF bilirubin positive

Capsular warning syndrome

Carotid aneurysm rupture

Carotid angioplasty

Carotid arterial embolus

Carotid arteriosclerosis

Carotid artery aneurysm

Carotid artery bypass

Carotid artery disease

Carotid artery dissection

Carotid artery insufficiency

Carotid artery occlusion

Carotid artery perforation

Carotid artery restenosis

Carotid artery stenosis

Carotid artery stent insertion

Carotid artery stent removal

Carotid artery thrombosis

Carotid endarterectomy

Carotid revascularisation

Central nervous system haemorrhage

Central nervous system vasculitis

Cerebellar artery occlusion

Cerebellar artery thrombosis

Cerebellar atherosclerosis

Cerebellar embolism

Cerebellar haematoma Cerebellar haemorrhage

Cerebellar infarction

Cerebellar ischaemia

Cerebellar microhaemorrhage

Cerebellar stroke

Cerebellar stroke

Cerebral aneurysm perforation

Cerebral aneurysm ruptured syphilitic

Cerebral arteriosclerosis

Cerebral arteriovenous malformation haemorrhagic

Cerebral arteritis

Cerebral artery embolism

Cerebral artery occlusion

Cerebral artery perforation

Cerebral artery restenosis

Cerebral artery stenosis

Cerebral artery stent insertion

Cerebral artery thrombosis

Cerebral capillary telangiectasia

Cerebral cavernous malformation

Cerebral circulatory failure

Cerebral congestion

Cerebral cyst haemorrhage

Cerebral endovascular aneurysm repair

Version: 1.0 Date: 01/06/2023

Cerebral gas embolism

Cerebral haematoma

Cerebral haemorrhage

Cerebral haemorrhage foetal

Cerebral haemorrhage neonatal

Cerebral hypoperfusion

Cerebral infarction

Cerebral infarction foetal

Cerebral ischaemia

Cerebral microembolism

Cerebral microhaemorrhage

Cerebral microinfarction

Cerebral reperfusion injury

Cerebral revascularisation

Cerebral septic infarct

Cerebral small vessel ischaemic disease

Cerebral thrombosis

Cerebral vascular occlusion

Cerebral vasoconstriction

Cerebral venous sinus thrombosis

Cerebral venous thrombosis

Cerebral ventricular rupture

Cerebrovascular accident

Cerebrovascular accident

Cerebrovascular accident prophylaxis

Cerebrovascular disorder

Cerebrovascular disorder

Cerebrovascular insufficiency

Cerebrovascular pseudoaneurysm

Cerebrovascular stenosis

Charcot-Bouchard microaneurysms

Claude's syndrome

Congenital hemiparesis

Delayed ischaemic neurological deficit

Delayed ischaemic neurological deficit

Dural arteriovenous fistula

Embolic cerebellar infarction

Embolic cerebral infarction

Embolic stroke

Epidural haemorrhage

Extra-axial haemorrhage

Extradural haematoma

Extradural haematoma evacuation

Extraischaemic cerebral haematoma

Foville syndrome

Foville syndrome

Haemorrhage intracranial

Haemorrhagic cerebellar infarction

Haemorrhagic cerebral infarction

Haemorrhagic stroke

Haemorrhagic transformation stroke

Hemianaesthesia

Hemiasomatognosia

Hemiataxia

Hemidysaesthesia

Hemihyperaesthesia

Hemihypoaesthesia

Hemiparaesthesia

Hemiparesis

Hemiplegia

Hypoxic-ischaemic encephalopathy

Version: 1.0 Date: 01/06/2023

Inner ear infarction

Internal capsule infarction

Intra-cerebral aneurysm operation

Intracerebral haematoma evacuation

Intracranial aneurysm

Intracranial haematoma

Intracranial haemorrhage neonatal

Intracranial tumour haemorrhage

Intraventricular haemorrhage

Intraventricular haemorrhage neonatal

Ischaemic cerebral infarction

Ischaemic stroke

Lacunar infarction

Lacunar stroke

Lateral medullary syndrome

Lateropulsion

Malignant middle cerebral artery syndrome

Meningorrhagia

Metabolic stroke

Migrainous infarction

Millard-Gubler syndrome

Moyamoya disease

Perinatal stroke

Perinatal stroke

Periventricular haemorrhage neonatal

Pituitary apoplexy

Pituitary haemorrhage

Post cardiac arrest syndrome

Post procedural stroke

Post stroke depression

Posthaemorrhagic hydrocephalus

Precerebral arteriosclerosis

Precerebral artery aneurysm

Precerebral artery dissection

Precerebral artery embolism Precerebral artery occlusion

Precerebral artery thrombosis

Pseudo-occlusion of internal carotid artery

Putamen haemorrhage

Reversible cerebral vasoconstriction syndrome

Reversible ischaemic neurological deficit

Ruptured cerebral aneurysm

Septic cerebral embolism

Spinal artery embolism

Spinal artery thrombosis

Spinal cord haematoma

Spinal cord haemorrhage

Spinal cord infarction

Spinal cord ischaemia

Spinal epidural haematoma

Spinal epidural haemorrhage

Spinal stroke

Spinal stroke

Spinal subarachnoid haemorrhage

Spinal subdural haematoma

Spinal subdural haemorrhage

Stroke in evolution

Stroke in evolution

Subarachnoid haematoma

Subarachnoid haemorrhage

Subarachnoid haemorrhage neonatal

Version: 1.0 Date: 01/06/2023

Subclavian steal syndrome

Subdural haematoma

Subdural haematoma evacuation

Subdural haemorrhage

Subdural haemorrhage neonatal Superior sagittal sinus thrombosis

Thalamic infarction

Thalamus haemorrhage

Thrombotic cerebral infarction

Thrombotic stroke

Transient ischaemic attack

Transverse sinus thrombosis

Vascular encephalopathy

Vascular stent occlusion

Vascular stent stenosis

Vein of Galen aneurysmal malformation

Vertebral artery aneurysm

Vertebral artery arteriosclerosis

Vertebral artery dissection

Vertebral artery occlusion

Vertebral artery perforation

Vertebral artery stenosis

Vertebral artery thrombosis Vertebrobasilar insufficiency

Vertebrobasilar stroke

Vertebrobasilar stroke

Weber's syndrome

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

3-hydroxyacetyl-coenzyme A dehydrogenase deficiency

Version: 1.0 Date: 01/06/2023

Acquired generalised lipodystrophy

Acquired mixed hyperlipidaemia

Apolipoprotein

EFFECT ON GLUCOSE

EFFECT ON LIPIDS

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

Version: 1.0 Date: 01/06/2023

Familial hypertriglyceridaemia

Familial partial lipodystrophy

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

Version: 1.0 Date: 01/06/2023

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

Lipoprotein metabolism disorder

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 fatty liver

Non-alcoholic steatohepatitis

Non-high-density lipoprotein cholesterol

Non-high-density lipoprotein cholesterol decreased

Non-high-density lipoprotein cholesterol increased

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

Version: 1.0 Date: 01/06/2023

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

Abnormal weight gain

Body mass index abnormal Body mass index increased

Obesity

Overweight

EFFECTS ON WEIGHT

EPS

Waist circumference increased

Weight fluctuation Weight increased

Abnormal involuntary movement scale

Action tremor Akathisia Akinesia Asterixis Athetosis Ballismus Blepharospasm Bradykinesia

