

Cover Page for Statistical Analysis Plan

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Official title of study:	Efficacy and Safety of Semaglutide 2.0 mg s.c. Once-weekly Compared to Semaglutide 1.0 mg s.c. Once-weekly in Subjects With Type 2 Diabetes
Document date*:	15 December 2020

*Document date refers to the date on which the document was most recently updated.

Note: The date in the header from Page 2 is the date of compilation of the documents and not of an update to content.

16.1.9 Documentation of statistical methods

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*Redacted statistical analysis plan
Includes redaction of personal identifiable information only.*

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Version history

This Statistical Analysis Plan (SAP) for trial NN9535-4506 is based on the protocol version 4.0 dated 15JUN2020.

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1 Introduction

This SAP covers specification of statistical considerations and analyses for efficacy data and safety data available at time of partial data base lock performed after the date of last subject last treatment, where Novo Nordisk will become unblinded and complete efficacy data will be available and analysed, but where safety data will only be partial complete.

Only additional statistical analyses have been included, hence there are no changes to protocol specified statistical analyses.

1.1 Objectives and endpoints

1.1.1 Primary objective

To establish the superior effect of semaglutide s.c. 2.0 mg once-weekly versus semaglutide s.c. 1.0 mg once-weekly on glycaemic control in subjects with T2D, on a background of metformin with or without SU treatment.

1.1.2 Secondary objective

To compare the effect of semaglutide s.c. 2.0 mg once-weekly versus semaglutide s.c. 1.0 mg once-weekly in subjects with T2D, on a background of metformin with or without SU treatment, on:

- Body weight
- Vital signs
- Hypoglycaemia
- General safety and tolerability

1.1.3 Primary endpoint

- Change from baseline (week 0) to week 40 in HbA_{1c} (%-point)

1.1.4 Secondary endpoints

1.1.4.1 Confirmatory secondary endpoint

- Change from baseline (week 0) to week 40 in body weight (kg)

1.1.4.2 Supportive secondary endpoints

Supportive secondary effect endpoints

Change from baseline (week 0) to week 40 in:

- Fasting plasma glucose (FPG) (mmol/l)
- Body mass index (BMI) (kg/m²)
- Waist circumference (cm)

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- $HbA_{1c} < 7\%$ at week 40 (yes/no)
- $HbA_{1c} \leq 6.5\%$ at week 40 (yes/no)
- Weight loss $\geq 5\%$ at week 40 (yes/no)
- Weight loss $\geq 10\%$ at week 40 (yes/no)

Supportive secondary safety endpoints

- Number of treatment emergent severe or blood glucose confirmed symptomatic hypoglycaemic episodes from first dose to week 40
- Change from baseline (week 0) to week 40 in pulse rate (bpm)

Table 1 Overview of estimands

Objective	Estimand strategy	Estimand category	Estimand
<p>Primary Objective:</p> <p>To establish the superior effect of semaglutide s.c. 2.0 mg once-weekly versus semaglutide s.c. 1.0 mg once-weekly on glycaemic control in subjects with T2D, on a background of metformin with or without SU treatment</p>	Hypothetical	Primary (except US)	<p>Treatment condition: 2.0 mg semaglutide s.c. once-weekly or 1.0 mg semaglutide s.c. once-weekly</p> <p>Variable/Endpoint: Change from baseline to week 40 in HbA_{1c}</p> <p>Population of interest: All randomised</p> <p>Intercurrent event strategy: Initiation of rescue medication: “had rescue medication not been available” (hypothetical). Discontinuation of trial product before week 40: “had patients adhered to treatment” (hypothetical). Change in dose during and after dose escalation: “regardless of change in dose” (treatment policy).</p> <p>Population level summary measure: Mean difference</p>
		Secondary*	<p>Treatment condition: 2.0 mg semaglutide s.c. once-weekly or 1.0 mg semaglutide s.c. once-weekly</p> <p>Variable/Endpoint: Change from baseline to week 40 in FPG</p> <p>Population of interest: All randomised</p> <p>Intercurrent event strategy: Initiation of rescue medication: “had rescue medication not been available” (hypothetical). Discontinuation of trial product before week 40: “had patients adhered to treatment” (hypothetical). Change in dose during and after dose escalation: “regardless of change in dose” (treatment policy).</p> <p>Population level summary measure: Mean difference</p>

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Objective	Estimand strategy	Estimand category	Estimand
		Secondary*	<p>Treatment condition: 2.0 mg semaglutide s.c. once-weekly or 1.0 mg semaglutide s.c. once-weekly</p> <p>Variable/Endpoint: $HbA_{1c} < 7\%$ at week 40</p> <p>Population of interest: All randomised</p> <p>Intercurrent event strategy: Initiation of rescue medication: “had rescue medication not been available” (hypothetical). Discontinuation of trial product before week 40: “had patients adhered to treatment” (hypothetical). Change in dose during and after dose escalation: “regardless of change in dose” (treatment policy).</p> <p>Population level summary measure: Odds ratio</p>
		Secondary*	<p>Treatment condition: 2.0 mg semaglutide s.c. once-weekly or 1.0 mg semaglutide s.c. once-weekly</p> <p>Variable/Endpoint: $HbA_{1c} \leq 6.5\%$ at week 40</p> <p>Population of interest: All randomised</p> <p>Intercurrent event strategy: Initiation of rescue medication: “had rescue medication not been available” (hypothetical). Discontinuation of trial product before week 40: “had patients adhered to treatment” (hypothetical). Change in dose during and after dose escalation: “regardless of change in dose” (treatment policy).</p> <p>Population level summary measure: Odds ratio</p>

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Objective	Estimand strategy	Estimand category	Estimand
	Treatment policy	Primary (US)	<p>Treatment condition: 2.0 mg semaglutide s.c. once-weekly or 1.0 mg semaglutide s.c. once-weekly</p> <p>Variable/Endpoint: Change from baseline to week 40 in HbA_{1c}</p> <p>Population of interest: All randomised</p> <p>Intercurrent event strategy: Initiation of rescue medication: “regardless of initiation of rescue medication” (treatment policy). Discontinuation of trial product due to adverse event: “regardless of trial product discontinuation due to adverse event” (treatment policy). Change in dose during and after dose escalation: “regardless of change in dose” (treatment policy).</p> <p>Population level summary measure: Mean difference</p>
<p>Secondary Objective:</p> <p>To compare the effect of semaglutide s.c. 2.0 mg once-weekly versus semaglutide s.c. 1.0 mg once-weekly in subjects with T2D, on a background of metformin with or without SU treatment, on body weight, vital signs, hypoglycaemia, general safety and tolerability</p>	Hypothetical	Secondary (except US)	<p>Treatment condition: 2.0 mg semaglutide s.c. once-weekly or 1.0 mg semaglutide s.c. once-weekly</p> <p>Variable/Endpoint: Change from baseline to week 40 in body weight</p> <p>Population of interest: All randomised</p> <p>Intercurrent event strategy: Initiation of rescue medication: “had rescue medication not been available” (hypothetical). Discontinuation of trial product before week 40: “had patients adhered to treatment” (hypothetical). Change in dose during and after dose escalation: “regardless of change in dose” (treatment policy).</p> <p>Population level summary measure: Mean difference</p>

Objective	Estimand strategy	Estimand category	Estimand
		Secondary*	<p>Treatment condition: 2.0 mg semaglutide s.c. once-weekly or 1.0 mg semaglutide s.c. once-weekly</p> <p>Variable/Endpoint: Change from baseline to week 40 in BMI</p> <p>Population of interest: All randomised</p> <p>Intercurrent event strategy: Initiation of rescue medication: “had rescue medication not been available” (hypothetical). Discontinuation of trial product before week 40: “had patients adhered to treatment” (hypothetical). Change in dose during and after dose escalation: “regardless of change in dose” (treatment policy).</p> <p>Population level summary measure: Mean difference</p>
		Secondary*	<p>Treatment condition: 2.0 mg semaglutide s.c. once-weekly or 1.0 mg semaglutide s.c. once-weekly</p> <p>Variable/Endpoint: Change from baseline to week 40 in waist circumference</p> <p>Population of interest: All randomised</p> <p>Intercurrent event strategy: Initiation of rescue medication: “had rescue medication not been available” (hypothetical). Discontinuation of trial product before week 40: “had patients adhered to treatment” (hypothetical). Change in dose during and after dose escalation: “regardless of change in dose” (treatment policy).</p> <p>Population level summary measure: Mean difference</p>

Objective	Estimand strategy	Estimand category	Estimand
		Secondary*	<p>Treatment condition: 2.0 mg semaglutide s.c. once-weekly or 1.0 mg semaglutide s.c. once-weekly</p> <p>Variable/Endpoint: Body weight loss $\geq 5\%$ at week 40</p> <p>Population of interest: All randomised</p> <p>Intercurrent event strategy: Initiation of rescue medication: “had rescue medication not been available” (hypothetical). Discontinuation of trial product before week 40: “had patients adhered to treatment” (hypothetical). Change in dose during and after dose escalation: “regardless of change in dose” (treatment policy).</p> <p>Population level summary measure: Odds ratio</p>
		Secondary*	<p>Treatment condition: 2.0 mg semaglutide s.c. once-weekly or 1.0 mg semaglutide s.c. once-weekly</p> <p>Variable/Endpoint: Body weight loss $\geq 10\%$ at week 40</p> <p>Population of interest: All randomised</p> <p>Intercurrent event strategy: Initiation of rescue medication: “had rescue medication not been available” (hypothetical). Discontinuation of trial product before week 40: “had patients adhered to treatment” (hypothetical). Change in dose during and after dose escalation: “regardless of change in dose” (treatment policy).</p> <p>Population level summary measure: Odds ratio</p>

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Objective	Estimand strategy	Estimand category	Estimand
	Treatment policy	Secondary (US)	<p>Treatment condition: 2.0 mg semaglutide s.c. once-weekly or 1.0 mg semaglutide s.c. once-weekly</p> <p>Variable/Endpoint: Change from baseline to week 40 in body weight</p> <p>Population of interest: All randomised</p> <p>Intercurrent event strategy: Initiation of rescue medication: “regardless of initiation of rescue medication” (treatment policy). Discontinuation of trial product due to adverse event: “regardless of trial product discontinuation due to adverse event” (treatment policy). Change in dose during and after dose escalation: “regardless of change in dose” (treatment policy).</p> <p>Population level summary measure: Mean difference</p>

The hypothetical estimand will be considered the primary estimand except in the US, where FDA specifically has requested the treatment policy estimand to be the primary.

*Not related to any confirmatory hypothesis

1.2 Trial design

See protocol section 5.

2 Statistical hypotheses

The statistical testing strategy will be performed for the primary analysis of each of the two estimand strategies separately. I.e. statistical testing will be performed separately for the hypothetical strategy and the treatment policy strategy. In order to preserve the overall type-I error in the strong sense at a 5% significance level (two-sided) within each estimand strategy, the conclusion of superiority of semaglutide 2.0 mg versus semaglutide 1.0 mg will be evaluated hierarchically according to the sequence below. The treatment difference is defined as $\mu =$ (semaglutide 2.0 mg minus semaglutide 1.0 mg).

1. Superiority of semaglutide 2.0 mg versus semaglutide 1.0 mg on change from baseline to week 40 in HbA_{1c}
 - $H_0: \mu \geq 0.0$ %-point against $H_a: \mu < 0.0$ %-point
2. Superiority of semaglutide 2.0 mg vs. semaglutide 1.0 mg on change from baseline to week 40 in body weight
 - $H_0: \mu \geq 0.0$ kg against $H_a: \mu < 0.0$ kg

3 Sample size determination

The primary endpoint is change from baseline (week 0) to week 40 in HbA_{1c} (%-point) and the confirmatory secondary endpoint is change from baseline (week 0) to week 40 in body weight (kg). Both endpoints will be tested for superiority. The type-I error rate will be controlled in the strong sense across the primary and the confirmatory secondary hypotheses, separately for each estimand, at an overall alpha level (two-sided) of 0.05. Multiplicity control and criteria for confirming the hypotheses is described in section [2](#).

The sample size calculation is performed to ensure sufficient power for confirming superiority of semaglutide 2.0 mg vs. semaglutide 1.0 mg on change from baseline to week 40 in HbA_{1c} (%-point) based on each estimand separately.

Primary endpoint

An on-treatment HbA_{1c} treatment effect of -0.26%-point was predicted based on exposure-response modelling.

To accommodate the treatment policy estimand, the on-treatment effect is adjusted by 15% based on results from the SUSTAIN phase 3a programme, where a lower effect was observed for the treatment policy estimand as compared to the on-treatment effect. With the adjusted HbA_{1c} treatment effect of -0.22%-point and a standard deviation of 1.1%-point, 964 subjects will be randomised in order to obtain 87% power for confirming superiority for the primary endpoint based on the treatment policy estimand and at least 87% power for confirming superiority for the primary

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endpoint based on the hypothetical estimand. This is based on a 1:1 randomisation, a two-sided significance level of 0.05, and a t-test. The assumed standard deviation is based on the SUSTAIN programme.

Confirmatory secondary endpoint

With 964 subjects randomised to ensure sufficient power (87%) for confirming superiority for the primary endpoint based on the treatment policy estimand, a marginal power of 90% for confirming that semaglutide 2.0 mg is superior to semaglutide 1.0 mg on change from baseline to week 40 in body weight (based on each estimand) is obtained if the true treatment difference is as low as - 0.84 kg. This is based on a 1:1 randomisation, a two-sided significance level of 0.05, a t-test, and a standard deviation of 4.0 kg. The assumed standard deviation is based on the SUSTAIN programme.

Sensitivity analyses for the sample size calculation

The sensitivity of power for confirming superiority for the primary endpoint based on the treatment policy estimand for a fixed sample size of 964 subjects is presented in [Table 2](#).

Table 2 Power for different scenarios

Scenario	On-treatment effect	Adjusted for the treatment policy estimand	Adjusted treatment effect	Randomised subjects	Power
Scenario 1	-0.25 %-point	15 %	-0.21	964	84 %
Scenario 2	-0.25 %-point	20 %	-0.20	964	81 %
Scenario 3	-0.27 %-point	15 %	-0.23	964	90 %
Scenario 4	-0.27 %-point	20 %	-0.22	964	87%
Scenario 5	-0.29 %-point	15 %	-0.25	964	94 %
Scenario 6	-0.29 %-point	20 %	-0.23	964	90 %

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4 Analysis sets

Data selection for statistical analyses will be a two-step process, first selecting subjects based on the analysis population and subsequently events/data for those subjects based on the observation period.

Full analysis set (FAS): All randomised subjects. Subjects will be analysed according to the treatment to which they were assigned at randomisation.

Safety analysis set (SAS): All subjects exposed to at least one dose of trial product. Subjects will be analysed according to the trial product received for the majority of the period they were on treatment.

'In-trial' observation period: This observation period is defined as the period from the date of randomisation to the first of the following dates, both inclusive:

- The follow-up visit (P11)
- Date of death
- Date when subject withdrew informed consent
- Date of last contact for subjects lost to follow-up

'On-treatment' observation period: This observation period is a sub-set of the 'in-trial' observation period and represents the time period where subjects are considered exposed to trial product. The observation period starts at the date of first dose of trial product and ends at an endpoint-specific end-date. For adverse events including hypoglycaemic events, the observation period ends at the first date of any of the following:

- The follow-up visit (P11)
- The treatment discontinuation follow-up visit (P11A)
- The date of last dose of trial product +49 days
- The end-date for the 'in-trial' observation period

The follow-up visit is scheduled to take place 7 weeks after the last date on trial product, i.e., 49 days.

For efficacy and other safety assessments (laboratory assessments, body measurements, and vital signs) the 'on-treatment' observation period ends at the last date on trial product with a visit window of +14 days. Hence, for these assessments, the 'on-treatment' observation period reflects the period in which subjects are treated.

'On-treatment without rescue medication' observation period: This observation period is a sub-set of the 'on-treatment' observation period and represents the time period where subjects are considered treated with trial product but have not initiated any rescue medications. The observation period starts at the date of first dose of trial product and ends at the first date of any of the following:

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- Initiation of rescue medication
- The date of last dose of trial product +14 days

Data points collected outside an observation period will be treated as missing in the analysis. Baseline data will always be included in an observation period.

Rescue medication is defined as any new anti-diabetic medication and/or intensification of anti-diabetic medication initiated at or after date of randomisation and before last date on trial product.

The following rules will be applied based on the concomitant medication data reported by the investigator, to determine whether or not the recorded anti-diabetic medication is 1. *New anti-diabetic medication* or 2. *Intensification of anti-diabetic medication*

New anti-diabetic medication: Anti-diabetic medication (4th-level ATC code) that is initiated after randomisation and is new compared to the anti-diabetic background medication at randomisation and with a dosing duration of more than 21 days.

Intensification of anti-diabetic medication: A more than 20% increase in the dose of anti-diabetic medication after randomisation as compared to the anti-diabetic medication dose at randomisation (5th-level ATC code not changed) and with a dosing duration of more than 21 days.

Before data are locked for statistical analysis, a review of all data will take place. In general subjects should not be excluded from an analysis set and observations should not be excluded from an observation period, if they fulfil the criteria. If subjects or observations are excluded, the reasons for their exclusion must be documented before database lock and described in the clinical trial report. Any decision to exclude either a subject or single observation from the statistical analysis is the joint responsibility of the members of the Novo Nordisk study group.

5 Statistical analyses

5.1 General considerations

The comparison presented from a statistical analysis will be semaglutide 2.0 mg versus semaglutide 1.0 mg and results will be presented by the estimated treatment contrast with associated two-sided 95% confidence intervals and *p*-values corresponding to two-sided tests of no difference if not otherwise specified.

Data from all sites will be analysed and reported together.

If no statistical analysis is specified, data will be presented using relevant summary statistics. Accordingly, adverse events will be summarised descriptively. Data collected before randomisation (V2) will only be summarised descriptively.

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A partial database lock will be performed at the end of the treatment period for all subjects, i.e. after the date of the last patient last treatment (LPLT) visit. The database will be updated after the partial database lock to include remaining PK data and any additional safety information. The full database lock will be performed after the date of the last patient last visit (LPLV).

Novo Nordisk will become unblinded at the time of the partial database lock, whereas subjects and investigators will remain blinded until after last patient last visit (LPLV). The analysis of the primary endpoint and all other efficacy endpoints will be performed based on the data from the partial database lock. Analysis of safety and PK data will be performed after the full database lock. This approach is implemented to allow earlier availability of semaglutide 2 mg to the patient population expected to benefit from a higher dose and to support further development activities with semaglutide s.c. A detailed plan for data handling and operational aspects of the partial database lock and the database update will be finalised before the partial database lock.

5.2 Subject disposition

See mock TFLs.

5.3 Primary endpoint analysis

5.3.1 Main analytical approach

5.3.1.1 Primary hypothetical estimand

The primary (except US) hypothetical estimand, see [Table 1](#), will be estimated based on FAS using post-baseline data collected up to and including week 40 from the ‘on-treatment without rescue medication’ observation period.

Imputation of missing data will be handled by multiple imputation (MI) assuming that missing data are missing at random (MAR). The imputation will be performed separately within each treatment group defined by randomised treatment. First, intermittent missing values are imputed using a Markov Chain Monte Carlo (MCMC) method, to obtain a monotone missing data pattern, generating 500 complete data sets. Secondly, a sequential conditional linear regression approach for imputing monotone missing values will be implemented starting with the first visit after baseline and sequentially continuing to the last planned visit at week 40. The model used for imputation will include the baseline and post-baseline HbA_{1c} values observed prior to the visit in question as covariates.

The 500 complete datasets will be analysed using an analysis of covariance (ANCOVA) with treatment and stratification as fixed factors and the baseline HbA_{1c} as covariate. Rubin’s rule¹ will be applied to obtain inference.

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5.3.1.2 Primary treatment policy estimand

The primary (US) treatment policy estimand, see [Table 1](#), will be estimated based on the FAS using week 40 data from the ‘in-trial’ observation period.

Imputation of missing data will be handled by MI assuming that missing data are missing at random. The imputation will be performed by imputing missing week 40 data separately within groups defined by randomised treatment and treatment status at week 40 (retrieved drop-out), in total, four groups as follows; (i) semaglutide 1.0 mg and on-treatment at week 40, (ii) semaglutide 1.0 mg and off-treatment at week 40, (iii) semaglutide 2.0 mg and on-treatment at week 40, (iv) semaglutide 2.0 mg and off-treatment at week 40.

For each of the four groups an ANCOVA with baseline HbA_{1c} as covariate will be fitted to observed values of the change from baseline in HbA_{1c} at week 40. The estimated parameters for location and dispersion will then be used to impute 500 values for each subject with missing week 40 data based on only baseline HbA_{1c}.

The 500 complete datasets will be analysed using an analysis of covariance (ANCOVA) with treatment and stratification as fixed factors and the baseline HbA_{1c} as covariate. Rubin’s rule¹ will be applied to obtain inference.

5.3.2 Sensitivity analyses

5.3.2.1 Primary hypothetical estimand

A tipping point sensitivity analysis will be performed for the primary (except US) hypothetical estimand, by repeating the ANCOVA described in section [5.3.1.1](#), however, prior to analysis subjects from the semaglutide 2.0 mg group with missing observations at week 40 will be given a penalty, i.e., it is assumed that subjects with missing observations who are randomised to semaglutide 2.0 mg will receive a treatment that is less beneficial than subjects with observed values who are randomised to semaglutide 2.0 mg. The addition of the penalty values and subsequent analysis steps should be repeated with increasing penalty values until a significant result in the corresponding superiority analysis is no longer significant. This analysis will only be performed if superiority is confirmed based on the primary analysis.

5.3.2.2 Primary treatment policy estimand

A tipping point sensitivity analysis for the primary (US) treatment policy estimand will be performed by repeating the ANCOVA described in section [5.3.1.2](#), however, prior to analysis subjects from the semaglutide 2.0 mg group with missing observations at week 40 will be given a penalty. The addition of the penalty values and subsequent analysis steps should be repeated with increasing penalty values until a significant result in the corresponding superiority analysis is no longer significant. This analysis will only be performed if superiority is confirmed based on the primary analysis.

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In addition, a two-way tipping point sensitivity analysis will be conducted as this may be a more reflective of a real-world situation for missing data from both treatment arms. The ANCOVA described in section 5.3.1.2 is repeated, however prior to analysis penalties of opposite sign are added to the imputed values at week 40 in both treatment arms simultaneously. The approach is to explore a range of penalties for both treatment groups, and the impact these would have on the study conclusions. This sensitivity analysis evaluates the robustness of the superiority conclusions to departures from the imputed change in HbA_{1c} in both treatment groups. The analysis will only be performed if superiority is confirmed based on the primary analysis.

Let $(\Delta_{2.0\text{mg}}, \Delta_{1.0\text{mg}})$ denote a pair of penalties to (semaglutide 2.0 mg, semaglutide 1.0 mg). Then, for a given superiority hypothesis that is confirmed, denote the corresponding ‘one-way’ tipping points with $(\Delta_{2.0\text{mg}}^1, 0)$ for semaglutide 2.0 mg and $(0, \Delta_{1.0\text{mg}}^1)$ for semaglutide 1.0 mg. It follows that the domain of penalties in a ‘two-way’ tipping point analysis should include a grid over $(0, 0)$ to $(\Delta_{2.0\text{mg}}^1, \Delta_{1.0\text{mg}}^1)$.

The analyses are presented as contour plots for the test probability (p -value) of superiority as a function of the penalties $(\Delta_{2.0\text{mg}}, \Delta_{1.0\text{mg}})$. In this representation the contour line corresponding to 0.05 will partition the grid of penalties into two regions: a region where superiority of semaglutide 2.0 mg is confirmed at a 5% significance level and a region where superiority is no longer confirmed.

5.3.3 Overview of statistical analyses and intercurrent events

An overview of all analyses addressing the two primary estimands for the confirmatory endpoints is provided in [Table 3](#).

Table 3 Statistical analyses of the confirmatory endpoints

Endpoint	Estimand	Analysis set	Observation period	Statistical model	Imputation approach	Sensitivity analysis
Primary endpoint						
Change in HbA _{1c} (%-point)	Hypothetical	FAS	On-treatment w/o rescue	ANCOVA	MAR within randomised treatment group	Tipping point analysis
	Treatment policy	FAS	In-trial	ANCOVA	MAR within group defined by randomised treatment and treatment status at week 40	One-way and two-way tipping point analyses
Confirmatory secondary endpoint						
Change in body weight (kg)	Hypothetical	FAS	On-treatment w/o rescue	ANCOVA	MAR within randomised treatment group	Tipping point analysis
	Treatment policy	FAS	In-trial	ANCOVA	MAR within group defined by randomised treatment and treatment status at week 40	One-way and two-way tipping point analyses

Abbreviations: ANCOVA; analysis of covariance; FAS: full analysis set; MAR: missing at random.

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The following [Table 4](#) describes how anticipated intercurrent events during the trial are handled for confirmatory endpoints. The different intercurrent events will be handled in the same manner for both confirmatory endpoints.

Table 4 Statistical handling of intercurrent events for the primary analyses of the confirmatory endpoints

Intercurrent event	Handling			
	Hypothetical estimand		Treatment policy estimand	
	Strategy	Data	Strategy	Data
<ul style="list-style-type: none"> Change in dose during and after the dose escalation period 	Treatment policy	Assessments will be performed and collected at scheduled visits after the intercurrent event and used in the analysis	Treatment policy	Assessments will be performed and collected at scheduled visits after the intercurrent event and used in the analysis
<ul style="list-style-type: none"> Treatment discontinuation due to AEs Initiation of rescue (anti-diabetic) medication 	Hypothetical	Assessments for scheduled visits after the time of the intercurrent event are considered missing and will be imputed assuming MAR as described in the analysis	Treatment policy	Assessments will be performed and collected at scheduled visits after the intercurrent event and used in the analysis

5.4 Secondary endpoint analysis

5.4.1 Confirmatory secondary endpoints

The confirmatory secondary endpoint is change from baseline (week 0) to week 40 in body weight (kg).

5.4.1.1 Main analytical approach

Secondary hypothetical estimand

Similar analyses as described in section [5.3.1.1](#) with body weight values instead of HbA_{1c} values will be performed.

Secondary treatment policy estimand

Similar analyses as described in section [5.3.1.2](#) with body weight values instead of HbA_{1c} values will be performed.

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5.4.1.2 Sensitivity analyses

Secondary hypothetical estimand

One-way tipping point sensitivity analysis as described in section [5.3.2.1](#) with body weight values instead of HbA_{1c} values will be performed.

Secondary treatment policy estimand

Both one-way and two-way tipping point analyses as those described in section [5.3.2.2](#) with body weight values instead of HbA_{1c} values will be performed.

5.4.2 Supportive secondary endpoints

The supportive secondary endpoints are listed in [Table 6](#) and all relevant estimands are described in [Table 1](#). A hypothetical estimand strategy will be applied for all supportive secondary endpoints.

Continuous endpoints

Analyses of change in FPG, BMI and waist circumference will be performed as described in section [5.3.1.1](#) with values for the given parameter instead of HbA_{1c} values based on FAS using data from the ‘on-treatment without rescue medication’ observation period. The analysis of change from baseline to week 40 in pulse rate will be based on SAS using data from the ‘on-treatment’ observation period, but otherwise using the same approach as described in section [5.3.1.1](#).

Responder endpoints

To account for missing data, the binary endpoints will be derived from the 500 imputed datasets described in section [5.3.1.1](#). Each of the complete data sets will be analysed using a logistic regression (LR) model with treatment and stratification as fixed effects and associated baseline response as covariate. Estimated odds ratios will be log-transformed and inference will be drawn using Rubin’s rule¹. The results will be back-transformed and described by the odds ratio between treatments and the associated 95% CI and p-value for no treatment difference.

Overview of statistical analyses

An overview of all analyses of the supportive secondary endpoints is provided in [Table 5](#).

Table 5 Statistical analyses of the supportive secondary endpoints

Endpoint	Estimand	Analysis set	Observation period	Statistical model	Imputation approach
Supportive secondary endpoints (effect related)					
Change in FPG (mmol/)	Hypothetical	FAS	On-treatment w/o rescue	ANCOVA	MAR within randomised treatment group
Change in BMI (kg/m ²)	Hypothetical	FAS	On-treatment w/o rescue	ANCOVA	MAR within randomised treatment group

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Endpoint	Estimand	Analysis set	Observation period	Statistical model	Imputation approach
Change in waist circumference (cm)	Hypothetical	FAS	On-treatment w/o rescue	ANCOVA	MAR within randomised treatment group
HbA _{1c} < 7% (yes/no)	Hypothetical	FAS	On-treatment w/o rescue	LR	MAR within randomised treatment group
HbA _{1c} ≤ 6.5% (yes/no)	Hypothetical	FAS	On-treatment w/o rescue	LR	MAR within randomised treatment group
Weight loss ≥ 5% (yes/no)	Hypothetical	FAS	On-treatment w/o rescue	LR	MAR within randomised treatment group
Weight loss ≥ 10% (yes/no)	Hypothetical	FAS	On-treatment w/o rescue	LR	MAR within randomised treatment group
Supportive secondary endpoints (safety related)					
Change in pulse (bpm)	-	SAS	On-treatment	ANCOVA	MAR within randomised treatment group
Number of hypoglycaemic episodes	-	SAS	On-treatment	NBR	-

Abbreviations: ANCOVA; analysis of covariance; FAS: full analysis set; LR: logistic regression; MAR: missing at random; NBR: negative binomial regression; SAS: safety analysis set

5.5 Exploratory endpoint analysis

Not applicable.

5.6 Other safety analyses

Number of treatment emergent severe or blood glucose confirmed symptomatic hypoglycaemic episodes at week 40 will be analysed using a negative binomial regression (NBR) model with a log-link function and the logarithm of the time period covered by the subject's 'on-treatment' observation period as offset. The model will include treatment and stratification as fixed factors and baseline HbA_{1c} as a covariate. This analysis will be based on the SAS using the 'on-treatment' observation period. The results will be described by the rate ratio between treatments and the associated 95% CI and *p*-value for no treatment difference.

The binary assessment indicating whether a subject has had no treatment emergent severe or blood glucose confirmed symptomatic hypoglycaemic episodes at week 40 or at least one will be analysed using a logistic regression model. The model will include treatment and stratification as fixed effects and baseline HbA_{1c} as covariate, and the analysis will be based on SAS using data from the 'on-treatment' observation period. The results will be described by the odds ratio between treatments and the associated 95% confidence interval and *p*-value for no treatment difference.

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5.7 Other analyses

Population PK modelling and exposure-response analyses may be included to support dose selection and to explore the benefits of high versus lower doses of semaglutide in subjects with T2D.

The modelling will include data from all randomised subjects that were exposed to semaglutide in this trial and might be performed as a meta-analysis including data from historical trials. Actual dose and date of administration of last dose before PK sampling will be registered in the CRF and used in the analysis, together with actual time point for PK sampling. The analysis will be further specified in a modelling analysis plan that is to be prepared before database lock.

The modelling analyses will be performed by Quantitative Clinical Pharmacology at Novo Nordisk A/S and will be reported separately from the CTR.

5.7.1 Subgroup analyses

Change from baseline to week 40 in HbA_{1c} will be analysed according to the following three subgroup splits:

- HbA_{1c} < 9% and HbA_{1c} ≥ 9% at baseline
- BMI < 30 and BMI ≥ 30 at baseline
- BMI < 35 and BMI ≥ 35 at baseline

The rationale for conducting these subgroup analyses is to generate evidence to support potential individualised treatment in clinically relevant subpopulations with high HbA_{1c} or BMI, where subjects may experience even further improvement of glycaemic control from advancing to a higher dose of semaglutide.

From each analysis the estimated treatment differences in change from baseline to week 40 in HbA_{1c} across subgroups with 95% confidence intervals will be presented.

5.7.1.1 Hypothetical strategy

The effect of randomised treatment on change from baseline to week 40 in HbA_{1c} across subgroups will be analysed based on a hypothetical estimand strategy by using the same 500 imputed and complete data sets as described in section [5.3.1.1](#). On these 500 complete data sets an ANCOVA having baseline HbA_{1c} level as covariate, treatment and stratification as well as the interaction between the relevant subgroup and treatment as fixed factors, will be applied. Rubin's rule¹ will be applied to obtain inference.

5.7.1.2 Treatment policy strategy

Addressing the effect of randomised treatment on change from baseline to week 40 in HbA_{1c} across subgroups by a treatment policy strategy the 500 imputed data described in section [5.3.1.2](#), will also

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be analysed by an ANCOVA having baseline HbA_{1c} level as covariate, treatment and stratification as well as the interaction between the relevant subgroup and treatment as fixed factors, will be applied. Rubin's rule¹ will be applied to obtain inference.

5.7.2 Subpopulation analysis

To further support individualised treatment, an analysis of change in HbA_{1c} from week 12 to week 40 will be performed in the subpopulation of all randomised subjects that are on-treatment, have not initiated rescue medication and are adherent to semaglutide 1.0 mg at week 12, having a week 12 HbA_{1c} \geq 7%.

This represents a clinically meaningful and important subpopulation of patients that are expected to particularly benefit from advancing to a higher dose of semaglutide.

Due to the trial design, where both treatment arms receive semaglutide unblinded for the first 12 weeks, subpopulation membership is arguably unrelated to treatment assignment. Accordingly, an analysis of change from week 12 to week 40 in HbA_{1c} in this subpopulation will still have the benefit of randomisation.

5.7.2.1 Hypothetical strategy

The endpoint change from week 12 to week 40 in HbA_{1c} in the subpopulation will be analysed with the hypothetical estimand strategy, see [Table 1](#) for definition of intercurrent events.

Imputation of missing data will be handled by MI assuming that missing data pattern is MAR. The imputation will be performed separately within each treatment group defined by randomised treatment. First, intermittent missing values are imputed using a Markov Chain Monte Carlo (MCMC) method, to obtain a monotone missing data pattern, generating 500 complete data sets. Secondly, a sequential conditional linear regression approach for imputing monotone missing values will be implemented starting with the first visit after week 12 and sequentially continuing to the last planned visit at week 40. The model used for imputation will include the HbA_{1c} at week 12 and post-baseline HbA_{1c} values observed prior to the visit in question as covariates.

The 500 complete datasets will be analysed using an analysis of covariance (ANCOVA) with treatment and stratification as fixed factors and HbA_{1c} at week 12 as covariate. Rubin's rule¹ will be applied to obtain inference.

5.7.2.2 Treatment policy strategy

The endpoint change from week 12 to week 40 in HbA_{1c} in the subpopulation will be analysed with the treatment policy estimand strategy, see [Table 1](#) for definition of intercurrent events.

Imputation of missing data will be handled by MI assuming that missing data pattern is MAR. The imputation will be performed by imputing missing week 40 data separately within groups defined

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by randomised treatment and treatment status at week 40 (retrieved drop-out), in total, four groups as follows; (i) semaglutide 1.0 mg and on-treatment at week 40, (ii) semaglutide 1.0 mg and off-treatment at week 40, (iii) semaglutide 2.0 mg and on-treatment at week 40, (iv) semaglutide 2.0 mg and off-treatment at week 40.

For each of the four groups an ANCOVA with HbA_{1c} at week 12 as covariate will be fitted to observed values of the change from week 12 to week 40 in HbA_{1c}. The estimated parameters for location and dispersion will then be used to impute 500 values for each subject with missing week 40 data based on only HbA_{1c} at week 12.

The 500 complete datasets will be analysed using an analysis of covariance (ANCOVA) with treatment and stratification as fixed factors and HbA_{1c} at week 12 as covariate. Rubin's rule¹ will be applied to obtain inference.

5.8 Interim analyses

Not applicable.

6 Supporting documentation

6.1 Appendix 1: List of abbreviations

AE	adverse event
ANCOVA	analysis of covariance
ATC	Anatomical Therapeutic Chemical
BMI	body mass index
bpm	beats per minute
CI	confidence interval
CRF	case report form
CTR	clinical trial report
EMA	European Medicines Agency
FAS	full analysis set
FDA	US Food and Drug Administration
FPG	fasting plasma glucose
ICH	International Council on Harmonization
LR	logistic regression
LPLT	last patient last treatment
LPLV	last patient last visit
MAR	missing at random
MCMC	Markov Chain Monte Carlo
MI	multiple imputation
NBR	negative binomial regression
PK	pharmacokinetics
SAS	safety analysis set
s.c.	subcutaneous

SU	sulfonylureas
T2D	Type 2 diabetes
TFL	Tables, figures and listings
w/o	without

6.2 Appendix 2: Changes to protocol-planned analyses

Corrected the end of the in-trial observation period, from end-of-treatment visit (V10) to the follow-up visit (P11).

A schematic overview of the estimands has been provided, see [Table 1](#).

Clarification in section [2](#) that statistical testing is performed for each estimand strategy separately.

A clarification of rescue medication has been included, see section [4](#).

A two-way tipping point sensitivity analysis has been added based on feedback from FDA, see sections [5.3.2.2](#) and [5.4.1.2](#).

Subgroup analyses have been included, see section [5.7.1](#), as well as a subpopulation analysis, see section [5.7.2](#).

6.3 Appendix 3: Definition and calculation of endpoints, assessments and derivations

Table 6 Endpoints

Type	Title	Time frame	Unit
Primary endpoint	Change from baseline (week 0) to week 40 in glycosylated haemoglobin (HbA _{1c})	From baseline (week 0) to week 40	%
Confirmatory secondary endpoint	Change from baseline (week 0) to week 40 in body weight	From baseline (week 0) to week 40	kg
Supportive secondary endpoint	Change from baseline (week 0) to week 40 in fasting plasma glucose	Week 40	mmol/L
Supportive secondary endpoint	Change from baseline (week 0) to week 40 in BMI	Week 40	kg/m ²
Supportive secondary endpoint	Change from baseline (week 0) to week 40 in waist circumference	Week 40	cm
Supportive secondary endpoint	HbA _{1c} < 7.0% (53 mmol/mol)	Week 40	Yes/no
Supportive secondary endpoint	HbA _{1c} ≤ 6.5% (48 mmol/mol)	Week 40	Yes/no
Supportive secondary endpoint	Weight loss ≥ 5 kg	Week 40	Yes/no

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Type	Title	Time frame	Unit
Supportive secondary endpoint	Weight loss \geq 10 kg	Week 40	Yes/no
Supportive secondary endpoint	Number of treatment emergent severe or blood glucose confirmed symptomatic hypoglycaemic episodes from baseline (week 0) to week 40	From week 0 to week 40	Count
Supportive secondary endpoint	Change from baseline (week 0) to week 40 in pulse	From week 0 to week 40	bpm

7 References

1. Little RJA, Rubin DB. Statistical analysis with missing data. New York: Wiley. 1987. xiv, 278 p. p.

Memo

From:

[REDACTED]

To:

Whom it may concern

Date: 28-Aug .2020

Ref.: [REDACTED]

Identification and presentation of Areas of Special Interest for NN9535-4506 – Memo version [2.0] – Task 088

This document aims to provide an overview of MedDRA queries (SMQs and NNMQs) in relation to CTR for the above trial

Areas of special interest are identified as outlined in the table below in MedDRA version [23.0]. Please make sure that no duplicate Preferred Terms are included in any of the separate searches.

*If the Safety area of special interest is covered by a custom query (e.g. NNMQ) the text included in the table under 'Safety Area of Special Interest' should be included as the **CQNAM** in the SAS data set (left blank if SMQ).*

*If the Safety area of special interest is covered by a SMQ, the title of the SMQ should be included as the **SMQNAM** in the SAS data.*

N	Safety Area of Special Interest (if defined by an NNMQ, CQNAM in SAS dataset)	Search criteria by NNMQ, SMQ, SOC and/or specific Preferred Terms (if defined by SMQ, SMQNAM in SAS dataset)	Scope / Filter - include scope for each component (tick one per area)
1	Gastrointestinal adverse events	NNMQ GI SOC	<input checked="" type="checkbox"/> Primary terms only <input type="checkbox"/> Both primary and secondary term
2	Cardiovascular disorders	NNMQ Cardiovascular disorders	<input checked="" type="checkbox"/> All terms <input type="checkbox"/> Narrow term only
3	Acute gallstone disease	NNMQ Gallbladder related disorders	<input type="checkbox"/> All terms <input checked="" type="checkbox"/> Narrow term only
4	Pancreatitis	NNMQ Pancreatitis	<input type="checkbox"/> All terms <input checked="" type="checkbox"/> Narrow term only
5	Acute renal failure	SMQ Acute renal failure	<input type="checkbox"/> All terms <input checked="" type="checkbox"/> Narrow term only
6	Diabetic retinopathy adverse events	NNMQ Retinopathy phase 3a - single PTs	<input checked="" type="checkbox"/> All terms <input type="checkbox"/> Narrow term only
7	Hepatic disorders	SMQ Drug related hepatic disorders	Comprehensive search
8	Allergic reactions	NNMQ Allergic reactions	<input type="checkbox"/> All terms

			<input checked="" type="checkbox"/> Narrow term only
9	Medication error/overdose	SMQ Medication error, NNMQ Abuse/Misuse, NNMQ Overdose	<input checked="" type="checkbox"/> All terms <input type="checkbox"/> Narrow term only Duplicate terms should be included only once
10	Rare events	NNMQ Rare	<input checked="" type="checkbox"/> All terms <input type="checkbox"/> Narrow term only Excluding terms caught in other searches
11	Neoplasms	NNMQ Neoplasms	<input checked="" type="checkbox"/> All terms <input type="checkbox"/> Narrow term only
12	Malignant neoplasms	SMQ Malignant tumours	<input type="checkbox"/> All terms <input checked="" type="checkbox"/> Narrow term only
13	Injection site reaction	NNMQ Injection site reaction	<input checked="" type="checkbox"/> All terms <input type="checkbox"/> Narrow term only
14	Suspected transmission of an infectious agent	NNMQ Transmission	<input checked="" type="checkbox"/> Primary terms only <input type="checkbox"/> Both primary and secondary term

Memo version	MedDRA version	Description of change
1.0	23.0	This is the first version of memo. To be used for task 088
2.0	23.0	Memo has been updated to include the diabetic retinopathy phase 3a search instead of retinal disorders which is in agreement with a safety committee decision taking 2017-09-08. The phase 3a search is using MedRA v. 13.1 and it is recognised that PT terms may have been demoted or other changes when used in data coded in the current version of MedDRA is affecting the output.

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1: Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Acute gallstone disease

AIDS cholangiopathy
Ampulla of Vater stenosis
Autoimmune cholangitis
Bile culture positive
Bile duct necrosis
Bile duct obstruction
Bile duct pressure increased
Bile duct reconstruction
Bile duct stenosis
Bile duct stenosis traumatic
Bile duct stent insertion
Bile duct stent removal
Bile duct stone
Bile output abnormal
Bile output decreased
Bile output increased
Biliary abscess
Biliary anastomosis
Biliary anastomosis complication
Biliary ascites
Biliary cast syndrome
Biliary catheter insertion
Biliary catheter removal
Biliary cirrhosis
Biliary colic
Biliary dilatation
Biliary dyskinesia
Biliary fibrosis
Biliary fistula
Biliary fistula repair
Biliary ischaemia
Biliary sepsis
Biliary sphincterotomy
Biliary stent placement
Biliary tract dilation procedure
Biliary tract disorder
Biliary tract infection
Biliary tract operation
Biliary-bronchial fistula
Biliary-vascular fistula
Bilirubin conjugated abnormal
Bilirubin conjugated increased
Bilirubin excretion disorder

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search Preferred term

- Acute gallstone disease
- Biloma rupture
- Bile duct abnormal
- Biopsy gallbladder abnormal
- Blood bilirubin abnormal
- Blood bilirubin increased
- Cholangiectasis acquired
- Cholangiogram abnormal
- Cholangiolitis
- Cholangiostomy
- Cholangitis
- Cholangitis acute
- Cholangitis chronic
- Cholangitis infective
- Cholangitis sclerosing
- Cholecystectomy
- Cholecystitis
- Cholecystitis acute
- Cholecystitis chronic
- Cholecystitis infective
- Cholecystocholangitis
- Cholecystoenterostomy
- Cholecystogram intravenous abnormal
- Cholecystogram oral abnormal
- Cholecystostomy
- Cholecholectomy
- Cholechoenterostomy
- Cholecholithotomy
- Cholecholestomy
- Cholecholestomy
- Cholelithiasis
- Cholelithiasis migration
- Cholelithiasis obstructive
- Cholelithotomy
- Cholelithotripsy
- Cholestasis
- Cholestasis of pregnancy
- Dilatation intrahepatic duct acquired
- Emphysematous cholecystitis
- Endoscopic retrograde cholangiopancreatography abnormal
- Endoscopy biliary tract abnormal
- Gallbladder abscess

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Acute gallstone disease

Gallbladder cholesterolosis
 Gallbladder disorder
 Gallbladder empyema
 Gallbladder enlargement
 Gallbladder fibrosis
 Gallbladder fistula
 Gallbladder fistula repair
 Gallbladder hyperfunction
 Gallbladder hypofunction
 Gallbladder injury
 Gallbladder mucocoele
 Gallbladder necrosis
 Gallbladder obstruction
 Gallbladder oedema
 Gallbladder operation
 Gallbladder palpable
 Gallbladder rupture
 Gallbladder varices
 Gallbladder volvulus
 Gallstone ileus
 Haemobilia
 Haemorrhagic cholecystitis
 Hepatitis cholestatic
 Hepatobiliary disease
 Hepatobiliary infection
 Hepatolithectomy
 Hydrocholecystis
 Hyperbilirubinaemia
 Hyperplastic cholecystopathy
 Immune-mediated cholangitis
 Ischaemic cholecystitis
 Jaundice
 Jaundice cholestatic
 Jaundice extrahepatic obstructive
 Lemmel's syndrome
 Limy bile syndrome
 Malignant biliary obstruction
 Pancreatobiliary sphincterotomy
 Parenteral nutrition associated liver disease
 Perforation bile duct
 Percutain gallbladder
 Post cholecystectomy syndrome
 Post procedural bile leak

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Acute gallstone disease

Primary biliary cholangitis
 Pseudocholelithiasis
 Recurrent pyogenic cholangitis
 Reynold's syndrome
 Sphincter of Oddi dysfunction
 Ultrasound biliary tract abnormal
 Vanishing bile duct syndrome
 X-ray hepatobiliary abnormal

Acute renal failure

Acute kidney injury
 Acute phosphate nephropathy
 Anuria
 Azotaemia
 Continuous haemodiafiltration
 Dialysis
 Foetal renal impairment
 Haemodialysis
 Haemofiltration
 Neonatal anuria
 Nephropathy toxic
 Oliguria
 Peritoneal dialysis
 Prerenal failure
 Renal failure
 Renal failure neonatal
 Renal impairment
 Renal impairment neonatal
 Subacute kidney injury

Allergic reactions

Acquired C1 inhibitor deficiency
 Acute generalised exanthematous pustulosis
 Administration related reaction
 Administration site dermatitis
 Administration site eczema
 Administration site hypersensitivity
 Administration site rash
 Administration site recall reaction
 Administration site urticaria
 Administration site vasculitis
 Allergic bronchitis
 Allergic colitis
 Allergic cough
 Allergic cystitis

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Allergic reactions

- Allergic eosinophilia
- Allergic gastroenteritis
- Allergic hepatitis
- Allergic keratitis
- Allergic oedema
- Allergic otitis externa
- Allergic otitis media
- Allergic pharyngitis
- Allergic reaction to excipient
- Allergic respiratory disease
- Allergic respiratory symptom
- Allergic stomatitis
- Allergic transfusion reaction
- Allergy alert test positive
- Allergy test positive
- Allergy to immunoglobulin therapy
- Allergy to surgical sutures
- Allergy to vaccine
- Anal eczema
- Anaphylactic reaction
- Anaphylactic shock
- Anaphylactic transfusion reaction
- Anaphylactoid reaction
- Anaphylactoid shock
- Anaphylaxis treatment
- Angioedema
- Anti-neutrophil cytoplasmic antibody positive vasculitis
- Anti-allergic therapy
- Antiendomyisial antibody positive
- Application site dermatitis
- Application site eczema
- Application site hypersensitivity
- Application site rash
- Application site recall reaction
- Application site urticaria
- Application site vasculitis
- Arthritis allergic
- Aspirin-exacerbated respiratory disease
- Atopy
- Blepharitis allergic

Pre-defined MedDRA search

Preferred term

Allergic reactions

Blood immunoglobulin E abnormal
 Blood immunoglobulin E increased
 Bromoderma
 Bronchospasm
 Bullous haemorrhagic dermatosis
 Catheter site dermatitis
 Catheter site eczema
 Catheter site hypersensitivity
 Catheter site rash
 Catheter site urticaria
 Catheter site vasculitis
 Chronic eosinophilic rhinosinusitis
 Chronic hyperplastic eosinophilic sinusitis
 Circulatory collapse
 Circumoral oedema
 Circumoral swelling
 Conjunctival oedema
 Conjunctivitis allergic
 Contact stomatitis
 Contrast media allergy
 Contrast media reaction
 Corneal oedema
 Cutaneous vasculitis
 Dennie-Morgan fold
 Dermatitis
 Dermatitis acneiform
 Dermatitis allergic
 Dermatitis atopic
 Dermatitis bullous
 Dermatitis contact
 Dermatitis exfoliative
 Dermatitis exfoliative generalised
 Dermatitis herpetiformis
 Dermatitis infected
 Dermatitis psoriasiform
 Device allergy
 Dialysis membrane reaction
 Distributive shock
 Documented hypersensitivity to administered product
 Drug eruption
 Drug hypersensitivity
 Drug provocation test

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Allergic reactions

Drug reaction with eosinophilia and systemic symptoms

- Eczema
- Eczema infantile
- Eczema nummular
- Eczema vaccinatum
- Eczema vesicular
- Eczema weeping
- Encephalitis allergic
- Encephalopathy allergic
- Eosinophilic granulomatosis with polyangiitis
- Epidermal necrosis
- Epidermolysis
- Epidermolysis bullosa
- Epiglottic oedema
- Erythema multiforme
- Erythema nodosum
- Erythrodermic atopic dermatitis
- Exfoliative rash
- Eye allergy
- Eye oedema
- Eye swelling
- Eyelid oedema
- Face oedema
- Fixed eruption
- Giant papillary conjunctivitis
- Gingival oedema
- Gingival swelling
- Gleich's syndrome
- Haemorrhagic urticaria
- Hand dermatitis
- Henoch-Schonlein purpura
- Henoch-Schonlein purpura nephritis
- Heparin-induced thrombocytopenia
- Hereditary angioedema
- Hereditary angioedema with C1 esterase inhibitor deficiency
- Hypersensitivity
- Hypersensitivity myocarditis
- Hypersensitivity pneumonitis
- Hypersensitivity vasculitis
- Idiopathic angioedema
- Idiopathic urticaria

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Allergic reactions

- Immediate post-injection reaction
- Immune thrombocytopenia
- Immune tolerance induction
- Implant site dermatitis
- Implant site hypersensitivity
- 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 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 rash
- Injection site recall reaction
- Injection site urticaria
- Injection site vasculitis
- Instillation site hypersensitivity
- Instillation site rash
- Instillation site urticaria
- Interstitial granulomatous dermatitis
- Interstitial angioedema
- Iodine allergy
- Kaposi's varicelliform eruption
- Kounis syndrome
- Laryngeal oedema
- Laryngitis allergic
- Laryngospasm
- Laryngotracheal oedema
- Limb swelling
- Lip oedema
- Lip swelling
- Mast cell degranulation present
- Medical device site dermatitis

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Pre-defined MedDRA search - list of preferred terms

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Preferred term

Allergic reactions

Medical device site eczema
Medical device site hypersensitivity
Medical device site rash
Medical device site recall reaction
Medical device site urticaria
Mouth swelling
Mucocutaneous rash
Multiple allergies
Nephritis allergic
Nikolsky's sign
Nodular rash
Nutritional supplement allergy
Oculomucocutaneous syndrome
Oculorespiratory syndrome
Oedema mouth
Oral allergy syndrome
Oropharyngeal blistering
Oropharyngeal oedema
Oropharyngeal spasm
Oropharyngeal swelling
Palatal oedema
Palatal swelling
Palisaded neutrophilic granulomatous dermatitis
Palpable purpura
Pathergy reaction
Perioral dermatitis
Periorbital oedema
Periorbital swelling
Pharyngeal oedema
Pharyngeal swelling
Procedural shock
Pruritus allergic
Radioallergosorbent test positive
Rash
Rash erythematous
Rash follicular
Rash macular
Rash maculo-papular
Rash maculovesicular
Rash morbilliform
Rash neonatal
Rash papulosquamous
Rash pruritic

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Allergic reactions

Rash pustular
 Rash rubelliform
 Rash scarlatiniform
 Rash vesicular
 Reaction to azo-dyes
 Reaction to colouring
 Reaction to excipient
 Reaction to food additive
 Reaction to preservatives
 Red man syndrome
 Rhinitis allergic
 SJS-TEN overlap
 Scleral oedema
 Scleritis allergic
 Scrotal dermatitis
 Scrotal oedema
 Serum sickness
 Serum sickness-like reaction
 Shock
 Shock symptom
 Skin necrosis
 Skin reaction
 Skin test positive
 Solar urticaria
 Solvent sensitivity
 Stevens-Johnson syndrome
 Stoma site hypersensitivity
 Stoma site rash
 Swelling face
 Swelling of eyelid
 Swollen tongue
 Symmetrical drug-related intertriginous and
 flexural exanthema
 Target skin lesion
 Therapeutic product cross-reactivity
 Tongue oedema
 Toxic epidermal necrolysis
 Toxic skin eruption
 Tracheal oedema
 Type I hypersensitivity
 Type II hypersensitivity
 Type III immune complex mediated reaction
 Type IV hypersensitivity reaction

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Allergic reactions

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 rash
 Vaccination site recall reaction
 Vaccination site urticaria
 Vaccination site vasculitis
 Vaccination site vesicles
 Vaginal ulceration
 Vasculitic rash
 Vernal keratoconjunctivitis
 Vessel puncture site rash
 Vessel puncture site vesicles
 Vulval eczema
 Vulval ulceration
 Vulvovaginal rash
 Vulvovaginal ulceration
 Vulvovaginitis allergic

Cardiovascular disorders

Acute kidney injury
 Anuria
 Neonatal anuria
 Prerenal failure
 Renal failure
 Renal failure neonatal
 Subacute kidney injury
 Administration site vasculitis
 Anaphylactic reaction
 Anaphylactic shock
 Anaphylactic transfusion reaction
 Anaphylactoid reaction
 Anaphylactoid shock

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Anti-neutrophil cytoplasmic antibody positive
 vasculitis
 Application site vasculitis
 Circulatory collapse
 Cutaneous vasculitis
 Distributive shock
 Eosinophilic granulomatosis with polyangiitis
 Henoch-Schonlein purpura
 Henoch-Schonlein purpura nephritis
 Heparin-induced thrombocytopenia
 Hypersensitivity myocarditis
 Hypersensitivity vasculitis
 Infusion site vasculitis
 Injection site vasculitis
 Kounis syndrome
 Palpable purpura
 Procedural shock
 Shock
 Shock symptom
 Urticarial vasculitis
 Vaccination site vasculitis
 Vasculitic rash
 Abnormal precordial movement
 Accelerated idioventricular rhythm
 Accessory cardiac pathway
 Acquired cardiac septal defect
 Acute aortic syndrome
 Acute cardiac event
 Acute coronary syndrome
 Acute haemorrhagic oedema of infancy
 Acute left ventricular failure
 Acute myocardial infarction
 Acute pulmonary oedema
 Acute respiratory failure
 Acute right ventricular failure
 Adams-Stokes syndrome
 Administration site thrombosis
 Adrenal thrombosis
 Agnosia
 Agonal rhythm
 Alcohol septal ablation
 Amaurosis
 Amaurosis fugax

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Amyloid related imaging abnormalities
 Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits
 Amyloid related imaging abnormality-oedema/effusion
 Andersen-Tawil syndrome
 Angina pectoris
 Angina unstable
 Anginal equivalent
 Angiogram abnormal
 Angiogram cerebral abnormal
 Angiogram peripheral abnormal
 Angioplasty
 Anomalous atrioventricular excitation
 Anti-glomerular basement membrane disease
 Antibody test abnormal
 Antibody test positive
 Antineutrophil cytoplasmic antibody increased
 Antineutrophil cytoplasmic antibody positive
 Antiphospholipid syndrome
 Aortic bypass
 Aortic embolus
 Aortic surgery
 Aortic thrombosis
 Aortitis
 Aortogram abnormal
 Aphasia
 Application site thrombosis
 Arrhythmia
 Arrhythmia neonatal
 Arrhythmia supraventricular
 Arrhythmogenic right ventricular dysplasia
 Arterectomy
 Arterectomy with graft replacement
 Arterial angioplasty
 Arterial bypass occlusion
 Arterial bypass operation
 Arterial bypass thrombosis
 Arterial graft
 Arterial occlusive disease
 Arterial stent insertion
 Arterial therapeutic procedure

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Arterial thrombosis
 Arteriogram abnormal
 Arteriogram carotid abnormal
 Arteriogram coronary abnormal
 Arteriosclerosis coronary artery
 Arteriospasm coronary
 Arteriotomy
 Arteriovenous fistula occlusion
 Arteriovenous fistula thrombosis
 Arteriovenous graft thrombosis
 Arteritis
 Arteritis coronary
 Artificial blood vessel occlusion
 Artificial heart implant
 Ascites
 Atherectomy
 Atherosclerotic plaque rupture
 Atrial appendage closure
 Atrial appendage resection
 Atrial conduction time prolongation
 Atrial enlargement
 Atrial fibrillation
 Atrial flutter
 Atrial hypertrophy
 Atrial natriuretic peptide abnormal
 Atrial natriuretic peptide increased
 Atrial parasystole
 Atrial pressure increased
 Atrial septal defect acquired
 Atrial tachycardia
 Atrial thrombosis
 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
 Autoimmune myocarditis
 Axillary vein thrombosis
 BRASH syndrome
 Balint's syndrome

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Basal ganglia haematoma
 Basal ganglia haemorrhage
 Basal ganglia infarction
 Basal ganglia stroke
 Baseline foetal heart rate variability disorder
 Basilar artery aneurysm
 Basilar artery occlusion
 Basilar artery perforation
 Basilar artery stenosis
 Basilar artery thrombosis
 Behcet's syndrome
 Bendopnoea
 Bezold-Jarisch reflex
 Bifascicular block
 Biopsy heart abnormal
 Blindness transient
 Blood brain barrier defect
 Blood creatine phosphokinase MB abnormal
 Blood creatine phosphokinase MB increased
 Blood creatine phosphokinase abnormal
 Blood creatine phosphokinase increased
 Blood pressure diastolic abnormal
 Blood pressure diastolic decreased
 Blood pressure diastolic increased
 Blood pressure fluctuation
 Blood pressure immeasurable
 Blood pressure inadequately controlled
 Blood pressure systolic abnormal
 Blood pressure systolic decreased
 Blood pressure systolic increased
 Blood viscosity increased
 Bone infarction
 Brachiocephalic arteriosclerosis
 Brachiocephalic artery occlusion
 Brachiocephalic artery stenosis
 Brachiocephalic vein occlusion
 Brachiocephalic vein thrombosis
 Bradyarrhythmia
 Bradycardia
 Bradycardia foetal
 Bradycardia neonatal
 Brain hypoxia
 Brain injury

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Brain natriuretic peptide abnormal
 Brain natriuretic peptide increased
 Brain stem embolism
 Brain stem haematoma
 Brain stem haemorrhage
 Brain stem infarction
 Brain stem ischaemia
 Brain stem microhaemorrhage
 Brain stem stroke
 Brain stem thrombosis
 Brain stent insertion
 Brugada syndrome
 Budd-Chiari syndrome
 Bundle branch block
 Bundle branch block bilateral
 Bundle branch block left
 Bundle branch block right
 CADASIL
 CARASIL syndrome
 CSF bilirubin positive
 CSF red blood cell count positive
 CT hypotension complex
 Capillaritis
 Capsular warning syndrome
 Cardiac amyloidosis
 Cardiac aneurysm
 Cardiac arrest
 Cardiac arrest neonatal
 Cardiac asthma
 Cardiac cirrhosis
 Cardiac contractility modulation therapy
 Cardiac death
 Cardiac device reprogramming
 Cardiac dysfunction
 Cardiac electrophysiologic study abnormal
 Cardiac failure
 Cardiac failure acute
 Cardiac failure chronic
 Cardiac failure congestive
 Cardiac failure high output
 Cardiac fibrillation
 Cardiac flutter
 Cardiac function test abnormal

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Cardiac hypertrophy
Cardiac imaging procedure abnormal
Cardiac index abnormal
Cardiac index decreased
Cardiac index increased
Cardiac iron overload
Cardiac monitoring abnormal
Cardiac operation
Cardiac output decreased
Cardiac perfusion defect
Cardiac pseudoaneurysm
Cardiac resynchronisation therapy
Cardiac sarcoidosis
Cardiac septal hypertrophy
Cardiac stress test abnormal
Cardiac telemetry abnormal
Cardiac ventricular scarring
Cardiac ventricular thrombosis
Cardiac ventriculogram abnormal
Cardiac ventriculogram left abnormal
Cardiac ventriculogram right abnormal
Cardio-respiratory arrest
Cardio-respiratory arrest neonatal
Cardio-respiratory distress
Cardiogenic shock
Cardiohepatic syndrome
Cardiomegaly
Cardiomyopathy
Cardiomyopathy acute
Cardiomyopathy alcoholic
Cardiomyopathy neonatal
Cardiopulmonary exercise test abnormal
Cardiopulmonary failure
Cardiorenal syndrome
Cardiothoracic ratio increased
Cardiotoxicity
Cardiovascular disorder
Cardiovascular event prophylaxis
Cardiovascular function test abnormal
Cardiovascular insufficiency
Carotid aneurysm rupture
Carotid angioplasty
Carotid arterial embolus

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Carotid arteriosclerosis
 Carotid artery aneurysm
 Carotid artery bypass
 Carotid artery disease
 Carotid artery dissection
 Carotid artery dolichoectasia
 Carotid artery insufficiency
 Carotid artery occlusion
 Carotid artery perforation
 Carotid artery restenosis
 Carotid artery stenosis
 Carotid artery stent insertion
 Carotid artery stent removal
 Carotid endarterectomy
 Carotid revascularisation
 Catheter site thrombosis
 Catheterisation venous
 Cavernous sinus thrombosis
 Central bradycardia
 Central nervous system haemorrhage
 Central nervous system vasculitis
 Central pain syndrome
 Central venous catheterisation
 Central venous pressure increased
 Cerebellar artery occlusion
 Cerebellar artery thrombosis
 Cerebellar embolism
 Cerebellar haematoma
 Cerebellar haemorrhage
 Cerebellar infarction
 Cerebellar ischaemia
 Cerebellar microhaemorrhage
 Cerebellar stroke
 Cerebral amyloid angiopathy
 Cerebral aneurysm perforation
 Cerebral aneurysm ruptured syphilitic
 Cerebral arteriosclerosis
 Cerebral arteriovenous malformation haemorrhagic
 Cerebral arteritis
 Cerebral artery embolism
 Cerebral artery occlusion
 Cerebral artery perforation

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Cerebral artery stenosis
 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
 Cerebral gas embolism
 Cerebral haematoma
 Cerebral haemorrhage
 Cerebral haemorrhage foetal
 Cerebral haemorrhage neonatal
 Cerebral haemosiderin deposition
 Cerebral hypoperfusion
 Cerebral infarction
 Cerebral infarction foetal
 Cerebral ischaemia
 Cerebral microangiopathy
 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
 Cerebrospinal thrombotic tamponade
 Cerebrovascular accident
 Cerebrovascular accident prophylaxis
 Cerebrovascular arteriovenous malformation
 Cerebrovascular disorder
 Cerebrovascular insufficiency
 Cerebrovascular operation
 Cerebrovascular pseudoaneurysm
 Cerebrovascular stenosis

Pre-defined MedDRA search	Preferred term
Cardiovascular disorders	Chagas' cardiomyopathy Charcot-Bouchard microaneurysms Chest X-ray abnormal Chest pain Choroidal infarction Chronic cerebrospinal venous insufficiency Chronic left ventricular failure Chronic pigmented purpura Chronic right ventricular failure Chronotropic incompetence Coeliac artery occlusion Cogan's syndrome Collateral circulation Compression garment application Computerised tomogram coronary artery abnormal Computerised tomogram thorax abnormal Conduction disorder Congenital cerebrovascular anomaly Congenital hemiparesis Congenital supraventricular tachycardia Congestive cardiomyopathy 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

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Coronary no-reflow phenomenon
 Coronary ostial stenosis
 Coronary revascularisation
 Coronary sinus dilatation
 Coronary steal syndrome
 Coronary vascular graft occlusion
 Coronary vascular graft stenosis
 Cocksackie carditis
 Cocksackie myocarditis
 Cryoglobulinaemia
 Cryoglobulins present
 Cytomegalovirus myocarditis
 Decreased ventricular preload
 Deep vein thrombosis
 Deep vein thrombosis postoperative
 Defect conduction intraventricular
 Delayed ischaemic neurological deficit
 Device embolisation
 Device occlusion
 Device related thrombosis
 Diabetic arteritis
 Diabetic cardiomyopathy
 Diabetic coronary microangiopathy
 Diastolic dysfunction
 Diffuse vasculitis
 Dilatation atrial
 Dilatation ventricular
 Diplegia
 Directional Doppler flow tests abnormal
 Disseminated intravascular coagulation
 Disseminated intravascular coagulation in newborn
 Dural arteriovenous fistula
 Dysarthria
 Dyspnoea
 Dyspnoea paroxysmal nocturnal
 ECG P wave inverted
 ECG electrically inactive area
 ECG signs of myocardial infarction
 ECG signs of myocardial ischaemia
 ECG signs of ventricular hypertrophy
 Echocardiogram abnormal
 Ejection fraction abnormal
 Ejection fraction decreased

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Elastic vessel recoil complication
 Electrocardiogram P wave abnormal
 Electrocardiogram PR prolongation
 Electrocardiogram PR segment depression
 Electrocardiogram PR shortened
 Electrocardiogram Q wave abnormal
 Electrocardiogram QRS complex prolonged
 Electrocardiogram QT interval abnormal
 Electrocardiogram QT prolonged
 Electrocardiogram RR interval prolonged
 Electrocardiogram ST segment abnormal
 Electrocardiogram ST segment depression
 Electrocardiogram ST segment elevation
 Electrocardiogram ST-T segment abnormal
 Electrocardiogram ST-T segment depression
 Electrocardiogram ST-T segment elevation
 Electrocardiogram T wave abnormal
 Electrocardiogram T wave inversion
 Electrocardiogram U wave inversion
 Electrocardiogram U wave present
 Electrocardiogram U-wave abnormality
 Electrocardiogram abnormal
 Electrocardiogram ambulatory abnormal
 Electrocardiogram change
 Electrocardiogram delta waves abnormal
 Electrocardiogram repolarisation abnormality
 Embolia cutis medicamentosa
 Embolic cerebellar infarction
 Embolic cerebral infarction
 Embolic pneumonia
 Embolic stroke
 Embolism
 Embolism arterial
 Embolism venous
 Endarterectomy
 Endocardial fibroelastosis
 Endotoxic shock
 Enterovirus myocarditis
 Eosinophilic myocarditis
 Epidural haemorrhage
 Erythema induratum
 Exercise electrocardiogram abnormal
 Exercise test abnormal

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

- Hemiataxia
- Hemidysaesthesia
- Hemihyparaesthesia
- Hemiparaesthesia
- Hemiparesis
- Hemiplegia
- Hepatic artery embolism
- Hepatic artery occlusion
- Hepatic artery thrombosis
- Hepatic infarction
- Hepatic vascular thrombosis
- Hepatic vein dilatation
- Hepatic vein embolism
- Hepatic vein occlusion
- Hepatic vein thrombosis
- Hepatojugular reflux
- Hepatomegaly
- Hepatorenal failure
- Holiday heart syndrome
- Homans' sign positive
- Hunt and Hess scale
- Hyperdynamic left ventricle
- Hypertensive cardiomyopathy
- Hypertensive cerebrovascular disease
- Hypertrophic cardiomyopathy
- Hypoperfusion
- Hypotensive crisis
- Hypothermic hammer syndrome
- Hypovolaemic shock
- Hypoxic-ischaemic encephalopathy
- Iliac artery embolism
- Iliac artery occlusion
- Iliac vein occlusion
- Immune-mediated myocarditis
- Implant site thrombosis
- Implantable cardiac monitor replacement
- Incision site vessel occlusion
- Increased ventricular preload
- Infarction
- Inferior vena cava syndrome
- Inferior vena caval occlusion
- Infusion site thrombosis
- Injection site thrombosis

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Inner ear infarction
 Instillation site thrombosis
 Internal capsule infarction
 Internal carotid artery deformity
 Intestinal infarction
 Intra-aortic balloon placement
 Intra-cerebral aneurysm operation
 Intracardiac mass
 Intracardiac pressure increased
 Intracardiac thrombus
 Intracerebral haematoma evacuation
 Intracranial aneurysm
 Intracranial artery dissection
 Intracranial haematoma
 Intracranial tumour haemorrhage
 Intraoperative cerebral artery occlusion
 Intraventricular haemorrhage
 Intraventricular haemorrhage neonatal
 Irregular breathing
 Ischaemic cardiomyopathy
 Ischaemic cerebral infarction
 Ischaemic mitral regurgitation
 Ischaemic stroke
 Jugular vein distension
 Jugular vein embolism
 Jugular vein occlusion
 Jugular vein thrombosis
 Junctional ectopic tachycardia
 Kawasaki's disease
 Labile blood pressure
 Lacunar infarction
 Lacunar stroke
 Lamb's excrescences
 Langerhans' cell histiocytosis
 Lateral medullary syndrome
 Lateropulsion
 Left atrial dilatation
 Left atrial enlargement
 Left atrial volume abnormal
 Left atrial volume decreased
 Left atrial volume increased
 Left ventricular diastolic collapse
 Left ventricular dilatation

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

- Left ventricular dysfunction
- Left ventricular end-diastolic pressure decreased
- Left ventricular enlargement
- Left ventricular failure
- Left ventricular heave
- Lenegre's disease
- Leriche syndrome
- Long QT syndrome
- Long QT syndrome congenital
- Loss of consciousness
- Low cardiac output syndrome
- Lower respiratory tract congestion
- Lown-Ganong-Levine syndrome
- Lung opacity
- Lupus myocarditis
- Lupus vasculitis
- Lyme carditis
- MAGIC syndrome
- Magnetic resonance imaging thoracic abnormal
- Mahler sign
- Malarial myocarditis
- May-Thurner syndrome
- Medical device site thrombosis
- Medical device site vasculitis
- Meningorrhagia
- Mental status changes
- Mesenteric arterial occlusion
- Mesenteric arteriosclerosis
- Mesenteric artery embolism
- Mesenteric artery stenosis
- Mesenteric artery stent insertion
- Mesenteric artery thrombosis
- Mesenteric vascular insufficiency
- Mesenteric vascular occlusion
- Mesenteric vein thrombosis
- Mesenteric venous occlusion
- Metabolic cardiomyopathy
- Microembolism
- Microscopic polyangiitis
- Microvascular coronary artery disease
- Migrainous infarction
- Millard-Gubler syndrome
- Modified Rankin score decreased

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Modified Rankin score increased
 Monoparesis
 Monoplegia
 Moyamoya disease
 Multiple gated acquisition scan abnormal
 Multiple organ dysfunction syndrome
 Myocardiac abscess
 Myocardial calcification
 Myocardial depression
 Myocardial fibrosis
 Myocardial haemorrhage
 Myocardial hypoperfusion
 Myocardial hypoxia
 Myocardial infarction
 Myocardial ischaemia
 Myocardial necrosis
 Myocardial necrosis marker increased
 Myocardial reperfusion injury
 Myocardial stunning
 Myocarditis
 Myocarditis bacterial
 Myocarditis helminthic
 Myocarditis infectious
 Myocarditis meningococcal
 Myocarditis mycotic
 Myocarditis post infection
 Myocarditis septic
 Myocarditis syphilitic
 Myocarditis toxoplasmal
 Myoglobinaemia
 Myoglobinuria
 N-terminal prohormone brain natriuretic peptide
 abnormal
 N-terminal prohormone brain natriuretic peptide
 increased
 NIH stroke scale abnormal
 NIH stroke scale score decreased
 NIH stroke scale score increased
 Neonatal bradyarrhythmia
 Neonatal cardiac failure
 Neonatal multi-organ failure
 Neonatal respiratory failure
 Neonatal sinus bradycardia

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Neonatal sinus tachycardia
 Neonatal tachyarrhythmia
 Neonatal tachycardia
 Neurogenic shock
 Nocturia
 Nocturnal dyspnoea
 Nodal arrhythmia
 Nodal rhythm
 Nodular vasculitis
 Non-obstructive cardiomyopathy
 Nonreassuring foetal heart rate pattern
 Obesity cardiomyopathy
 Obstetrical pulmonary embolism
 Obstructive shock
 Ocular vasculitis
 Oedema
 Oedema blister
 Oedema due to cardiac disease
 Oedema neonatal
 Oedema peripheral
 Ophthalmic artery thrombosis
 Ophthalmic vein thrombosis
 Optic nerve infarction
 Organ failure
 Orthopnoea
 Orthostatic hypotension
 Ovarian vein thrombosis
 Pacemaker generated arrhythmia
 Pacemaker syndrome
 Paget-Schroetter syndrome
 Palpitations
 Pancreatic infarction
 Papillary muscle disorder
 Papillary muscle haemorrhage
 Papillary muscle infarction
 Paradoxical embolism
 Paralysis
 Paraneoplastic thrombosis
 Paraparesis
 Paraplegia
 Parasystole
 Paresis
 Paroxysmal arrhythmia

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Paroxysmal atrioventricular block
 Pelvic venous thrombosis
 Penile artery occlusion
 Penile vein thrombosis
 Percutaneous coronary intervention
 Perinatal stroke
 Peripartum cardiomyopathy
 Peripheral arterial occlusive disease
 Peripheral arterial reocclusion
 Peripheral artery angioplasty
 Peripheral artery bypass
 Peripheral artery occlusion
 Peripheral artery stent insertion
 Peripheral artery surgery
 Peripheral artery thrombosis
 Peripheral embolism
 Peripheral endarterectomy
 Peripheral oedema neonatal
 Peripheral revascularisation
 Peripheral swelling
 Peripheral vein occlusion
 Peripheral vein thrombus extension
 Periprocedural myocardial infarction
 Periventricular haemorrhage neonatal
 Phlebectomy
 Pituitary apoplexy
 Pituitary haemorrhage
 Pituitary infarction
 Placental infarction
 Plasma viscosity abnormal
 Pneumatic compression therapy
 Polyarteritis nodosa
 Polymyalgia rheumatica
 Popliteal artery entrapment syndrome
 Portal shunt procedure
 Portal vein cavernous transformation
 Portal vein embolism
 Portal vein occlusion
 Portal vein thrombosis
 Portosplenomesenteric venous thrombosis
 Post angioplasty restenosis
 Post cardiac arrest syndrome
 Post procedural myocardial infarction