Bradyphrenia

Buccoglossal syndrome

Chorea

Chronic tic disorder Chronic tic disorder

Clumsiness Cogwheel rigidity Complex tic

Complex tic

Dopamine dysregulation syndrome

Drooling Drooling Drooling Dysarthria Dyskinesia

Dyskinesia neonatal

Dyskinesia oesophageal

Dyslalia Dysphonia Dystonia Dystonic tremor Emprosthotonus Essential tremor

Excessive eye blinking Extrapyramidal disorder Extrapyramidal disorder Extrapyramidal disorder 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

Version: 1.0 Date: 01/06/2023

Intention tremor

Laryngeal tremor

Laryngospasm

Meige's syndrome

Micrographia

Mobility decreased

Motor dysfunction

Motor dysfunction

Motor dysfunction

Motor dysfunction

Movement disorder

Movement disorder

Movement disorder

Movement disorder

Muscle contractions involuntary

Muscle contracture

Muscle rigidity

Muscle spasms

Muscle spasticity

Muscle tightness

Muscle tone disorder

Muscle tone disorder

Muscle twitching

Muscle twitching

Musculoskeletal stiffness

Musculoskeletal stiffness

Myoclonus

Myotonia

Nuchal rigidity

Oculogyric crisis

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

Provisional tic disorder

Psychomotor hyperactivity

Rabbit syndrome

Reduced facial expression

Respiratory dyskinesia

Resting tremor

Restless legs syndrome

Version: 1.0 Date: 01/06/2023

Restlessness

Risus sardonicus

Saliva altered

Salivary hypersecretion

Secondary tic

Secondary tic

Spasmodic dysphonia

Tardive dyskinesia

Tic Tic

Tongue paralysis

Tongue parary

Tongue spasm

Torticollis

Torticollis psychogenic

Tremor

Tremor neonatal

Trismus

Uvular spasm

Walking disability

Writer's cramp

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 V 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

HAEMATOPOIETIC/LEUKOPENIA

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

Agranulocytosis

Aleukaemic leukaemia

Allergic bronchopulmonary mycosis

Allergic eosinophilia

Allergic lymphangitis

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

Anaemic retinopathy

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-platelet factor 4 antibody negative

Version: 1.0 Date: 01/06/2023

Anti-platelet factor 4 antibody positive

Anti-platelet factor 4 antibody test

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 lymphoma unclassifiable

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 abnormalities

B-lymphocyte count

B-lymphocyte count abnormal

B-lymphocyte count abnormal

B-lymphocyte count decreased

B-lymphocyte count decreased

B-lymphocyte count increased

Babesiosis

Band neutrophil count

Band neutrophil count decreased

Band neutrophil count decreased

Band neutrophil count increased

Version: 1.0 Date: 01/06/2023

Band neutrophil percentage

Band neutrophil percentage decreased

Band neutrophil percentage decreased

Band neutrophil percentage increased

Bandaemia

Banti's syndrome

Basophil count

Basophil count abnormal

Basophil count abnormal

Basophil count decreased

Basophil count decreased

Basophil count increased

Basophil count normal

Basophil morphology

Basophil morphology abnormal

Basophil morphology normal

Basophil percentage

Basophil percentage decreased

Basophil percentage decreased

Basophil percentage increased

Basophilia

Basophilopenia

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

Version: 1.0 Date: 01/06/2023

Bleeding time

Bleeding time abnormal

Bleeding time normal

Bleeding time prolonged

Bleeding time shortened

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

Version: 1.0 Date: 01/06/2023

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

CD19 lymphocyte count abnormal

CD19 lymphocytes decreased

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

CHAPLE syndrome

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

Version: 1.0 Date: 01/06/2023

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

Version: 1.0 Date: 01/06/2023

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

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 abnormal

Differential white blood cell count normal

Diffuse infiltrative lymphocytosis syndrome

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

Eosinopenia

Eosinophil count

Eosinophil count abnormal

Eosinophil count abnormal

Eosinophil count decreased

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 decreased

Eosinophil percentage increased

Eosinophilia

Eosinophilia myalgia syndrome

Eosinophilic angiocentric fibrosis

Version: 1.0 Date: 01/06/2023

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 electrophoretic index increased