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Post procedural pulmonary embolism
Post procedural stroke
Post stroke depression
Post thrombotic syndrome
Posthaemorrhagic hydrocephalus
Postinfarction angina
Postoperative thrombosis
Postpartum thrombosis
Postpartum venous thrombosis
Precerebral arteriosclerosis
Precerebral artery occlusion
Precerebral artery thrombosis
Primary familial brain calcification
Prinzmetal angina
Profundoplasty
Prohormone brain natriuretic peptide abnormal
Prohormone brain natriuretic peptide increased
Propofol infusion syndrome
Prosthetic cardiac valve thrombosis
Prosthetic vessel implantation
Pseudovasculitis
Pulmonary arterial wedge pressure increased
Pulmonary artery occlusion
Pulmonary artery therapeutic procedure
Pulmonary artery thrombosis
Pulmonary congestion
Pulmonary embolism
Pulmonary endarterectomy
Pulmonary infarction
Pulmonary microemboli
Pulmonary oedema
Pulmonary oedema neonatal
Pulmonary thrombosis
Pulmonary tumour thrombotic microangiopathy
Pulmonary vasculitis
Pulmonary vein occlusion
Pulmonary veno-occlusive disease
Pulmonary venous thrombosis
Pulse absent
Pulseless electrical activity
Putamen haemorrhage
Quadriplegia

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Radiation associated cardiac failure
 Radiation myocarditis
 Radiation vasculitis
 Rebound tachycardia
 Renal arteritis
 Renal artery angioplasty
 Renal artery occlusion
 Renal artery thrombosis
 Renal embolism
 Renal infarct
 Renal vascular thrombosis
 Renal vasculitis
 Renal vein embolism
 Renal vein occlusion
 Renal vein thrombosis
 Reperfusion arrhythmia
 Respiratory failure
 Respiratory sinus arrhythmia magnitude abnormal
 Respiratory sinus arrhythmia magnitude decreased
 Respiratory sinus arrhythmia magnitude increased
 Restenosis
 Restrictive cardiomyopathy
 Retinal artery embolism
 Retinal artery occlusion
 Retinal artery thrombosis
 Retinal infarction
 Retinal vascular thrombosis
 Retinal vasculitis
 Retinal vein occlusion
 Retinal vein thrombosis
 Retrograde p-waves
 Revascularisation procedure
 Reversible cerebral vasoconstriction syndrome
 Reversible ischaemic neurological deficit
 Rheumatoid vasculitis
 Rhythm idioventricular
 Right atrial dilatation
 Right atrial enlargement
 Right atrial pressure increased
 Right hemisphere deficit syndrome
 Right ventricle outflow tract obstruction
 Right ventricular diastolic collapse
 Right ventricular dilatation

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

- Right ventricular dysfunction
- Right ventricular ejection fraction decreased
- Right ventricular enlargement
- Right ventricular failure
- Right ventricular heave
- Right ventricular systolic pressure decreased
- Ruptured cerebral aneurysm
- SI QIII TIII pattern
- Scan myocardial perfusion abnormal
- Segmented hyalinising vasculitis
- Septic pulmonary embolism
- Septic shock
- Shock haemorrhagic
- Shock hypoglycaemic
- Shunt occlusion
- Shunt thrombosis
- Silent myocardial infarction
- Sinoatrial block
- Sinus arrest
- Sinus arrhythmia
- Sinus bradycardia
- Sinus node dysfunction
- Sinus tachycardia
- Sneddon's syndrome
- 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 subarachnoid haemorrhage
- Spinal subdural haematoma
- Spinal subdural haemorrhage
- Spinal vascular disorder
- Spinal vessel congenital anomaly
- Splenic artery thrombosis
- Splenic embolism
- Splenic infarction
- Splenic thrombosis
- Splenic vein occlusion

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Splenic vein thrombosis
 Stoma site thrombosis
 Stress cardiomyopathy
 Stress echocardiogram abnormal
 Stroke in evolution
 Stroke volume decreased
 Subarachnoid haematoma
 Subarachnoid haemorrhage
 Subarachnoid haemorrhage neonatal
 Subclavian artery embolism
 Subclavian artery occlusion
 Subclavian artery thrombosis
 Subclavian coronary steal syndrome
 Subclavian steal syndrome
 Subclavian vein occlusion
 Subclavian vein thrombosis
 Subdural haematoma
 Subdural haematoma evacuation
 Subdural haemorrhage
 Subdural haemorrhage neonatal
 Subendocardial haemorrhage
 Subendocardial ischaemia
 Sudden cardiac death
 Sudden death
 Superficial siderosis of central nervous system
 Superior sagittal sinus thrombosis
 Superior vena cava occlusion
 Superior vena cava syndrome
 Supraventricular extrasystoles
 Supraventricular tachyarrhythmia
 Supraventricular tachycardia
 Surgical vascular shunt
 Surgical ventricular restoration
 Susac's syndrome
 Syncope
 Systolic anterior motion of mitral valve
 Systolic dysfunction
 Tachyarrhythmia
 Tachycardia
 Tachycardia foetal
 Tachycardia induced cardiomyopathy
 Tachycardia paroxysmal
 Takayasu's arteritis

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

Temporal arteritis
 Testicular infarction
 Thalamic infarction
 Thalamus haemorrhage
 Thrombectomy
 Thromboangiitis obliterans
 Thromboembolectomy
 Thrombolysis
 Thrombophlebitis
 Thrombophlebitis migrans
 Thrombophlebitis neonatal
 Thrombophlebitis superficial
 Thrombosed varicose vein
 Thrombosis
 Thrombosis corpora cavernosa
 Thrombosis in device
 Thrombosis mesenteric vessel
 Thrombosis prophylaxis
 Thrombotic cerebral infarction
 Thrombotic microangiopathy
 Thrombotic stroke
 Thrombotic thrombocytopenic purpura
 Thyroid infarction
 Thyrototoxic cardiomyopathy
 Torsade de pointes
 Toxic cardiomyopathy
 Toxic shock syndrome
 Toxic shock syndrome staphylococcal
 Toxic shock syndrome streptococcal
 Transient ischaemic attack
 Transverse sinus thrombosis
 Trifascicular block
 Troponin I increased
 Troponin T increased
 Troponin increased
 Truncus coeliacus thrombosis
 Tumour embolism
 Tumour thrombectomy
 Tumour thrombosis
 Type 2 lepra reaction
 Ultrasonic angiogram abnormal
 Ultrasound Doppler abnormal
 Umbilical cord occlusion

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

- Umbilical cord thrombosis
- Vaccination site thrombosis
- Vascular access site thrombosis
- Vascular device occlusion
- Vascular encephalopathy
- Vascular graft
- Vascular graft occlusion
- Vascular graft thrombosis
- Vascular operation
- Vascular pseudoaneurysm thrombosis
- Vascular purpura
- Vascular resistance pulmonary increased
- Vascular stent insertion
- Vascular stent occlusion
- Vascular stent stenosis
- Vascular stent thrombosis
- Vasculitis
- Vasculitis gastrointestinal
- Vasculitis necrotising
- Vasodilatation procedure
- Vein of Galen aneurysmal malformation
- Vena cava embolism
- Vena cava filter insertion
- Vena cava filter removal
- Vena cava thrombosis
- Venogram abnormal
- Venocclusive disease
- Venocclusive liver disease
- Venous angioplasty
- Venous occlusion
- Venous operation
- Venous pressure increased
- Venous pressure jugular abnormal
- Venous pressure jugular increased
- Venous recanalisation
- Venous repair
- Venous stent insertion
- Venous thrombosis
- Venous thrombosis in pregnancy
- Venous thrombosis limb
- Venous thrombosis neonatal
- Ventricular arrhythmia
- Ventricular assist device insertion

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Cardiovascular disorders

- Ventricular asystole
- Ventricular compliance decreased
- Ventricular dysfunction
- Ventricular dyskinesia
- Ventricular dyssynchrony
- Ventricular enlargement
- Ventricular extrasystoles
- Ventricular failure
- Ventricular fibrillation
- Ventricular flutter
- Ventricular hyperkinesia
- Ventricular hypertrophy
- Ventricular hypokinesia
- Ventricular parasystole
- Ventricular pre-excitation
- Ventricular remodelling
- Ventricular septal defect acquired
- Ventricular tachyarrhythmia
- Ventricular tachycardia
- Vertebral artery aneurysm
- Vertebral artery dissection
- Vertebral artery occlusion
- Vertebral artery perforation
- Vertebral artery stenosis
- Vertebral artery thrombosis
- Vertebrobasilar dolichoectasia
- Vertebrobasilar insufficiency
- Vertebrobasilar stroke
- Vessel puncture site occlusion
- Vessel puncture site thrombosis
- Viral cardiomyopathy
- Viral myocarditis
- Viral vasculitis
- Visceral venous thrombosis
- Visual acuity reduced transiently
- Visual agnosia
- Visual midline shift syndrome
- Wall motion score index abnormal
- Wandering pacemaker
- Wellens' syndrome
- Withdrawal arrhythmia
- Wolff-Parkinson-White syndrome
- Wolff-Parkinson-White syndrome congenital

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Diabetic retinopathy adverse events

Anaurosis
 Visual acuity reduced transiently
 Cystoid macular oedema
 Diabetic blindness
 Diabetic eye disease
 Diabetic glaucoma
 Diabetic retinal oedema
 Diabetic retinopathy
 Diabetic uveitis
 Exudative retinopathy
 Macular ischaemia
 Macular oedema
 Macular opacity
 Macular pseudohole
 Maculopathy
 Night blindness
 Papilloedema
 Papillophlebitis
 Retinal deposits
 Retinal detachment
 Retinal exudates
 Retinal haemorrhage
 Retinal ischaemia
 Retinal neovascularisation
 Retinal oedema
 Retinal pallor
 Retinal vascular occlusion
 Retinopathy proliferative
 Sudden visual loss
 Visual acuity reduced
 Vitreal cells
 Vitreous detachment
 Vitreous haemorrhage
 Vitreous opacities

Drug related hepatic disorders - comprehensive search (SMQ)

Bile output abnormal
 Bile output decreased
 Biliary ascites
 Biliary cirrhosis
 Biliary fibrosis
 Bilirubin conjugated abnormal

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Drug related hepatic disorders - comprehensive search (SMQ)

Bilirubin conjugated increased

Bilirubin excretion disorder

Blood bilirubin abnormal

Blood bilirubin increased

Cholestasis

Gallbladder varices

Hepatitis cholestatic

Hepatobiliary disease

Hyperbilirubinaemia

Immune-mediated cholangitis

Jaundice

Jaundice cholestatic

Parenteral nutrition associated liver disease

Primary biliary cholangitis

Reynold's syndrome

X-ray hepatobiliary abnormal

Allergic hepatitis

Ascites

Cardiohepatic syndrome

Congestive hepatopathy

Hepatomegaly

Hepatorenal failure

Portal shunt procedure

Portal vein cavernous transformation

5'nucleotidase increased

AST/ALT ratio abnormal

Acquired antithrombin III deficiency

Acquired factor IX deficiency

Acquired factor VIII deficiency

Acquired factor XI deficiency

Acquired hepatocerebral degeneration

Acquired protein S deficiency

Acute graft versus host disease in liver

Acute hepatic failure

Acute on chronic liver failure

Acute yellow liver atrophy

Alanine aminotransferase abnormal

Alanine aminotransferase increased

Alloimmune hepatitis

Ammonia abnormal

Ammonia increased

Anorectal varices

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Drug related hepatic disorders - comprehensive search (SMQ)	Anorectal varices haemorrhage
	Anti factor X activity abnormal
	Anti factor X activity decreased
	Anti factor X activity increased
	Antithrombin III decreased
	Aspartate aminotransferase abnormal
	Aspartate aminotransferase increased
	Asterixis
	Autoimmune hepatitis
	Bacterascites
	Benign hepatic neoplasm
	Benign hepatobiliary neoplasm
	Bilirubin urine present
	Biopsy liver abnormal
	Blood alkaline phosphatase abnormal
	Blood alkaline phosphatase increased
	Blood bilirubin unconjugated increased
	Blood cholinesterase abnormal
	Blood cholinesterase decreased
	Blood fibrinogen abnormal
	Blood fibrinogen decreased
	Blood thrombin abnormal
	Blood thrombin decreased
	Blood thromboplastin abnormal
	Blood thromboplastin decreased
	Bromsulphthalein test abnormal
	Child-Pugh-Turcotte score abnormal
	Child-Pugh-Turcotte score increased
	Cholaemia
	Cholangiosarcoma
	Cholestatic liver injury
	Cholestatic pruritus
	Chronic graft versus host disease in liver
	Chronic hepatic failure
	Chronic hepatitis
	Coagulation factor IX level abnormal
	Coagulation factor IX level decreased
	Coagulation factor V level abnormal
	Coagulation factor V level decreased
	Coagulation factor VII level abnormal
	Coagulation factor VII level decreased
	Coagulation factor X level abnormal

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Drug related hepatic disorders - comprehensive search (SMQ)

- Coagulation factor X level decreased
- Coagulation factor decreased
- Coma hepatic
- Complications of transplanted liver
- Computerised tomogram liver abnormal
- Cryptogenic cirrhosis
- Deficiency of bile secretion
- Diabetic hepatopathy
- Drug-induced liver injury
- Duodenal varices
- Focal nodular hyperplasia
- Foetor hepaticus
- Galactose elimination capacity test abnormal
- Galactose elimination capacity test decreased
- Gamma-glutamyltransferase abnormal
- Gamma-glutamyltransferase increased
- Gastric variceal injection
- Gastric variceal ligation
- Gastric varices
- Gastric varices haemorrhage
- Gastroesophageal variceal haemorrhage prophylaxis
- Glutamate dehydrogenase increased
- Glycocholic acid increased
- Graft versus host disease in liver
- Granulomatous liver disease
- Guanase increased
- Haemangioma of liver
- Haemorrhagic ascites
- Haemorrhagic hepatic cyst
- Hepaplastin abnormal
- Hepaplastin decreased
- Hepatectomy
- Hepatic adenoma
- Hepatic angiosarcoma
- Hepatic artery flow decreased
- Hepatic atrophy
- Hepatic calcification
- Hepatic cancer
- Hepatic cancer metastatic
- Hepatic cancer recurrent
- Hepatic cancer stage I
- Hepatic cancer stage II

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Drug related hepatic disorders - comprehensive search (SMQ)	Hepatic cancer stage III
	Hepatic cancer stage IV
	Hepatic cirrhosis
	Hepatic cyst
	Hepatic cyst ruptured
	Hepatic encephalopathy
	Hepatic encephalopathy prophylaxis
	Hepatic enzyme abnormal
	Hepatic enzyme decreased
	Hepatic enzyme increased
	Hepatic failure
	Hepatic fibrosis
	Hepatic fibrosis marker abnormal
	Hepatic fibrosis marker increased
	Hepatic function abnormal
	Hepatic haemangioma rupture
	Hepatic hamartoma
	Hepatic hydrothorax
	Hepatic hypertrophy
	Hepatic infiltration eosinophilic
	Hepatic lesion
	Hepatic lymphocytic infiltration
	Hepatic mass
	Hepatic necrosis
	Hepatic neoplasm
	Hepatic pain
	Hepatic perfusion disorder
	Hepatic sequestration
	Hepatic steato-fibrosis
	Hepatic steatosis
	Hepatic vascular resistance increased
	Hepatic venous pressure gradient abnormal
	Hepatic venous pressure gradient increased
	Hepatitis
	Hepatitis acute
	Hepatitis chronic active
	Hepatitis chronic persistent
	Hepatitis fulminant
	Hepatitis toxic
	Hepatobiliary cancer
	Hepatobiliary cancer in situ
	Hepatobiliary cyst

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Drug related hepatic disorders - comprehensive search (SMQ)

Hepatobiliary neoplasm
 Hepatobiliary scan abnormal
 Hepatoblastoma
 Hepatoblastoma recurrent
 Hepatoceellular carcinoma
 Hepatoceellular foamy cell syndrome
 Hepatoceellular injury
 Hepatopulmonary syndrome
 Hepatorenal syndrome
 Hepatosplenomegaly
 Hepatotoxicity
 Hyperammonaemia
 Hypercholia
 Hyperfibrinolysis
 Hypertransaminaemia
 Hypoalbuminaemia
 Hypocoagulable state
 Hypofibrinogenaemia
 Hypoprotrombinaemia
 Hypothrombinaemia
 Hypothromboplastinaemia
 Icterus index increased
 Immune-mediated hepatic disorder
 Immune-mediated hepatitis
 Increased liver stiffness
 International normalised ratio abnormal
 International normalised ratio increased
 Intestinal varices
 Intestinal varices haemorrhage
 Intrahepatic portal hepatic venous fistula
 Ischaemic hepatitis
 Jaundice hepatocellular
 Kayser-Fleischer ring
 Leucine aminopeptidase increased
 Liver ablation
 Liver and pancreas transplant rejection
 Liver carcinoma ruptured
 Liver dialysis
 Liver disorder
 Liver function test abnormal
 Liver function test decreased
 Liver function test increased

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Drug related hepatic disorders - comprehensive search (SMQ)

- Liver induration
- Liver injury
- Liver iron concentration abnormal
- Liver iron concentration increased
- Liver opacity
- Liver operation
- Liver palpable
- Liver sarcoidosis
- Liver scan abnormal
- Liver tenderness
- Liver transplant
- Liver transplant failure
- Liver transplant rejection
- Lupoid hepatic cirrhosis
- Lupus hepatitis
- Magnetic resonance imaging liver abnormal
- Magnetic resonance proton density fat fraction measurement
- Minimal hepatic encephalopathy
- Mitochondrial aspartate aminotransferase increased
- Mixed hepatocellular cholangiocarcinoma
- Mixed liver injury
- Model for end stage liver disease score abnormal
- Model for end stage liver disease score increased
- Molar ratio of total branched-chain amino acid to tyrosine
- Multivisceral transplantation
- Nodular regenerative hyperplasia
- Non-alcoholic steatohepatitis
- Non-cirrhotic portal hypertension
- Nonalcoholic fatty liver disease
- Ocular icterus
- Oedema due to hepatic disease
- Oesophageal varices haemorrhage
- Perihepatic discomfort
- Peripancratic varices
- Periportal oedema
- Peritoneal fluid protein abnormal
- Peritoneal fluid protein decreased
- Peritoneal fluid protein increased
- Peritoneovenous shunt
- Pneumobilia

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Drug related hepatic disorders - comprehensive search (SMQ)	Portal fibrosis
	Portal hypertension
	Portal hypertensive colopathy
	Portal hypertensive enteropathy
	Portal hypertensive gastropathy
	Portal shunt
	Portal tract inflammation
	Portal vein dilatation
	Portal vein flow decreased
	Portal vein pressure increased
	Portopulmonary hypertension
	Protein C decreased
	Protein S abnormal
	Protein S decreased
	Prothrombin level abnormal
	Prothrombin level decreased
	Prothrombin time abnormal
	Prothrombin time prolonged
	Prothrombin time ratio abnormal
	Prothrombin time ratio increased
	Radiation hepatitis
	Regenerative siderotic hepatic nodule
	Renal and liver transplant
	Retinol binding protein decreased
	Retrograde portal vein flow
	Reye's syndrome
	Small-for-size liver syndrome
	Spider naevus
	Splenic artery embolisation
	Splenic varices
	Splenic varices haemorrhage
	Splenorenal shunt
	Splenorenal shunt procedure
	Spontaneous intrahepatic portosystemic venous shunt
	Steatohepatitis
	Stomal varices
	Subacute hepatic failure
	Sugiura procedure
	Thrombin time abnormal
	Thrombin time prolonged
	Total bile acids increased

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Drug related hepatic disorders - comprehensive search (SMQ)

Transaminases abnormal

Transaminases increased
 Ultrasound liver abnormal
 Urine bilirubin increased
 Urobilinogen urine decreased
 Urobilinogen urine increased
 Varices oesophageal
 Varicose veins of abdominal wall
 White nipple sign
 Yellow skin

Gastrointestinal adverse events

Biliary ascites
 Gallstone ileus
 Allergic colitis
 Allergic gastroenteritis
 Allergic stomatitis
 Anal eczema
 Contact stomatitis
 Gingival oedema
 Gingival swelling
 Intestinal angioedema
 Lip oedema
 Lip swelling
 Mouth swelling
 Oedema mouth
 Palatal oedema
 Palatal swelling
 Swollen tongue
 Tongue oedema
 Ascites
 Haemorrhoids thrombosed
 Intestinal infarction
 Mesenteric arterial occlusion
 Mesenteric arteriosclerosis
 Mesenteric artery embolism
 Mesenteric artery stenosis
 Mesenteric artery thrombosis
 Mesenteric vascular insufficiency
 Mesenteric vascular occlusion
 Mesenteric vein thrombosis
 Pancreatic infarction

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

Thrombosis mesenteric vessel
Truncus coeliacus thrombosis
Vasculitis gastrointestinal
Visceral venous thrombosis
Anorectal varices
Anorectal varices haemorrhage
Duodenal varices
Gastric varices
Gastric varices haemorrhage
Haemorrhagic ascites
Intestinal varices
Intestinal varices haemorrhage
Oesophageal varices haemorrhage
Peripancreatic varices
Portal hypertensive colopathy
Portal hypertensive enteropathy
Portal hypertensive gastropathy
Varices oesophageal
Varicose veins of abdominal wall
White nipple sign
Abdominal adhesions
Abdominal compartment syndrome
Abdominal discomfort
Abdominal distension
Abdominal fat apron
Abdominal hernia
Abdominal hernia obstructive
Abdominal hernia perforation
Abdominal incarcerated hernia
Abdominal mass
Abdominal migraine
Abdominal pain
Abdominal pain lower
Abdominal pain upper
Abdominal rebound tenderness
Abdominal rigidity
Abdominal strangulated hernia
Abdominal symptom
Abdominal tenderness
Abdominal wall cyst
Abdominal wall disorder
Abdominal wall haematoma
Abdominal wall haemorrhage

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

- Abdominal wall mass
- Abdominal wall oedema
- Abnormal faeces
- Acetonaemic vomiting
- Achlorhydria
- Acid peptic disease
- Acquired enamel hypoplasia
- Acquired macroglossia
- Acquired oesophageal web
- Acute abdomen
- Acute haemorrhagic ulcerative colitis
- Acute oesophageal mucosal lesion
- Aerophagia
- Alcoholic pancreatitis
- Alcoholic pancreopathy
- Alveolar bone resorption
- Amalgam tattoo
- Ampullary polyp
- Anaesthesia oral
- Anal blister
- Anal dilatation
- Anal erosion
- Anal fissure
- Anal fissure haemorrhage
- Anal fistula
- Anal haemorrhage
- Anal hypoaesthesia
- Anal incontinence
- Anal inflammation
- Anal leukoplakia
- Anal paraesthesia
- Anal polyp
- Anal prolapse
- Anal pruritus
- Anal skin tags
- Anal spasm
- Anal sphincter atony
- Anal sphincter hypertonia
- Anal stenosis
- Anal trichiasis
- Anal ulcer
- Anal ulcer haemorrhage
- Anastomotic ulcer perforation

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

- Anastomotic ulcer, obstructive
- Angina bullosa haemorrhagica
- Angular cheilitis
- Ankyloglossia acquired
- Anogenital dysplasia
- Anorectal discomfort
- Anorectal disorder
- Anorectal sensory loss
- Anorectal squamous cell metaplasia
- Anorectal stenosis
- Anorectal swelling
- Anorectal ulcer
- Anovulvar fistula
- Aorto-oesophageal fistula
- Aortoenteric fistula
- Apthous ulcer
- Apical granuloma
- Apoptotic colonopathy
- Appendiceal mucocoele
- Appendicitis noninfective
- Appendicolith
- Appendix disorder
- Aptyalism
- Atrophic glossitis
- Auriculotemporal syndrome
- Autoimmune colitis
- Autoimmune enteropathy
- Autoimmune pancreatitis
- Barrett's oesophagus
- Bezoar
- Bile acid malabsorption
- Bloody peritoneal effluent
- Bowel movement irregularity
- Breath odour
- Brunner's gland hyperplasia
- Buccal polyp
- Buccoglossal syndrome
- Burning mouth syndrome
- Cannabinoid hyperemesis syndrome
- Cardiospasm
- Cascade stomach
- Cemento osseous dysplasia
- Change of bowel habit

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

Chapped lips
 Cheilitis
 Cheilitis granulomatosa
 Cheilosis
 Chilaiditi's syndrome
 Chronic cheek biting
 Chronic gastritis
 Chronic gastrointestinal bleeding
 Coating in mouth
 Cobble stone tongue
 Coeliac artery aneurysm
 Coeliac artery compression syndrome
 Coeliac artery stenosis
 Coeliac disease
 Colitis
 Colitis cystica profunda
 Colitis erosive
 Colitis ischaemic
 Colitis microscopic
 Colitis ulcerative
 Colon dysplasia
 Colonic fistula
 Colonic haematoma
 Constipation
 Constipation neonatal
 Creatorrhoea
 Cricopharyngeal achalasia
 Crohn's disease
 Cronkhite-Canada syndrome
 Cryptitis
 Cyclic vomiting syndrome
 Defaecation disorder
 Defaecation urgency
 Dental abfraction
 Dental alveolar anomaly
 Dental attrition
 Dental caries
 Dental cyst
 Dental discomfort
 Dental dysaesthesia
 Dental necrosis
 Dental paraesthesia
 Dental plaque

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

Dental pulp disorder
 Diabetic enteropathy
 Diabetic gastroenteropathy
 Diabetic gastroparesis
 Diabetic gastropathy
 Diaphragmatic hernia
 Diaphragmatic hernia, obstructive
 Diarrhoea
 Diarrhoea haemorrhagic
 Diarrhoea neonatal
 Diastema
 Dieulafoy's vascular malformation
 Discoloured vomit
 Distal intestinal obstruction syndrome
 Diverticular fistula
 Diverticular hernia
 Diverticular perforation
 Diverticulitis oesophageal
 Diverticuloma
 Diverticulum
 Diverticulum gastric
 Diverticulum intestinal
 Diverticulum intestinal haemorrhagic
 Diverticulum oesophageal
 Dolichocolon acquired
 Douglas' pouch mass
 Dry mouth
 Dumping syndrome
 Duodenal obstruction
 Duodenal papillitis
 Duodenal perforation
 Duodenal polyp
 Duodenal stenosis
 Duodenal ulcer
 Duodenal ulcer haemorrhage
 Duodenal ulcer perforation
 Duodenal ulcer perforation, obstructive
 Duodenal ulcer, obstructive
 Duodenal vascular ectasia
 Duodenitis
 Duodenitis haemorrhagic
 Duodenogastric reflux
 Dysbiosis

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

Dyschezia
Dyskinesia oesophageal
Dyspepsia
Dysphagia
Dysphagia lusoria
Ectopic gastric mucosa
Enamel anomaly
Encapsulating peritoneal sclerosis
Enlarged uvula
Enteric neuropathy
Enteritis
Enteritis leukopenic
Enterocele
Enterochromaffin cell hyperplasia
Enterocolitis
Enterocolitis haemorrhagic
Enterocolonic fistula
Enterocutaneous fistula
Enterovesical fistula
Eosinophilic colitis
Eosinophilic gastritis
Eosinophilic oesophagitis
Epigastric discomfort
Epiploic appendagitis
Epulis
Erosive duodenitis
Erosive oesophagitis
Eructation
Faecal vomiting
Faecalolith
Faecaloma
Faeces discoloured
Faeces hard
Faeces pale
Faeces soft
Feline oesophagus
Femoral hernia
Femoral hernia incarcerated
Femoral hernia strangulated
Femoral hernia, obstructive
Fibrosing colonopathy
Fistula of small intestine
Fixed bowel loop

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

Flatulence
 Fluorosis dental
 Food poisoning
 Frequent bowel movements
 Functional gastrointestinal disorder
 Gastric antral vascular ectasia
 Gastric atony
 Gastric cyst
 Gastric dilatation
 Gastric disorder
 Gastric dysplasia
 Gastric fibrosis
 Gastric fistula
 Gastric haemorrhage
 Gastric hypermotility
 Gastric hypertonia
 Gastric hypomotility
 Gastric ileus
 Gastric mucosa erythema
 Gastric mucosal calcinosis
 Gastric mucosal hypertrophy
 Gastric mucosal lesion
 Gastric perforation
 Gastric pneumatosis
 Gastric polyps
 Gastric prolapse
 Gastric stenosis
 Gastric ulcer
 Gastric ulcer haemorrhage
 Gastric ulcer haemorrhage, obstructive
 Gastric ulcer perforation
 Gastric ulcer perforation, obstructive
 Gastric ulcer, obstructive
 Gastric volvulus
 Gastric xanthoma
 Gastritis
 Gastritis alcoholic
 Gastritis alcoholic haemorrhagic
 Gastritis erosive
 Gastritis haemorrhagic
 Gastritis hypertrophic
 Gastrocoele
 Gastroduodenal haemorrhage

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

- Gastroduodenal ulcer
- Gastroenteritis eosinophilic
- Gastrointestinal amyloidosis
- Gastrointestinal angiectasia
- Gastrointestinal angiodysplasia
- Gastrointestinal disorder
- Gastrointestinal dysplasia
- Gastrointestinal erosion
- Gastrointestinal fistula
- Gastrointestinal haemorrhage
- Gastrointestinal hypermotility
- Gastrointestinal hypomotility
- Gastrointestinal inflammation
- Gastrointestinal ischaemia
- Gastrointestinal melanosis
- Gastrointestinal motility disorder
- Gastrointestinal mucocoele
- Gastrointestinal mucosa hyperaemia
- Gastrointestinal mucosal disorder
- Gastrointestinal mucosal exfoliation
- Gastrointestinal mucosal necrosis
- Gastrointestinal necrosis
- Gastrointestinal obstruction
- Gastrointestinal oedema
- Gastrointestinal pain
- Gastrointestinal perforation
- Gastrointestinal polyp
- Gastrointestinal polyp haemorrhage
- Gastrointestinal scarring
- Gastrointestinal sounds abnormal
- Gastrointestinal stenosis
- Gastrointestinal toxicity
- Gastrointestinal tract irritation
- Gastrointestinal tract mucosal discolouration
- Gastrointestinal tract mucosal pigmentation
- Gastrointestinal ulcer
- Gastrointestinal ulcer haemorrhage
- Gastrointestinal ulcer perforation
- Gastrointestinal vascular malformation
- Gastrointestinal vascular malformation haemorrhagic
- Gastrointestinal wall abnormal
- Gastrointestinal wall thickening

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

Gastrointestinal wall thinning
 Gastrolithiasis
 Gastroesophageal reflux disease
 Gastroesophageal sphincter insufficiency
 Gastropleural fistula
 Gastroptosis
 Gastrosplenic fistula
 Giant cell epulis
 Gingival atrophy
 Gingival bleeding
 Gingival blister
 Gingival cyst
 Gingival discolouration
 Gingival discomfort
 Gingival disorder
 Gingival erosion
 Gingival erythema
 Gingival hyperpigmentation
 Gingival hypertrophy
 Gingival hypoplasia
 Gingival pain
 Gingival polyp
 Gingival pruritus
 Gingival recession
 Gingival ulceration
 Gingivitis ulcerative
 Glossitis
 Glossodynia
 Glossoptosis
 Glycogenic acanthosis
 Gut fermentation syndrome
 Haematemesis
 Haematochezia
 Haemoperitoneum
 Haemorrhagic erosive gastritis
 Haemorrhagic necrotic pancreatitis
 Haemorrhoidal haemorrhage
 Haemorrhoids
 Hernial eventration
 Heyde's syndrome
 Hiatus hernia
 Hiatus hernia strangulated
 Hiatus hernia, obstructive

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

- Hyperaesthesia teeth
- Hypercementosis
- Hyperchlorhydria
- Hypergastrinaemia
- Hypertrophic anal papilla
- Hypertrophy of tongue papillae
- Hypoaesthesia oral
- Hypoaesthesia teeth
- Ileal perforation
- Ileal stenosis
- Ileal ulcer
- Ileal ulcer perforation
- Ileus
- Ileus paralytic
- Ileus spastic
- Immune-mediated enterocolitis
- Immune-mediated pancreatitis
- Impaired gastric emptying
- Incarcerated hiatus hernia
- Incarcerated inguinal hernia
- Incarcerated umbilical hernia
- Increased intraperitoneal volume
- Infant dyschezia
- Infantile colic
- Infantile spitting up
- Infantile vomiting
- Inflammatory bowel disease
- Infrequent bowel movements
- Inguinal hernia
- Inguinal hernia perforation
- Inguinal hernia strangulated
- Inguinal hernia, obstructive
- Internal hernia
- Intestinal angina
- Intestinal atony
- Intestinal calcification
- Intestinal congestion
- Intestinal cyst
- Intestinal diaphragm disease
- Intestinal dilatation
- Intestinal fibrosis
- Intestinal fistula
- Intestinal haematoma

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

Intestinal haemorrhage
 Intestinal ischaemia
 Intestinal mass
 Intestinal metaplasia
 Intestinal mucosal atrophy
 Intestinal mucosal hypertrophy
 Intestinal mucosal tear
 Intestinal obstruction
 Intestinal perforation
 Intestinal polyp
 Intestinal prolapse
 Intestinal pseudo-obstruction
 Intestinal smooth muscle hypertrophy
 Intestinal steatosis
 Intestinal stenosis
 Intestinal strangulation
 Intestinal ulcer
 Intestinal ulcer perforation
 Intestinal villi atrophy
 Intra-abdominal fluid collection
 Intra-abdominal haematoma
 Intra-abdominal haemorrhage
 Intrinsic factor deficiency
 Intussusception
 Irritable bowel syndrome
 Ischaemic enteritis
 Ischaemic gastritis
 Ischaemic pancreatitis
 Ischiatic hernia
 Ischiorectal hernia
 Jejunal perforation
 Jejunal stenosis
 Jejunal ulcer
 Jejunal ulcer perforation
 Large intestinal haemorrhage
 Large intestinal obstruction
 Large intestinal stenosis
 Large intestinal ulcer
 Large intestinal ulcer haemorrhage
 Large intestinal ulcer perforation
 Large intestine erosion
 Large intestine perforation
 Large intestine polyp

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

- Leukoplakia oesophageal
- Leukoplakia oral
- Levator syndrome
- Lichenoid dysplasia
- Lip blister
- Lip discoloration
- Lip disorder
- Lip dry
- Lip erosion
- Lip erythema
- Lip exfoliation
- Lip haematoma
- Lip haemorrhage
- Lip pain
- Lip pruritus
- Lip scab
- Lip ulceration
- Loose tooth
- Lower gastrointestinal haemorrhage
- Lower gastrointestinal perforation
- Lumbar hernia
- Lupus enteritis
- Lupus pancreatitis
- Lymphangiectasia intestinal
- Lymphocytic oesophagitis
- Lymphoid hyperplasia of intestine
- Malabsorption
- Malacoplakia gastrointestinal
- Malignant dysphagia
- Malignant gastrointestinal obstruction
- Mallory-Weiss syndrome
- Malocclusion
- Malpositioned teeth
- Mastocytic enterocolitis
- Mechanical ileus
- Meconium cyst
- Meconium ileus
- Meconium peritonitis
- Meconium plug syndrome
- Megacolon
- Melaena
- Melaena neonatal
- Melanoplakia oral

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

- Mesenteric artery aneurysm
- Mesenteric cyst
- Mesenteric fibrosis
- Mesenteric haematoma
- Mesenteric haemorrhage
- Mesenteric panniculitis
- Mesenteric phleboscлерosis
- Mesenteritis
- Mikulicz's disease
- Mikulicz's syndrome
- Mouth cyst
- Mouth haemorrhage
- Mouth ulceration
- Mucosal prolapse syndrome
- Mucous stools
- Myochosis
- Narcotic bowel syndrome
- Nausea
- Necrotising colitis
- Necrotising enterocolitis neonatal
- Necrotising gastritis
- Necrotising oesophagitis
- Neonatal gastrointestinal disorder
- Neonatal gastrointestinal haemorrhage
- Neonatal intestinal dilatation
- Neonatal intestinal obstruction
- Neonatal intestinal perforation
- Neurogenic bowel
- Neutropenic colitis
- Nicotinic stomatitis
- Noninfectious peritonitis
- Noninfective gingivitis
- Noninfective sialoadenitis
- Obstruction gastric
- Obstructive defaecation
- Obstructive pancreatitis
- Obturator hernia
- Odynophagia
- Oedematous pancreatitis
- Oesophageal achalasia
- Oesophageal atony
- Oesophageal compression
- Oesophageal dilatation

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

Oesophageal discomfort
Oesophageal disorder
Oesophageal dysplasia
Oesophageal fibrosis
Oesophageal fistula
Oesophageal food impaction
Oesophageal haemorrhage
Oesophageal hypomotility
Oesophageal intramural haematoma
Oesophageal irritation
Oesophageal mass
Oesophageal motility disorder
Oesophageal mucosa erythema
Oesophageal mucosal blister
Oesophageal mucosal dissection
Oesophageal mucosal hyperplasia
Oesophageal mucosal tear
Oesophageal obstruction
Oesophageal oedema
Oesophageal pain
Oesophageal perforation
Oesophageal polyp
Oesophageal rupture
Oesophageal spasm
Oesophageal stenosis
Oesophageal stent stenosis
Oesophageal ulcer
Oesophageal ulcer haemorrhage
Oesophageal ulcer perforation
Oesophageal-pulmonary fistula
Oesophagitis
Oesophagitis haemorrhagic
Oesophagitis ulcerative
Oesophagomediastinal fistula
Oesophagopleural fistula
Omental infarction
Omental necrosis
Oral blood blister
Oral cavity fistula
Oral discharge
Oral discomfort
Oral disorder
Oral dysaesthesia

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

- Oral hyperaesthesia
- Oral hyperkeratosis
- Oral leukoedema
- Oral lichen planus
- Oral lichenoid reaction
- Oral macule
- Oral mucosa atrophy
- Oral mucosa erosion
- Oral mucosa haematoma
- Oral mucosal blistering
- Oral mucosal discoloration
- Oral mucosal eruption
- Oral mucosal erythema
- Oral mucosal exfoliation
- Oral mucosal hypertrophy
- Oral mucosal roughening
- Oral mucosal scab
- Oral pain
- Oral papule
- Oral pigmentation
- Oral pruritus
- Oral purpura
- Oral submucosal fibrosis
- Oral toxicity
- Oroantral fistula
- Palatal disorder
- Palatal dysplasia
- Palatal polyp
- Palatal ulcer
- Pancreatic atrophy
- Pancreatic calcification
- Pancreatic cyst
- Pancreatic cyst rupture
- Pancreatic disorder
- Pancreatic duct dilatation
- Pancreatic duct obstruction
- Pancreatic duct stenosis
- Pancreatic enlargement
- Pancreatic enzyme abnormality
- Pancreatic failure
- Pancreatic fibrosis
- Pancreatic fistula
- Pancreatic haemorrhage

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

Pancreatic mass
Pancreatic necrosis
Pancreatic phlegmon
Pancreatic pseudoaneurysm
Pancreatic pseudocyst
Pancreatic pseudocyst haemorrhage
Pancreatic pseudocyst rupture
Pancreatic steatosis
Pancreatic toxicity
Pancreatitis
Pancreatitis acute
Pancreatitis chronic
Pancreatitis haemorrhagic
Pancreatitis necrotising
Pancreatitis relapsing
Pancreatolithiasis
Papilla of Vater stenosis
Paraesthesia oral
Paresis anal sphincter
Parotid duct obstruction
Parotid gland enlargement
Parotid gland haemorrhage
Parotid lipomatosis
Pathological tooth fracture
Pelvic floor dysfunction
Peptic ulcer
Peptic ulcer haemorrhage
Peptic ulcer perforation
Peptic ulcer perforation, obstructive
Peptic ulcer, obstructive
Perianal erythema
Periodontal disease
Periodontal inflammation
Peristalsis visible
Peritoneal adhesions
Peritoneal cloudy effluent
Peritoneal cyst
Peritoneal disorder
Peritoneal fibrosis
Peritoneal haematoma
Peritoneal hernia
Peritoneal lesion
Peritoneal mesothelial hyperplasia

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

Peritoneal necrosis
 Peritoneal perforation
 Peritoneocutaneous fistula
 Peritonitis lupus
 Pharyngo-oesophageal diverticulum
 Pigmentation lip
 Plicated tongue
 Pneumatosis intestinalis
 Pneumoperitoneum
 Pneumoretroperitoneum
 Poor dental condition
 Portal venous gas
 Post-tussive vomiting
 Pouchitis
 Precancerous lesion of digestive tract
 Prepyloric stenosis
 Presbyoesophagus
 Proctalgia
 Proctitis
 Proctitis haemorrhagic
 Proctitis ulcerative
 Proctoparalysis
 Protein-losing gastroenteropathy
 Protrusion tongue
 Pseudoachalasia
 Pseudodiverticular disease
 Pseudopolyposis
 Pudental hernia
 Pulpless tooth
 Pyloric sphincter insufficiency
 Pylorospasm
 Pylorus dilatation
 Pyostomatitis vegetans
 Ranula
 Rebound acid hypersecretion
 Rectal discharge
 Rectal dysplasia
 Rectal fissure
 Rectal haemorrhage
 Rectal lesion
 Rectal obstruction
 Rectal perforation
 Rectal polyp

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

Rectal prolapse
Rectal spasm
Rectal stenosis
Rectal tenesmus
Rectal ulcer
Rectal ulcer haemorrhage
Rectourethral fistula
Reflux gastritis
Regurgitation
Retained deciduous tooth
Retching
Retroperitoneal effusion
Retroperitoneal fibrosis
Retroperitoneal haematoma
Retroperitoneal haemorrhage
Retroperitoneal hernia
Retroperitoneal mass
Retroperitoneal oedema
Retroperitoneum cyst
Richter's hernia
Saliva altered
Saliva discolouration
Salivary duct inflammation
Salivary duct obstruction
Salivary duct stenosis
Salivary gland atrophy
Salivary gland calculus
Salivary gland cyst
Salivary gland disorder
Salivary gland enlargement
Salivary gland fistula
Salivary gland induration
Salivary gland mass
Salivary gland mucocoele
Salivary gland pain
Salivary hypersecretion
Sandifer's syndrome
Scalloped tongue
Scaphoid abdomen
Sciatic hernia
Segmental diverticular colitis
Short-bowel syndrome
Sialadenosis

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

Sialectasia
 Sialoceles
 Sialodochitis fibrinosa
 Sialometaplasia
 Sideropenic dysphagia
 Sigmoid mesocolon hernia
 Small intestinal haemorrhage
 Small intestinal obstruction
 Small intestinal perforation
 Small intestinal stenosis
 Small intestinal ulcer haemorrhage
 Small intestinal ulcer perforation
 Small intestine polyp
 Small intestine ulcer
 Sordes
 Spigelian hernia
 Splenic artery aneurysm
 Splenic vein aneurysm
 Sprue-like enteropathy
 Stasis syndrome
 Steatorrhea
 Stiff tongue
 Stomach granuloma
 Stomach mass
 Stomatitis
 Stomatitis haemorrhagic
 Stomatitis necrotising
 Strangulated umbilical hernia
 Strawberry tongue
 Stress ulcer
 Subileus
 Submaxillary gland enlargement
 Superior mesenteric artery syndrome
 Supernumerary teeth
 Teeth brittle
 Teething
 Terminal ileitis
 Tongue amyloidosis
 Tongue atrophy
 Tongue blistering
 Tongue coated
 Tongue cyst
 Tongue discolouration

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

- Tongue discomfort
- Tongue disorder
- Tongue dry
- Tongue dysplasia
- Tongue eruption
- Tongue erythema
- Tongue exfoliation
- Tongue geographic
- Tongue haematoma
- Tongue haemorrhage
- Tongue infarction
- Tongue movement disturbance
- Tongue necrosis
- Tongue pigmentation
- Tongue polyp
- Tongue pruritus
- Tongue rough
- Tongue spasm
- Tongue thrust
- Tongue ulceration
- Tooth ankylosis
- Tooth delamination
- Tooth demineralisation
- Tooth deposit
- Tooth development disorder
- Tooth discolouration
- Tooth disorder
- Tooth erosion
- Tooth impacted
- Tooth loss
- Tooth malformation
- Tooth pulp haemorrhage
- Tooth resorption
- Tooth socket haemorrhage
- Toothache
- Toxic dilatation of intestine
- Transient lingual papillitis
- Traumatic occlusion
- Traumatic ulcerative granuloma with stromal eosinophilia
- Trichoglossia
- Ulcerative duodenitis
- Ulcerative gastritis

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Gastrointestinal adverse events

Ultrafiltration failure
 Umbilical hernia
 Umbilical hernia perforation
 Umbilical hernia, obstructive
 Upper gastrointestinal haemorrhage
 Upper gastrointestinal perforation
 Uraemic gastropathy
 Urinary ascites
 Uvulitis
 Varicose veins sublingual
 Visceroptosis
 Volvulus
 Volvulus of small bowel
 Vomiting
 Vomiting projectile
 Wischnewsky spots

Injection site reactions

Administration site dermatitis
 Administration site eczema
 Administration site hypersensitivity
 Administration site rash
 Administration site recall reaction
 Administration site urticaria
 Administration site vasculitis
 Application site dermatitis
 Application site eczema
 Application site hypersensitivity
 Application site rash
 Application site recall reaction
 Application site urticaria
 Application site vasculitis
 Infusion site dermatitis
 Infusion site eczema
 Infusion site hypersensitivity
 Infusion site rash
 Infusion site recall reaction
 Infusion site urticaria
 Infusion site vasculitis
 Injection site dermatitis
 Injection site eczema
 Injection site hypersensitivity
 Injection site rash
 Injection site recall reaction

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Injection site reactions

Injection site urticaria
Injection site vasculitis
Instillation site hypersensitivity
Instillation site rash
Instillation site urticaria
Vessel puncture site rash
Vessel puncture site vesicles
Administration site thrombosis
Application site thrombosis
Erbolla cutis medicamentosa
Infusion site thrombosis
Injection site thrombosis
Instillation site thrombosis
Vessel puncture site occlusion
Vessel puncture site thrombosis
Administration site abscess
Administration site abscess sterile
Administration site acne
Administration site anaesthesia
Administration site atrophy
Administration site bruise
Administration site calcification
Administration site cellulitis
Administration site coldness
Administration site cyst
Administration site discharge
Administration site discolouration
Administration site discomfort
Administration site dryness
Administration site dysaesthesia
Administration site erosion
Administration site erythema
Administration site exfoliation
Administration site extravasation
Administration site fibrosis
Administration site granuloma
Administration site haematoma
Administration site haemorrhage
Administration site hyperaesthesia
Administration site hypertrichosis
Administration site hypertrophy
Administration site hypoaesthesia
Administration site indentation

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Injection site reactions

Administration site induration
Administration site infection
Administration site inflammation
Administration site injury
Administration site irritation
Administration site ischaemia
Administration site joint discomfort
Administration site joint effusion
Administration site joint erythema
Administration site joint infection
Administration site joint inflammation
Administration site joint movement impairment
Administration site joint pain
Administration site joint warmth
Administration site laceration
Administration site lymphadenopathy
Administration site macule
Administration site mass
Administration site movement impairment
Administration site necrosis
Administration site nerve damage
Administration site nodule
Administration site odour
Administration site oedema
Administration site pain
Administration site pallor
Administration site papule
Administration site paraesthesia
Administration site phlebitis
Administration site photosensitivity reaction
Administration site plaque
Administration site pruritus
Administration site pustule
Administration site reaction
Administration site reaction neonatal
Administration site scab
Administration site scar
Administration site streaking
Administration site swelling
Administration site ulcer
Administration site vesicles
Administration site warmth
Administration site wound

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Injection site reactions

- Application site abscess
- Application site abscess sterile
- Application site acne
- Application site alopecia
- Application site anaesthesia
- Application site atrophy
- Application site bruise
- Application site burn
- Application site calcification
- Application site cellulitis
- Application site coldness
- Application site cyst
- Application site discharge
- Application site discolouration
- Application site discomfort
- Application site dryness
- Application site dysaesthesia
- Application site erosion
- Application site erythema
- Application site exfoliation
- Application site extravasation
- Application site fibrosis
- Application site fissure
- Application site folliculitis
- Application site granuloma
- Application site haematoma
- Application site haemorrhage
- Application site hyperaesthesia
- Application site hypertrichosis
- Application site hypertrophy
- Application site hypoaesthesia
- Application site induration
- Application site infection
- Application site inflammation
- Application site injury
- Application site irritation
- Application site ischaemia
- Application site joint discomfort
- Application site joint effusion
- Application site joint erythema
- Application site joint infection
- Application site joint inflammation
- Application site joint movement impairment

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Injection site reactions

Application site joint pain
 Application site joint swelling
 Application site joint warmth
 Application site laceration
 Application site lymphadenopathy
 Application site macule
 Application site mass
 Application site movement impairment
 Application site necrosis
 Application site nerve damage
 Application site nodule
 Application site odour
 Application site oedema
 Application site pain
 Application site pallor
 Application site papules
 Application site paraesthesia
 Application site perspiration
 Application site phlebitis
 Application site photosensitivity reaction
 Application site plaque
 Application site pruritus
 Application site purpura
 Application site pustules
 Application site reaction
 Application site scab
 Application site scar
 Application site streaking
 Application site swelling
 Application site telangiectasia
 Application site ulcer
 Application site vesicles
 Application site warmth
 Challenge site reaction
 Infusion site abscess
 Infusion site abscess sterile
 Infusion site anaesthesia
 Infusion site atrophy
 Infusion site bruising
 Infusion site calcification
 Infusion site cellulitis
 Infusion site coldness

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Injection site reactions

Infusion site cyst
Infusion site discharge
Infusion site discolouration
Infusion site discomfort
Infusion site dryness
Infusion site dysaesthesia
Infusion site erosion
Infusion site erythema
Infusion site eschar
Infusion site exfoliation
Infusion site extravasation
Infusion site fibrosis
Infusion site granuloma
Infusion site haematoma
Infusion site haemorrhage
Infusion site hyperaesthesia
Infusion site hypertrichosis
Infusion site hypertrophy
Infusion site hypoaesthesia
Infusion site induration
Infusion site infection
Infusion site inflammation
Infusion site injury
Infusion site irritation
Infusion site ischaemia
Infusion site joint discomfort
Infusion site joint effusion
Infusion site joint erythema
Infusion site joint infection
Infusion site joint inflammation
Infusion site joint movement impairment
Infusion site joint pain
Infusion site joint swelling
Infusion site joint warmth
Infusion site laceration
Infusion site lymphadenopathy
Infusion site macule
Infusion site mass
Infusion site mobility decreased
Infusion site necrosis
Infusion site nerve damage
Infusion site nodule
Infusion site oedema

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Injection site reactions

- Infusion site pain
- Infusion site pallor
- Infusion site papule
- Infusion site paraesthesia
- Infusion site phlebitis
- Infusion site photosensitivity reaction
- Infusion site plaque
- Infusion site pruritus
- Infusion site pustule
- Infusion site reaction
- Infusion site scab
- Infusion site scar
- Infusion site streaking
- Infusion site swelling
- Infusion site ulcer
- Infusion site vesicles
- Infusion site warmth
- Injected limb mobility decreased
- Injection site abscess
- Injection site abscess sterile
- Injection site alopecia
- Injection site anaesthesia
- Injection site atrophy
- Injection site bruising
- Injection site calcification
- Injection site cellulitis
- Injection site coldness
- Injection site cyst
- Injection site deformation
- Injection site discharge
- Injection site discolouration
- Injection site discomfort
- Injection site dryness
- Injection site dysaesthesia
- Injection site erosion
- Injection site erythema
- Injection site exfoliation
- Injection site extravasation
- Injection site fibrosis
- Injection site granuloma
- Injection site haematoma
- Injection site haemorrhage
- Injection site hyperaesthesia

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Injection site reactions

Injection site hypertrichosis
Injection site hypertrophy
Injection site hypoesthesia
Injection site indentation
Injection site induration
Injection site infection
Injection site inflammation
Injection site injury
Injection site irritation
Injection site ischaemia
Injection site joint discomfort
Injection site joint effusion
Injection site joint erythema
Injection site joint infection
Injection site joint inflammation
Injection site joint movement impairment
Injection site joint pain
Injection site joint swelling
Injection site joint warmth
Injection site laceration
Injection site lymphadenopathy
Injection site macule
Injection site mass
Injection site movement impairment
Injection site necrosis
Injection site nerve damage
Injection site nodule
Injection site oedema
Injection site pain
Injection site pallor
Injection site panniculitis
Injection site papule
Injection site paraesthesia
Injection site phlebitis
Injection site photosensitivity reaction
Injection site plaque
Injection site pruritus
Injection site pustule
Injection site reaction
Injection site scab
Injection site scar
Injection site streaking
Injection site swelling

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Injection site reactions

Injection site telangiectasia
Injection site ulcer
Injection site vesicles
Injection site warmth
Instillation site abscess
Instillation site anaesthesia
Instillation site atrophy
Instillation site bruise
Instillation site burn
Instillation site coldness
Instillation site complication
Instillation site discharge
Instillation site discolouration
Instillation site discomfort
Instillation site dryness
Instillation site erosion
Instillation site erythema
Instillation site exfoliation
Instillation site foreign body sensation
Instillation site haematoma
Instillation site haemorrhage
Instillation site hyperaesthesia
Instillation site hypoaesthesia
Instillation site induration
Instillation site infection
Instillation site inflammation
Instillation site irritation
Instillation site lacrimation
Instillation site necrosis
Instillation site nodule
Instillation site odour
Instillation site oedema
Instillation site pain
Instillation site papules
Instillation site paraesthesia
Instillation site pruritus
Instillation site pustules
Instillation site reaction
Instillation site scab
Instillation site swelling
Instillation site ulcer
Instillation site vesicles
Instillation site warmth

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Injection site reactions

Malabsorption from administration site
 Malabsorption from application site
 Malabsorption from injection site
 Oral administration complication
 Puncture site abscess
 Puncture site bruise
 Puncture site discharge
 Puncture site erythema
 Puncture site haematoma
 Puncture site haemorrhage
 Puncture site hernia
 Puncture site hypoaesthesia
 Puncture site induration
 Puncture site infection
 Puncture site injury
 Puncture site oedema
 Puncture site pain
 Puncture site pruritus
 Puncture site reaction
 Puncture site swelling
 Systemic leakage
 Vessel puncture site anaesthesia
 Vessel puncture site bruise
 Vessel puncture site cellulitis
 Vessel puncture site discharge
 Vessel puncture site erythema
 Vessel puncture site haematoma
 Vessel puncture site haemorrhage
 Vessel puncture site hypoaesthesia
 Vessel puncture site induration
 Vessel puncture site infection
 Vessel puncture site inflammation
 Vessel puncture site injury
 Vessel puncture site pain
 Vessel puncture site paraesthesia
 Vessel puncture site phlebitis
 Vessel puncture site pruritus
 Vessel puncture site reaction
 Vessel puncture site swelling

Malignant tumours (SMQ)

Cholangiosarcoma
 Hepatic angiosarcoma
 Hepatic cancer

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

Hepatic cancer metastatic
 Hepatic cancer recurrent
 Hepatic cancer stage I
 Hepatic cancer stage II
 Hepatic cancer stage III
 Hepatic cancer stage IV
 Hepatobiliary cancer
 Hepatobiliary cancer in situ
 Hepatoblastoma
 Hepatoblastoma recurrent
 Hepatoceellular carcinoma
 Mixed hepatocellular cholangiocarcinoma
 5q minus syndrome
 Abdominal wall neoplasm malignant
 Acinar cell carcinoma of pancreas
 Acinic cell carcinoma of salivary gland
 Acral lentiginous melanoma
 Acral lentiginous melanoma stage I
 Acral lentiginous melanoma stage II
 Acral lentiginous melanoma stage III
 Acral lentiginous melanoma stage IV
 Acute bilineal leukaemia
 Acute biphenotypic leukaemia
 Acute erythroid leukaemia
 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
 Adenocarcinoma
 Adenocarcinoma gastric

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

Adenocarcinoma metastatic
 Adenocarcinoma of appendix
 Adenocarcinoma of colon
 Adenocarcinoma of salivary gland
 Adenocarcinoma of the cervix
 Adenocarcinoma pancreas
 Adenoid cystic carcinoma
 Adenoid cystic carcinoma of salivary gland
 Adenosquamous carcinoma of the cervix
 Adenosquamous carcinoma of vagina
 Adenosquamous cell carcinoma
 Adenosquamous cell lung cancer
 Adenosquamous cell lung cancer recurrent
 Adenosquamous cell lung cancer stage 0
 Adenosquamous cell lung cancer stage I
 Adenosquamous cell lung cancer stage II
 Adenosquamous cell lung cancer stage III
 Adenosquamous cell lung cancer stage IV
 Adrenal gland cancer
 Adrenal gland cancer metastatic
 Adrenocortical carcinoma
 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
 Aesthesioneuroblastoma
 Aleukaemic leukaemia
 Alveolar rhabdomyosarcoma
 Alveolar soft part sarcoma
 Alveolar soft part sarcoma metastatic
 Alveolar soft part sarcoma recurrent
 Ameloblastic carcinoma
 Anal cancer
 Anal cancer metastatic
 Anal cancer recurrent
 Anal cancer stage 0
 Anal cancer stage I
 Anal cancer stage II
 Anal cancer stage III
 Anal cancer stage IV

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

Anal squamous cell carcinoma
 Anaplastic astrocytoma
 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
 Anaplastic meningioma
 Anaplastic oligodendroglioma
 Anaplastic thyroid cancer
 Angiocentric glioma
 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
 Angiosarcoma
 Angiosarcoma metastatic
 Angiosarcoma non-metastatic
 Angiosarcoma recurrent
 Apocrine breast carcinoma
 Appendix cancer
 Astrocytoma
 Astrocytoma malignant

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

Atypical teratoid/rhabdoid tumour of CNS
 B precursor type acute leukaemia
 B-cell lymphoma
 B-cell lymphoma recurrent
 B-cell lymphoma refractory
 B-cell lymphoma stage I
 B-cell lymphoma stage II
 B-cell lymphoma stage III
 B-cell lymphoma stage IV
 B-cell prolymphocytic leukaemia
 B-cell small lymphocytic lymphoma
 B-cell small lymphocytic lymphoma recurrent
 B-cell small lymphocytic lymphoma refractory
 B-cell small lymphocytic lymphoma stage I
 B-cell small lymphocytic lymphoma stage II
 B-cell small lymphocytic lymphoma stage III
 B-cell small lymphocytic lymphoma stage IV
 B-cell type acute leukaemia
 B-cell unclassifiable lymphoma high grade
 B-cell unclassifiable lymphoma low grade
 Basal cell carcinoma
 Basal cell carcinoma metastatic
 Basosquamous carcinoma
 Basosquamous carcinoma of skin
 Bile duct adenocarcinoma
 Bile duct adenosquamous carcinoma
 Bile duct cancer
 Bile duct cancer recurrent
 Bile duct cancer stage 0
 Bile duct cancer stage I
 Bile duct cancer stage II
 Bile duct cancer stage III
 Bile duct cancer stage IV
 Bile duct squamous cell carcinoma
 Biliary cancer metastatic
 Biphasic mesothelioma
 Bladder adenocarcinoma recurrent
 Bladder adenocarcinoma stage 0
 Bladder adenocarcinoma stage I
 Bladder adenocarcinoma stage II
 Bladder adenocarcinoma stage III
 Bladder adenocarcinoma stage IV
 Bladder adenocarcinoma stage unspecified

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Preferred term

Malignant tumours (SMQ)

Bladder cancer
 Bladder cancer recurrent
 Bladder cancer stage 0, with cancer in situ
 Bladder cancer stage 0, without cancer in situ
 Bladder cancer stage I, with cancer in situ
 Bladder cancer stage I, without cancer in situ
 Bladder cancer stage II
 Bladder cancer stage III
 Bladder cancer stage IV
 Bladder squamous cell carcinoma recurrent
 Bladder squamous cell carcinoma stage 0
 Bladder squamous cell carcinoma stage I
 Bladder squamous cell carcinoma stage II
 Bladder squamous cell carcinoma stage III
 Bladder squamous cell carcinoma stage IV
 Bladder squamous cell carcinoma stage unspecified
 Bladder transitional cell carcinoma
 Bladder transitional cell carcinoma metastatic
 Bladder transitional cell carcinoma recurrent
 Bladder transitional cell carcinoma stage 0
 Bladder transitional cell carcinoma stage I
 Bladder transitional cell carcinoma stage II
 Bladder transitional cell carcinoma stage III
 Bladder transitional cell carcinoma stage IV
 Blast cell crisis
 Blast crisis in myelogenous leukaemia
 Blastic plasmacytoid dendritic cell neoplasia
 Bone cancer
 Bone cancer metastatic
 Bone giant cell tumour malignant
 Bone marrow leukaemic cell infiltration
 Bone marrow tumour cell infiltration
 Bone sarcoma
 Bowen's disease
 Brain cancer metastatic
 Brain neoplasm malignant
 Brain sarcoma
 Brain stem glioma
 Breast angiosarcoma
 Breast angiosarcoma metastatic
 Breast cancer
 Breast cancer female
 Breast cancer in situ

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Malignant tumours (SMQ)

Breast cancer male
 Breast cancer metastatic
 Breast cancer recurrent
 Breast cancer stage I
 Breast cancer stage II
 Breast cancer stage III
 Breast cancer stage IV
 Breast implant-associated anaplastic large cell lymphoma
 Breast sarcoma
 Breast sarcoma metastatic
 Breast sarcoma recurrent
 Bronchial carcinoma
 Bronchioloalveolar carcinoma
 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
 Buschke-Lowenstein's tumour
 CNS germinoma
 Cancer in remission
 Carcinoid tumour
 Carcinoid tumour of the appendix
 Carcinoid tumour of the caecum
 Carcinoid tumour of the duodenum
 Carcinoid tumour of the gastrointestinal tract
 Carcinoid tumour of the liver
 Carcinoid tumour of the ovary
 Carcinoid tumour of the pancreas
 Carcinoid tumour of the prostate
 Carcinoid tumour of the small bowel
 Carcinoid tumour of the stomach
 Carcinoid tumour pulmonary
 Carcinoma ex-pleomorphic adenoma
 Carcinoma in situ
 Carcinoma in situ of eye
 Carcinoma in situ of penis
 Carcinoma in situ of skin
 Carcinoma in situ of trachea

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Malignant tumours (SMQ)

Cardiac neoplasm malignant
 Central nervous system leukaemia
 Central nervous system lymphoma
 Central nervous system melanoma
 Central nervous system neuroblastoma
 Cervix cancer metastatic
 Cervix carcinoma
 Cervix carcinoma recurrent
 Cervix carcinoma stage 0
 Cervix carcinoma stage I
 Cervix carcinoma stage II
 Cervix carcinoma stage III
 Cervix carcinoma stage IV
 Chloroma
 Choroma (in remission)
 Cholangiocarcinoma
 Chondrosarcoma
 Chondrosarcoma metastatic
 Chondrosarcoma recurrent
 Chordoma
 Choriocarcinoma
 Choroid melanoma
 Choroid plexus carcinoma
 Chromophobe renal cell carcinoma
 Chronic eosinophilic leukaemia
 Chronic leukaemia
 Chronic leukaemia in remission
 Chronic lymphocytic leukaemia
 Chronic lymphocytic leukaemia (in remission)
 Chronic lymphocytic leukaemia recurrent
 Chronic lymphocytic leukaemia refractory
 Chronic lymphocytic leukaemia stage 0
 Chronic lymphocytic leukaemia stage 1
 Chronic lymphocytic leukaemia stage 2
 Chronic lymphocytic leukaemia stage 3
 Chronic lymphocytic leukaemia stage 4
 Chronic lymphocytic leukaemia transformation
 Chronic myeloid leukaemia
 Chronic myeloid leukaemia (in remission)
 Chronic myeloid leukaemia recurrent
 Chronic myeloid leukaemia transformation
 Chronic myelomonocytic leukaemia
 Chronic myelomonocytic leukaemia (in remission)

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Malignant tumours (SMQ)

Ciliary body melanoma
 Clear cell carcinoma of cervix
 Clear cell endometrial carcinoma
 Clear cell renal cell carcinoma
 Clear cell sarcoma of soft tissue
 Clear cell sarcoma of the kidney
 Colon cancer
 Colon cancer metastatic
 Colon cancer recurrent
 Colon cancer stage 0
 Colon cancer stage I
 Colon cancer stage II
 Colon cancer stage III
 Colon cancer stage IV
 Colorectal adenocarcinoma
 Colorectal cancer
 Colorectal cancer metastatic
 Colorectal cancer recurrent
 Colorectal cancer stage I
 Colorectal cancer stage II
 Colorectal cancer stage III
 Colorectal cancer stage IV
 Colorectal carcinoma stage 0
 Composite lymphoma
 Congenital fibrosarcoma
 Congenital malignant neoplasm
 Congenital retinoblastoma
 Conjunctival melanoma
 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 lymphoma
 Cystadenocarcinoma ovary
 Cystadenocarcinoma pancreas
 Dedifferentiated liposarcoma
 Dermatofibrosarcoma protuberans
 Dermatofibrosarcoma protuberans metastatic
 Desmoplastic melanoma
 Desmoplastic mesothelioma

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Malignant tumours (SMQ)

Desmoplastic small round cell tumour
 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
 Disseminated large cell lymphoma
 Double hit lymphoma
 Ductal adenocarcinoma of pancreas
 Ear neoplasm malignant
 Eccrine carcinoma
 Embryonal rhabdomyosarcoma
 Endocrine neoplasm malignant
 Endometrial adenocarcinoma
 Endometrial cancer
 Endometrial cancer metastatic
 Endometrial cancer recurrent
 Endometrial cancer stage 0
 Endometrial cancer stage I
 Endometrial cancer stage II
 Endometrial cancer stage III
 Endometrial cancer stage IV
 Endometrial sarcoma
 Endometrial sarcoma metastatic
 Endometrial sarcoma recurrent
 Endometrial stromal sarcoma
 Endotheliomatosis
 Enteropathy-associated T-cell lymphoma
 Eosinophilic leukaemia
 Ependymoma malignant
 Epididymal cancer
 Epiglottic cancer
 Epithelioid mesothelioma
 Epithelioid sarcoma
 Epithelioid sarcoma metastatic
 Epithelioid sarcoma recurrent
 Epstein-Barr virus associated lymphoma
 Erythraemic myelosis (in remission)
 Ewing's sarcoma
 Ewing's sarcoma metastatic
 Ewing's sarcoma recurrent

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Malignant tumours (SMQ)

Ewing-like sarcoma
 External ear neoplasm malignant
 Extra-osseous Ewing's sarcoma
 Extra-osseous Ewing's sarcoma metastatic
 Extra-osseous Ewing's sarcoma recurrent
 Extranodal primary embryonal carcinoma
 Extranodal primary germ cell tumour
 Extranodal primary germ cell tumour mixed
 Extranodal primary germ cell tumour mixed stage I
 Extranodal primary germ cell tumour mixed stage II
 Extranodal primary germ cell tumour mixed stage III
 Extranodal primary malignant teratoma
 Extranodal primary non-seminoma
 Extranodal primary non-seminoma stage I
 Extranodal primary non-seminoma stage II
 Extranodal primary non-seminoma stage III
 Extranodal primary non-seminoma stage IV
 Extranodal primary seminoma (pure)
 Extranodal primary seminoma (pure) stage I
 Extranodal primary seminoma (pure) stage II
 Extranodal primary seminoma (pure) stage III
 Extranodal primary seminoma (pure) stage IV
 Extramammary Paget's disease
 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
 Extraocular retinoblastoma

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Preferred term

Malignant tumours (SMQ)

Extraskeletal chondrosarcoma metastatic
 Extraskeletal chondrosarcoma recurrent
 Extraskeletal myxoid chondrosarcoma
 Extraskeletal osteosarcoma
 Extraskeletal osteosarcoma metastatic
 Extraskeletal osteosarcoma recurrent
 Fallopian tube cancer
 Fallopian tube cancer metastatic
 Fallopian tube cancer stage I
 Fallopian tube cancer stage II
 Fallopian tube cancer stage III
 Fallopian tube cancer stage IV
 Familial medullary thyroid cancer
 Female reproductive tract carcinoma in situ
 Fibrosarcoma
 Fibrosarcoma metastatic
 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

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Malignant tumours (SMQ)

Follicle centre lymphoma, follicular grade I, II, III stage IV
 Follicular dendritic cell sarcoma
 Follicular thyroid cancer
 Gallbladder adenocarcinoma
 Gallbladder adenosquamous carcinoma
 Gallbladder cancer
 Gallbladder cancer metastatic
 Gallbladder cancer recurrent
 Gallbladder cancer stage 0
 Gallbladder cancer stage I
 Gallbladder cancer stage II
 Gallbladder cancer stage III
 Gallbladder cancer stage IV
 Gallbladder squamous cell carcinoma
 Ganglioglioma
 Ganglioneuroblastoma
 Gastric cancer
 Gastric cancer recurrent
 Gastric cancer stage 0
 Gastric cancer stage I
 Gastric cancer stage II
 Gastric cancer stage III
 Gastric cancer stage IV
 Gastric sarcoma
 Gastrinoma malignant
 Gastroenteropancreatic neuroendocrine tumour disease
 Gastrointestinal adenocarcinoma
 Gastrointestinal cancer metastatic
 Gastrointestinal carcinoma
 Gastrointestinal carcinoma in situ
 Gastrointestinal lymphoma
 Gastrointestinal melanoma
 Gastrointestinal stromal tumour
 Gastrooesophageal cancer
 Gastrooesophageal cancer recurrent
 Genital cancer male
 Genital cancer male in situ
 Genital neoplasm malignant female
 Genitourinary melanoma
 Germ cell cancer
 Germ cell cancer metastatic

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

Gestational trophoblastic tumour
Gingival cancer
Glioblastoma
Glioblastoma multiforme
Glioma
Gliomatosis cerebri
Glioneuronal tumour
Gliosarcoma
Glomangiopericytoma
Glottis carcinoma
Glucagonoma
HER2 negative breast cancer
HER2 positive breast cancer
HER2 positive gastric cancer
Haemangiopericytoma
Haemangiopericytoma of meninges
Haematological malignancy
Hairy cell leukaemia
Hairy cell leukaemia recurrent
Head and neck cancer
Head and neck cancer metastatic
Head and neck cancer stage I
Head and neck cancer stage II
Head and neck cancer stage III
Head and neck cancer stage IV
Hepatosplenic T-cell lymphoma
Hereditary leiomyomatosis renal cell carcinoma
Hereditary papillary renal carcinoma
Hidradenocarcinoma
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

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Malignant tumours (SMQ)

Histiocytic medullary reticulosis
 Histiocytic sarcoma
 Hodgkin's disease
 Hodgkin's disease lymphocyte depletion stage I
 site unspecified
 Hodgkin's disease lymphocyte depletion stage I
 subdiaphragm
 Hodgkin's disease lymphocyte depletion stage I
 supradiaphragm
 Hodgkin's disease lymphocyte depletion stage II
 site unspecified
 Hodgkin's disease lymphocyte depletion stage II
 subdiaphragm
 Hodgkin's disease lymphocyte depletion stage II
 supradiaphragm
 Hodgkin's disease lymphocyte depletion type
 recurrent
 Hodgkin's disease lymphocyte depletion type
 refractory
 Hodgkin's disease lymphocyte depletion type stage
 III
 Hodgkin's disease lymphocyte depletion type stage
 IV
 Hodgkin's disease lymphocyte depletion type stage
 unspecified
 Hodgkin's disease lymphocyte predominance stage I
 site unspec
 Hodgkin's disease lymphocyte predominance stage I
 subdiaphragm
 Hodgkin's disease lymphocyte predominance stage I
 supradiaphragm
 Hodgkin's disease lymphocyte predominance stage
 II site unspec
 Hodgkin's disease lymphocyte predominance stage
 II subdiaphragm
 Hodgkin's disease lymphocyte predominance stage
 II supradiaphragm
 Hodgkin's disease lymphocyte predominance type
 recurrent
 Hodgkin's disease lymphocyte predominance type
 refractory
 Hodgkin's disease lymphocyte predominance type
 stage III

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Malignant tumours (SMQ)

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
 Hormone receptor positive breast cancer
 Hormone refractory breast cancer
 Hormone-dependent prostate cancer
 Hormone-refractory prostate cancer
 Huerthle cell carcinoma
 Hypopharyngeal cancer
 Hypopharyngeal cancer recurrent
 Hypopharyngeal cancer stage 0
 Hypopharyngeal cancer stage I

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Malignant tumours (SMQ)

Hypopharyngeal cancer stage II
 Hypopharyngeal cancer stage III
 Hypopharyngeal cancer stage IV
 Immune reconstitution inflammatory syndrome associated Kaposi's sarcoma
 Immunoblastic lymphoma
 Inflammatory carcinoma of breast recurrent
 Inflammatory carcinoma of breast stage III
 Inflammatory carcinoma of breast stage IV
 Inflammatory carcinoma of the breast
 Inflammatory malignant fibrous histiocytoma
 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
 Intestinal adenocarcinoma
 Intestinal metastasis
 Intracranial germ cell tumour
 Intracranial meningioma malignant
 Intraductal papillary breast neoplasm
 Intraductal papillary-mucinous carcinoma of pancreas
 Intraductal proliferative breast lesion
 Intraocular melanoma
 Invasive breast carcinoma
 Invasive ductal breast carcinoma
 Invasive lobular breast carcinoma
 Invasive papillary breast carcinoma
 Iris melanoma
 Juvenile chronic myelomonocytic leukaemia
 Kaposi's sarcoma
 Kaposi's sarcoma AIDS related
 Kaposi's sarcoma classical type
 Keratinising squamous cell carcinoma of nasopharynx
 Keratoacanthoma
 Langerhans cell sarcoma
 Large cell lung cancer
 Large cell lung cancer metastatic
 Large cell lung cancer recurrent

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Malignant tumours (SMQ)

Large cell lung cancer stage 0
 Large cell lung cancer stage I
 Large cell lung cancer stage II
 Large cell lung cancer stage III
 Large cell lung cancer stage IV
 Laryngeal cancer
 Laryngeal cancer metastatic
 Laryngeal cancer recurrent
 Laryngeal cancer stage 0
 Laryngeal cancer stage I
 Laryngeal cancer stage II
 Laryngeal cancer stage III
 Laryngeal cancer stage IV
 Laryngeal squamous cell carcinoma
 Leiomyosarcoma
 Leiomyosarcoma metastatic
 Leiomyosarcoma recurrent
 Lentigo maligna
 Lentigo maligna recurrent
 Lentigo maligna stage I
 Lentigo maligna stage II
 Lentigo maligna stage III
 Lentigo maligna stage IV
 Leptomeningeal myelomatosis
 Leukaemia
 Leukaemia basophilic
 Leukaemia cutis
 Leukaemia granulocytic
 Leukaemia in remission
 Leukaemia monocytic
 Leukaemia recurrent
 Leukaemia 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
 Leydig cell tumour of the testis
 Linitis plastica

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Malignant tumours (SMQ)