Erythrocyte osmotic fragility test

Erythroid dysplasia

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 activity test

Factor VIII deficiency

Factor VIII inhibition

Factor X deficiency

Factor X inhibition

T dettor 74 miniorition

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

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

Version: 1.0 Date: 01/06/2023

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 abnormal

Full blood count decreased

Full blood count increased

Full blood count normal

GATA2 deficiency

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 decreased

Granulocyte count increased

Granulocyte percentage

Granulocyte percentage decreased

Granulocyte percentage decreased

Granulocyte percentage increased

Granulocytes abnormal

Granulocytes abnormal

Granulocytes maturation arrest

Granulocytes maturation arrest

Granulocytopenia

Granulocytopenia

Granulocytopenia neonatal

Granulocytopenia neonatal

Granulocytosis

Granulomatous T-cell pseudolymphoma

Granulomatous lymphadenitis

Grey zone lymphoma

HELLP syndrome

Haemangioma of spleen

Haemangioma-thrombocytopenia syndrome

Version: 1.0 Date: 01/06/2023

Haematocrit

Haematocrit abnormal

Haematocrit decreased

Haematocrit increased

Haematocrit normal

Haematological cyst

Haematological malignancy

Haematological neoplasm

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 J present

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

Version: 1.0 Date: 01/06/2023

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 cofactor II deficiency

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 microcytic anaemia

Hereditary persistence of foetal haemoglobin

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

Histiocytosis-lymphadenopathy plus syndrome

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

Troughin's disease lymphocyte predominance stage I site thispee

Hodgkin's disease lymphocyte predominance stage I subdiaphragm

Version: 1.0 Date: 01/06/2023

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

Hypergammaglobulinaemic purpura of Waldenstrom

Version: 1.0 Date: 01/06/2023

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

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

Leukopenia neonatal

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

Version: 1.0 Date: 01/06/2023

Lymphoblast morphology normal

Lymphoblastosis

Lymphocele

Lymphocyte count

Lymphocyte count abnormal

Lymphocyte count abnormal

Lymphocyte count decreased

Lymphocyte count decreased

Lymphocyte count increased

Lymphocyte count normal

Lymphocyte morphology

Lymphocyte morphology abnormal

Lymphocyte morphology normal

Lymphocyte percentage

Lymphocyte percentage abnormal

Lymphocyte percentage abnormal

Lymphocyte percentage decreased

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

Lymphocyte/monocyte ratio increased

Lymphocytic infiltration

Lymphocytic leukaemia

Lymphocytic lymphoma

Lymphocytic oesophagitis

Lymphocytopenia neonatal

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

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

Malignant unclassifiable lymphoma

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

Version: 1.0 Date: 01/06/2023

Megakaryocytes

Megakaryocytes abnormal

Megakaryocytes decreased

Megakaryocytes increased

Megakaryocytes normal

Megaloblasts increased

Melanaemia

Meningitis eosinophilic

Metamyelocyte count

Metamyelocyte count decreased

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 decreased

Monoblast count increased

Monoclonal B-cell lymphocytosis

Monoclonal gammopathy

Monocyte count

Monocyte count abnormal

Monocyte count abnormal

Monocyte count decreased

Monocyte count decreased

Monocyte count increased

Monocyte count normal Monocyte morphology

Monocyte morphology abnormal

Monocyte percentage

Monocyte percentage abnormal

Monocyte percentage decreased

Monocyte percentage decreased

Monocyte percentage increased Monocytic leukaemia in remission

Monocytopenia

Monocytopenia

Monocytosis

Mononuclear cell count

Mononuclear cell count abnormal

Mononuclear cell count decreased

Mononuclear cell count decreased

Mononuclear cell count increased

Mononuclear cell percentage

Mononucleosis syndrome

Multicentric reticulohistiocytosis

Myeloblast count

Myeloblast count decreased

Myeloblast count decreased

Myeloblast count increased

Myeloblast percentage

Myeloblast percentage decreased

Myeloblast percentage decreased

Myeloblast percentage increased

Myeloblast present

Myeloblastoma

Myelocyte count

Myelocyte count decreased

Myelocyte count decreased

Myelocyte count increased

Myelocyte percentage

Myelocyte percentage decreased

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 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

Neutropenia neonatal

Neutropenia neonatal

Neutropenic colitis

Neutropenic infection

Neutropenic infection

Neutropenic sepsis

Neutropenic sepsis

Neutrophil Fc gamma RIIIb deficiency

Neutrophil Pelger-Huet anomaly present

Version: 1.0 Date: 01/06/2023

Neutrophil chemotaxis

Neutrophil chemotaxis abnormal

Neutrophil chemotaxis normal

Neutrophil count

Neutrophil count abnormal

Neutrophil count abnormal

Neutrophil count decreased

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 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

Paraneoplastic eosinophilia

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 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 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 hypercoagulability

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

Version: 1.0 Date: 01/06/2023

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 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

Pure white cell aplasia

Purpura

Purpura fulminans

Purpura neonatal

Purpura non-thrombocytopenic

Purpura senile

Pyruvate kinase deficiency anaemia

Radiation anaemia

Radiation leukopenia

Radiation leukopenia

Radiation lymphoedema

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 decreased

Reticulocyte haemoglobin equivalent

Reticulocyte haemoglobin increased

Reticulocyte percentage

Reticulocyte percentage abnormal

Reticulocyte percentage decreased

Reticulocyte percentage increased

Reticulocyte percentage normal

Reticulocytopenia

Reticulocytosis

Reticuloendothelial dysfunction

Reticuloendothelial system stimulated

Version: 1.0 Date: 01/06/2023

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

Sarcoidosis of lymph node

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

Scorbutic anaemia

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

Version: 1.0 Date: 01/06/2023

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

Spreme infection ducter

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 lymphoma unclassifiable

T-cell prolymphocytic leukaemia

T-cell type acute leukaemia T-cell unclassifiable lymphoma high grade

T-cell unclassifiable lymphoma low grade

Version: 1.0 Date: 01/06/2023

T-lymphocyte count

T-lymphocyte count abnormal

T-lymphocyte count abnormal

T-lymphocyte count decreased

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 generation assay

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

Thrombomodulin increased

Thrombopoietin level abnormal

Thrombosis with thrombocytopenia syndrome

Thrombotic microangiopathy

Thrombotic thrombocytopenic purpura

Thromboxane decreased

Thromboxane increased

Thymic cancer metastatic

Thymic carcinoma

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

Version: 1.0 Date: 01/06/2023

Triple hit lymphoma

Trisomy 12

Tropical eosinophilia

Tropical sprue

Tuberculosis of intrathoracic lymph nodes

Tuberculosis of peripheral lymph nodes

Ultrasound 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 autoimmune haemolytic anaemia

White blood cell agglutination present

White blood cell analysis

White blood cell analysis abnormal

White blood cell analysis abnormal

White blood cell analysis normal

White blood cell count

White blood cell count abnormal

White blood cell count abnormal

White blood cell count decreased

White blood cell count decreased White blood cell count increased

White blood cell count normal

White blood cell disorder

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

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

Version: 1.0 Date: 01/06/2023

Administration site rash

Administration site recall reaction

Administration site urticaria

Administration site vasculitis

HYPERSENSITIVITY

Airway remodelling

Allergic bronchitis

Allergic colitis

Allergic cough

Allergic cystitis

Allergic eosinophilia

Allergic gastroenteritis

Allergic hepatitis

Allergic keratitis

Allergic lymphangitis

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

and the state of t

Blood immunoglobulin G increased

Blood immunoglobulin M abnormal Blood immunoglobulin M increased

- ...

Bone cement allergy

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

Dermal filler reaction

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 angiocentric fibrosis

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

Foreskin oedema

Gastrointestinal oedema

Generalised bullous fixed drug eruption

Version: 1.0 Date: 01/06/2023

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

Version: 1.0 Date: 01/06/2023

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

Version: 1.0 Date: 01/06/2023

Palpable purpura

Panniculitis

Pathergy reaction

Penile exfoliation

Penile oedema

Penile rash

Penile swelling

Perineal rash

Perioral dermatitis

Periorbital dermatitis

D : 1: 1 1

Periorbital oedema

Periorbital swelling

Pharyngeal oedema

Pharyngeal swelling Photosensitivity reaction

Pneumonitis

Polymers allergy

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 flavouring

Reaction to food additive

Reaction to preservatives

Reaction to sweetener

Reactive airways dysfunction syndrome

Version: 1.0 Date: 01/06/2023

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

Skiii 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

Superficial inflammatory dermatosis

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

Vancomycin infusion reaction

Vascular access site dermatitis

Vascular access site eczema

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

Acinetobacter infection

Acinetobacter test positive

Actinomycotic pulmonary infection

Acute pulmonary histoplasmosis

Adenovirus infection

Adenovirus test positive

Aspergillus infection

Aspergillus test positive

Aspiration tracheal abnormal

Atelectasis

Atypical mycobacterial infection

Atypical mycobacterial lower respiratory tract infection

Atypical mycobacterial pneumonia

Atypical pneumonia

Auscultation

Avian influenza

Bacterial test positive

Blastomycosis

Bronchopneumopathy

Bronchopulmonary aspergillosis

Burkholderia cepacia complex infection

Burkholderia pseudomallei infection

Burkholderia test positive

COVID-19

COVID-19 pneumonia

Candida pneumonia

Carbon dioxide abnormal

Carbon dioxide increased

Chest X-ray abnormal

Chlamydia test positive

Chlamydial infection

Chronic pulmonary histoplasmosis

Version: 1.0 Date: 01/06/2023

Coccidioidomycosis

Coronavirus infection

Coronavirus pneumonia

Coronavirus test positive

Coxiella test positive

Crepitations

Cryptococcosis

Culture throat positive

PNEUMONIA

Disseminated aspergillosis

Disseminated blastomycosis

Disseminated coccidioidomycosis

Disseminated mucormycosis

Disseminated paracoccidioidomycosis

Disseminated sporotrichosis

Disseminated tuberculosis

Egobronchophony

Embolic pneumonia

Empyema

Enterobacter infection

Enterobacter pneumonia

Enterobacter test positive

Escherichia infection

Escherichia test positive

Francisella test positive

Fungal test positive

H1N1 influenza

H2N2 influenza

H3N2 influenza

Haemophilus infection

Haemophilus test positive

Haemoptysis

Haemorrhagic pneumonia

Hantavirus pulmonary infection

Hantavirus test positive

Herpes simplex pneumonia

Histoplasmosis

Human metapneumovirus test positive

Hypoventilation

Hypoxia

Increased bronchial secretion

Infectious pleural effusion

Influenza

Influenza A virus test positive

Influenza virus test positive

Klebsiella infection

Klebsiella test positive

Legionella infection

Legionella test positive

Low lung compliance

Lower respiratory tract congestion

Lower respiratory tract herpes infection

Lower respiratory tract infection

Lower respiratory tract infection bacterial

Lower respiratory tract infection fungal

Lower respiratory tract infection viral

Lung abscess

Lung consolidation

Lung infiltration

Lung opacity

MERS-CoV test positive

Metapneumovirus infection

Metapneumovirus pneumonia

Middle East respiratory syndrome

Miliary pneumonia

Moraxella infection

Moraxella test positive

Mucormycosis

Mycobacterial infection

Mycobacterium test positive

Mycoplasma infection

Mycoplasma test positive

Nocardiosis

Organising pneumonia

Oxygen saturation abnormal

Oxygen saturation decreased

PCO2 abnormal

PCO2 decreased

PO2 abnormal

PO2 decreased

Paracancerous pneumonia

Paracoccidioides infection

Parasitic pneumonia

Percussion test abnormal

Pleural effusion

Pleural infection

Pleural infection bacterial

Pleural rub

Pleurisy bacterial

Pleurisy viral

Pleuritic pain

Pneumococcal bacteraemia

Pneumococcal infection

Pneumococcal sepsis

Pneumocystis jirovecii pneumonia

Pneumocystis test positive

Pneumonia

Pneumonia acinetobacter

Pneumonia adenoviral

Pneumonia anthrax

Pneumonia bacterial

Pneumonia bordetella Pneumonia chlamydial

Pneumonia cryptococcal

Pneumonia cytomegaloviral

Pneumonia escherichia

Pneumonia fungal

Pneumonia haemophilus

Pneumonia helminthic

Pneumonia herpes viral

Pneumonia influenzal

Pneumonia klebsiella

Pneumonia legionella

Pneumonia measles

Pneumonia moraxella

Pneumonia mycoplasmal

Pneumonia necrotising

Pneumonia parainfluenzae viral

Pneumonia pneumococcal

Pneumonia proteus

Pneumonia pseudomonal

Pneumonia respiratory syncytial viral

Pneumonia salmonella

Pneumonia serratia

Pneumonia staphylococcal

Pneumonia streptococcal

Pneumonia toxoplasmal

Pneumonia tularaemia

Pneumonia viral Pneumonic plague

Pneumovirus test positive

Post procedural pneumonia

Productive cough

Proteus infection

Proteus test positive

Pseudomonas infection

Pseudomonas test positive

Psittacosis

Pulmonary blastomycosis

Pulmonary congestion

Pulmonary echinococciasis

Pulmonary histoplasmosis

Pulmonary imaging procedure abnormal

Pulmonary mucormycosis

Pulmonary nocardiosis

Pulmonary paracoccidioidomycosis

Pulmonary sepsis

Pulmonary sporotrichosis

Pulmonary syphilis

Pulmonary trichosporonosis

Pulmonary tuberculoma

Pulmonary tuberculosis

Pyopneumothorax

Q fever

Rales

Respiratory tract infection

Respiratory tract infection bacterial

Respiratory tract infection fungal

Respiratory tract infection viral

Rhonchi

SARS-CoV-1 test positive

SARS-CoV-2 antibody test positive

SARS-CoV-2 test false negative

SARS-CoV-2 test positive

Septic pulmonary embolism

Serratia infection

Serratia test positive

Severe acute respiratory syndrome

Sporotrichosis

Sputum abnormal

Sputum culture positive

Sputum discoloured

Sputum purulent

Staphylococcal infection

Staphylococcus test positive

Streptococcal infection

Streptococcus test positive

Suspected COVID-19

Tachypnoea

Tuberculosis

Tuberculous pleurisy

Tularaemia

Use of accessory respiratory muscles

Varicella zoster pneumonia

Venous oxygen saturation abnormal

Venous oxygen saturation decreased

Pneumonia aspiration

NEUROLEPTIC MALIGNANT SYNDROME Altered state of consciousness

Autonomic nervous system imbalance

Blood creatine phosphokinase MM increased

Version: 1.0 Date: 01/06/2023

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

Version: 1.0 Date: 01/06/2023

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 Arrhythmic storm 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

Version: 1.0 Date: 01/06/2023

Long QT syndrome

Long QT syndrome congenital

Loss of consciousness

QT PROLONGATION

RHABDOMYOLYSIS AND CPK ELEVATION

Sudden cardiac death

Sudden death

Syncope

Torsade de pointes

Ventricular arrhythmia

Ventricular fibrillation

Ventricular flutter

Ventricular tachyarrhythmia

Ventricular tachycardia

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 infarction

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

SEIZURES

Subacute kidney injury
Tendon discomfort
Thyrotoxic myopathy
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

Epilepsia partialis continua

Epilepsy

Epilepsy of infancy with migrating focal seizures

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

PURA syndrome

Parietal lobe epilepsy

Partial seizures

Partial seizures with secondary generalisation

Petit mal epilepsy

Photosensitive seizure

Polymicrogyria

Torynnerogyna

Post stroke epilepsy Post stroke seizure

Post-traumatic epilepsy

Postictal headache

Postictal paralysis

Postictal psychosis

Postictal state

Preictal state

Progressive encephalopathy, hypsarrhythmia and optic atrophy

syndrome

Schizencephaly

Seizure

Seizure anoxic

Seizure cluster

Seizure like phenomena

Seizure prophylaxis

Severe myoclonic epilepsy of infancy

Simple partial seizures

Sleep related hypermotor epilepsy

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

VTE (THROMBOTIC AND EMBOLIC EVENTS)