Lip and/or oral cavity cancer
 Lip and/or oral cavity cancer recurrent
 Lip and/or oral cavity cancer stage 0
 Lip and/or oral cavity cancer stage I
 Lip and/or oral cavity cancer stage II
 Lip and/or oral cavity cancer stage III
 Lip and/or oral cavity cancer stage IV
 Lip neoplasm malignant stage unspecified
 Lip squamous cell carcinoma
 Liposarcoma
 Liposarcoma metastatic
 Liposarcoma recurrent
 Lobular breast carcinoma in situ
 Lung adenocarcinoma
 Lung adenocarcinoma recurrent
 Lung adenocarcinoma stage 0
 Lung adenocarcinoma stage I
 Lung adenocarcinoma stage II
 Lung adenocarcinoma stage III
 Lung adenocarcinoma stage IV
 Lung cancer metastatic
 Lung carcinoma cell type unspecified recurrent
 Lung carcinoma cell type unspecified stage 0
 Lung carcinoma cell type unspecified stage I
 Lung carcinoma cell type unspecified stage II
 Lung carcinoma cell type unspecified stage III
 Lung carcinoma cell type unspecified stage IV
 Lung infiltration malignant
 Lung neoplasm malignant
 Lung squamous cell carcinoma metastatic
 Lung squamous cell carcinoma recurrent
 Lung squamous cell carcinoma stage 0
 Lung squamous cell carcinoma stage I
 Lung squamous cell carcinoma stage II
 Lung squamous cell carcinoma stage III
 Lung squamous cell carcinoma stage IV
 Lymphangiosarcoma
 Lymphangiosis carcinomatosa
 Lymphocytic leukaemia
 Lymphocytic lymphoma
 Lymphoid leukaemia (in remission)
 Lymphoma
 Lymphoma AIDS related

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Malignant tumours (SMQ)

Lymphoma transformation
 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
 Malignant anorectal neoplasm
 Malignant blue naevus
 Malignant connective tissue neoplasm
 Malignant cranial nerve neoplasm
 Malignant fibrous histiocytoma
 Malignant fibrous histiocytoma metastatic
 Malignant fibrous histiocytoma of bone
 Malignant fibrous histiocytoma recurrent
 Malignant genitourinary tract neoplasm
 Malignant giant cell fibrous histiocytoma
 Malignant glioma
 Malignant haemangiopericytoma
 Malignant haemangiopericytoma metastatic
 Malignant haemangiopericytoma recurrent
 Malignant histiocytosis
 Malignant hydatidiform mole
 Malignant joint neoplasm
 Malignant lymphoid neoplasm
 Malignant lymphoma unclassifiable high grade
 Malignant lymphoma unclassifiable low grade
 Malignant mast cell neoplasm
 Malignant mediastinal neoplasm
 Malignant melanoma
 Malignant melanoma in situ
 Malignant melanoma of eyelid
 Malignant melanoma of sites other than skin
 Malignant melanoma stage I
 Malignant melanoma stage II
 Malignant melanoma stage III
 Malignant melanoma stage IV
 Malignant meningioma metastatic
 Malignant mesenchymoma
 Malignant mesenchymoma metastatic
 Malignant mesenchymoma recurrent

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Malignant tumours (SMQ)

Malignant mesenteric neoplasm
 Malignant middle ear neoplasm
 Malignant muscle neoplasm
 Malignant neoplasm of ampulla of Vater
 Malignant neoplasm of choroid
 Malignant neoplasm of conjunctiva
 Malignant neoplasm of cornea
 Malignant neoplasm of eye
 Malignant neoplasm of eyelid
 Malignant neoplasm of islets of Langerhans
 Malignant neoplasm of lacrimal duct
 Malignant neoplasm of lacrimal gland
 Malignant neoplasm of orbit
 Malignant neoplasm of paraurethral glands
 Malignant neoplasm of placenta
 Malignant neoplasm of pleura
 Malignant neoplasm of pleura metastatic
 Malignant neoplasm of renal pelvis
 Malignant neoplasm of retina
 Malignant neoplasm of seminal vesicle
 Malignant neoplasm of spermatic cord
 Malignant neoplasm of spinal cord
 Malignant neoplasm of thorax
 Malignant neoplasm of thymus
 Malignant neoplasm of unknown primary site
 Malignant neoplasm of uterine adnexa
 Malignant neoplasm papilla of Vater
 Malignant nervous system neoplasm
 Malignant nipple neoplasm
 Malignant nipple neoplasm female
 Malignant nipple neoplasm male
 Malignant oligodendroglioma
 Malignant ovarian cyst
 Malignant palate neoplasm
 Malignant pericardial neoplasm
 Malignant peritoneal neoplasm
 Malignant pituitary tumour
 Malignant polyp
 Malignant respiratory tract neoplasm
 Malignant splenic neoplasm
 Malignant sweat gland neoplasm
 Malignant transformation
 Malignant urinary tract neoplasm

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Malignant tumours (SMQ)

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
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
Marjolin's ulcer
Mastocytic leukaemia
Maternal cancer in pregnancy
Mature B-cell type acute leukaemia
Medullary carcinoma of breast
Medullary thyroid cancer
Medulloblastoma
Medulloblastoma recurrent
Melanoma recurrent
Meningioma malignant
Mesothelioma malignant
Mesothelioma malignant recurrent
Metaplastic breast carcinoma
Metastases to Eustachian tube
Metastases to abdominal cavity
Metastases to abdominal wall
Metastases to adrenals
Metastases to biliary tract
Metastases to bladder
Metastases to bone
Metastases to bone marrow
Metastases to breast
Metastases to central nervous system
Metastases to chest wall
Metastases to diaphragm
Metastases to eye
Metastases to fallopian tube
Metastases to gallbladder
Metastases to gastrointestinal tract

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Malignant tumours (SMQ)

- Metastases to heart
- Metastases to kidney
- Metastases to larynx
- Metastases to liver
- Metastases to lung
- Metastases to lymph nodes
- Metastases to meninges
- Metastases to mouth
- Metastases to muscle
- Metastases to nasal sinuses
- Metastases to neck
- Metastases to nervous system
- Metastases to oesophagus
- Metastases to ovary
- Metastases to pancreas
- Metastases to pelvis
- Metastases to penis
- Metastases to perineum
- Metastases to peripheral nervous system
- Metastases to peripheral vascular system
- Metastases to peritoneum
- Metastases to pharynx
- Metastases to pituitary gland
- Metastases to placenta
- Metastases to pleura
- Metastases to prostate
- Metastases to rectum
- Metastases to reproductive organ
- Metastases to retroperitoneum
- Metastases to salivary gland
- Metastases to skin
- Metastases to soft tissue
- Metastases to spinal cord
- Metastases to spine
- Metastases to spleen
- Metastases to stomach
- Metastases to testicle
- Metastases to the mediastinum
- Metastases to the respiratory system
- Metastases to thorax
- Metastases to thyroid
- Metastases to tonsils
- Metastases to trachea

Pre-defined MedDRA search - list of preferred terms

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Malignant tumours (SMQ)

Metastases to urinary tract
 Metastases to uterus
 Metastases to vagina
 Metastasis
 Metastatic bronchial carcinoma
 Metastatic carcinoma of the bladder
 Metastatic choriocarcinoma
 Metastatic gastric cancer
 Metastatic glioma
 Metastatic glucagonoma
 Metastatic lymphoma
 Metastatic malignant melanoma
 Metastatic neoplasm
 Metastatic nervous system neoplasm
 Metastatic ocular melanoma
 Metastatic renal cell carcinoma
 Metastatic salivary gland cancer
 Metastatic squamous cell carcinoma
 Metastatic uterine cancer
 Microsatellite instability cancer
 Minimal residual disease
 Mismatch repair cancer syndrome
 Mixed adenoneuroendocrine carcinoma
 Mixed-type liposarcoma
 Monocytic leukaemia in remission
 Mucinous adenocarcinoma of appendix
 Mucinous breast carcinoma
 Mucinous cystadenocarcinoma ovary
 Mucinous endometrial carcinoma
 Mucoepidermoid carcinoma
 Mucoepidermoid carcinoma of salivary gland
 Musculoskeletal cancer
 Myeloblastoma
 Myeloid leukaemia
 Myeloid leukaemia in remission
 Myxofibrosarcoma
 Myxoid liposarcoma
 NUT midline carcinoma
 Naevoid melanoma
 Nasal cavity cancer
 Nasal sinus cancer
 Nasopharyngeal cancer

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Preferred term

Malignant tumours (SMQ)

Nasopharyngeal cancer metastatic
 Nasopharyngeal cancer recurrent
 Nasopharyngeal cancer stage 0
 Nasopharyngeal cancer stage I
 Nasopharyngeal cancer stage II
 Nasopharyngeal cancer stage III
 Nasopharyngeal cancer stage IV
 Natural killer-cell leukaemia
 Natural killer-cell lymphoblastic lymphoma
 Neonatal leukaemia
 Neonatal neuroblastoma
 Neoplasm malignant
 Nephroblastoma
 Neuroblastoma
 Neuroblastoma recurrent
 Neuroendocrine breast tumour
 Neuroendocrine carcinoma
 Neuroendocrine carcinoma metastatic
 Neuroendocrine carcinoma of prostate
 Neuroendocrine carcinoma of the bladder
 Neuroendocrine carcinoma of the skin
 Neuroendocrine tumour
 Neuroendocrine tumour of the lung
 Neuroendocrine tumour of the lung metastatic
 Neurofibrosarcoma
 Neurofibrosarcoma metastatic
 Neurofibrosarcoma recurrent
 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
 Nodular melanoma
 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

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Malignant tumours (SMQ)

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-renal cell carcinoma of kidney
 Non-small cell lung cancer
 Non-small cell lung cancer metastatic
 Non-small cell lung cancer recurrent
 Non-small cell lung cancer stage 0
 Non-small cell lung cancer stage I
 Non-small cell lung cancer stage II
 Non-small cell lung cancer stage III
 Non-small cell lung cancer stage IIIA
 Non-small cell lung cancer stage IIIB
 Non-small cell lung cancer stage IV
 Nonkeratinomatous germ cell tumour of the CNS
 Nonkeratinising carcinoma of nasopharynx
 Ocular cancer metastatic
 Ocular haemangiopericytoma
 Ocular lymphoma
 Oesophageal adenocarcinoma

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

Oesophageal adenocarcinoma recurrent
 Oesophageal adenocarcinoma stage 0
 Oesophageal adenocarcinoma stage I
 Oesophageal adenocarcinoma stage II
 Oesophageal adenocarcinoma stage III
 Oesophageal adenocarcinoma stage IV
 Oesophageal adenocarcinoma stage 0
 Oesophageal adenocarcinoma stage I
 Oesophageal adenocarcinoma stage II
 Oesophageal adenocarcinoma stage III
 Oesophageal adenocarcinoma stage IV
 Oesophageal cancer metastatic
 Oesophageal carcinoma
 Oesophageal carcinoma recurrent
 Oesophageal carcinoma stage 0
 Oesophageal squamous cell carcinoma
 Oesophageal squamous cell carcinoma metastatic
 Oesophageal squamous cell carcinoma recurrent
 Oesophageal squamous cell carcinoma stage 0
 Oesophageal squamous cell carcinoma stage I
 Oesophageal squamous cell carcinoma stage II
 Oesophageal squamous cell carcinoma stage III
 Oesophageal squamous cell carcinoma stage IV
 Oligoastrocytoma
 Oligodendroglioma
 Optic glioma
 Oral cavity cancer metastatic
 Oropharyngeal cancer
 Oropharyngeal cancer recurrent
 Oropharyngeal cancer stage 0
 Oropharyngeal cancer stage I
 Oropharyngeal cancer stage II
 Oropharyngeal cancer stage III
 Oropharyngeal cancer stage IV
 Oropharyngeal lymphoepithelioma
 Oropharyngeal squamous cell carcinoma
 Osteosarcoma
 Osteosarcoma metastatic
 Osteosarcoma recurrent
 Otic cancer metastatic
 Ovarian cancer
 Ovarian cancer metastatic
 Ovarian cancer recurrent
 Ovarian cancer stage I
 Ovarian cancer stage II
 Ovarian cancer stage III
 Ovarian cancer stage IV

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

- Ovarian clear cell carcinoma
- Ovarian dysgerminoma stage I
- Ovarian dysgerminoma stage II
- Ovarian dysgerminoma stage III
- Ovarian dysgerminoma stage IV
- Ovarian dysgerminoma stage unspecified
- Ovarian embryonal carcinoma
- Ovarian endometrioid carcinoma
- Ovarian epithelial cancer
- Ovarian epithelial cancer metastatic
- Ovarian epithelial cancer recurrent
- Ovarian epithelial cancer stage I
- Ovarian epithelial cancer stage II
- Ovarian epithelial cancer stage III
- Ovarian epithelial cancer stage IV
- Ovarian germ cell cancer
- Ovarian germ cell cancer stage I
- Ovarian germ cell cancer stage II
- Ovarian germ cell cancer stage III
- Ovarian germ cell cancer stage IV
- Ovarian germ cell choriocarcinoma
- Ovarian germ cell choriocarcinoma stage I
- Ovarian germ cell choriocarcinoma stage II
- Ovarian germ cell choriocarcinoma stage III
- Ovarian germ cell choriocarcinoma stage IV
- Ovarian germ cell embryonal carcinoma stage I
- Ovarian germ cell embryonal carcinoma stage II
- Ovarian germ cell embryonal carcinoma stage III
- Ovarian germ cell embryonal carcinoma stage IV
- Ovarian germ cell endodermal sinus tumour
- Ovarian germ cell endodermal sinus tumour stage I
- Ovarian germ cell endodermal sinus tumour stage II
- Ovarian germ cell endodermal sinus tumour stage III
- Ovarian germ cell endodermal sinus tumour stage IV
- Ovarian germ cell polyembryoma
- Ovarian germ cell polyembryoma stage I
- Ovarian germ cell polyembryoma stage II
- Ovarian germ cell polyembryoma stage III
- Ovarian germ cell polyembryoma stage IV
- Ovarian germ cell teratoma
- Ovarian germ cell teratoma stage I
- Ovarian germ cell teratoma stage II

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

Ovarian germ cell teratoma stage III
 Ovarian germ cell teratoma stage IV
 Ovarian germ cell tumour mixed
 Ovarian granulosa-theca cell tumour
 Ovarian low malignant potential tumour
 Ovarian melanoma
 Ovarian stromal cancer
 Paget's disease of nipple
 Paget's disease of penis
 Paget's disease of the vulva
 Pancoast's tumour
 Pancreatic carcinoma
 Pancreatic carcinoma metastatic
 Pancreatic carcinoma recurrent
 Pancreatic carcinoma stage 0
 Pancreatic carcinoma stage I
 Pancreatic carcinoma stage II
 Pancreatic carcinoma stage III
 Pancreatic carcinoma stage IV
 Pancreatic neuroendocrine tumour
 Pancreatic neuroendocrine tumour metastatic
 Pancreatic sarcoma
 Pancreatoblastoma
 Papillary renal cell carcinoma
 Papillary serous endometrial carcinoma
 Papillary thyroid cancer
 Paraganglion neoplasm malignant
 Paranasal sinus and nasal cavity malignant neoplasm
 Paranasal sinus and nasal cavity malignant neoplasm recurrent
 Paranasal sinus and nasal cavity malignant neoplasm stage 0
 Paranasal sinus and nasal cavity malignant neoplasm stage I
 Paranasal sinus and nasal cavity malignant neoplasm stage II
 Paranasal sinus and nasal cavity malignant neoplasm stage III
 Paranasal sinus and nasal cavity malignant neoplasm stage IV
 Parathyroid tumour malignant
 Penile cancer

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

Penile squamous cell carcinoma
 Penis carcinoma metastatic
 Penis carcinoma recurrent
 Penis carcinoma stage I
 Penis carcinoma stage II
 Penis carcinoma stage III
 Penis carcinoma stage IV
 Pericardial mesothelioma malignant
 Pericardial mesothelioma malignant recurrent
 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
 Peripheral neuroepithelioma of bone
 Peripheral neuroepithelioma of bone metastatic
 Peripheral neuroepithelioma of bone recurrent
 Peripheral neuroepithelioma of soft tissue
 Peripheral primitive neuroectodermal bone tumour
 Peripheral primitive neuroectodermal tumour of soft tissue
 Peritoneal carcinoma metastatic
 Peritoneal mesothelioma malignant
 Peritoneal mesothelioma malignant recurrent
 Peritoneal sarcoma
 Phaeochromocytoma malignant
 Pharyngeal cancer
 Pharyngeal cancer metastatic
 Pharyngeal cancer recurrent
 Pharyngeal cancer stage 0
 Pharyngeal cancer stage I
 Pharyngeal cancer stage II
 Pharyngeal cancer stage III
 Pharyngeal cancer stage IV
 Pilomatrix carcinoma
 Pineal germinoma
 Pineal parenchymal neoplasm malignant
 Pinealoblastoma
 Pituitary cancer metastatic
 Pituitary neoplasm malignant recurrent
 Plasma cell leukaemia

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

Plasma cell leukaemia in remission
 Plasma cell myeloma
 Plasma cell myeloma in remission
 Plasma cell myeloma recurrent
 Plasma cell myeloma refractory
 Plasmablastic lymphoma
 Plasmacytoma
 Pleomorphic leiomyosarcoma
 Pleomorphic liposarcoma
 Pleomorphic malignant fibrous histiocytoma
 Pleural mesothelioma
 Pleural mesothelioma malignant
 Pleural mesothelioma malignant recurrent
 Pleural sarcoma
 Pleuropulmonary blastoma
 Poorly differentiated thyroid carcinoma
 Porocarcinoma
 Postcricoid cancer
 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
 Primary breast lymphoma
 Primary cardiac lymphoma
 Primary effusion lymphoma
 Primary gastrointestinal follicular lymphoma

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

Primary mediastinal large B-cell lymphoma
 Primary mediastinal large B-cell lymphoma recurrent
 Primary mediastinal large B-cell lymphoma refractory
 Primary mediastinal large B-cell lymphoma stage I
 Primary mediastinal large B-cell lymphoma stage II
 Primary mediastinal large B-cell lymphoma stage III
 Primary mediastinal large B-cell lymphoma stage IV
 Primary pulmonary melanoma
 Primitive neuroectodermal tumour
 Primitive neuroectodermal tumour metastatic
 Prolymphocytic leukaemia
 Prostate cancer
 Prostate cancer metastatic
 Prostate cancer recurrent
 Prostate cancer stage 0
 Prostate cancer stage I
 Prostate cancer stage II
 Prostate cancer stage III
 Prostate cancer stage IV
 Pseudosarcoma
 Queyrat erythroplasia
 Rectal adenocarcinoma
 Rectal cancer
 Rectal cancer metastatic
 Rectal cancer recurrent
 Rectal cancer stage 0
 Rectal cancer stage I
 Rectal cancer stage II
 Rectal cancer stage III
 Rectal cancer stage IV
 Rectosigmoid cancer
 Rectosigmoid cancer metastatic
 Rectosigmoid cancer recurrent
 Rectosigmoid cancer stage 0
 Rectosigmoid cancer stage I
 Rectosigmoid cancer stage II
 Rectosigmoid cancer stage III
 Rectosigmoid cancer stage IV
 Recurrent cancer
 Refractory cancer

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

Renal cancer
 Renal cancer metastatic
 Renal cancer recurrent
 Renal cancer stage I
 Renal cancer stage II
 Renal cancer stage III
 Renal cancer stage IV
 Renal cell carcinoma
 Renal cell carcinoma recurrent
 Renal cell carcinoma stage I
 Renal cell carcinoma stage II
 Renal cell carcinoma stage III
 Renal cell carcinoma stage IV
 Respiratory tract carcinoma in situ
 Retinal melanoma
 Retinoblastoma
 Retroperitoneal cancer
 Retroperitoneal neoplasm metastatic
 Rhabdoid tumour
 Rhabdoid tumour of the kidney
 Rhabdomyosarcoma
 Rhabdomyosarcoma recurrent
 Richter's syndrome
 Round cell liposarcoma
 Salivary gland cancer
 Salivary gland cancer recurrent
 Salivary gland cancer stage 0
 Salivary gland cancer stage I
 Salivary gland cancer stage II
 Salivary gland cancer stage III
 Salivary gland cancer stage IV
 Sarcoma
 Sarcoma metastatic
 Sarcoma of skin
 Sarcoma uterus
 Sarcomatoid carcinoma
 Sarcomatoid carcinoma of the lung
 Sarcomatoid mesothelioma
 Sarcomatosis
 Scrotal cancer
 Sebaceous carcinoma
 Second primary malignancy
 Seminoma

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

Serous cystadenocarcinoma ovary
 Signet-ring cell carcinoma
 Sinus cancer metastatic
 Skin angiosarcoma
 Skin cancer
 Skin cancer metastatic
 Skin squamous cell carcinoma metastatic
 Skin squamous cell carcinoma recurrent
 Small cell carcinoma
 Small cell carcinoma of the cervix
 Small cell lung cancer
 Small cell lung cancer extensive stage
 Small cell lung cancer limited stage
 Small cell lung cancer metastatic
 Small cell lung cancer recurrent
 Small intestine adenocarcinoma
 Small intestine carcinoma
 Small intestine carcinoma metastatic
 Small intestine carcinoma recurrent
 Small intestine carcinoma stage 0
 Small intestine carcinoma stage I
 Small intestine carcinoma stage II
 Small intestine carcinoma stage III
 Small intestine carcinoma stage IV
 Small intestine leiomyosarcoma
 Soft tissue sarcoma
 Solid pseudopapillary tumour of the pancreas
 Spermatocytic seminoma
 Spinal meningioma malignant
 Spindle cell sarcoma
 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
 Squamous cell breast carcinoma
 Squamous cell carcinoma
 Squamous cell carcinoma of head and neck
 Squamous cell carcinoma of lung
 Squamous cell carcinoma of pharynx
 Squamous cell carcinoma of skin



Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

Squamous cell carcinoma of the cervix
 Squamous cell carcinoma of the hypopharynx
 Squamous cell carcinoma of the oral cavity
 Squamous cell carcinoma of the parotid gland
 Squamous cell carcinoma of the tongue
 Squamous cell carcinoma of the vagina
 Squamous cell carcinoma of the vulva
 Squamous endometrial carcinoma
 Stewart-Treves syndrome
 Superficial spreading melanoma stage I
 Superficial spreading melanoma stage II
 Superficial spreading melanoma stage III
 Superficial spreading melanoma stage IV
 Superficial spreading melanoma stage unspecified
 Synovial sarcoma
 Synovial sarcoma metastatic
 Synovial sarcoma recurrent
 T-cell chronic lymphocytic leukaemia
 T-cell lymphoma
 T-cell lymphoma recurrent
 T-cell lymphoma refractory
 T-cell lymphoma stage I
 T-cell lymphoma stage II
 T-cell lymphoma stage III
 T-cell lymphoma stage IV
 T-cell prolymphocytic leukaemia
 T-cell type acute leukaemia
 T-cell unclassifiable lymphoma high grade
 T-cell unclassifiable lymphoma low grade
 Testicular cancer metastatic
 Testicular choriocarcinoma
 Testicular choriocarcinoma recurrent
 Testicular choriocarcinoma stage I
 Testicular choriocarcinoma stage II
 Testicular choriocarcinoma stage III
 Testicular embryonal carcinoma
 Testicular embryonal carcinoma stage I
 Testicular embryonal carcinoma stage II
 Testicular embryonal carcinoma stage III
 Testicular germ cell cancer
 Testicular germ cell cancer metastatic
 Testicular germ cell tumour mixed
 Testicular germ cell tumour mixed stage I

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

Testicular germ cell tumour mixed stage II
 Testicular germ cell tumour mixed stage III
 Testicular leiomyosarcoma
 Testicular malignant teratoma
 Testicular malignant teratoma stage I
 Testicular malignant teratoma stage II
 Testicular malignant teratoma stage III
 Testicular seminoma (pure)
 Testicular seminoma (pure) stage I
 Testicular seminoma (pure) stage II
 Testicular seminoma (pure) stage III
 Testicular yolk sac tumour
 Testicular yolk sac tumour stage I
 Testicular yolk sac tumour stage II
 Testicular yolk sac tumour stage III
 Testis cancer
 Testis cancer recurrent
 Throat cancer
 Thymic cancer metastatic
 Thymoma malignant
 Thymoma malignant recurrent
 Thyroid B-cell lymphoma
 Thyroid cancer
 Thyroid cancer metastatic
 Thyroid cancer recurrent
 Thyroid cancer stage 0
 Thyroid cancer stage I
 Thyroid cancer stage II
 Thyroid cancer stage III
 Thyroid cancer stage IV
 Tongue cancer metastatic
 Tongue cancer recurrent
 Tongue carcinoma stage 0
 Tongue carcinoma stage I
 Tongue carcinoma stage II
 Tongue carcinoma stage III
 Tongue carcinoma stage IV
 Tongue neoplasm malignant stage unspecified
 Tonsil cancer
 Tonsil cancer metastatic
 Tracheal cancer
 Transformation to acute myeloid leukaemia

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

Transitional cell cancer of renal pelvis and
 ureter metastatic
 Transitional cell cancer of the renal pelvis and
 ureter
 Transitional cell cancer of the renal pelvis and
 ureter localised
 Transitional cell cancer of the renal pelvis and
 ureter recurrent
 Transitional cell cancer of the renal pelvis and
 ureter regional
 Transitional cell carcinoma
 Transitional cell carcinoma metastatic
 Transitional cell carcinoma recurrent
 Transitional cell carcinoma urethra
 Trichoblastic carcinoma
 Triple hit lymphoma
 Triple negative breast cancer
 Triple positive breast cancer
 Tubular breast carcinoma
 Tumour budding
 Undifferentiated carcinoma of colon
 Undifferentiated nasopharyngeal carcinoma
 Undifferentiated sarcoma
 Ureteric cancer
 Ureteric cancer local
 Ureteric cancer metastatic
 Ureteric cancer recurrent
 Ureteric cancer regional
 Urethral cancer
 Urethral cancer metastatic
 Urethral cancer recurrent
 Urethral melanoma metastatic
 Urinary bladder sarcoma
 Urinary tract carcinoma in situ
 Uterine cancer
 Uterine carcinoma in situ
 Uterine leiomyosarcoma
 Uveal melanoma
 Vaginal adenocarcinoma
 Vaginal cancer
 Vaginal cancer metastatic
 Vaginal cancer recurrent
 Vaginal cancer stage 0

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Malignant tumours (SMQ)

Vaginal cancer stage I
Vaginal cancer stage II
Vaginal cancer stage III
Vaginal cancer stage IVA
Vaginal cancer stage IVB
Vulval cancer
Vulval cancer metastatic
Vulval cancer recurrent
Vulval cancer stage 0
Vulval cancer stage I
Vulval cancer stage II
Vulval cancer stage III
Vulval cancer stage IV
Vulvar adenocarcinoma
Vulvar basal cell carcinoma
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

Medication error overdose

Documented hypersensitivity to administered product
Accidental device ingestion
Accidental device ingestion by a child
Accidental exposure to product
Accidental exposure to product by child
Accidental exposure to product packaging
Accidental overdose
Accidental poisoning
Accidental underdose
Accidental use of placebo
Assisted suicide
Booster dose missed
Circumstance or information capable of leading to device use error
Circumstance or information capable of leading to medication error
Completed suicide
Contraindicated device used

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search Preferred term

- Medication error overdose
- Contraindicated product administered
- Contraindicated product prescribed
- Contraindication to medical treatment
- Contraindication to vaccination
- Deprescribing error
- Device adhesion issue
- Device connection issue
- Device difficult to use
- Device dispensing error
- Device infusion issue
- Device maintenance issue
- Device malfunction
- Device monitoring procedure not performed
- Device placement issue
- Device programming error
- Device use confusion
- Device use error
- Device use issue
- Device-device incompatibility
- Dietary supplement prescribing error
- Discontinued product administered
- Dopamine dysregulation syndrome
- Dose calculation error
- Drug abuse
- Drug abuser
- Drug administered in wrong device
- Drug delivery system issue
- Drug delivery system malfunction
- Drug dependence
- Drug dependence, antepartum
- Drug dependence, postpartum
- Drug dispensed to wrong patient
- Drug dose omission by device
- Drug dose titration not performed
- Drug monitoring procedure incorrectly performed
- Drug monitoring procedure not performed
- Drug titration error
- Drug use disorder
- Drug use disorder, antepartum
- Drug use disorder, postpartum
- Duplicate therapy error
- Expired device used
- Expired product administered

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Medication error overdose	Preferred term
	Exposure to contaminated device
	Exposure via contaminated device
	Exposure via direct contact
	Exposure via eye contact
	Exposure via ingestion
	Exposure via inhalation
	Exposure via partner
	Exposure via skin contact
	Exposure via unknown route
	Extra dose administered
	Failure of child resistant product closure
	Failure to suspend medication
	Inadequate aseptic technique in use of product
	Inappropriate schedule of product administration
	Incomplete course of vaccination
	Incorrect disposal of product
	Incorrect dosage administered
	Incorrect dose administered
	Incorrect dose administered by device
	Incorrect dose administered by product
	Incorrect drug administration rate
	Incorrect product administration duration
	Incorrect product dosage form administered
	Incorrect product formulation administered
	Incorrect route of product administration
	Injury associated with device
	Intentional device misuse
	Intentional dose omission
	Intentional misuse of drug delivery system
	Intentional overdose
	Intentional product misuse
	Intentional self-injury
	Intercepted accidental exposure to product by child
	Intercepted medication error
	Intercepted product administration error
	Intercepted product dispensing error
	Intercepted product monitoring error
	Intercepted product preparation error
	Intercepted product prescribing error
	Intercepted product selection error
	Intercepted product storage error
	Intercepted wrong patient selected

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Medication error overdose

Interchange of vaccine products
Labelled drug-disease interaction medication error
Labelled drug-drug interaction medication error
Labelled drug-food interaction medication error
Lack of administration site rotation
Lack of application site rotation
Lack of infusion site rotation
Lack of injection site rotation
Lack of vaccination site rotation
Maternal use of illicit drugs
Medical device monitoring error
Medication error
Multiple use of single-use product
Needle issue
Neonatal complications of substance abuse
Occupational exposure to product
Occupational exposure to radiation
Out of specification product use
Overdose
Paravenous drug administration
Performance enhancing product use
Poisoning deliberate
Poor quality device used
Poor quality product administered
Prescribed overdose
Prescribed underdose
Product adhesion issue
Product administered at inappropriate site
Product administered to patient of inappropriate age
Product administration error
Product administration interrupted
Product appearance confusion
Product barcode issue
Product commingling
Product communication issue
Product compounding quality issue
Product confusion
Product design confusion
Product dispensing error
Product dispensing issue
Product dosage form confusion
Product dosage form issue

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Medication error overdose

- Product dose omission
- Product dropper issue
- Product identification number issue
- Product label confusion
- Product label issue
- Product label on wrong product
- Product lot number issue
- Product monitoring error
- Product name confusion
- Product packaging confusion
- Product packaging difficult to open
- Product packaging issue
- Product preparation error
- Product preparation issue
- Product prescribing error
- Product prescribing issue
- Product reconstitution quality issue
- Product selection error
- Product storage error
- Product substitution error
- Product use complaint
- Product use in unapproved indication
- Product use in unapproved therapeutic environment
- Product use issue
- Radiation overdose
- Radiation underdose
- Recalled product administered
- Single component of a two-component product administered
- Substance abuse
- Substance abuser
- Substance dependence
- Substance use disorder
- Suicide attempt
- Suspected suicide
- Suspected suicide attempt
- Syringe issue
- Therapeutic drug monitoring analysis incorrectly performed
- Therapeutic drug monitoring analysis not performed
- Transcription medication error
- Transfusion with incompatible blood
- Underdose

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Medication error overdose
 Unintentional medical device removal
 Unintentional use for unapproved indication
 Vaccination error
 Wrong device used
 Wrong dosage form
 Wrong dosage formulation
 Wrong dose
 Wrong drug
 Wrong patient received product
 Wrong product administered
 Wrong product procured
 Wrong product stored
 Wrong rate
 Wrong schedule
 Wrong strength
 Wrong technique in device usage process
 Wrong technique in product usage process

Neoplasm

Biopsy bile duct abnormal
 Biopsy gallbladder abnormal
 Malignant biliary obstruction
 Acquired CI inhibitor deficiency
 Biopsy heart abnormal
 Cerebral cyst haemorrhage
 Inferior vena cava syndrome
 Intracranial tumour haemorrhage
 Langerhans' cell histiocytosis
 Multiple gated acquisition scan abnormal
 Paraneoplastic thrombosis
 Pulmonary tumour thrombotic microangiopathy
 Scan myocardial perfusion abnormal
 Superior vena cava occlusion
 Superior vena cava syndrome
 Thrombophlebitis migrans
 Tumour embolism
 Tumour thrombectomy
 Tumour thrombosis
 Benign hepatic neoplasm
 Benign hepatobiliary neoplasm
 Biopsy liver abnormal
 Cholangiosarcoma
 Computerised tomogram liver abnormal
 Focal nodular hyperplasia

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Haemangioma of liver
Haemorrhagic hepatic cyst
Hepatectomy
Hepatic adenoma
Hepatic angiosarcoma
Hepatic cancer
Hepatic cancer metastatic
Hepatic cancer recurrent
Hepatic cancer stage I
Hepatic cancer stage II
Hepatic cancer stage III
Hepatic cancer stage IV
Hepatic cyst
Hepatic cyst ruptured
Hepatic haemangioma rupture
Hepatic hamartoma
Hepatic neoplasm
Hepatobiliary cancer
Hepatobiliary cancer in situ
Hepatobiliary cyst
Hepatobiliary neoplasm
Hepatoblastoma
Hepatoblastoma recurrent
Hepatocellular carcinoma
Liver ablation
Liver carcinoma ruptured
Liver scan abnormal
Mixed hepatocellular cholangiocarcinoma
Peritoneal fluid protein increased
Splenic artery embolisation
Abdominal wall cyst
Ampullary polyp
Anal leukoplakia
Anal polyp
Anogenital dysplasia
Barrett's oesophagus
Buccal polyp
Colon dysplasia
Crohn's disease
Cronkhite-Canada syndrome
Dental cyst
Duodenal polyp
Epulis

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Gastric cyst
Gastric dysplasia
Gastric polyps
Gastrointestinal dysplasia
Gastrointestinal polyp
Gastrointestinal polyp haemorrhage
Giant cell epulis
Gingival cyst
Gingival polyp
Intestinal cyst
Intestinal polyp
Large intestine polyp
Leukoplakia esophageal
Leukoplakia oral
Lichenoid dysplasia
Malignant dysphagia
Malignant gastrointestinal obstruction
Melanoplakia oral
Mesenteric cyst
Mouth cyst
Oesophageal dysplasia
Oesophageal polyp
Palatal polyp
Pancreatic cyst
Pancreatic cyst rupture
Peritoneal cyst
Precancerous lesion of digestive tract
Pseudoachalasia
Rectal dysplasia
Rectal polyp
Retroperitoneum cyst
Salivary gland cyst
Salivary gland induration
Small intestine polyp
Terminal ileitis
Tongue cyst
Tongue dysplasia
Tongue polyp
Administration site cyst
Application site cyst
Infusion site cyst
Injection site cyst
5q minus syndrome

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Abdominal wall neoplasm malignant
 Acinar cell carcinoma of pancreas
 Acinic cell carcinoma of salivary gland
 Acral lentiginous melanoma
 Acral lentiginous melanoma stage I
 Acral lentiginous melanoma stage II
 Acral lentiginous melanoma stage III
 Acral lentiginous melanoma stage IV
 Acute bilineal leukaemia
 Acute biphenotypic leukaemia
 Acute erythroid leukaemia
 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
 Adenocarcinoma
 Adenocarcinoma gastric
 Adenocarcinoma metastatic
 Adenocarcinoma of appendix
 Adenocarcinoma of colon
 Adenocarcinoma of salivary gland
 Adenocarcinoma of the cervix
 Adenocarcinoma pancreas
 Adenoid cystic carcinoma
 Adenoid cystic carcinoma of salivary gland
 Adenosquamous carcinoma of the cervix
 Adenosquamous carcinoma of vagina
 Adenosquamous cell carcinoma
 Adenosquamous cell lung cancer
 Adenosquamous cell lung cancer recurrent

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Adenosquamous cell lung cancer stage 0
 Adenosquamous cell lung cancer stage I
 Adenosquamous cell lung cancer stage II
 Adenosquamous cell lung cancer stage III
 Adenosquamous cell lung cancer stage IV
 Adrenal gland cancer
 Adrenal gland cancer metastatic
 Adrenocortical carcinoma
 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
 Aesthesioneuroblastoma
 Leukaemic leukaemia
 Alveolar thabdonysarcoma
 Alveolar soft part sarcoma
 Alveolar soft part sarcoma metastatic
 Alveolar soft part sarcoma recurrent
 Ameloblastic carcinoma
 Anal cancer
 Anal cancer metastatic
 Anal cancer recurrent
 Anal cancer stage 0
 Anal cancer stage I
 Anal cancer stage II
 Anal cancer stage III
 Anal cancer stage IV
 Anal squamous cell carcinoma
 Anaplastic astrocytoma
 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

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

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
 Anaplastic meningioma
 Anaplastic oligodendroglioma
 Anaplastic thyroid cancer
 Angiocentric glioma
 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
 Angiosarcoma
 Angiosarcoma metastatic
 Angiosarcoma non-metastatic
 Angiosarcoma recurrent
 Apocrine breast carcinoma
 Appendix cancer
 Astrocytoma
 Astrocytoma malignant
 Atypical teratoid/rhabdoid tumour of CNS
 B precursor type acute leukaemia
 B-cell lymphoma
 B-cell lymphoma recurrent
 B-cell lymphoma refractory
 B-cell lymphoma stage I
 B-cell lymphoma stage II
 B-cell lymphoma stage III
 B-cell lymphoma stage IV
 B-cell prolymphocytic leukaemia
 B-cell small lymphocytic lymphoma
 B-cell small lymphocytic lymphoma recurrent