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

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 thrombosis

Peripheral vein thrombus extension

Phlebectomy

Portal vein cavernous transformation

Portal vein embolism

Portal vein occlusion

Portal vein thrombosis

Portosplenomesenteric venous thrombosis

Version: 1.0 Date: 01/06/2023

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

Sigmoid sinus thrombosis

Splenic vein occlusion

Splenic vein thrombosis

Subclavian vein occlusion

Subclavian vein thrombosis

Superficial vein thrombosis

Superior sagittal sinus thrombosis

Superior vena cava occlusion

Superior vena cava syndrome

Thrombophlebitis

Thrombophlebitis migrans

Thrombophlebitis neonatal

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

Version: 1.0 Date: 01/06/2023

Appendix 5	List of Summary Tables
CT-1	Subject Disposition (Enrolled Subjects)
CT-2	Reasons for Discontinuation (Randomized Subjects)
CT-3.1.1	Demographic Characteristics (Full Analysis Set)
CT-3.1.2	Demographic Characteristics (Safety Analysis Set)
CT-3.1.3	Demographic Characteristics (Pharmacokinetic Analysis Set)
CT-3.1.3 CT-3.2.1	Baseline Disease Characteristics (Full Analysis Set)
	• • • • • • • • • • • • • • • • • • • •
CT-3.2.2	Baseline Disease Characteristics (Safety Analysis Set)
CT-4.1.1	Concomitant Medications (Antipsychotic): Medications Taken Prior to Start of Study Therapy (Safety Analysis Set)
CT-4.1.2	Concomitant Medications (Antipsychotic): Medications Taken During Study Therapy (Safety Analysis Set)
CT-4.1.3	Concomitant Medications (Antipsychotic): Medications Taken Post Study Therapy (Safety Analysis Set)
CT-4.2.1	Concomitant Medications (Antidementia Drug): Medications Taken Prior to Start of Study Therapy (Safety Analysis Set)
CT-4.2.2	Concomitant Medications (Antidementia Drug): Medications Taken During Study Therapy (Safety Analysis Set)
CT-4.2.3	Concomitant Medications (Antidementia Drug): Medications Taken Post Study Therapy (Safety Analysis Set)
CT-4.3.1	Concomitant Medications (Other): Medications Taken Prior to Start of Study Therapy (Safety Analysis Set)
CT-4.3.2	Concomitant Medications (Other): Medications Taken During Study Therapy (Safety Analysis Set)
CT-4.3.3	Concomitant Medications (Other): Medications Taken Post Study Therapy (Safety Analysis Set)
CT-4.4	Summary of Major Protocol Deviations by Center and Type of Deviation (Randomized Subjects)
CT-5.1	Summary of Efficacy Results at Week 10 (Full Analysis Set)
CT-5.2	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score - MMRM (Full Analysis Set)
CT-5.3	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Subscale Score - MMRM (Full Analysis Set)
CT-5.4	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CGI-S Scale - MMRM (Full Analysis Set)
CT-5.5.1	Summary of Mean CGI-I Score by Study Week in Double Blind Treatment Period Relative to Baseline - LOCF (Full Analysis Set)
CT-5.5.2	Summary of Mean CGI-I Score by Study Week in Double Blind Treatment Period Relative to Baseline - OC (Full Analysis Set)
CT-5.6.1	
CT-5.6.2	
CT-5.6.3	
CT-5.6.4	
CT-5.7.1	

CT-5.7.2	
CT-5.7.3	
CT-5.7.4	
CT-5.8.1	
CT-5.8.2	
C1-3.6.2	
CT 5.0.2	
CT-5.8.3	
CT-5.8.4	
CT-5.9.1	
CT-5.9.2	
C1-3.9.2	
CT-5.10.1	
CT-5.10.2	
C1-3.10.2	
CT-5.11.1	Sensitivity Analysis of MNAR using Tipping Point Analysis in CMAI Total Score
CT-5.11.2	Assume All Dropouts as MNAR (Full Analysis Set) Sensitivity Analysis of MNAR using Tipping Point Analysis in CMAI Total Score
C1 3.11.2	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 CMAI Total Score
CT-5.11.4	Dropout due to AE or LOE as MNAR (Full Analysis Set) Sensitivity Analysis of MNAR using Placebo Based Imputation in CMAI Total
01 0.11	Score (Full Analysis Set)
CT-5.11.5	Summary of Mean Change From Baseline to Double Blind Treatment Period by
	Study Week in CMAI Total Score - Van Elteren Test, Robust Regression - MI (Full Analysis Set)
CT-5.11.6	Summary of Mean Change From Baseline to Double Blind Treatment Period by
	Study Week in CMAI Total Score - Van Elteren Test, Robust Regression - OC (Full
CT-6.1.1	Analysis Set) Summary of Mean Change From Baseline to Double Blind Treatment Period by
	Study Week in CMAI Total Score by Medical Care Category: In-patient - MMRM
CT (1 2	(Full Analysis Set)
CT-6.1.2	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Medical Care Category: Out-patient - MMRM
	(Full Analysis Set)
CT-6.2.1	Summary of Mean Change From Baseline to Double Blind Treatment Period by
	Study Week in CMAI Total Score by Prior Antipsychotics: Present - MMRM (Full Analysis Set)
CT-6.2.2	Summary of Mean Change From Baseline to Double Blind Treatment Period by
	Study Week in CMAI Total Score by Prior Antipsychotics: Absent - MMRM (Full
	Analysis Set)

CT-6.3.1	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Main Care Giver: Staff of Hospital - MMRM
CT-6.3.2	(Full Analysis Set) Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Main Care Giver: Staff of Care Facility - MMRM (Full Analysis Set)
CT-6.3.3	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Main Care Giver: Family - MMRM (Full Analysis Set)
CT-6.4.1	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Gender: Male - MMRM (Full Analysis Set)
CT-6.4.2	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Gender: Female - MMRM (Full Analysis Set)
CT-6.5.1	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Age: < 80 Years - MMRM (Full Analysis Set)
CT-6.5.2	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Age: >= 80 Years - MMRM (Full Analysis Set)
CT-6.5.3	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Age: < 65 Years - MMRM (Full Analysis Set)
CT-6.5.4	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Age: >= 65 - < 75 Years - MMRM (Full Analysis Set)
CT-6.5.5	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Age: >= 75 Years - MMRM (Full Analysis Set)
CT-6.6.1	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Baseline CMAI Total Score: <= Median - MMRM (Full Analysis Set)
CT-6.6.2	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Baseline CMAI Total Score: > Median - MMRM (Full Analysis Set)
CT-6.7.1	WWINWI (I dil 7 marysis Set)
CT-6.7.2	
CT-6.8.1	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Baseline Weight: <= Median - MMRM (Full Analysis Set)
CT-6.8.2	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Baseline Weight: > Median - MMRM (Full Analysis Set)
CT-6.9.1	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Baseline BMI: <= Median - MMRM (Full Analysis Set)
CT-6.9.2	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Baseline BMI: > Median - MMRM (Full Analysis Set)
CT-6.10.1	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by CYP2D6 Metabolism Status: IM - MMRM (Full Analysis Set)