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

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
 Basal cell carcinoma
 Basal cell carcinoma metastatic
 Basosquamous carcinoma
 Basosquamous carcinoma of skin
 Bile duct adenocarcinoma
 Bile duct adenocarcinoma carcinoma
 Bile duct cancer
 Bile duct cancer recurrent
 Bile duct cancer stage 0
 Bile duct cancer stage I
 Bile duct cancer stage II
 Bile duct cancer stage III
 Bile duct cancer stage IV
 Bile duct squamous cell carcinoma
 Biliary cancer metastatic
 Biphasic mesothelioma
 Bladder adenocarcinoma recurrent
 Bladder adenocarcinoma stage 0
 Bladder adenocarcinoma stage I
 Bladder adenocarcinoma stage II
 Bladder adenocarcinoma stage III
 Bladder adenocarcinoma stage IV
 Bladder adenocarcinoma stage unspecified
 Bladder cancer
 Bladder cancer recurrent
 Bladder cancer stage 0, with cancer in situ
 Bladder cancer stage 0, without cancer in situ
 Bladder cancer stage I, with cancer in situ
 Bladder cancer stage I, without cancer in situ
 Bladder cancer stage II
 Bladder cancer stage III
 Bladder cancer stage IV
 Bladder squamous cell carcinoma recurrent
 Bladder squamous cell carcinoma stage 0
 Bladder squamous cell carcinoma stage I

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

- Bladder squamous cell carcinoma stage II
- Bladder squamous cell carcinoma stage III
- Bladder squamous cell carcinoma stage IV
- Bladder squamous cell carcinoma stage unspecified
- Bladder transitional cell carcinoma
- Bladder transitional cell carcinoma metastatic
- Bladder transitional cell carcinoma recurrent
- Bladder transitional cell carcinoma stage 0
- Bladder transitional cell carcinoma stage I
- Bladder transitional cell carcinoma stage II
- Bladder transitional cell carcinoma stage III
- Bladder transitional cell carcinoma stage IV
- Blast cell crisis
- Blast crisis in myelogenous leukaemia
- Blastic plasmacytoid dendritic cell neoplasia
- Bone cancer
- Bone cancer metastatic
- Bone giant cell tumour malignant
- Bone marrow leukaemic cell infiltration
- Bone marrow tumour cell infiltration
- Bone sarcoma
- Bowen's disease
- Brain cancer metastatic
- Brain neoplasm malignant
- Brain sarcoma
- Brain stem glioma
- Breast angiosarcoma
- Breast angiosarcoma metastatic
- Breast cancer
- Breast cancer female
- Breast cancer in situ
- Breast cancer male
- Breast cancer metastatic
- Breast cancer recurrent
- Breast cancer stage I
- Breast cancer stage II
- Breast cancer stage III
- Breast cancer stage IV
- Breast implant-associated anaplastic large cell lymphoma
- Breast sarcoma
- Breast sarcoma metastatic
- Breast sarcoma recurrent

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Bronchial carcinoma
 Bronchioloalveolar carcinoma
 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
 Buschke-Lowenstein's tumour
 CNS germinoma
 Cancer in remission
 Carcinoid tumour
 Carcinoid tumour of the appendix
 Carcinoid tumour of the caecum
 Carcinoid tumour of the duodenum
 Carcinoid tumour of the gastrointestinal tract
 Carcinoid tumour of the liver
 Carcinoid tumour of the ovary
 Carcinoid tumour of the pancreas
 Carcinoid tumour of the prostate
 Carcinoid tumour of the small bowel
 Carcinoid tumour of the stomach
 Carcinoid tumour pulmonary
 Carcinoma ex-pleomorphic adenoma
 Carcinoma in situ
 Carcinoma in situ of eye
 Carcinoma in situ of penis
 Carcinoma in situ of skin
 Carcinoma in situ of trachea
 Cardiac neoplasm malignant
 Central nervous system leukaemia
 Central nervous system lymphoma
 Central nervous system melanoma
 Central nervous system neuroblastoma
 Cervix cancer metastatic
 Cervix carcinoma
 Cervix carcinoma recurrent
 Cervix carcinoma stage 0
 Cervix carcinoma stage I
 Cervix carcinoma stage II
 Cervix carcinoma stage III

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Cervix carcinoma stage IV
 Chloroma
 Chloroma (in remission)
 Cholangiocarcinoma
 Chondrosarcoma
 Chondrosarcoma metastatic
 Chondrosarcoma recurrent
 Chordoma
 Choriocarcinoma
 Choroid melanoma
 Choroid plexus carcinoma
 Chromophobe renal cell carcinoma
 Chronic eosinophilic leukaemia
 Chronic leukaemia
 Chronic leukaemia in remission
 Chronic lymphocytic leukaemia
 Chronic lymphocytic leukaemia (in remission)
 Chronic lymphocytic leukaemia recurrent
 Chronic lymphocytic leukaemia refractory
 Chronic lymphocytic leukaemia stage 0
 Chronic lymphocytic leukaemia stage 1
 Chronic lymphocytic leukaemia stage 2
 Chronic lymphocytic leukaemia stage 3
 Chronic lymphocytic leukaemia stage 4
 Chronic lymphocytic leukaemia transformation
 Chronic myeloid leukaemia
 Chronic myeloid leukaemia (in remission)
 Chronic myeloid leukaemia recurrent
 Chronic myeloid leukaemia transformation
 Chronic myelomonocytic leukaemia
 Chronic myelomonocytic leukaemia (in remission)
 Ciliary body melanoma
 Clear cell carcinoma of cervix
 Clear cell endometrial carcinoma
 Clear cell renal cell carcinoma
 Clear cell sarcoma of soft tissue
 Clear cell sarcoma of the kidney
 Colon cancer
 Colon cancer metastatic
 Colon cancer recurrent
 Colon cancer stage 0
 Colon cancer stage I
 Colon cancer stage II

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Colon cancer stage III
 Colon cancer stage IV
 Colorectal adenocarcinoma
 Colorectal cancer
 Colorectal cancer metastatic
 Colorectal cancer recurrent
 Colorectal cancer stage I
 Colorectal cancer stage II
 Colorectal cancer stage III
 Colorectal cancer stage IV
 Colorectal carcinoma stage 0
 Composite lymphoma
 Congenital fibrosarcoma
 Congenital malignant neoplasm
 Congenital retinoblastoma
 Conjunctival melanoma
 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 lymphoma
 Cystadenocarcinoma ovary
 Cystadenocarcinoma pancreas
 Dedifferentiated liposarcoma
 Dermatofibrosarcoma protuberans
 Dermatofibrosarcoma protuberans metastatic
 Desmoplastic melanoma
 Desmoplastic mesothelioma
 Desmoplastic small round cell tumour
 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
 Disseminated large cell lymphoma
 Double hit lymphoma
 Ductal adenocarcinoma of pancreas
 Ear neoplasm malignant

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Eccrine carcinoma
 Embryonal rhabdomyosarcoma
 Endocrine neoplasm malignant
 Endometrial adenocarcinoma
 Endometrial cancer
 Endometrial cancer metastatic
 Endometrial cancer recurrent
 Endometrial cancer stage 0
 Endometrial cancer stage I
 Endometrial cancer stage II
 Endometrial cancer stage III
 Endometrial cancer stage IV
 Endometrial sarcoma
 Endometrial sarcoma metastatic
 Endometrial sarcoma recurrent
 Endometrial stromal sarcoma
 Endotheliomatosis
 Enteropathy-associated T-cell lymphoma
 Eosinophilic leukaemia
 Ependymoma malignant
 Epididymal cancer
 Epiglottic cancer
 Epithelioid mesothelioma
 Epithelioid sarcoma
 Epithelioid sarcoma metastatic
 Epithelioid sarcoma recurrent
 Epstein-Barr virus associated lymphoma
 Erythraemic myelosis (in remission)
 Ewing's sarcoma
 Ewing's sarcoma metastatic
 Ewing's sarcoma recurrent
 Ewing-like sarcoma
 External ear neoplasm malignant
 Extra-osseous Ewing's sarcoma
 Extra-osseous Ewing's sarcoma metastatic
 Extra-osseous Ewing's sarcoma recurrent
 Extragonadal primary embryonal carcinoma
 Extragonadal primary germ cell tumour
 Extragonadal primary germ cell tumour mixed
 Extragonadal primary germ cell tumour mixed stage I
 Extragonadal primary germ cell tumour mixed stage II

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Extragenadal primary germ cell tumour mixed stage III
 Extragenadal primary malignant teratoma
 Extragenadal primary non-seminoma
 Extragenadal primary non-seminoma stage I
 Extragenadal primary non-seminoma stage II
 Extragenadal primary non-seminoma stage III
 Extragenadal primary non-seminoma stage IV
 Extragenadal primary seminoma (pure)
 Extragenadal primary seminoma (pure) stage I
 Extragenadal primary seminoma (pure) stage II
 Extragenadal primary seminoma (pure) stage III
 Extragenadal primary seminoma (pure) stage IV
 Extramammary Paget's disease
 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
 Extraocular retinoblastoma
 Extraskeletal chondrosarcoma metastatic
 Extraskeletal chondrosarcoma recurrent
 Extraskeletal myxoid chondrosarcoma
 Extraskeletal osteosarcoma
 Extraskeletal osteosarcoma metastatic
 Extraskeletal osteosarcoma recurrent
 Fallopian tube cancer
 Fallopian tube cancer metastatic
 Fallopian tube cancer stage I
 Fallopian tube cancer stage II
 Fallopian tube cancer stage III
 Fallopian tube cancer stage IV

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Familial medullary thyroid cancer
 Female reproductive tract carcinoma in situ
 Fibrosarcoma
 Follicle centre lymphoma diffuse small cell lymphoma
 Follicle centre lymphoma diffuse small cell lymphoma recurrent
 Follicle centre lymphoma diffuse small cell lymphoma refractory
 Follicle centre lymphoma diffuse small cell lymphoma stage I
 Follicle centre lymphoma diffuse small cell lymphoma stage II
 Follicle centre lymphoma diffuse small cell lymphoma stage III
 Follicle centre lymphoma diffuse small cell lymphoma stage IV
 Follicle centre lymphoma, follicular grade I, II, III
 Follicle centre lymphoma, follicular grade I, II, III recurrent
 Follicle centre lymphoma, follicular grade I, II, III refractory
 Follicle centre lymphoma, follicular grade I, II, III stage I
 Follicle centre lymphoma, follicular grade I, II, III stage II
 Follicle centre lymphoma, follicular grade I, II, III stage III
 Follicle centre lymphoma, follicular grade I, II, III stage IV
 Follicular dendritic cell sarcoma
 Follicular thyroid cancer
 Gallbladder adenocarcinoma
 Gallbladder adenosquamous carcinoma
 Gallbladder cancer
 Gallbladder cancer metastatic
 Gallbladder cancer recurrent
 Gallbladder cancer stage 0
 Gallbladder cancer stage I
 Gallbladder cancer stage II
 Gallbladder cancer stage III

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Gallbladder cancer stage IV
 Gallbladder squamous cell carcinoma
 Ganglioglioma
 Ganglioneuroblastoma
 Gastric cancer
 Gastric cancer recurrent
 Gastric cancer stage 0
 Gastric cancer stage I
 Gastric cancer stage II
 Gastric cancer stage III
 Gastric cancer stage IV
 Gastric sarcoma
 Gastrinoma malignant
 Gastroenteropancreatic neuroendocrine tumour
 disease
 Gastrointestinal adenocarcinoma
 Gastrointestinal cancer metastatic
 Gastrointestinal carcinoma
 Gastrointestinal carcinoma in situ
 Gastrointestinal lymphoma
 Gastrointestinal melanoma
 Gastrointestinal stromal tumour
 Gastrooesophageal cancer
 Gastrooesophageal cancer recurrent
 Genital cancer male
 Genital cancer male in situ
 Genital neoplasm malignant female
 Genitourinary melanoma
 Germ cell cancer
 Germ cell cancer metastatic
 Gestational trophoblastic tumour
 Gingival cancer
 Glioblastoma
 Glioblastoma multiforme
 Glioma
 Gliomatosis cerebri
 Glioneuronal tumour
 Gliosarcoma
 Glomangiopericytoma
 Glottis carcinoma
 Glucagonoma
 HER2 negative breast cancer
 HER2 positive breast cancer

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

HER2 positive gastric cancer
 Haemangiopericytoma
 Haemangiopericytoma of meninges
 Haematological malignancy
 Hairy cell leukaemia
 Hairy cell leukaemia recurrent
 Head and neck cancer
 Head and neck cancer metastatic
 Head and neck cancer stage I
 Head and neck cancer stage II
 Head and neck cancer stage III
 Head and neck cancer stage IV
 Hepatosplenic T-cell lymphoma
 Hereditary leiomyomatosis renal cell carcinoma
 Hereditary papillary renal carcinoma
 Hidradenocarcinoma
 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
 Histiocytic medullary reticulosis
 Histiocytic sarcoma
 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

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Hodgkin's disease lymphocyte depletion stage II
supradiaphragm
Hodgkin's disease lymphocyte depletion type
recurrent
Hodgkin's disease lymphocyte depletion type
refractory
Hodgkin's disease lymphocyte depletion type stage
III
Hodgkin's disease lymphocyte depletion type stage
IV
Hodgkin's disease lymphocyte depletion type stage
unspecified
Hodgkin's disease lymphocyte predominance stage I
site unspec
Hodgkin's disease lymphocyte predominance stage I
subdiaphragm
Hodgkin's disease lymphocyte predominance stage I
supradiaphragm
Hodgkin's disease lymphocyte predominance stage
II site unspec
Hodgkin's disease lymphocyte predominance stage
II subdiaphragm
Hodgkin's disease lymphocyte predominance stage
II supradiaphragm
Hodgkin's disease lymphocyte predominance type
recurrent
Hodgkin's disease lymphocyte predominance type
refractory
Hodgkin's disease lymphocyte predominance type
stage III
Hodgkin's disease lymphocyte predominance type
stage IV
Hodgkin's disease lymphocyte predominance type
stage unspecified
Hodgkin's disease mixed cellularity recurrent
Hodgkin's disease mixed cellularity refractory
Hodgkin's disease mixed cellularity stage I site
unspecified
Hodgkin's disease mixed cellularity stage I
subdiaphragmatic
Hodgkin's disease mixed cellularity stage I
supradiaphragmatic

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Neoplasm

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
 Hormone receptor positive breast cancer
 Hormone refractory breast cancer
 Hormone-dependent prostate cancer
 Hormone-refractory prostate cancer
 Huerthle cell carcinoma
 Hypopharyngeal cancer
 Hypopharyngeal cancer recurrent
 Hypopharyngeal cancer stage 0
 Hypopharyngeal cancer stage I
 Hypopharyngeal cancer stage II
 Hypopharyngeal cancer stage III
 Hypopharyngeal cancer stage IV
 Immune reconstitution inflammatory syndrome
 associated Kaposi's sarcoma
 Immunoblastic lymphoma
 Inflammatory carcinoma of breast recurrent
 Inflammatory carcinoma of breast stage III
 Inflammatory carcinoma of breast stage IV
 Inflammatory carcinoma of the breast
 Inflammatory malignant fibrous histiocytoma
 Inflammatory myofibroblastic tumour

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

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
 Intestinal adenocarcinoma
 Intestinal metastasis
 Intracranial germ cell tumour
 Intracranial meningioma malignant
 Intraductal papillary breast neoplasm
 Intraductal papillary-mucinous carcinoma of pancreas
 Intraductal proliferative breast lesion
 Intraocular melanoma
 Invasive breast carcinoma
 Invasive ductal breast carcinoma
 Invasive lobular breast carcinoma
 Invasive papillary breast carcinoma
 Iris melanoma
 Juvenile chronic myelomonocytic leukaemia
 Kaposi's sarcoma
 Kaposi's sarcoma AIDS related
 Kaposi's sarcoma classical type
 Keratinising squamous cell carcinoma of nasopharynx
 Keratoacanthoma
 Langerhans cell sarcoma
 Large cell lung cancer
 Large cell lung cancer metastatic
 Large cell lung cancer recurrent
 Large cell lung cancer stage 0
 Large cell lung cancer stage I
 Large cell lung cancer stage II
 Large cell lung cancer stage III
 Large cell lung cancer stage IV
 Laryngeal cancer
 Laryngeal cancer metastatic
 Laryngeal cancer recurrent
 Laryngeal cancer stage 0
 Laryngeal cancer stage I
 Laryngeal cancer stage II
 Laryngeal cancer stage III

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Laryngeal cancer stage IV
 Laryngeal squamous cell carcinoma
 Leiomyosarcoma
 Leiomyosarcoma metastatic
 Leiomyosarcoma recurrent
 Leiomyosarcoma recurrent
 Lentigo maligna
 Lentigo maligna recurrent
 Lentigo maligna stage I
 Lentigo maligna stage II
 Lentigo maligna stage III
 Lentigo maligna stage IV
 Leptomeningeal myelomatosis
 Leukaemia
 Leukaemia basophilic
 Leukaemia cutis
 Leukaemia granulocytic
 Leukaemia in remission
 Leukaemia monocytic
 Leukaemia recurrent
 Leukaemia 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
 Leydig cell tumour of the testis
 Linitis plastica
 Lip and/or oral cavity cancer
 Lip and/or oral cavity cancer recurrent
 Lip and/or oral cavity cancer stage 0
 Lip and/or oral cavity cancer stage I
 Lip and/or oral cavity cancer stage II
 Lip and/or oral cavity cancer stage III
 Lip and/or oral cavity cancer stage IV
 Lip neoplasm malignant stage unspecified
 Lip squamous cell carcinoma
 Liposarcoma
 Liposarcoma metastatic
 Liposarcoma recurrent

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Lobular breast carcinoma in situ
 Lung adenocarcinoma
 Lung adenocarcinoma recurrent
 Lung adenocarcinoma stage 0
 Lung adenocarcinoma stage I
 Lung adenocarcinoma stage II
 Lung adenocarcinoma stage III
 Lung adenocarcinoma stage IV
 Lung cancer metastatic
 Lung carcinoma cell type unspecified recurrent
 Lung carcinoma cell type unspecified stage 0
 Lung carcinoma cell type unspecified stage I
 Lung carcinoma cell type unspecified stage II
 Lung carcinoma cell type unspecified stage III
 Lung carcinoma cell type unspecified stage IV
 Lung infiltration malignant
 Lung neoplasm malignant
 Lung squamous cell carcinoma metastatic
 Lung squamous cell carcinoma recurrent
 Lung squamous cell carcinoma stage 0
 Lung squamous cell carcinoma stage I
 Lung squamous cell carcinoma stage II
 Lung squamous cell carcinoma stage III
 Lung squamous cell carcinoma stage IV
 Lymphangiosarcoma
 Lymphangiosis carcinomatosa
 Lymphocytic leukaemia
 Lymphocytic lymphoma
 Lymphoid leukaemia (in remission)
 Lymphoma
 Lymphoma AIDS related
 Lymphoma transformation
 Lymphoplasmacytoid lymphoma/immunocytoma
 Lymphoplasmacytoid lymphoma/immunocytoma recurrent
 refractory
 Lymphoplasmacytoid lymphoma/immunocytoma stage I
 Lymphoplasmacytoid lymphoma/immunocytoma stage II
 Lymphoplasmacytoid lymphoma/immunocytoma stage III
 Lymphoplasmacytoid lymphoma/immunocytoma stage IV
 Malignant anorectal neoplasm
 Malignant blue naevus
 Malignant connective tissue neoplasm

Pre-defined MedDRA search

Preferred term

Neoplasm

- Malignant cranial nerve neoplasm
- Malignant fibrous histiocytoma
- Malignant fibrous histiocytoma metastatic
- Malignant fibrous histiocytoma of bone
- Malignant fibrous histiocytoma recurrent
- Malignant genitourinary tract neoplasm
- Malignant giant cell fibrous histiocytoma
- Malignant glioma
- Malignant haemangiopericytoma
- Malignant haemangiopericytoma metastatic
- Malignant haemangiopericytoma recurrent
- Malignant histiocytosis
- Malignant hydatidiform mole
- Malignant joint neoplasm
- Malignant lymphoid neoplasm
- Malignant lymphoma unclassifiable high grade
- Malignant lymphoma unclassifiable low grade
- Malignant mast cell neoplasm
- Malignant mediastinal neoplasm
- Malignant melanoma
- Malignant melanoma in situ
- Malignant melanoma of eyelid
- Malignant melanoma of sites other than skin
- Malignant melanoma stage I
- Malignant melanoma stage II
- Malignant melanoma stage III
- Malignant melanoma stage IV
- Malignant meningioma metastatic
- Malignant mesenchymoma
- Malignant mesenchymoma metastatic
- Malignant mesenchymoma recurrent
- Malignant mesenteric neoplasm
- Malignant middle ear neoplasm
- Malignant muscle neoplasm
- Malignant neoplasm of ampulla of Vater
- Malignant neoplasm of choroid
- Malignant neoplasm of conjunctiva
- Malignant neoplasm of cornea
- Malignant neoplasm of eye
- Malignant neoplasm of eyelid
- Malignant neoplasm of islets of Langerhans
- Malignant neoplasm of lacrimal duct
- Malignant neoplasm of lacrimal gland

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

- Malignant neoplasm of orbit
- Malignant neoplasm of paraurethral glands
- Malignant neoplasm of placenta
- Malignant neoplasm of pleura
- Malignant neoplasm of pleura metastatic
- Malignant neoplasm of renal pelvis
- Malignant neoplasm of retina
- Malignant neoplasm of seminal vesicle
- Malignant neoplasm of spermatic cord
- Malignant neoplasm of spinal cord
- Malignant neoplasm of thorax
- Malignant neoplasm of thymus
- Malignant neoplasm of unknown primary site
- Malignant neoplasm of uterine adnexa
- Malignant neoplasm papilla of Vater
- Malignant nervous system neoplasm
- Malignant nipple neoplasm
- Malignant nipple neoplasm female
- Malignant nipple neoplasm male
- Malignant oligodendroglioma
- Malignant ovarian cyst
- Malignant palate neoplasm
- Malignant pericardial neoplasm
- Malignant peritoneal neoplasm
- Malignant pituitary tumour
- Malignant polyP
- Malignant respiratory tract neoplasm
- Malignant splenic neoplasm
- Malignant sweat gland neoplasm
- Malignant transformation
- Malignant urinary tract neoplasm
- Mantle cell lymphoma
- Mantle cell lymphoma recurrent
- Mantle cell lymphoma refractory
- Mantle cell lymphoma stage I
- Mantle cell lymphoma stage II
- Mantle cell lymphoma stage III
- Mantle cell lymphoma stage IV
- Marginal zone lymphoma
- Marginal zone lymphoma recurrent
- Marginal zone lymphoma refractory
- Marginal zone lymphoma stage I
- Marginal zone lymphoma stage II

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Marginal zone lymphoma stage III
Marginal zone lymphoma stage IV
Marjolin's ulcer
Mastocytic leukaemia
Maternal cancer in pregnancy
Mature B-cell type acute leukaemia
Medullary carcinoma of breast
Medullary thyroid cancer
Medulloblastoma
Medulloblastoma recurrent
Melanoma recurrent
Meningioma malignant
Mesothelioma malignant
Mesothelioma malignant recurrent
Metaplastic breast carcinoma
Metastases to Eustachian tube
Metastases to abdominal cavity
Metastases to abdominal wall
Metastases to adrenals
Metastases to biliary tract
Metastases to bladder
Metastases to bone
Metastases to bone marrow
Metastases to breast
Metastases to central nervous system
Metastases to chest wall
Metastases to diaphragm
Metastases to eye
Metastases to fallopian tube
Metastases to gallbladder
Metastases to gastrointestinal tract
Metastases to heart
Metastases to kidney
Metastases to larynx
Metastases to liver
Metastases to lung
Metastases to lymph nodes
Metastases to meninges
Metastases to mouth
Metastases to muscle
Metastases to nasal sinuses
Metastases to neck
Metastases to nervous system

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Metastases to oesophagus
Metastases to ovary
Metastases to pancreas
Metastases to pelvis
Metastases to penis
Metastases to perineum
Metastases to peripheral nervous system
Metastases to peripheral vascular system
Metastases to peritoneum
Metastases to pharynx
Metastases to pituitary gland
Metastases to placenta
Metastases to pleura
Metastases to prostate
Metastases to rectum
Metastases to reproductive organ
Metastases to retroperitoneum
Metastases to salivary gland
Metastases to skin
Metastases to soft tissue
Metastases to spinal cord
Metastases to spine
Metastases to spleen
Metastases to stomach
Metastases to testicle
Metastases to the mediastinum
Metastases to the respiratory system
Metastases to thorax
Metastases to thyroid
Metastases to tonsils
Metastases to trachea
Metastases to urinary tract
Metastases to uterus
Metastases to vagina
Metastasis
Metastatic bronchial carcinoma
Metastatic carcinoid tumour
Metastatic carcinoma of the bladder
Metastatic choriocarcinoma
Metastatic gastric cancer
Metastatic glioma
Metastatic glucagonoma
Metastatic lymphoma

Pre-defined MedDRA search - list of preferred terms

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Preferred term

Neoplasm

Metastatic malignant melanoma
 Metastatic neoplasm
 Metastatic nervous system neoplasm
 Metastatic ocular melanoma
 Metastatic renal cell carcinoma
 Metastatic salivary gland cancer
 Metastatic squamous cell carcinoma
 Metastatic uterine cancer
 Microsatellite instability cancer
 Minimal residual disease
 Mismatch repair cancer syndrome
 Mixed adenoneuroendocrine carcinoma
 Mixed-type liposarcoma
 Monocytic leukaemia in remission
 Mucinous adenocarcinoma of appendix
 Mucinous breast carcinoma
 Mucinous cystadenocarcinoma ovary
 Mucinous endometrial carcinoma
 Mucoepidermoid carcinoma
 Mucoepidermoid carcinoma of salivary gland
 Musculoskeletal cancer
 Myeloblastoma
 Myeloid leukaemia
 Myeloid leukaemia in remission
 Myxofibrosarcoma
 Myxoid liposarcoma
 NUT midline carcinoma
 Naevoid melanoma
 Nasal cavity cancer
 Nasal sinus cancer
 Nasopharyngeal cancer
 Nasopharyngeal cancer metastatic
 Nasopharyngeal cancer recurrent
 Nasopharyngeal cancer stage 0
 Nasopharyngeal cancer stage I
 Nasopharyngeal cancer stage II
 Nasopharyngeal cancer stage III
 Nasopharyngeal cancer stage IV
 Natural killer-cell leukaemia
 Natural killer-cell lymphoblastic lymphoma
 Neonatal leukaemia
 Neonatal neuroblastoma
 Neoplasm malignant

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Nephroblastoma
 Neuroblastoma
 Neuroblastoma recurrent
 Neuroendocrine breast tumour
 Neuroendocrine carcinoma
 Neuroendocrine carcinoma metastatic
 Neuroendocrine carcinoma of prostate
 Neuroendocrine carcinoma of the bladder
 Neuroendocrine carcinoma of the skin
 Neuroendocrine tumour
 Neuroendocrine tumour of the lung
 Neuroendocrine tumour of the lung metastatic
 Neurofibrosarcoma
 Neurofibrosarcoma metastatic
 Neurofibrosarcoma recurrent
 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
 Nodular melanoma
 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

Pre-defined MedDRA search

Preferred term

Neoplasm

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-renal cell carcinoma of kidney
Non-small cell lung cancer
Non-small cell lung cancer metastatic
Non-small cell lung cancer recurrent
Non-small cell lung cancer stage 0
Non-small cell lung cancer stage I
Non-small cell lung cancer stage II
Non-small cell lung cancer stage III
Non-small cell lung cancer stage IIIA
Non-small cell lung cancer stage IIIB
Non-small cell lung cancer stage IV
Nongerminomatous germ cell tumour of the CNS
Nonkeratinising carcinoma of nasopharynx
Ocular cancer metastatic
Ocular haemangiopericytoma
Ocular lymphoma
Oesophageal adenocarcinoma
Oesophageal adenocarcinoma recurrent
Oesophageal adenocarcinoma stage 0
Oesophageal adenocarcinoma stage I
Oesophageal adenocarcinoma stage II
Oesophageal adenocarcinoma stage III
Oesophageal adenocarcinoma stage IV
Oesophageal adenosquamous carcinoma
Oesophageal cancer metastatic
Oesophageal carcinoma
Oesophageal carcinoma recurrent
Oesophageal carcinoma stage 0
Oesophageal squamous cell carcinoma

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Oesophageal squamous cell carcinoma metastatic
 Oesophageal squamous cell carcinoma recurrent
 Oesophageal squamous cell carcinoma stage 0
 Oesophageal squamous cell carcinoma stage I
 Oesophageal squamous cell carcinoma stage II
 Oesophageal squamous cell carcinoma stage III
 Oesophageal squamous cell carcinoma stage IV
 Oligoastrocytoma
 Oligodendroglioma
 Optic glioma
 Oral cavity cancer metastatic
 Oropharyngeal cancer
 Oropharyngeal cancer recurrent
 Oropharyngeal cancer stage 0
 Oropharyngeal cancer stage I
 Oropharyngeal cancer stage II
 Oropharyngeal cancer stage III
 Oropharyngeal cancer stage IV
 Oropharyngeal lymphoepithelioma
 Oropharyngeal squamous cell carcinoma
 Osteosarcoma
 Osteosarcoma metastatic
 Osteosarcoma recurrent
 Otic cancer metastatic
 Ovarian cancer
 Ovarian cancer metastatic
 Ovarian cancer recurrent
 Ovarian cancer stage I
 Ovarian cancer stage II
 Ovarian cancer stage III
 Ovarian cancer stage IV
 Ovarian clear cell carcinoma
 Ovarian dysgerminoma stage I
 Ovarian dysgerminoma stage II
 Ovarian dysgerminoma stage III
 Ovarian dysgerminoma stage IV
 Ovarian dysgerminoma stage unspecified
 Ovarian embryonal carcinoma
 Ovarian endometrioid carcinoma
 Ovarian epithelial cancer
 Ovarian epithelial cancer metastatic
 Ovarian epithelial cancer recurrent
 Ovarian epithelial cancer stage I

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term
Neoplasm
Ovarian epithelial cancer stage II
Ovarian epithelial cancer stage III
Ovarian epithelial cancer stage IV
Ovarian germ cell cancer
Ovarian germ cell cancer stage I
Ovarian germ cell cancer stage II
Ovarian germ cell cancer stage III
Ovarian germ cell cancer stage IV
Ovarian germ cell choriocarcinoma
Ovarian germ cell choriocarcinoma stage I
Ovarian germ cell choriocarcinoma stage II
Ovarian germ cell choriocarcinoma stage III
Ovarian germ cell choriocarcinoma stage IV
Ovarian germ cell embryonal carcinoma stage I
Ovarian germ cell embryonal carcinoma stage II
Ovarian germ cell embryonal carcinoma stage III
Ovarian germ cell embryonal carcinoma stage IV
Ovarian germ cell endodermal sinus tumour
Ovarian germ cell endodermal sinus tumour stage I
Ovarian germ cell endodermal sinus tumour stage II
Ovarian germ cell endodermal sinus tumour stage III
Ovarian germ cell endodermal sinus tumour stage IV
Ovarian germ cell polyembryoma
Ovarian germ cell polyembryoma stage I
Ovarian germ cell polyembryoma stage II
Ovarian germ cell polyembryoma stage III
Ovarian germ cell polyembryoma stage IV
Ovarian germ cell teratoma
Ovarian germ cell teratoma stage I
Ovarian germ cell teratoma stage II
Ovarian germ cell teratoma stage III
Ovarian germ cell teratoma stage IV
Ovarian germ cell tumour mixed
Ovarian granulosa-theca cell tumour
Ovarian low malignant potential tumour
Ovarian melanoma
Ovarian stromal cancer
Paget's disease of nipple
Paget's disease of penis
Paget's disease of the vulva
Pancoast's tumour
Pancreatic carcinoma

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Pancreatic carcinoma metastatic
 Pancreatic carcinoma recurrent
 Pancreatic carcinoma stage 0
 Pancreatic carcinoma stage I
 Pancreatic carcinoma stage II
 Pancreatic carcinoma stage III
 Pancreatic carcinoma stage IV
 Pancreatic neuroendocrine tumour
 Pancreatic neuroendocrine tumour metastatic
 Pancreatic sarcoma
 Pancreatoblastoma
 Papillary renal cell carcinoma
 Papillary serous endometrial carcinoma
 Papillary thyroid cancer
 Paraganglion neoplasm malignant
 Paranasal sinus and nasal cavity malignant
 neoplasm
 Paranasal sinus and nasal cavity malignant
 neoplasm recurrent
 Paranasal sinus and nasal cavity malignant
 neoplasm stage 0
 Paranasal sinus and nasal cavity malignant
 neoplasm stage I
 Paranasal sinus and nasal cavity malignant
 neoplasm stage II
 Paranasal sinus and nasal cavity malignant
 neoplasm stage III
 Paranasal sinus and nasal cavity malignant
 neoplasm stage IV
 Parathyroid tumour malignant
 Penile cancer
 Penile squamous cell carcinoma
 Penis carcinoma metastatic
 Penis carcinoma recurrent
 Penis carcinoma stage I
 Penis carcinoma stage II
 Penis carcinoma stage III
 Penis carcinoma stage IV
 Pericardial mesothelioma malignant
 Pericardial mesothelioma malignant recurrent
 Peripheral T-cell lymphoma unspecified
 Peripheral T-cell lymphoma unspecified recurrent
 Peripheral T-cell lymphoma unspecified refractory

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

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
 Peripheral neuroepithelioma of bone
 Peripheral neuroepithelioma of bone metastatic
 Peripheral neuroepithelioma of bone recurrent
 Peripheral neuroepithelioma of soft tissue
 Peripheral primitive neuroectodermal bone tumour
 Peripheral primitive neuroectodermal tumour of soft tissue
 Peritoneal carcinoma metastatic
 Peritoneal mesothelioma malignant
 Peritoneal mesothelioma malignant recurrent
 Peritoneal sarcoma
 Phaeochromocytoma malignant
 Pharyngeal cancer
 Pharyngeal cancer metastatic
 Pharyngeal cancer recurrent
 Pharyngeal cancer stage 0
 Pharyngeal cancer stage I
 Pharyngeal cancer stage II
 Pharyngeal cancer stage III
 Pharyngeal cancer stage IV
 Pilomatrix carcinoma
 Pineal germinoma
 Pineal parenchymal neoplasm malignant
 Pinealoblastoma
 Pituitary cancer metastatic
 Pituitary neoplasm malignant recurrent
 Plasma cell leukaemia
 Plasma cell leukaemia in remission
 Plasma cell myeloma
 Plasma cell myeloma in remission
 Plasma cell myeloma recurrent
 Plasma cell myeloma refractory
 Plasmablastic lymphoma
 Plasmacytoma
 Pleomorphic leiomyosarcoma
 Pleomorphic liposarcoma
 Pleomorphic malignant fibrous histiocytoma
 Pleural mesothelioma
 Pleural mesothelioma malignant

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Pleural mesothelioma malignant recurrent
 Pleural sarcoma
 Pleuropulmonary blastoma
 Poorly differentiated thyroid carcinoma
 Porocarcinoma
 Posttrichoid cancer
 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
 Primary breast lymphoma
 Primary cardiac lymphoma
 Primary effusion lymphoma
 Primary gastrointestinal follicular lymphoma
 Primary mediastinal large B-cell lymphoma
 Primary mediastinal large B-cell lymphoma recurrent
 Primary mediastinal large B-cell lymphoma refractory
 Primary mediastinal large B-cell lymphoma stage I
 Primary mediastinal large B-cell lymphoma stage II
 Primary mediastinal large B-cell lymphoma stage III
 Primary mediastinal large B-cell lymphoma stage IV
 Primary pulmonary melanoma
 Primitive neuroectodermal tumour

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

- Neoplasm
 - Primitive neuroectodermal tumour metastatic
 - Prolymphocytic leukaemia
 - Prostate cancer
 - Prostate cancer metastatic
 - Prostate cancer recurrent
 - Prostate cancer stage 0
 - Prostate cancer stage I
 - Prostate cancer stage II
 - Prostate cancer stage III
 - Prostate cancer stage IV
 - Pseudosarcoma
 - Queyrat erythroplasia
 - Rectal adenocarcinoma
 - Rectal cancer
 - Rectal cancer metastatic
 - Rectal cancer recurrent
 - Rectal cancer stage 0
 - Rectal cancer stage I
 - Rectal cancer stage II
 - Rectal cancer stage III
 - Rectal cancer stage IV
 - Rectosigmoid cancer
 - Rectosigmoid cancer metastatic
 - Rectosigmoid cancer recurrent
 - Rectosigmoid cancer stage 0
 - Rectosigmoid cancer stage I
 - Rectosigmoid cancer stage II
 - Rectosigmoid cancer stage III
 - Rectosigmoid cancer stage IV
 - Recurrent cancer
 - Refractory cancer
 - Renal cancer
 - Renal cancer metastatic
 - Renal cancer recurrent
 - Renal cancer stage I
 - Renal cancer stage II
 - Renal cancer stage III
 - Renal cancer stage IV
 - Renal cell carcinoma
 - Renal cell carcinoma recurrent
 - Renal cell carcinoma stage I
 - Renal cell carcinoma stage II
 - Renal cell carcinoma stage III

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Renal cell carcinoma stage IV
 Respiratory tract carcinoma in situ
 Retinal melanoma
 Retinoblastoma
 Retroperitoneal cancer
 Retroperitoneal neoplasm metastatic
 Rhabdoid tumour
 Rhabdoid tumour of the kidney
 Rhabdomyosarcoma
 Rhabdomyosarcoma recurrent
 Richter's syndrome
 Round cell liposarcoma
 Salivary gland cancer
 Salivary gland cancer recurrent
 Salivary gland cancer stage 0
 Salivary gland cancer stage I
 Salivary gland cancer stage II
 Salivary gland cancer stage III
 Salivary gland cancer stage IV
 Sarcoma
 Sarcoma metastatic
 Sarcoma of skin
 Sarcoma uterus
 Sarcomatoid carcinoma
 Sarcomatoid carcinoma of the lung
 Sarcomatoid mesothelioma
 Sarcomatosis
 Scrotal cancer
 Sebaceous carcinoma
 Second primary malignancy
 Seminoma
 Serous cystadenocarcinoma ovary
 Signet-ring cell carcinoma
 Sinus cancer metastatic
 Skin angiosarcoma
 Skin cancer
 Skin cancer metastatic
 Skin squamous cell carcinoma metastatic
 Skin squamous cell carcinoma recurrent
 Small cell carcinoma
 Small cell carcinoma of the cervix
 Small cell lung cancer
 Small cell lung cancer extensive stage

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Small cell lung cancer limited stage
 Small cell lung cancer metastatic
 Small cell lung cancer recurrent
 Small intestine adenocarcinoma
 Small intestine carcinoma
 Small intestine carcinoma metastatic
 Small intestine carcinoma recurrent
 Small intestine carcinoma stage 0
 Small intestine carcinoma stage I
 Small intestine carcinoma stage II
 Small intestine carcinoma stage III
 Small intestine carcinoma stage IV
 Small intestine leiomyosarcoma
 Soft tissue sarcoma
 Solid pseudopapillary tumour of the pancreas
 Spermatocytic seminoma
 Spinal meningioma malignant
 Spindle cell sarcoma
 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
 Squamous cell breast carcinoma
 Squamous cell carcinoma
 Squamous cell carcinoma of head and neck
 Squamous cell carcinoma of lung
 Squamous cell carcinoma of pharynx
 Squamous cell carcinoma of skin
 Squamous cell carcinoma of the cervix
 Squamous cell carcinoma of the hypopharynx
 Squamous cell carcinoma of the oral cavity
 Squamous cell carcinoma of the parotid gland
 Squamous cell carcinoma of the tongue
 Squamous cell carcinoma of the vulva
 Squamous endometrial carcinoma
 Stewart-Treves syndrome
 Superficial spreading melanoma stage I
 Superficial spreading melanoma stage II
 Superficial spreading melanoma stage III

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Superficial spreading melanoma stage IV
 Superficial spreading melanoma stage unspecified
 Synovial sarcoma
 Synovial sarcoma metastatic
 Synovial sarcoma recurrent
 T-cell chronic lymphocytic leukaemia
 T-cell lymphoma
 T-cell lymphoma recurrent
 T-cell lymphoma refractory
 T-cell lymphoma stage I
 T-cell lymphoma stage II
 T-cell lymphoma stage III
 T-cell lymphoma stage IV
 T-cell prolymphocytic leukaemia
 T-cell type acute leukaemia
 T-cell unclassifiable lymphoma high grade
 T-cell unclassifiable lymphoma low grade
 Testicular cancer metastatic
 Testicular choriocarcinoma
 Testicular choriocarcinoma recurrent
 Testicular choriocarcinoma stage I
 Testicular choriocarcinoma stage II
 Testicular choriocarcinoma stage III
 Testicular embryonal carcinoma
 Testicular embryonal carcinoma stage I
 Testicular embryonal carcinoma stage II
 Testicular embryonal carcinoma stage III
 Testicular germ cell cancer
 Testicular germ cell cancer metastatic
 Testicular germ cell tumour mixed
 Testicular germ cell tumour mixed stage I
 Testicular germ cell tumour mixed stage II
 Testicular germ cell tumour mixed stage III
 Testicular leiomyosarcoma
 Testicular malignant teratoma
 Testicular malignant teratoma stage I
 Testicular malignant teratoma stage II
 Testicular malignant teratoma stage III
 Testicular seminoma (pure)
 Testicular seminoma (pure) stage I
 Testicular seminoma (pure) stage II
 Testicular seminoma (pure) stage III
 Testicular yolk sac tumour

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Testicular yolk sac tumour stage I
 Testicular yolk sac tumour stage II
 Testicular yolk sac tumour stage III
 Testis cancer
 Testis cancer recurrent
 Throat cancer
 Thymic cancer metastatic
 Thymoma malignant
 Thymoma malignant recurrent
 Thyroid B-cell lymphoma
 Thyroid cancer
 Thyroid cancer metastatic
 Thyroid cancer recurrent
 Thyroid cancer stage 0
 Thyroid cancer stage I
 Thyroid cancer stage II
 Thyroid cancer stage III
 Thyroid cancer stage IV
 Tongue cancer metastatic
 Tongue cancer recurrent
 Tongue carcinoma stage 0
 Tongue carcinoma stage I
 Tongue carcinoma stage II
 Tongue carcinoma stage III
 Tongue carcinoma stage IV
 Tongue neoplasm malignant stage unspecified
 Tonsil cancer
 Tonsil cancer metastatic
 Tracheal cancer
 Transformation to acute myeloid leukaemia
 Transitional cell cancer of renal pelvis and
 ureter metastatic
 Transitional cell cancer of the renal pelvis and
 ureter
 Transitional cell cancer of the renal pelvis and
 ureter localised
 Transitional cell cancer of the renal pelvis and
 ureter recurrent
 Transitional cell cancer of the renal pelvis and
 ureter regional
 Transitional cell carcinoma
 Transitional cell carcinoma metastatic
 Transitional cell carcinoma recurrent

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm
Transitional cell carcinoma urethra
Trichoblastic carcinoma
Triple hit lymphoma
Triple negative breast cancer
Triple positive breast cancer
Tubular breast carcinoma
Tumour budding
Undifferentiated carcinoma of colon
Undifferentiated nasopharyngeal carcinoma
Undifferentiated sarcoma
Ureteric cancer
Ureteric cancer local
Ureteric cancer metastatic
Ureteric cancer recurrent
Ureteric cancer regional
Urethral cancer
Urethral cancer metastatic
Urethral cancer recurrent
Urethral melanoma metastatic
Urinary bladder sarcoma
Urinary tract carcinoma in situ
Uterine cancer
Uterine carcinoma in situ
Uterine leiomyosarcoma
Uveal melanoma
Vaginal adenocarcinoma
Vaginal cancer
Vaginal cancer metastatic
Vaginal cancer recurrent
Vaginal cancer stage 0
Vaginal cancer stage I
Vaginal cancer stage II
Vaginal cancer stage III
Vaginal cancer stage IVA
Vaginal cancer stage IVB
Vulval cancer
Vulval cancer metastatic
Vulval cancer recurrent
Vulval cancer stage 0
Vulval cancer stage I
Vulval cancer stage II
Vulval cancer stage III
Vulval cancer stage IV

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Vulvar adenocarcinoma
 Vulvar basal cell carcinoma
 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
 ACTH-producing pituitary tumour
 APUDoma
 Abdominal neoplasm
 Abdominal wall neoplasm
 Abdominal wall neoplasm benign
 Acanthoma
 Acanthosis nigricans
 Acoustic neuroma
 Acquired bronchial cyst
 Acquired chromosomal abnormality
 Acquired cystic kidney disease
 Acquired thalassaemia
 Acrochordon
 Acrokeratosis paraneoplastica
 Actinic keratosis
 Adenolipoma
 Adenolymphoma
 Adenoma benign
 Adenomatous polyposis coli
 Adnexa uteri cyst
 Adrenal adenoma
 Adrenal cyst
 Adrenal neoplasm
 Adrenal rest tumour of the testis
 Alcoholisation procedure
 Allogenic stem cell transplantation
 Alpha 1 foetoprotein abnormal
 Alpha 1 foetoprotein increased
 Alpha interferon therapy
 Alpha-L-fucosidase increased
 Ameloblastoma
 Amputation of penis
 Amyloidoma
 Anal neoplasm

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Anal polypectomy
 Anaplastic lymphoma kinase gene and nucleophosmin
 gene fusion overexpression
 Androgen therapy
 Aneurysmal bone cyst
 Angiofibroma
 Angiogenesis biomarker increased
 Angiolipoma
 Angiomyofibroblastoma
 Angiomyolipoma
 Angiomyxoma
 Anogenital warts
 Anorectal haemangioma
 Anti-NMDA antibody positive
 Anti-VGCC antibody positive
 Anti-androgen withdrawal syndrome
 Antiandrogen therapy
 Antioestrogen therapy
 Appendix adenoma
 Arachnoid cyst
 Arsenical keratosis
 Aspiration bone marrow abnormal
 Astroblastoma
 Astrocytoma, low grade
 Atypical fibroxanthoma
 Aural cystadenoma
 Aural polyp
 Autologous bone marrow transplantation therapy
 Autologous haematopoietic stem cell transplant
 Axillary lymphadenectomy
 B-cell depletion therapy
 Bannayan-Riley-Ruvalcaba syndrome
 Bartholin's cyst
 Basal cell naevus syndrome
 Becker's naevus
 Bence Jones proteinuria
 Benign abdominal neoplasm
 Benign anorectal neoplasm
 Benign biliary neoplasm
 Benign bone neoplasm
 Benign breast neoplasm
 Benign cardiac neoplasm
 Benign cartilage neoplasm

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

- Benign connective tissue neoplasm
- Benign duodenal neoplasm
- Benign ear neoplasm
- Benign endocrine neoplasm
- Benign fallopian tube neoplasm
- Benign female reproductive tract neoplasm
- Benign gastric neoplasm
- Benign gastrointestinal neoplasm
- Benign genitourinary tract neoplasm
- Benign hydatidiform mole
- Benign joint neoplasm
- Benign laryngeal neoplasm
- Benign lung neoplasm
- Benign lymph node neoplasm
- Benign male reproductive tract neoplasm
- Benign mediastinal neoplasm
- Benign mesenteric neoplasm
- Benign mesothelioma
- Benign middle ear neoplasm
- Benign muscle neoplasm
- Benign neoplasm
- Benign neoplasm of adrenal gland
- Benign neoplasm of ampulla of Vater
- Benign neoplasm of bladder
- Benign neoplasm of cervix uteri
- Benign neoplasm of choroid
- Benign neoplasm of conjunctiva
- Benign neoplasm of cornea
- Benign neoplasm of epididymis
- Benign neoplasm of eye
- Benign neoplasm of eyelid
- Benign neoplasm of islets of Langerhans
- Benign neoplasm of lacrimal duct
- Benign neoplasm of lacrimal gland
- Benign neoplasm of optic nerve
- Benign neoplasm of orbit
- Benign neoplasm of pineal gland
- Benign neoplasm of prostate
- Benign neoplasm of retina
- Benign neoplasm of scrotum
- Benign neoplasm of seminal vesicle
- Benign neoplasm of skin
- Benign neoplasm of spinal cord

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Benign neoplasm of testis
Benign neoplasm of thymus
Benign neoplasm of thyroid gland
Benign neoplasm of ureter
Benign neoplasm of urethra
Benign nipple neoplasm
Benign oesophageal neoplasm
Benign ovarian tumour
Benign pancreatic neoplasm
Benign penile neoplasm
Benign pericardium neoplasm
Benign peritoneal neoplasm
Benign pleural mesothelioma
Benign pleural neoplasm
Benign renal neoplasm
Benign respiratory tract neoplasm
Benign salivary gland neoplasm
Benign small intestinal neoplasm
Benign soft tissue neoplasm
Benign spleen tumour
Benign tracheal neoplasm
Benign urinary tract neoplasm
Benign uterine neoplasm
Benign vaginal neoplasm
Benign vascular neoplasm
Benign vulval neoplasm
Beta interferon therapy
Biliary adenoma
Biliary cyst
Biliary hamartoma
Biliary neoplasm
Biliary polyp
Bing-Neel syndrome
Biopsy abdominal wall abnormal
Biopsy adrenal gland abnormal
Biopsy anus abnormal
Biopsy artery abnormal
Biopsy bladder abnormal
Biopsy blood vessel abnormal
Biopsy bone abnormal
Biopsy bone marrow abnormal
Biopsy brain abnormal
Biopsy breast abnormal

Pre-defined MedDRA search	Preferred term
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Neoplasm

- Biopsy bronchus abnormal
- Biopsy cartilage abnormal
- Biopsy cervix abnormal
- Biopsy chest wall abnormal
- Biopsy chorionic villous abnormal
- Biopsy colon abnormal
- Biopsy conjunctiva abnormal
- Biopsy cornea abnormal
- Biopsy diaphragm abnormal
- Biopsy ear abnormal
- Biopsy endometrium abnormal
- Biopsy epididymis abnormal
- Biopsy eyelid abnormal
- Biopsy fallopian tube abnormal
- Biopsy foetal abnormal
- Biopsy intestine abnormal
- Biopsy kidney abnormal
- Biopsy larynx abnormal
- Biopsy ligament abnormal
- Biopsy lip abnormal
- Biopsy lung abnormal
- Biopsy lymph gland abnormal
- Biopsy mucosa abnormal
- Biopsy muscle abnormal
- Biopsy oesophagus abnormal
- Biopsy ovary abnormal
- Biopsy palate abnormal
- Biopsy pancreas abnormal
- Biopsy parathyroid gland abnormal
- Biopsy penis abnormal
- Biopsy pericardium abnormal
- Biopsy peripheral nerve abnormal
- Biopsy peritoneum abnormal
- Biopsy pharynx abnormal
- Biopsy pleura abnormal
- Biopsy prostate abnormal
- Biopsy rectum abnormal
- Biopsy retina abnormal
- Biopsy salivary gland abnormal
- Biopsy sclera abnormal
- Biopsy seminal vesicle abnormal
- Biopsy site unspecified abnormal
- Biopsy skin abnormal

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Biopsy small intestine abnormal
Biopsy spinal cord abnormal
Biopsy spleen abnormal
Biopsy stomach abnormal
Biopsy tendon abnormal
Biopsy testes abnormal
Biopsy thymus gland abnormal
Biopsy thyroid gland abnormal
Biopsy tongue abnormal
Biopsy trachea abnormal
Biopsy urethra abnormal
Biopsy uterus abnormal
Biopsy vagina abnormal
Biopsy vocal cord abnormal
Biopsy vulva abnormal
Biotherapy
Birt-Hogg-Dube syndrome
Bladder cyst
Bladder dysplasia
Bladder leukoplakia
Bladder mapping
Bladder neck resection
Bladder neoplasm
Bladder neoplasm surgery
Bladder papilloma
Bladder polypectomy
Blast cell count increased
Blast cell proliferation
Blast cells present
Blepharal papilloma
Blood chromogranin A increased
Bone cyst
Bone giant cell tumour
Bone giant cell tumour benign
Bone marrow infiltration
Bone marrow reticulin fibrosis
Bone neoplasm
Bone scan abnormal
Borderline mucinous tumour of ovary
Borderline ovarian tumour
Borderline serous tumour of ovary
Bowenoid papulosis
Brachytherapy

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Brachytherapy to eye
Brachytherapy to penis
Brachytherapy to tongue
Brachytherapy to tonsil
Brain neoplasm
Brain neoplasm benign
Brain scan abnormal
Brain stem glioma benign
Brain teratoma
Brain tumour operation
Branchial cyst
Breakthrough pain
Breast adenoma
Breast calcifications
Breast capsulotomy
Breast conserving surgery
Breast cyst
Breast cyst rupture
Breast dysplasia
Breast fibroma
Breast neoplasm
Breast proliferative changes
Breast reconstruction
Breast tumour excision
Brenner tumour
Bronchial neoplasm
Bronchial neoplasm benign
Bronchial polyp
C-kit gene negative
CD20 antigen positive
CD25 antigen positive
CD30 expression
CLOVES syndrome
CSF lymphocyte count abnormal
CSF lymphocyte count increased
Cachexia
Calcifying fibrous pseudotumour
Cancer fatigue
Cancer hormonal therapy
Cancer pain
Cancer staging
Cancer surgery
Carbohydrate antigen 125 increased

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Carbohydrate antigen 15-3 increased
 Carbohydrate antigen 19-9 increased
 Carbohydrate antigen 27.29 increased
 Carbohydrate antigen 50 increased
 Carbohydrate antigen 549 increased
 Carbohydrate antigen 72-4
 Carbohydrate antigen 72-4 increased
 Carcinoembryonic antigen decreased
 Carcinoembryonic antigen increased
 Carcinogenic effect in offspring
 Carcinoid crisis
 Carcinoid heart disease
 Carcinoid syndrome
 Carcinomatous polyarthritis
 Cardiac fibroma
 Cardiac haemangioma benign
 Cardiac lymphangioma
 Cardiac myxoma
 Cardiac neoplasm unspecified
 Cardiac neurofibroma
 Cardiac teratoma
 Cardiac valve fibroelastoma
 Carney complex
 Cartilage neoplasm
 Castleman's disease
 Cell marker increased
 Cell-free and concentrated ascites reinfusion therapy
 Cementoblastoma
 Cementoplasty
 Central nervous system dermoid tumour
 Central nervous system neoplasm
 Cerebellar haemangioma
 Cerebellar tumour
 Cerebellopontine angle tumour
 Cerebral cyst
 Cerebral haemangioma
 Cervical cyst
 Cervical dysplasia
 Cervical polyp
 Cervix adenomatous polyp
 Cervix cryotherapy
 Cervix neoplasm

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Cervix tumour excision
Cervix warts
Chemical peel of skin
Chemotherapy
Chemotherapy cardiotoxicity attenuation
Chemotherapy cytokine prophylaxis
Chemotherapy extravasation management
Chemotherapy multiple agents systemic
Chemotherapy neurotoxicity attenuation
Chemotherapy sensitivity and resistance assay
Chemotherapy side effect prophylaxis
Chemotherapy single agent systemic
Chemotherapy toxicity attenuation
Chemotherapy urothelial toxicity attenuation
Chest wall cyst
Chest wall tumour
Chiasma syndrome
Cholangioadenoma
Cholangiojejunostomy
Cholechal cyst
Cholesteatoma
Cholesterin granuloma of middle ear
Cholesterol granuloma
Chondroblastoma
Chondroma
Chondromatosis
Choroid fissure cyst
Choroid neoplasm
Choroid plexus papilloma
Choroid tumour excision
Choroidal haemangioma
Chronic rhinosinusitis with nasal polyps
Clonal evolution
Colectomy
Colectomy total
Colloid brain cyst
Colon adenoma
Colon neoplasm
Colony stimulating factor therapy
Computerised tomogram breast abnormal
Computerised tomogram pancreas abnormal
Congenital LUMBAR syndrome
Congenital acrochordon

Pre-defined MedDRA search	Preferred term
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Neoplasm

- Congenital benign neoplasm
- Congenital cerebral cyst
- Congenital cerebral haemangioma
- Congenital choroid plexus cyst
- Congenital cyst
- Congenital cystic kidney disease
- Congenital eye naevus
- Congenital melanocytic naevus
- Congenital naevus
- Congenital neoplasm
- Congenital renal cyst
- Congenital teratoma
- Congenital vaginal cyst
- Conjunctival cyst
- Conjunctival neoplasm
- Conjunctival primary acquired melanosis
- Connective tissue neoplasm
- Corneal cyst
- Cowden's disease
- Cranial nerve neoplasm benign
- Craniopharyngioma
- Craniopharyngioma benign
- Cutaneous T-cell dyscrasia
- Cyclotron therapy
- Cyst
- Cyst rupture
- Cystadenofibroma of fallopian tube
- Cystic angiomatosis
- Cystic eyeball, congenital
- Cystic lymphangioma
- Cystoprostatectomy
- Cytokeratin 18 increased
- Cytokeratin 19 increased
- Denys-Drash syndrome
- Dermal cyst
- Dermoid cyst
- Desmoid tumour
- Desmoplastic fibroblastoma
- Diaphragm neoplasm
- Differentiation syndrome
- Diffuse uveal melanocytic proliferation
- Duodenal neoplasm
- Duodenectomy

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Dysplasia
 Dysplastic naevus
 Dysplastic naevus syndrome
 Ear neoplasm
 Eastern Cooperative Oncology Group performance status improved
 Eastern Cooperative Oncology Group performance status worsened
 Ectopic ACTH syndrome
 Ectopic aldosterone secretion
 Ectopic antidiuretic hormone secretion
 Ectopic calcitonin production
 Ectopic chorionic gonadotrophin secretion
 Ectopic growth hormone secretion
 Ectopic hormone secretion
 Ectopic parathyroid hormone production
 Ectopic prolactin secretion
 Ectopic renin secretion
 Elastofibroma
 Electron radiation therapy
 Electron radiation therapy to bladder
 Electron radiation therapy to blood
 Electron radiation therapy to bone
 Electron radiation therapy to brain
 Electron radiation therapy to breast
 Electron radiation therapy to colon
 Electron radiation therapy to ear, nose, or throat
 Electron radiation therapy to liver
 Electron radiation therapy to lung
 Electron radiation therapy to pancreas
 Electron radiation therapy to prostate
 Electron radiation therapy to skin
 Electron radiation therapy to soft tissue
 Electron radiation therapy to uterus
 Elephantiasis nostras verrucosa
 Encephalitis autoimmune
 Enchondromatosis
 Endobronchial lipoma
 Endocervical mucosal thickening
 Endocrine neoplasm
 Endometrial adenoma
 Endometrial dysplasia
 Endometrial hyperplasia

Pre-defined MedDRA search

Preferred term

Neoplasm

Endometrial neoplasm
 Ependymoma
 Ependymoma benign
 Epidermal naevus syndrome
 Epidermodysplasia verruciformis
 Epidermoidal cyst
 Epidermoidal neoplasm
 Epiglottic cyst
 Epiglottic mass
 Epiglottidectomy
 Epithelioma adenoides cysticum
 Epstein Barr virus positive mucocutaneous ulcer
 Epstein-Barr virus associated lymphoproliferative disorder
 Erdheim-Chester disease
 Erythroplasia
 Erythroplasia of lip
 Erythroplasia of penis
 Erythroplasia of vulva
 Essential thrombocythaemia
 Ex vivo gene therapy
 Exploratory operation
 Extended radical mastectomy
 Extradural neoplasm
 Eye haemangioma
 Eye naevus
 Eyelid haemangioma
 Eyelid naevus
 Eyelid seborrhoeic keratosis
 Eyelid tumour
 Fallopian tube cyst
 Fallopian tube leiomyoma
 Fallopian tube neoplasm
 Familial acromegaly
 Familial gigantiform cementoma
 Familial haemophagocytic lymphohistiocytosis
 Familial multiple lipomatosis
 Female reproductive neoplasm
 Fibroadenoma of breast
 Fibrocystic breast disease
 Fibroma
 Fibromatosis
 Fibromatosis colli of infancy

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Fibrous cortical defect
 Fibrous histiocytoma
 Fiducial marker placement
 Fms-like tyrosine kinase 3 positive
 Foetal cystic hygroma
 Follicular cystitis
 Fraser syndrome
 Free prostate-specific antigen increased
 Free prostate-specific antigen positive
 Fungating wound
 Gallbladder adenoma
 Gallbladder neoplasm
 Gallbladder papilloma
 Gallbladder polyp
 Gamma interferon therapy
 Gamma radiation therapy
 Gamma radiation therapy to bladder
 Gamma radiation therapy to blood
 Gamma radiation therapy to bone
 Gamma radiation therapy to brain
 Gamma radiation therapy to breast
 Gamma radiation therapy to colon
 Gamma radiation therapy to ear, nose, or throat
 Gamma radiation therapy to liver
 Gamma radiation therapy to lung
 Gamma radiation therapy to pancreas
 Gamma radiation therapy to pleura
 Gamma radiation therapy to prostate
 Gamma radiation therapy to skin
 Gamma radiation therapy to soft tissue
 Gamma radiation therapy to thyroid
 Gamma radiation therapy to uterus
 Gammopathy
 Ganglioneuroma
 Garcin syndrome
 Gastric adenoma
 Gastric haemangioma
 Gastric leiomyoma
 Gastric neoplasm
 Gastric polypectomy
 Gastric stent insertion
 Gastrin-releasing peptide precursor increased

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

- Gastrinoma
- Gastrointestinal neoplasm
- Gastrointestinal submucosal tumour
- Gastrointestinal tract adenoma
- Genital cyst
- Genitourinary tract neoplasm
- Germ cell neoplasm
- Giant cell tumour of tendon sheath
- Glomus tumour
- Glossectomy
- Good syndrome
- Gorham's disease
- Granular cell tumour
- Granulosa cell tumour of the testis
- Growth hormone-producing pituitary tumour
- Haemangioblastoma
- Haemangioma
- Haemangioma congenital
- Haemangioma of bone
- Haemangioma of breast
- Haemangioma of retina
- Haemangioma of skin
- Haemangioma of spleen
- Haemangioma rupture
- Haemangioma-thrombocytopenia syndrome
- Haematopoietic neoplasm
- Haemophagocytic lymphohistiocytosis
- Haemophilic pseudotumour
- Haemorrhagic breast cyst
- Haemorrhagic cyst
- Haemorrhagic ovarian cyst
- Haemorrhagic thyroid cyst
- Haemorrhagic tumour necrosis
- Hair follicle tumour benign
- Hamartoma
- Hamartoma vascular
- Heavy chain disease
- Hemiorporectomy
- Hemipelvectomy
- Hepatic cyst infection
- Hereditary multiple osteochondromas
- Hereditary non-polyposis colorectal cancer syndrome

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

High frequency ablation
 High intensity focused ultrasound
 Histiocytic necrotising lymphadenitis
 Histiocytosis
 Hormone suppression therapy
 Hormone therapy
 Hormone-secreting ovarian tumour
 Horner's syndrome
 Human chorionic gonadotropin increased
 Human chorionic gonadotropin positive
 Human epidermal growth factor receptor increased
 Hygroma colli
 Hypercalcaemia of malignancy
 Hypercalcaitoninaemia
 Hypergammaglobulinaemia benign monoclonal
 Hyperleukocytosis
 Hyperreactio luteinalis
 Hyperthermia therapy
 Hyperthermic chemotherapy
 Hypertrophic osteoarthropathy
 Hypopharyngeal neoplasm
 Hypopharyngeal neoplasm benign
 Hypophosphataemic osteomalacia
 Hypophysectomy
 Hypothalamic hamartoma
 Hysterectomy
 Hysterosalpingectomy
 Hysterosalpingo-oophorectomy
 Iatrogenic metastasis
 Ileectomy
 Ileocaecal resection
 Ileocelectomy
 Imaging procedure abnormal
 Immune enhancement therapy
 Immunotherapy
 Immunoglobulin clonality assay
 Implant site cyst
 In vivo gene therapy
 Infantile fibromatosis
 Infantile haemangioma
 Infantile septic granulomatosis
 Infected cyst
 Infected dermal cyst

Pre-defined MedDRA search

Preferred term

Neoplasm

Infected lymphocele
 Infected naevus
 Infected neoplasm
 Inflammatory pseudotumour
 Insulinoma
 Interleukin therapy
 Intestinal angioma
 Intestinal polypectomy
 Intestinal resection
 Intra-abdominal haemangioma
 Intracranial haemangioma
 Intracystic breast papilloma
 Intraductal papillary mucinous neoplasm
 Intraductal papilloma of breast
 Intraneural cyst
 Intraosseous angioma
 Intraosseous meningioma
 Intratumoural aneurysm
 Intravascular lipoma
 Intravascular papillary endothelial hyperplasia
 Intravenous leiomyomatosis
 Intravesical immunotherapy
 Iris cyst
 Iris hamartoma
 Iris neoplasm
 Irreversible electroporation
 Isocitrate dehydrogenase gene mutation
 Jaw cyst
 Jejunectomy
 Joint neoplasm
 Juvenile angiofibroma
 Juvenile melanoma benign
 Knuckle pads
 Lacrimal cyst
 Lacrimal duct neoplasm
 Lacrimal gland neoplasm
 Large granular lymphocytosis
 Large intestinal polypectomy
 Large intestine benign neoplasm
 Large intestine fibroma
 Laryngeal cyst
 Laryngeal dysplasia
 Laryngeal leukoplakia

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Laryngeal neoplasm
Laryngeal papilloma
Laryngeal polyp
Laryngeal polypectomy
Laryngectomy
Laryngopharyngectomy
Laser brain ablation
Leiomyoma
Leser-Trelat sign
Leukoerythroblastosis
Leukoplakia
Leukoplakia of penis
Leukostasis syndrome
Light chain disease
Limbic encephalitis
Lip neoplasm
Lip neoplasm benign
Lipoblastoma
Lipodermoid tumour
Lipofibroma
Lipoma
Lipoma of breast
Lung cyst
Lung lobectomy
Lung neoplasm
Lung neoplasm surgery
Lymph nodes scan abnormal
Lymphadenectomy
Lymphangioma
Lymphatic mapping
Lymphatic system neoplasm
Lymphocele
Lymphocyte adoptive therapy
Lymphocyte morphology abnormal
Lymphoid tissue operation
Lymphoma operation
Lymphoproliferative disorder
Lymphoproliferative disorder in remission
Maffucci syndrome
Male reproductive tract neoplasm
Malignant ascites
Malignant exophthalmos
Malignant neoplasm progression

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Malignant pleural effusion
Malignant psoas syndrome
Malignant urinary tract obstruction
Marrow hyperplasia
Mastectomy
Mastocytoma
Mastoid cyst
Mastoidectomy
Maxillofacial sinus neoplasm
Mazabraud's syndrome
Mediastinal biopsy abnormal
Mediastinal cyst
Mediastinum neoplasm
Medical device site cyst
Megaloblasts increased
Meigs' syndrome
Melanocytic naevus
Meningeal neoplasm
Meningioma
Meningioma benign
Meniscus cyst
Mesenteric neoplasm
Mesoblastic nephroma
Mesonephric duct cyst
Mesothelioma
Metastatic bone disease prophylaxis
Metastatic pulmonary embolism
Micrographic skin surgery
Modified radical mastectomy
Monoclonal gammopathy
Mucosal cyst of postmastoidectomy cavity
Mueller's mixed tumour
Muir-Torre syndrome
Multicentric reticulohistiocytosis
Multilocular cystic nephroma
Multinucleate cell angiohistiocytoma
Multiple cutaneous and uterine leiomyomatosis
Multiple endocrine neoplasia Type 1
Multiple endocrine neoplasia Type 2
Multiple endocrine neoplasia Type 2A
Multiple endocrine neoplasia Type 2B
Muscle neoplasm

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Myasthenic syndrome
 Myectomy
 Myeloblast present
 Myelodysplastic syndrome
 Myelodysplastic syndrome transformation
 Myelodysplastic syndrome unclassifiable
 Myelofibrosis
 Myeloid metaplasia
 Myelolipoma
 Myeloma cast nephropathy
 Myeloproliferative neoplasm
 Myolipoma
 Myopericytoma
 NMP22 test abnormal
 Naevus haemorrhage
 Naevus lipomatosus cutaneus superficialis
 Nasal cyst
 Nasal neoplasm
 Nasal neoplasm benign
 Nasal polyps
 Nasopharyngeal neoplasm benign
 Nasopharyngeal polyp
 Nasopharyngeal tumour
 Neck dissection
 Necrolytic migratory erythema
 Needle biopsy site unspecified abnormal
 Neoadjuvant therapy
 Neobladder surgery
 Neoplasm
 Neoplasm of appendix
 Neoplasm of cornea unspecified malignancy
 Neoplasm of orbit
 Neoplasm of thymus
 Neoplasm progression
 Neoplasm prostate
 Neoplasm recurrence
 Neoplasm skin
 Neoplasm swelling
 Nephrectomy
 Nephroureterectomy
 Nervous system cyst
 Nervous system neoplasm
 Nervous system neoplasm benign

Pre-defined MedDRA search

Preferred term

Neoplasm

Nervous system neoplasm surgery
 Neurolemmoma benign
 Neuroectodermal neoplasm
 Neuroendoscopy
 Neurofibroma
 Neurofibromatosis
 Neurogenic tumour
 Neuroma
 Neuromyotonia
 Neurotensinoma
 Nipple neoplasm
 Nipple resection
 Nodular fasciitis
 Non-secretory adenoma of pituitary
 Numb chin syndrome
 Ocular neoplasm
 Ocular surface squamous neoplasia
 Odontogenic cyst
 Odontoma
 Oesophageal cyst
 Oesophageal neoplasm
 Oesophageal papilloma
 Oesophageal polypectomy
 Oesophageal prosthesis insertion
 Oesophagectomy
 Oesophagogastrrectomy
 Oestrogen receptor assay positive
 Oligodendroglioma benign
 Omenn syndrome
 Omentectomy
 Oncocytoma
 Oncologic complication
 Oophorectomy
 Oophorectomy bilateral
 Optic nerve neoplasm
 Oral cavity neoplasm surgery
 Oral fibroma
 Oral haemangioma
 Oral hairy leukoplakia
 Oral neoplasm
 Oral neoplasm benign
 Oral papilloma
 Oral polypectomy

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

- Orbital exenteration
- Orchidectomy
- Orchidotomy
- Oropharyngeal dysplasia
- Oropharyngeal neoplasm
- Oropharyngeal neoplasm benign
- Ostectomy
- Osteochondroma
- Osteofibroma
- Osteoma
- Osteoma cutis
- Ota's naevus
- Ovarian Sertoli-Leydig cell tumour
- Ovarian adenoma
- Ovarian cyst
- Ovarian cyst ruptured
- Ovarian cyst torsion
- Ovarian dysplasia
- Ovarian fibroma
- Ovarian germ cell teratoma benign
- Ovarian germ cell tumour
- Ovarian granulosa cell tumour
- Ovarian neoplasm
- Ovarian neoplasm surgery
- Ovarian stromal hyperplasia
- Ovarian theca cell tumour
- PHACES syndrome
- PML/RAR alpha expression
- POEMS syndrome
- Pachydermodactyly
- Palliative care
- Palmar fasciitis
- Pancoast's syndrome
- Pancraestatin abnormal
- Pancraestatin increased
- Pancreatotomy
- Pancreatic neoplasm
- Pancreaticoduodenectomy
- Pancreaticosplenectomy
- Papillary cystadenoma lymphomatosum
- Papillary tumour of renal pelvis
- Papilloma
- Papilloma conjunctival

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Paraneuritic pneumonia
Paraneuritic neoplasm
Paraneuritic neoplasm benign
Paraneuritic biopsy abnormal
Paraneuritic cyst
Paraneuritic sinus benign neoplasm
Paraneuritic sinus neoplasm
Paraneuritic arthritides
Paraneuritic dermatomyositis
Paraneuritic dermatosis
Paraneuritic encephalomyelitis
Paraneuritic glomerulonephritis
Paraneuritic hypoglycaemia
Paraneuritic myelopathy
Paraneuritic nephrotic syndrome
Paraneuritic neurological syndrome
Paraneuritic pemphigus
Paraneuritic pleural effusion
Paraneuritic rash
Paraneuritic retinopathy
Paraneuritic syndrome
Paraneuritic
Parapsoriasis
Paraneuritic cyst
Paraneuritic scan abnormal
Paraneuritic tumour
Paraneuritic tumour benign
Paraneuriticectomy
Paraneuriticectomy
Paraneuriticectomy
Paraneuritic fracture
Paraneuritic papules
Paraneuritic cyst
Paraneuritic neoplasm
Paraneuritic dysplasia
Paraneuritic neoplasm
Paraneuritic operation
Paraneuritic wart
Paraneuritic warts excision
Paraneuritic test positive
Paraneuritic ethanol injection therapy
Paraneuritic cyst
Paraneuritic effusion malignant

Pre-defined MedDRA search

Preferred term

Neoplasm

- Pericardial lipoma
- Pericardial neoplasm
- Pericarditis malignant
- Perineal cyst
- Perineurial cyst
- Peripheral nervous system neoplasm
- Peritoneal gliomatosis
- Peritoneal neoplasm
- Peritonectomy
- Peritumoural oedema
- Peutz-Jeghers syndrome
- Phaeochromocytoma
- Phaeochromocytoma crisis
- Phaeochromocytoma excision
- Phakomatosis
- Pharyngeal cyst
- Pharyngeal leukoplakia
- Pharyngeal mass
- Pharyngeal neoplasm
- Pharyngeal neoplasm benign
- Pharyngeal polyp
- Pharyngectomy
- Philadelphia chromosome positive
- Phosphatitic mesenchymal tumour
- Photodynamic diagnostic procedure
- Photon radiation therapy
- Photon radiation therapy to bladder
- Photon radiation therapy to blood
- Photon radiation therapy to bone
- Photon radiation therapy to brain
- Photon radiation therapy to breast
- Photon radiation therapy to colon
- Photon radiation therapy to ear, nose, or throat
- Photon radiation therapy to liver
- Photon radiation therapy to lung
- Photon radiation therapy to pancreas
- Photon radiation therapy to pleura
- Photon radiation therapy to prostate
- Photon radiation therapy to skin
- Photon radiation therapy to soft tissue
- Photon radiation therapy to thyroid
- Photon radiation therapy to uterus
- Phylloides tumour

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Pineal gland cyst
Pineal neoplasm
Pinealoma
Pineocytoma
Pituitary cyst
Pituitary gland radiotherapy
Pituitary scan abnormal
Pituitary tumour
Pituitary tumour benign
Pituitary tumour recurrent
Placental chorioangioma
Placental cyst
Placental neoplasm
Placental polyp
Pleomorphic adenoma
Pleural cyst
Pleural neoplasm
Pleurectomy
Pneumectomy
Polycythaemia vera
Polyneuropathy in malignant disease
Polyp
Portal vein embolisation
Post breast therapy pain syndrome
Post transplant lymphoproliferative disorder
Posterior fossa syndrome
Postmastectomy lymphoedema syndrome
Precancerous condition
Precancerous lesion excision
Precancerous mucosal lesion
Precancerous skin lesion
Primary myelofibrosis
Proctectomy
Proctocolectomy
Progesterone receptor assay positive
Prolactin-producing pituitary tumour
Prophylactic chemotherapy
Prostate ablation
Prostate cryoablation
Prostate interstitial hyperthermia therapy
Prostatectomy
Prostatic adenoma
Prostatic cyst