CT-6.10.2	Summary of Mean Change From Baseline to Double Blind Treatment Period by
	Study Week in CMAI Total Score by CYP2D6 Metabolism Status: EM - MMRM
	(Full Analysis Set)
CT-6.11.1	Summary of Mean Change From Baseline to Double Blind Treatment Period by
	Study Week in CMAI Total Score by Impact of COVID-19 Pandemic: Subjects
CT (11 A	Completed/Discontinued before 07APR2020 - MMRM (Full Analysis Set)
CT-6.11.2	Summary of Mean Change From Baseline to Double Blind Treatment Period by
	Study Week in CMAI Total Score by Impact of COVID-19 Pandemic: Subjects
CT (10 1	Completed/Discontinued on or after 07APR2020 - MMRM (Full Analysis Set)
CT-6.12.1	Summary of Mean Change From Baseline to Double Blind Treatment Period by Study Week in CMAI Total Score by Concomitant Antidementia Drugs: Present -
	MMRM (Full Analysis Set)
CT-6.12.2	Summary of Mean Change From Baseline to Double Blind Treatment Period by
0.12.2	Study Week in CMAI Total Score by Concomitant Antidementia Drugs: Absent -
	MMRM (Full Analysis Set)
CF-1	LS Mean Change From Baseline to Double Blind Treatment Period in CMAI Total
	Score - MMRM (Full Analysis Set)
CT-7.1	Extent of Exposure (Safety Analysis Set)
CT-7.2	Duration of Exposure Summary (Safety Analysis Set)
CT-7.3	Summary of Treatment Compliance (Full Analysis Set)
CT-8.1	Adverse Events (All Causalities) (Safety Analysis Set)
CT-8.2.1	Incidence of TEAEs by MedDRA System Organ Class and Preferred
01 0.2.1	Term (Safety Analysis Set)
CT-8.2.2	Incidence of Drug-related TEAEs by MedDRA System Organ Class and Preferred
	Term (Safety Analysis Set)
CT-8.3.1	Incidence of TEAEs by MedDRA System Organ Class, Preferred Term and Severity
	(Safety Analysis Set)
CT-8.3.2	Incidence of Drug-related TEAEs by MedDRA System Organ Class, Preferred Term
CT 0.4.1	and Severity (Safety Analysis Set)
CT-8.4.1	Incidence of Deaths due to TEAEs by MedDRA System Organ Class and Preferred
CT-8.4.2	Term (Safety Analysis Set) Incidence of Deaths due to Drug-related TEAEs by MedDRA System Organ Class
C1-6.4.2	and Preferred Term (Safety Analysis Set)
CT-8.5.1	Incidence of Serious TEAEs by MedDRA System Organ Class and Preferred Term
0.0	(Safety Analysis Set)
CT-8.5.2	Incidence of Serious Drug-related TEAEs by MedDRA System Organ Class and
	Preferred Term (Safety Analysis Set)
CT-8.6.1	Incidence of TEAEs Resulting in Discontinuation of IMP 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 by MedDRA
CT 0.7.1	System Organ Class and Preferred Term (Safety Analysis Set)
CT-8.7.1	Incidence of TEAEs of at Least 2% in Any Brex Group and Greater Than Placebo
CT-8.7.2	by MedDRA System Organ Class and Preferred Term (Safety Analysis Set) Incidence of Drug-related TEAEs of at Least 2% in Any Brex Group and Greater
C1-6.7.2	Than Placebo by MedDRA System Organ Class and Preferred Term (Safety
	Analysis Set)
CT-8.8.1	Incidence of TEAEs by MedDRA System Organ Class, Preferred Term and Time to
0.0	First Onset (Safety Analysis Set)
CT-8.8.2	Incidence of Drug-related TEAEs 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 for Accidents and Injuries Including Fall (Safety Analysis Set)
CT-8.9.3	Incidence of TEAEs for Cerebrovascular Events (Safety Analysis Set)
CT-8.9.4	Incidence of TEAEs for Cardiovascular Events (Safety Analysis Set)
	· · · · · · · · · · · · · · · · · · ·

CT-8.9.5	Incidence of TEAEs for Effect on Glucose (Safety Analysis Set)
CT-8.9.6	Incidence of TEAEs for Effect on Lipids (Safety Analysis Set)
CT-8.9.7	Incidence of TEAEs for Effect on Weight (Safety Analysis Set)
CT-8.9.8	Incidence of TEAEs for Haematopoietic/Leukopenia (Safety Analysis Set)
CT-8.9.9	Incidence of TEAEs for Hypersensitivity (Safety Analysis Set)
CT-8.9.10	Incidence of TEAEs for Neuroleptic Malignant Syndrome (Safety Analysis Set)
CT-8.9.11	Incidence of TEAEs for Orthostatic Hypotension, Dizziness, and Syncope (Safety Analysis Set)
CT-8.9.12	Incidence of TEAEs for Effect on Prolactin (Safety Analysis Set)
CT-8.9.13	Incidence of TEAEs for QT Prolongation (Safety Analysis Set)
CT-8.9.14	Incidence of TEAEs for Rhabdomyolysis and CPK Elevation (Safety Analysis Set)
CT-8.9.15	Incidence of TEAEs for Seizures (Safety Analysis Set)
CT-8.9.16	Incidence of TEAEs for Somnolence (Safety Analysis Set)
CT-8.9.17	Incidence of TEAEs for Suicidality (Safety Analysis Set)
CT-8.9.18	Incidence of TEAEs for VTE (Thrombotic and Embolic Events) (Safety Analysis Set)
CT-8.9.19	Incidence of TEAEs for Pneumonia (Safety Analysis Set)
CT-8.10.1	Incidence of TEAEs by MedDRA System Organ Class and Preferred Term by Medical Care Category (Safety Analysis Set)
CT-8.10.2	Incidence of TEAEs by MedDRA System Organ Class and Preferred Term by Prior Antipsychotics (Safety Analysis Set)
CT-8.10.3	Incidence of TEAEs by MedDRA System Organ Class and Preferred Term by Main Care Giver (Safety Analysis Set)
CT-8.10.4	Incidence of TEAEs by MedDRA System Organ Class and Preferred Term by Gender (Safety Analysis Set)
CT-8.10.5.1	Incidence of TEAEs by MedDRA System Organ Class and Preferred Term by Age (< 80, >= 80) (Safety Analysis Set)
CT-8.10.5.2	Incidence of TEAEs by MedDRA System Organ Class and Preferred Term by Age (< 65, >= 65 - < 75, >= 75) (Safety Analysis Set)
CT-8.10.6	Incidence of TEAEs by MedDRA System Organ Class and Preferred Term by Baseline Weight (Safety Analysis Set)
CT-8.10.7	Incidence of TEAEs by MedDRA System Organ Class and Preferred Term by Baseline BMI (Safety Analysis Set)
CT-8.10.8	Incidence of TEAEs by MedDRA System Organ Class and Preferred Term by CYP2D6 Metabolism Status (Safety Analysis Set)
CT-8.10.9	Incidence of TEAEs by MedDRA System Organ Class and Preferred Term by Impact of COVID-19 Pandemic (Safety Analysis Set)
CT-8.10.10	Incidence of TEAEs by MedDRA System Organ Class and Preferred Term by Concomitant Antidementia Drugs (Safety Analysis Set)
CT-9.1	Listing of Deaths (Safety Analysis Set)
CT-9.2	Listing of Serious Adverse Events (Safety Analysis Set) Listing of Discontinuation of IMP due to Adverse Events (Safety Analysis Set)
CT-9.3	Listing of Discontinuation of IMP due to Adverse Events (Safety Analysis Set)
CT-9.4.1	Listing of TEAEs for EPS (Safety Analysis Set)
CT-9.4.2	Listing of TEAEs for Accidents and Injuries Including Fall (Safety Analysis Set)
CT-9.4.3	Listing of TEAEs for Cerebrovascular Events (Safety Analysis Set)
CT-9.4.4	Listing of TEAEs for Cardiovascular Events (Safety Analysis Set)
CT-9.4.5	Listing of TEAEs for Effect on Glucose (Safety Analysis Set)
CT-9.4.6	Listing of TEAEs for Effect on Lipids (Safety Analysis Set)
CT-9.4.7	Listing of TEAEs for Effect on Weight (Safety Analysis Set)
CT-9.4.8	Listing of TEAEs for Haematopoietic/Leukopenia (Safety Analysis Set)
CT-9.4.9	Listing of TEAEs for Hypersensitivity (Safety Analysis Set)

CT-9.4.10	Listing of TEAEs for Neuroleptic Malignant Syndrome (Safety Analysis Set)
CT-9.4.11	Listing of TEAEs for Orthostatic Hypotension, Dizziness, and Syncope (Safety
CT 0.4.12	Analysis Set) Listing of TEAEs for Effect on Prolectin (Sefety Analysis Set)
CT-9.4.12 CT-9.4.13	Listing of TEAEs for Effect on Prolactin (Safety Analysis Set) Listing of TEAEs for QT Prolongation (Safety Analysis Set)
CT-9.4.14	Listing of TEAEs for Q1 Prolongation (Safety Analysis Set) Listing of TEAEs for Rhabdomyolysis and CPK Elevation (Safety Analysis Set)
CT-9.4.14 CT-9.4.15	Listing of TEAEs for Knaudofflyofysis and CFK Elevation (Safety Analysis Set) Listing of TEAEs for Seizures (Safety Analysis Set)
CT-9.4.16	Listing of TEAEs for Somnolence (Safety Analysis Set) Listing of TEAEs for Somnolence (Safety Analysis Set)
CT-9.4.17	Listing of TEAEs for Suicidality (Safety Analysis Set)
CT-9.4.17	Listing of TEAEs for VTE (Thrombotic and Embolic Events) (Safety Analysis Set)
CT-9.4.19	Listing of TEAEs for VTE (Thromootic and Embonic Events) (Safety Analysis Set) Listing of TEAEs for Pneumonia (Safety Analysis Set)
CT-10.1.1	Mean Change From Baseline in Clinical Laboratory Test Results - Serum Chemistry
C1-10.1.1	(Safety Analysis Set)
CT-10.1.2	Mean Change From Baseline in Clinical Laboratory Test Results - Hematology
	(Safety Analysis Set)
CT-10.1.3	Mean Change From Baseline in Clinical Laboratory Test Results - Urinalysis (Safety
CT-10.1.4	Analysis Set) Mean Change From Baseline in Clinical Laboratory Test Results - Prolactin, by
C1-10.1.4	Gender (Safety Analysis Set)
CT-10.1.5	Mean Change From Baseline 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
CT-10.2.2	Set) Shift Tables of Clinical Laboratory Test Results - Hematology (Safety Analysis Set)
CT-10.2.2 CT-10.2.3	Shift Tables of Clinical Laboratory Test Results - Hematology (Safety Analysis Set) Shift Tables of Clinical Laboratory Test Results - Urinalysis 1 (Safety Analysis Set)
CT-10.2.3 CT-10.2.4	Shift Tables of Clinical Laboratory Test Results - Urinalysis? (Safety Analysis Set) Shift Tables of Clinical Laboratory Test Results - Urinalysis? (Safety Analysis Set)
CT-10.2.4 CT-10.2.5	Shift Tables of Clinical Laboratory Test Results - Prolactin, by Gender (Safety
C1-10.2.3	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 (Safety
CT 10.00	Analysis Set)
CT-10.3.2	Listing of Laboratory Test Values With Potential Clinical Relevance by Subject
CT-10.4.1	(Safety Analysis Set) Incidence of Potential Hy's Law Cases (Safety Analysis Set)
CT-10.4.2	Listing of Potential Hy's Law Cases (Safety Analysis Set)
CT-10.5.1	Incidence of Laboratory Test Values With Potential Clinical Relevance - Prolactin
	(Safety Analysis Set)
CT-10.5.2	Listing of Laboratory Test Values With Potential Clinical Relevance - Prolactin
CT 10.61	(Safety Analysis Set)
CT-10.6.1	Incidence of Treatment-emergent Significant Change in Lipids (Safety Analysis Set)
CT-10.6.2	Listing of Treatment-emergent Significant Change in Lipids (Safety Analysis Set)
CT-10.7.1	Incidence of Treatment-emergent Significant Change in Glucose (Safety Analysis
01 101/11	Set)
CT-10.7.2	Listing of Treatment-emergent Significant Change in Glucose (Safety Analysis Set)
CT-11.1	Mean Change From Baseline in Vital Signs (Safety Analysis Set)
CT-11.2	Incidence of Potentially Clinically Relevant Abnormalities in Vital Signs (Safety
OT 11.2	Analysis Set)
CT-11.3	Listing of Potentially Clinically Relevant Abnormalities in Vital Signs (Safety
CT-11.4	Analysis Set) Summary of Mean Change From Baseline to Double Blind Treatment Period by
	Study Week in Body Weight (kg) (Safety Analysis Set)

CT-11.5	Summary of Mean Change From Baseline to Double Blind Treatment Period by
CT-11.6	Study Week in BMI (kg/m^2) (Safety Analysis Set) Incidence of Potentially Clinically Relevant Weight Gain or Loss by Baseline BMI
	(Safety Analysis Set)
CT-12.1	Mean Change From Baseline in ECG Results (Safety Analysis Set)
CT-12.2	Shift Tables of ECG (Safety Analysis Set)
CT-12.3	Incidence of Categorical Increases in QT Evaluations (Safety Analysis Set)
CT-12.4	Incidence of Potentially Clinically Relevant Abnormalities in ECG
	Evaluations (Safety Analysis Set)
CT-12.5	Listing of Potentially Clinically Relevant Abnormalities in ECG Evaluations (Safety
	Analysis Set)
CT-13.1	Summary of Mean Change From Baseline to Double Blind Treatment Period by
CIT. 12.2	Study Week in DIEPSS (Safety Analysis Set)
CT-13.2	Summary of Mean Change From Baseline to Double Blind Treatment Period by
CT-13.3	Study Week in AIMS Total Score and Item Scores 8, 9 and 10 (Safety Analysis Set) Summary of Mean Change From Baseline to Double Blind Treatment Period by
C1-13.3	Study Week in BARS, Global Clinical Assessment of Akathisia (Safety Analysis
	Set)
CT-14.1	Summary of Mean Change From Baseline to Double Blind Treatment Period by
	Study Week in Sheehan-STS Score (Safety Analysis Set)
CT-14.2	Summary of Mean Change From Baseline to Double Blind Treatment Period by
	Study Week in Sheehan-STS - Total Score (Safety Analysis Set)
CT-14.3	Summary of Mean Change From Baseline to Double Blind Treatment Period by
	Study Week in Sheehan-STS - Suicidal Ideation Subscale Score (Safety Analysis
OT 14.4	Set)
CT-14.4	Summary of Mean Change From Baseline to Double Blind Treatment Period by
	Study Week in Sheehan-STS - Suicidal Behavior Subscale Score (Safety Analysis Set)
CT-15.1	Summary of Mean Change From Baseline to Double Blind Treatment Period by
01 13.1	Study Week in ADCS-ADL Total Score (Safety Analysis Set)
CT-15.2	Summary of Mean Change From Baseline to Double Blind Treatment Period by
	Study Week in MMSE Total Score (Safety Analysis Set)
CT-15.3.1	Summary of Mean Change From Baseline to Double Blind Treatment Period by
	Study Week in EQ-5D-5L - Proxy Version (Safety Analysis Set)
CT-15.3.2	Summary of Mean Change From Baseline to Double Blind Treatment Period by
DIZT 1	Study Week in EQ-5D-5L (Safety Analysis Set) Individual Subject and Summary of Brexpiprazole Plasma Concentrations Following
PKT-1	, , , , , , , , , , , , , , , , , , , ,
PKT-2	1 mg/day Doses of Brexpiprazole at Week 10 (Pharmacokinetic Analysis Set) Individual Subject and Summary of Brexpiprazole Plasma Concentrations Following
1 K1 2	2 mg/day Doses of Brexpiprazole at Week 10 (Pharmacokinetic Analysis Set)
PKT-3	Summary of Brexpiprazole Plasma Concentrations for Each CYP2D6 Phenotype
	Following 1 mg/day Doses of Brexpiprazole at Week 10 (Pharmacokinetic Analysis
	Set)
PKT-4	Summary of Brexpiprazole Plasma Concentrations for Each CYP2D6 Phenotype
	Following 2 mg/day Doses of Brexpiprazole at Week 10 (Pharmacokinetic Analysis
DIZE 1	Set)
PKF-1	Mean (SD) and Scatter Plots of Brexpiprazole Plasma Concentrations Following 1
PKF-2	mg/day Doses of Brexpiprazole at Week 10 (Pharmacokinetic Analysis Set) Mean (SD) and Scatter Plots of Brexpiprazole Plasma Concentrations Following 2
1 IXI -2	mg/day Doses of Brexpiprazole at Week 10 (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 10
	(Pharmacokinetic Analysis Set)

Protocol 331-102-00088

ch
)
ses of
ses of
otype
nalysis
•
otype
nalysis
•
<u></u>

Appendix 6	List of Subject Data Listings
AE-1	Adverse Events (Randomized Subjects)
DEMOG-1	Demographic Characteristics (Randomized Subjects)
DREAS-1	Discontinued Subjects and Reason for Discontinuation (Randomized Subjects)
LAB-1	Laboratory Test Results: Serum Chemistry (Randomized Subjects)
LAB-2	Laboratory Test Results: Hematology (Randomized Subjects)
LAB-3	Laboratory Test Results: Urinalysis (Randomized Subjects)
LAB-4	Laboratory Test Results: Other Laboratory Tests (Randomized Subjects)
LAB-5	Pregnancy Test (Randomized Subjects)
EFF-1	Cohen-Mansfield Agitation Inventory (CMAI) (Randomized Subjects)
EFF-2	Clinical Global Impression - Severity of Illness (CGI-S) (Randomized Subjects)
EFF-3	Clinical Global Impression - Improvement (CGI-I) (Randomized Subjects)
EFF-4	
EFF-5	
PDATA-1.1	Inclusion and Exclusion Criteria (Randomized Subjects)
PDATA-1.2	Inclusion and Exclusion Criteria (Screening Failure)
PDATA-2	Subject Randomization List (Randomized Subjects)
PDATA-3	Study Completion Status and Reasons for Discontinuation (Randomized Subjects)
PDATA-4	Medical History (Randomized Subjects)
PDATA-5	Alzheimer's Disease History (Randomized Subjects)
PDATA-6	Patient Care (Randomized Subjects)
PDATA-7.1	Prior and Concomitant Medications (Antipsychotic) (Randomized Subjects)
PDATA-7.2	Prior and Concomitant Medications (Antidementia Drug) (Randomized Subjects)
PDATA-7.3	Prior and Concomitant Medications (Other) (Randomized Subjects)
PDATA-7.4	Prior and Concomitant Therapy (Randomized Subjects)
PDATA-8	Physical Examination (Randomized Subjects)
PDATA-9	Vital Signs (Randomized Subjects)
PDATA-10	Electrocardiogram Results (Randomized Subjects)
PDATA-11.1	Sheehan-Suicidality Tracking Scale (S-STS) - Other than Q15 and Q16 (Randomized Subjects)
PDATA-11.2	Sheehan-Suicidality Tracking Scale (S-STS) - Q15 (Randomized Subjects)
PDATA-11.3	Sheehan-Suicidality Tracking Scale (S-STS) - Q16 (Randomized Subjects)
PDATA-12	Drug-Induced Extrapyramidal Symptoms Scale (DIEPSS) (Randomized Subjects)
PDATA-13	Barnes Akathisia Rating Scale (BARS) (Randomized Subjects)
PDATA-14	Abnormal Involuntary Movement Scale (AIMS) (Randomized Subjects)
PDATA-15	Mini-Mental State Examination (MMSE) (Randomized Subjects)
PDATA-16	Alzheimer's Disease Cooperative Study - Activities of Daily Living (ADCS-ADL) (Randomized Subjects)
PDATA-17	EuroQol 5 Dimension 5 Level Health Questionnaire (EQ-5D-5L) - Proxy Version (Randomized Subjects)
PDATA-18	EuroQol 5 Dimension 5 Level Health Questionnaire (EQ-5D-5L) (Randomized Subjects)
PDATA-19	Pharmacokinetic Blood Draw Time (Randomized Subjects)
PDATA-20	CYP2D6 Genetic Test (Randomized Subjects)
PDATA-21	Blood Draw Time for DNA Storage and Biomar ker (Randomized Subjects)
PDATA-22	Post-treatment Follow-up (Randomized Subjects)
PDATA-23	Screening Failures
PDEV-1	Major Protocol Deviations by Type of Deviation (Randomized Subjects)

Protocol 331-102-00088

SMED-1	Study Medication Administration (Randomized Subjects)
SMED-2	Study Medication Compliance (Randomized Subjects)
SUBEX-1	Subjects Excluded From Analysis Set (Randomized Subjects)

Version: 1.0 Date: 01/06/2023