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Prostatic dysplasia
 Prostatic polyp
 Prostatic specific antigen abnormal
 Prostatic specific antigen increased
 Pseudocirrhosis
 Pseudomyxoma peritonei
 Pulmonary resection
 Pylorectomy
 Pyoderma gangrenosum
 Pyogenic granuloma
 Radiation therapy to ear, nose, or throat
 Radical cystectomy
 Radical hysterectomy
 Radical mastectomy
 Radical parametrectomy
 Radical prostatectomy
 Radioactive iodine therapy
 Radioembolisation
 Radiofrequency ablation of oesophagus
 Radiofrequency-induced thermochemotherapeutic effect
 Radioisotope scan abnormal
 Radiosensitisation therapy
 Radiotherapy
 Radiotherapy to abdomen
 Radiotherapy to adrenal gland
 Radiotherapy to blood
 Radiotherapy to bone
 Radiotherapy to brain
 Radiotherapy to breast
 Radiotherapy to colon
 Radiotherapy to ear
 Radiotherapy to eye
 Radiotherapy to gallbladder
 Radiotherapy to gastrointestinal tract
 Radiotherapy to head and neck
 Radiotherapy to joint
 Radiotherapy to kidney
 Radiotherapy to liver
 Radiotherapy to lung
 Radiotherapy to lymph nodes
 Radiotherapy to mediastinum
 Radiotherapy to nose

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Radiotherapy to oesophagus
Radiotherapy to oral cavity
Radiotherapy to ovary
Radiotherapy to pancreas
Radiotherapy to pharynx
Radiotherapy to pleura
Radiotherapy to prostate
Radiotherapy to rectum
Radiotherapy to skin
Radiotherapy to soft tissue
Radiotherapy to spleen
Radiotherapy to stomach
Radiotherapy to thymus
Radiotherapy to thyroid
Radiotherapy to tongue
Radiotherapy to urinary bladder
Radiotherapy to uterus
Radiotherapy to vagina
Radiotherapy toxicity attenuation
Rectal adenoma
Rectal neoplasm
Rectal polypectomy
Refractory anaemia with an excess of blasts
Refractory anaemia with ringed sideroblasts
Refractory cytopenia with multilineage dysplasia
Refractory cytopenia with unilineage dysplasia
Regional chemotherapy
Renal adenoma
Renal artery embolisation
Renal cell dysplasia
Renal cyst
Renal cyst haemorrhage
Renal cyst infection
Renal cyst ruptured
Renal haemangioma
Renal hamartoma
Renal neoplasm
Renal oncocytoma
Renal scan abnormal
Renal tumour excision
Respiratory papilloma
Respiratory tract neoplasm
Retention cyst

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Retinal melanocytoma
 Retinal neoplasm
 Retinal tumour excision
 Retro-orbital neoplasm
 Retro-pubic prostatectomy
 Retroperitoneal neoplasm
 Rhabdomyoma
 Rosai-Dorfman syndrome
 Sacrectomy
 Salivary bypass tube insertion
 Salivary gland adenoma
 Salivary gland neoplasm
 Salivary gland resection
 Salivary gland scan abnormal
 Salpingectomy
 Salpingo-oophorectomy
 Salpingo-oophorectomy bilateral
 Salpingo-oophorectomy unilateral
 Sarcoma excision
 Scan abdomen abnormal
 Scan abnormal
 Scan adrenal gland abnormal
 Scan bone marrow abnormal
 Scan gallium abnormal
 Scan with contrast abnormal
 Schwannoma
 Sclerosing pneumocytoma
 Scrotal cyst
 Sebaceous adenoma
 Sebaceous naevus
 Seborrheic keratosis
 Secondary cerebellar degeneration
 Secretory adenoma of pituitary
 Seminal vesicular cyst
 Senior-Loken syndrome
 Sertoli cell testicular tumour
 Sezary cells increased
 Sigmoidectomy
 Silicon granuloma
 Simple mastectomy
 Sinonasal papilloma
 Sinus polyp
 Sinus polyp degeneration

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

Skin cryotherapy
 Skin neoplasm bleeding
 Skin neoplasm excision
 Skin papilloma
 Small intestinal polypectomy
 Small intestinal resection
 Smooth muscle cell neoplasm
 Soft tissue neoplasm
 Solitary epithelioid histiocytoma
 Solitary fibrous tumour
 Somatostatin receptor scan abnormal
 Somatostatinoma
 Spermatic cord cyst
 Spermatocele
 Spinal cord lipoma
 Spinal cord neoplasm
 Spinal meningeal cyst
 Spinal meningioma benign
 Spinal synovial cyst
 Spleen scan abnormal
 Splenectomy
 Splenic cyst
 Splenic hamartoma
 Splenic neoplasm malignancy unspecified
 Squamous cell carcinoma antigen increased
 Stauffer's syndrome
 Steatocystoma multiplex
 Stem cell therapy
 Stem cell transplant
 Stoma site polyp
 Stomach scan abnormal
 Suprapubic prostatectomy
 Sweat gland tumour
 Synovial cyst
 Systemic mastocytosis
 TEMPI syndrome
 Targeted cancer therapy
 Tendon neoplasm
 Teratoma
 Teratoma benign
 Testicle adenoma
 Testicular cyst
 Testicular germ cell tumour

Pre-defined MedDRA search

Preferred term

Neoplasm

Testicular neoplasm
 Testicular papilloma
 Testicular scan abnormal
 Testicular teratoma benign
 Therapeutic ovarian suppression
 Thymic cyst
 Thymoma
 Thyroglossal cyst
 Thyroid C-cell hyperplasia
 Thyroid adenoma
 Thyroid cyst
 Thyroid electron radiation therapy
 Thyroid gland scan abnormal
 Thyroid neoplasm
 Thyroid stimulating hormone-producing pituitary tumour
 Thyroidectomy
 Tissue polypeptide antigen increased
 Tongue neoplasm
 Tongue neoplasm benign
 Tonsillar cyst
 Tonsillar neoplasm
 Tonsillar neoplasm benign
 Tornwaldt cyst
 Total adrenalectomy
 Tracheal neoplasm
 Tracheal papilloma
 Tracheal polyp
 Tracheal resection
 Transcatheter arterial chemoembolisation
 Transcranial electrical motor evoked potential monitoring abnormal
 Transdifferentiation of neoplasm
 Transurethral bladder resection
 Transurethral prostatectomy
 Trisomy 12
 Tuberosus sclerosis complex
 Tumour ablation
 Tumour associated fever
 Tumour cavitation
 Tumour cell mobilisation
 Tumour compression
 Tumour excision

Pre-defined MedDRA search	Preferred term
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Neoplasm

- Tumour exudation
- Tumour fistulisation
- Tumour flare
- Tumour haemorrhage
- Tumour hyperprogression
- Tumour inflammation
- Tumour invasion
- Tumour lysis syndrome
- Tumour marker abnormal
- Tumour marker decreased
- Tumour marker increased
- Tumour necrosis
- Tumour obstruction
- Tumour of ampulla of Vater
- Tumour pain
- Tumour perforation
- Tumour pruritus
- Tumour pseudoprogression
- Tumour rupture
- Tumour treating fields therapy
- Tumour ulceration
- Tumour vaccine therapy
- Ulcerated haemangioma
- Ultrasound pancreas abnormal
- Ultrasound scan abnormal
- Ultrasound scan vagina abnormal
- Umbilical cord cyst
- Ureteral cyst
- Ureteral neoplasm
- Ureteral polyp
- Ureteric papilloma
- Urethral adenoma
- Urethral cyst
- Urethral neoplasm
- Urethral papilloma
- Urethral polyp
- Urethrectomy
- Urinary bladder adenoma
- Urinary bladder polyp
- Urinary cystectomy
- Urinary tract neoplasm
- Urinary tract polyp
- Uterine cyst

Pre-defined MedDRA search

Preferred term

Neoplasm

Uterine leiomyoma
 Uterine myoma expulsion
 Uterine neoplasm
 Uterine polyp
 Uterine tumour excision
 Uvulectomy
 Vaccination site cyst
 Vaginal cyst
 Vaginal dysplasia
 Vaginal neoplasm
 Vaginal polyp
 Vaginectomy
 Vascular neoplasm
 Venous angioma of brain
 Vipoma
 Viral acanthoma
 Vitreous cyst
 Vocal cord cyst
 Vocal cord leukoplakia
 Vocal cord neoplasm
 Vocal cord polyp
 Vocal cordectomy
 Vulva cyst
 Vulval neoplasm
 Vulval operation
 Vulval polyp
 Vulval warts removal
 Vulvar dysplasia
 Vulvectomy
 Vulvovaginal adenosis
 Vulvovaginal warts
 Warty dyskeratoma
 White sponge naevus
 X-linked lymphoproliferative syndrome
 X-ray therapy to bladder
 X-ray therapy to blood
 X-ray therapy to bone
 X-ray therapy to brain
 X-ray therapy to breast
 X-ray therapy to colon
 X-ray therapy to ear, nose, or throat
 X-ray therapy to joint
 X-ray therapy to liver

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Neoplasm

X-ray therapy to lung
 X-ray therapy to pancreas
 X-ray therapy to pleura
 X-ray therapy to prostate
 X-ray therapy to skin
 X-ray therapy to soft tissue
 X-ray therapy to thyroid
 X-ray therapy to uterus
 X-ray treatment
 Xanthogranuloma
 Yolk sac tumour site unspecified

Pancreatitis

Alcoholic pancreatitis
 Alcoholic pancreopathy
 Autoimmune pancreatitis
 Haemorrhagic necrotic pancreatitis
 Immune-mediated pancreatitis
 Ischaemic pancreatitis
 Lupus pancreatitis
 Obstructive pancreatitis
 Oedematous pancreatitis
 Pancreatic haemorrhage
 Pancreatic necrosis
 Pancreatic phlegmon
 Pancreatic pseudoaneurysm
 Pancreatic pseudocyst
 Pancreatic pseudocyst haemorrhage
 Pancreatic pseudocyst rupture
 Pancreatitis
 Pancreatitis acute
 Pancreatitis chronic
 Pancreatitis haemorrhagic
 Pancreatitis necrotising
 Pancreatitis relapsing
 Cullen's sign
 Cytomegalovirus pancreatitis
 Grey Turner's sign
 Hereditary pancreatitis
 Pancreas infection
 Pancreatic abscess
 Pancreatic cyst drainage
 Pancreatic pseudocyst drainage
 Pancreatitis bacterial

Pre-defined MedDRA search

Preferred term

Pancreatitis

Pancreatitis fungal
 Pancreatitis helminthic
 Pancreatitis mumps
 Pancreatitis viral
 Pancreatorenal syndrome
 Radiation pancreatitis
 Traumatic pancreatitis

Rare events

11-beta-hydroxylase deficiency
 17,20-desmolase deficiency
 17-alpha-hydroxylase deficiency
 18q minus syndrome
 1p36 deletion syndrome
 2-Hydroxyglutaric aciduria
 20,22-desmolase deficiency
 21-hydroxylase deficiency
 3-hydroxyacetyl-coenzyme A dehydrogenase deficiency
 3M syndrome
 5-alpha-reductase deficiency
 ABO haemolytic disease of newborn
 ACAD9 deficiency
 ADCY5-related dyskinesia
 ADNP syndrome
 AIDS dysmorphic syndrome
 ASAH1 related disorder
 Aase syndrome
 Abdominal transposition
 Abdominal wall anomaly
 Aberrant aortic arch
 Abetalipoproteinaemia
 Ablepharon macrostomia syndrome
 Abnormal palmar/plantar creases
 Acardia
 Accessory auricle
 Accessory breast
 Accessory carpal bone
 Accessory kidney
 Accessory liver lobe
 Accessory muscle
 Accessory navicular syndrome
 Accessory renal artery
 Accessory salivary gland

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Accessory spleen
 Acetylcholinesterase deficiency
 Achard Thiers syndrome
 Achromotrichia congenital
 Acquired amegakaryocytic thrombocytopenia
 Acquired gene mutation
 Acquired mitochondrial DNA deletion
 Acquired mitochondrial DNA mutation
 Acral peeling skin syndrome
 Acrocallosal syndrome
 Acrocephalosyndactyly
 Acrodermatitis enteropathica
 Acrodysostosis
 Acrokeratosis verruciformis
 Acromesomelic dysplasia
 Acromicric dysplasia
 Activated P13 kinase delta syndrome
 Acute interstitial pneumonitis
 Acute motor axonal neuropathy
 Acute motor-sensory axonal neuropathy
 Adactyly
 Adams-Oliver syndrome
 Adenine phosphoribosyl transferase deficiency
 Adenylosuccinate lyase deficiency
 Adrenal insufficiency neonatal
 Adrenogenital syndrome
 Adrenoleukodystrophy
 Adult polyglucosan body disease
 Aglossia
 Agranulocytosis
 Aicardi's syndrome
 Aicardi-Goutieres syndrome
 Alagille syndrome
 Albinism
 Albright's disease
 Alexander disease
 Alkaptonuria
 Allan-Herndon-Dudley syndrome
 Alpers disease
 Alpha-1 antitrypsin deficiency
 Alpha-mannosidosis
 Alpha-thalassaemia-intellectual deficit syndrome
 Alport's syndrome

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

- Alstroem syndrome
- Alternating hemiplegia of childhood
- Alveolar capillary dysplasia
- Alveolar lung disease
- Alveolar proteinosis
- Alveolitis
- Alveolitis necrotising
- Amblyopia congenital
- Amegakaryocytic thrombocytopenia
- Aminoaciduria
- Amniotic band syndrome
- Amytrophic lateral sclerosis gene carrier
- Anal atresia
- Anaplastic lymphoma kinase gene mutation
- Androgen insensitivity syndrome
- Androgen receptor gene overexpression
- Anencephaly
- Angelman's syndrome
- Angiotensin converting enzyme inhibitor foetopathy
- Aniridia
- Aniridia-cerebellar ataxia-mental deficiency
- Ankyloglossia congenital
- Annular pancreas
- Anodontia
- Anomalous arrangement of pancreaticobiliary duct
- Anomalous pulmonary venous connection
- Anomaly of external ear congenital
- Anomaly of middle ear congenital
- Anomaly of orbit, congenital
- Anophthalmos
- Anorchism
- Anorectal agenesis
- Anorectal malformation
- Anotia
- Anterior chamber cleavage syndrome
- Anterior displaced anus
- Antibiotic associated colitis
- Antithrombin III deficiency
- Antley-Bixler syndrome
- Aorta hypoplasia
- Aortic valve atresia
- Aorticopulmonary septal defect
- Aphakia congenital

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

- Aplasia
- Aplasia cutis congenita
- Aplastic anaemia
- Apolipoprotein E e4 gene carrier
- Apparent mineralocorticoid excess
- Arachnodactyly
- Arcuate foramen
- Arginase deficiency
- Argininosuccinate lyase deficiency
- Argininosuccinate synthetase deficiency
- Arnold-Chiari malformation
- Aromatic L-amino acid decarboxylase deficiency
- Arterial tortuosity syndrome
- Arteriovenous malformation
- Ash leaf macule
- Aspartate-glutamate-transporter deficiency
- Aspartylglucosaminuria
- Asphyxiating thoracic dystrophy
- Asplenia
- Asymptomatic gene carrier
- Ataxia telangiectasia
- Atrial septal defect
- Atrioventricular septal defect
- Auditory neuropathy spectrum disorder
- Autoimmune aplastic anaemia
- Autoimmune lung disease
- Autoimmune lymphoproliferative syndrome
- Autoimmune nephritis
- Autosomal chromosome anomaly
- Autosomal recessive megaloblastic anaemia
- Azygos lobe
- B-lymphocyte abnormalities
- B-lymphocyte count abnormal
- B-lymphocyte count decreased
- BLYS polymorphism
- BPEIS syndrome
- BRAF gene mutation
- BRCA1 gene mutation
- BRCA2 gene mutation
- Baller-Gerold syndrome
- Baltic myoclonic epilepsy
- Band neutrophil count decreased
- Band neutrophil percentage decreased

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Baraitser Rodeck Garner syndrome
 Barakat syndrome
 Barth syndrome
 Bartter's syndrome
 Basophil count abnormal
 Basophil count decreased
 Basophil percentage decreased
 Basophilopenia
 Becker's muscular dystrophy
 Beckwith-Wiedemann syndrome
 Benign congenital hypotonia
 Benign familial haematuria
 Benign familial neonatal convulsions
 Benign familial pemphigus
 Benjamin syndrome
 Berdon's syndrome
 Bergmeister's papilla
 Beta ketothiolase deficiency
 Bickerstaff's encephalitis
 Bicuspid aortic valve
 Bicuspid pulmonary valve
 Bicytopenia
 Biotinidase deficiency
 Birth mark
 Bladder agenesis
 Blau syndrome
 Blepharophimosis congenital
 Blindness congenital
 Bloch-Sulzberger syndrome
 Blood count abnormal
 Blood disorder
 Blood incompatibility haemolytic anaemia of newborn
 Bloom syndrome
 Bone marrow disorder
 Bone marrow failure
 Bone marrow myelogram abnormal
 Bone marrow necrosis
 Bone marrow toxicity
 Bosch-Boonstra-Schaaf optic atrophy syndrome
 Brachycephaly
 Brachydactyly
 Brachymetatarsia

Pre-defined MedDRA search

Preferred term

Rare events

Brachyolmia
 Brain malformation
 Branchial cleft sinus
 Branchio-oto-renal syndrome
 Branchiogenic syndrome
 Breast malformation
 Bronchial atresia
 Bronchiolitis
 Bronchogenic cyst
 Brown-Vialetto-Van Laere syndrome
 Brunner syndrome
 Bruton's agammaglobulinaemia
 Bulbospinal muscular atrophy congenital
 Buried penis syndrome
 C-kit gene mutation
 C-kit gene overexpression
 Clq nephropathy
 C3 glomerulopathy
 CANDLE syndrome
 CARD9 deficiency
 CDKL5 deficiency disorder
 CEC syndrome
 CFTR gene mutation
 CHARGE syndrome
 CHILD syndrome
 COPA syndrome
 CTLA4 deficiency
 CYP1A2 polymorphism
 CYP2B6 polymorphism
 CYP2C19 polymorphism
 CYP2C9 polymorphism
 CYP2D6 polymorphism
 CYP3A4 polymorphism
 CYP3A5 polymorphism
 Campomelic syndrome
 Camptodactyly congenital
 Camptodactyly-arthropathy-coxa vara-pericarditis syndrome
 Camptomelia
 Canavan disease
 Cancer gene carrier
 Carbamoyl phosphate synthetase deficiency
 Carbohydrate metabolism disorder

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Carbonic anhydrase gene mutation
 Cardiac malposition
 Cardiac septal defect
 Cardiofaciocutaneous syndrome
 Carnitine palmitoyltransferase deficiency
 Carnitine-acylcarnitine translocase deficiency
 Carpenter syndrome
 Carpus curvus
 Cartilage-hair hypoplasia
 Cataract congenital
 Cateel Manzke syndrome
 Caudal regression syndrome
 Central core disease
 Cerebellar dysplasia
 Cerebellar hypoplasia
 Cerebral atrophy congenital
 Cerebral dysgenesis
 Cerebral palsy
 Cerebrohepatorenal syndrome
 Cervical auricle
 Cervical rib
 Checkpoint kinase 2 gene mutation
 Chediak-Higashi syndrome
 Chiari network
 Chimerism
 Choanal atresia
 Choanal stenosis
 Cholangiectasis congenital
 Chondrodystrophy
 Chondroectodermal dysplasia
 Chordee
 Chorea-acanthocytosis
 Choriorretinal degeneration congenital
 Choroidal coloboma
 Chromosomal deletion
 Chromosomal mutation
 Chronic autoimmune glomerulonephritis
 Chronic granulomatous disease
 Chronic infantile neurological cutaneous and
 articular syndrome
 Chronic inflammatory demyelinating
 polyradiculoneuropathy
 Citrate transporter deficiency

Pre-defined MedDRA search

Preferred term

Rare events

Cleft lip
Cleft lip and palate
Cleft palate
Cleft uvula
Cleidocranial dysostosis
Clinodactyly
Cloacal exstrophy
Clostridial infection
Clostridial sepsis
Clostridium bacteraemia
Clostridium colitis
Clostridium difficile colitis
Clostridium difficile infection
Clostridium test positive
Coagulation factor mutation
Coarctation of the aorta
Cobb syndrome
Cockayne's syndrome
Coffin Siris syndrome
Coffin-Lowry syndrome
Cohen syndrome
Collodion baby
Coloboma
Colour blindness
Combined immunodeficiency
Combined pulmonary fibrosis and emphysema
Complement deficiency disease
Cone dystrophy
Confined placental mosaicism
Congenital Ebola virus infection
Congenital Eustachian tube anomaly
Congenital HIV infection
Congenital Horner's syndrome
Congenital Zika syndrome
Congenital abdominal hernia
Congenital absence of bile ducts
Congenital absence of cranial vault
Congenital absence of vertebra
Congenital adrenal gland hypoplasia
Congenital amputation
Congenital anaemia
Congenital androgen deficiency
Congenital anomalies of ear ossicles

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Congenital anomaly
 Congenital anomaly in offspring
 Congenital anomaly of adrenal gland
 Congenital anomaly of inner ear
 Congenital anosmia
 Congenital aortic anomaly
 Congenital aortic atresia
 Congenital aortic dilatation
 Congenital aortic stenosis
 Congenital aortic valve incompetence
 Congenital aortic valve stenosis
 Congenital aplastic anaemia
 Congenital aqueductal stenosis
 Congenital arterial malformation
 Congenital arterial occlusion
 Congenital arteriovenous fistula
 Congenital astigmatism
 Congenital aural fistula
 Congenital bilateral perisylvian syndrome
 Congenital bladder anomaly
 Congenital bladder diverticulum
 Congenital bladder neck obstruction
 Congenital bowing of long bones
 Congenital brain damage
 Congenital bronchiectasis
 Congenital bronchomalacia
 Congenital calyceal diverticulum
 Congenital cardiovascular anomaly
 Congenital carnitine deficiency
 Congenital central diabetes insipidus
 Congenital central hypoventilation syndrome
 Congenital central nervous system anomaly
 Congenital cerebellar agenesis
 Congenital choroidal anomaly
 Congenital chylothorax
 Congenital clavicular agenesis
 Congenital claw toe
 Congenital coagulopathy
 Congenital condyloma
 Congenital corneal anomaly
 Congenital coronary artery malformation
 Congenital cranial nerve paralysis
 Congenital cutis laxa

Pre-defined MedDRA search

Preferred term

Rare events

- Congenital cystic lung
- Congenital cytomegalovirus infection
- Congenital deformity of clavicle
- Congenital dengue disease
- Congenital dermal sinus
- Congenital diaphragmatic anomaly
- Congenital diaphragmatic eventration
- Congenital diaphragmatic hernia
- Congenital disorder of glycosylation
- Congenital dyserythropoietic anaemia
- Congenital dysfibrinogenaemia
- Congenital dyskeratosis
- Congenital ectodermal dysplasia
- Congenital ectopic bladder
- Congenital ectopic pancreas
- Congenital elevation of scapula
- Congenital emphysema
- Congenital endocrine anomaly
- Congenital epiblepharon
- Congenital epiglottal anomaly
- Congenital eye disorder
- Congenital eyelid malformation
- Congenital facial nerve hypoplasia
- Congenital fallopian tube anomaly
- Congenital flaccid paralysis
- Congenital flat feet
- Congenital floppy infant
- Congenital foot malformation
- Congenital gastric anomaly
- Congenital gastrointestinal vessel anomaly
- Congenital generalised lipodystrophy
- Congenital genital malformation
- Congenital genital malformation female
- Congenital genital malformation male
- Congenital genitourinary abnormality
- Congenital great vessel anomaly
- Congenital growth hormone deficiency
- Congenital haematological disorder
- Congenital hair disorder
- Congenital hand malformation
- Congenital hearing disorder
- Congenital heart valve disorder
- Congenital heart valve incompetence

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Congenital hepatic fibrosis
 Congenital hepatitis B infection
 Congenital hepatobiliary anomaly
 Congenital hepatomegaly
 Congenital herpes simplex infection
 Congenital hiatus hernia
 Congenital high airway obstruction syndrome
 Congenital hydrocele renalis
 Congenital hydrocephalus
 Congenital hydronephrosis
 Congenital hypercoagulation
 Congenital hyperextension of knee
 Congenital hyperextension of spine
 Congenital hyperinsulinaemic hypoglycaemia
 Congenital hyperthyroidism
 Congenital hypertrichosis
 Congenital hypogammaglobulinaemia
 Congenital hypogonadotropic hypogonadism
 Congenital hypoparathyroidism
 Congenital hypoplasia of depressor angularis oris muscle
 Congenital hypothyroidism
 Congenital hypotransferrinaemia
 Congenital infection
 Congenital inguinal hernia
 Congenital intestinal malformation
 Congenital intestinal obstruction
 Congenital intrinsic factor deficiency
 Congenital iris anomaly
 Congenital jaw malformation
 Congenital joint malformation
 Congenital knee deformity
 Congenital knee dislocation
 Congenital kyphoscoliosis
 Congenital labia pudendi adhesions
 Congenital lacrimal gland anomaly
 Congenital lacrimal passage anomaly
 Congenital large intestinal atresia
 Congenital laryngeal stridor
 Congenital lenticonus
 Congenital limb hyperextension
 Congenital lip fistula
 Congenital lymphoedema

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

- Congenital malaria
- Congenital megacolon
- Congenital megalureter
- Congenital melanosis
- Congenital methaemoglobinaemia
- Congenital midline defect
- Congenital mitochondrial cytopathy
- Congenital mitral valve incompetence
- Congenital mitral valve stenosis
- Congenital monorchidism
- Congenital multiple arthrogyposis
- Congenital muscle absence
- Congenital musculoskeletal anomaly
- Congenital myasthenic syndrome
- Congenital myopathy
- Congenital myopia
- Congenital nail disorder
- Congenital nasal septum deviation
- Congenital nephrogenic diabetes insipidus
- Congenital nephrotic syndrome
- Congenital neurological degeneration
- Congenital neurological disorder
- Congenital neuropathy
- Congenital night blindness
- Congenital nipple anomaly
- Congenital nipple inversion
- Congenital nose malformation
- Congenital nystagmus
- Congenital oculomotor apraxia
- Congenital oesophageal anomaly
- Congenital oesophageal stenosis
- Congenital oesophageal web
- Congenital optic nerve anomaly
- Congenital oral malformation
- Congenital osteodystrophy
- Congenital ovarian anomaly
- Congenital oxalosis
- Congenital pancreatic anomaly
- Congenital perforated nasal septum
- Congenital pharyngeal anomaly
- Congenital pigmentation disorder
- Congenital pneumonia
- Congenital poikiloderma

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

- Congenital pseudarthrosis
- Congenital pulmonary artery anomaly
- Congenital pulmonary hypertension
- Congenital pulmonary valve atresia
- Congenital pulmonary valve disorder
- Congenital pyelocaliectasis
- Congenital renal disorder
- Congenital rubella infection
- Congenital rubella syndrome
- Congenital salivary gland anomaly
- Congenital scleral disorder
- Congenital scoliosis
- Congenital scrotal hypertrophy
- Congenital skin dimples
- Congenital skin disorder
- Congenital small intestinal atresia
- Congenital spinal cord anomaly
- Congenital spinal fusion
- Congenital spinal stenosis
- Congenital spondylolisthesis
- Congenital spondylolysis
- Congenital syphilis
- Congenital syphilitic encephalitis
- Congenital syphilitic meningitis
- Congenital syphilitic osteochondritis
- Congenital thrombocyte disorder
- Congenital thrombocytopenia
- Congenital thymus absence
- Congenital thyroid disorder
- Congenital tongue anomaly
- Congenital torticollis
- Congenital toxoplasmosis
- Congenital tracheomalacia
- Congenital trichomegaly
- Congenital tricuspid valve atresia
- Congenital tricuspid valve incompetence
- Congenital tricuspid valve stenosis
- Congenital tuberculosis
- Congenital umbilical hernia
- Congenital ureteric anomaly
- Congenital ureterocele
- Congenital ureteropelvic junction obstruction
- Congenital ureterovesical junction anomaly

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Congenital urethral anomaly
 Congenital urinary tract obstruction
 Congenital uterine anomaly
 Congenital varicella infection
 Congenital varicocele
 Congenital vas deferens absence
 Congenital vesicoureteric reflux
 Congenital visual acuity reduced
 Congenital vitreous anomaly
 Congenital white blood cell disorder
 Conjoined twins
 Conjunctivitis gonococcal neonatal
 Connective tissue dysplasia
 Conradi-Huenermann syndrome
 Constricted ear deformity
 Cor biloculare
 Cor triatriatum
 Corneal dystrophy
 Corneal opacity congenital
 Cornelia de Lange syndrome
 Corrected transposition of great vessels
 Cortical dysplasia
 Costello syndrome
 Craniofacial deformity
 Craniofacial dysostosis
 Craniofacunia
 Craniorachischisis
 Craniosynostosis
 Craniotabes
 Creatine deficiency syndrome
 Cri du Chat syndrome
 Crigler-Najjar syndrome
 Cryopyrin associated periodic syndrome
 Cryptophthalmos
 Cryptorchism
 Currarino syndrome
 Cutaneous mucopolysaccharidosis with thrombocytopenia
 Cyclic neutropenia
 Cyclopia
 Cystathionine beta-synthase deficiency
 Cystic fibrosis
 Cystic fibrosis carrier
 Cystic fibrosis gastrointestinal disease

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Cystic fibrosis hepatic disease
 Cystic fibrosis lung
 Cystic fibrosis pancreatic
 Cystic fibrosis related diabetes
 Cystinosis
 Cystinuria
 Cytogenetic abnormality
 Cytomegalovirus nephritis
 Cytopenia
 DNA mismatch repair protein gene mutation
 DOOR syndrome
 Dacryocystocele
 Dacryostenosis congenital
 Dandy-Walker syndrome
 De Barys syndrome
 Deaf mutism
 Deafness congenital
 Deficiency of the interleukin-1 receptor
 antagonist
 Deficiency of the interleukin-36 receptor
 antagonist
 Delayed foetal renal development
 Delta-beta thalassaemia
 Demyelinating polyneuropathy
 Dent's disease
 Dentatorubral-pallidoluysian atrophy
 Dentofacial anomaly
 Dermatofibrosis lenticularis disseminata
 Dermatoglyphic anomaly
 Desmin myopathy
 Developmental glaucoma
 Developmental hip dysplasia
 Dextrocardia
 DiGeorge's syndrome
 Diabetic footopathy
 Diaphragmatic aplasia
 Diastematomyelia
 Diastrophic dysplasia
 Diencephalic syndrome of infancy
 Diethylstilboestrol syndrome
 Differential white blood cell count abnormal
 Diffuse alveolar damage
 Dihydropyrimidine dehydrogenase deficiency

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Dilatation intrahepatic duct congenital
 Disorder of sex development
 Disseminated neonatal herpes simplex
 Distichiasis
 Diverticulitis Meckel's
 Diverticulum of pharynx, congenital
 Dolichocolon
 Donohue syndrome
 Dopa-responsive dystonia
 Double cortex syndrome
 Double heterozygous sickling disorders
 Double inlet left ventricle
 Double outlet left ventricle
 Double outlet right ventricle
 Double ureter
 Dowling-Degos disease
 Duane's syndrome
 Dubin-Johnson syndrome
 Dubowitz syndrome
 Duchenne muscular dystrophy
 Duchenne muscular dystrophy gene carrier
 Ductus arteriosus premature closure
 Ductus arteriosus stenosis foetal
 Ductus venosus agenesis
 Duodenal atresia
 Duplex appendix
 Duplication of inferior vena cava
 Dyke-Davidoff-Masson syndrome
 Dyschondrosteosis
 Dyschromatosis
 Dysgnathia
 Dysmorphism
 Demyelination
 EGFR gene mutation
 EGFR gene overexpression
 Eagle-Barrett syndrome
 Ear malformation
 Early onset familial Alzheimer's disease
 Early onset primary dystonia
 Ebstein's anomaly
 Ectonucleotide pyrophosphatase/phosphodiesterase
 1 deficiency
 Ectopia cordis

Pre-defined MedDRA search

Preferred term

Rare events

Ectopic kidney
 Ectopic ovary
 Ectopic posterior pituitary gland
 Ectopic thyroid
 Ectopic ureter
 Ectrodactyly
 Ehlers-Danlos syndrome
 Elbow synostosis
 Elliptocytosis hereditary
 Ellis-van Creveld syndrome
 Emanuel syndrome
 Emery-Dreifuss muscular dystrophy
 Encephalocele
 Encephalocutaneous angiomatosis
 Endothelial protein C receptor polymorphism
 Enteric duplication
 Entropion congenital
 Eosinopenia
 Eosinophil count abnormal
 Eosinophil count decreased
 Eosinophil percentage decreased
 Eosinophilia myalgia syndrome
 Eosinophilic pneumonia
 Eosinophilic pneumonia acute
 Eosinophilic pneumonia chronic
 Epidermal naevus
 Epilepsy congenital
 Epilepsy with myoclonic-atonic seizures
 Epispadias
 Erythroblastosis foetalis
 Erythrodermia variabilis
 Essential fructosuria
 Exomphalos
 Exophthalmos congenital
 External auditory canal atresia
 Extrarenal pelvis
 Eye anterior chamber congenital anomaly
 Eyelid ptosis congenital
 Fabry's disease
 Faciodigitogenital dysplasia
 Facioscapulothoracic muscular dystrophy
 Factor I deficiency
 Factor II deficiency

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

- Factor II mutation
- Factor III deficiency
- Factor IX deficiency
- Factor V Leiden carrier
- Factor V Leiden mutation
- Factor V deficiency
- Factor VII deficiency
- Factor VIII deficiency
- Factor X deficiency
- Factor XI deficiency
- Factor XII deficiency
- Factor XIII deficiency
- Falot's pentalogy
- Falot's tetralogy
- Falot's trilogy
- Familial amyloidosis
- Familial amyotrophic lateral sclerosis
- Familial cold autoinflammatory syndrome
- Familial glucocorticoid deficiency
- Familial hemiplegic migraine
- Familial high density lipoprotein deficiency
- Familial hypertriglyceridaemia
- Familial hypocalcaemic hypercalcaemia
- Familial infantile bilateral striatal necrosis
- Familial isolated hyperparathyroidism
- Familial mediterranean fever
- Familial periodic paralysis
- Familial polycythaemia
- Familial renal glycosuria
- Familial scaphocephaly syndrome
- Familial tremor
- Farconi syndrome
- Fatal familial insomnia
- Fatty acid oxidation disorder
- Febrile bone marrow aplasia
- Febrile neutropenia
- Femoral anteversion
- Femoral facial syndrome
- Femoral retroversion
- Femur-fibula-ulna complex
- Fibrillary glomerulonephritis
- Fibrodysplasia ossificans progressiva
- Fibrous dysplasia of bone

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Fibrous dysplasia of jaw
 Fibula agenesis
 Filippi syndrome
 Fissure of tongue, congenital
 Floating-Harbor syndrome
 Focal segmental glomerulosclerosis
 Foetal alcohol syndrome
 Foetal anticonvulsant syndrome
 Foetal chromosome abnormality
 Foetal malformation
 Foetal megacystis
 Foetal methotrexate syndrome
 Foetal retinoid syndrome
 Foetal warfarin syndrome
 Foramen magnum stenosis
 Fountain syndrome
 Fragile X carrier
 Fragile X syndrome
 Fraser syndrome
 Freeman-Sheldon syndrome
 Frenulum breve
 Friedreich's ataxia
 Fructose-1,6-bisphosphatase deficiency
 Fryns syndrome
 Full blood count abnormal
 Full blood count decreased
 GM2 gangliosidosis
 GNE myopathy
 GRACILE syndrome
 Galactosaemia
 Galactosialidosis
 Gallbladder agenesis
 Gallbladder anomaly congenital
 Gap junction protein beta 2 gene mutation
 Gastroenteritis clostridial
 Gastrointestinal arteriovenous malformation
 Gastrointestinal disorder congenital
 Gastrointestinal malformation
 Gastroschisis
 Gata2b associated neurodevelopmental disorder
 Gaucher's disease
 Gaucher's disease type I
 Gaucher's disease type II

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Gaucher's disease type III
 Gelatinous transformation of the bone marrow
 Gene mutation
 Generalised resistance to thyroid hormone
 Genetic polymorphism
 Genitalia external ambiguous
 Gilbert's syndrome
 Gitelman's syndrome
 Glomerulonephritis
 Glomerulonephritis acute
 Glomerulonephritis chronic
 Glomerulonephritis membranoproliferative
 Glomerulonephritis membranous
 Glomerulonephritis minimal lesion
 Glomerulonephritis proliferative
 Glomerulonephritis rapidly progressive
 Glucose transporter type 1 deficiency syndrome
 Glucose-6-phosphate dehydrogenase deficiency
 Glucose-galactose malabsorption
 Glutathione synthetase deficiency
 Glycogen storage disease type I
 Glycogen storage disease type II
 Glycogen storage disease type III
 Glycogen storage disease type IV
 Glycogen storage disease type IX
 Glycogen storage disease type V
 Glycogen storage disease type VI
 Glycogen storage disease type VII
 Glycogen storage disease type VIII
 Glycogen storage disorder
 Gnathosthisis
 Goitre congenital
 Gollop-Wolfgang complex
 Gonadal dysgenesis
 Granulocyte count decreased
 Granulocytes abnormal
 Granulocytes maturation arrest
 Granulocytopenia
 Granulocytopenia neonatal
 Greig's syndrome
 Grey matter heterotopia
 Griscelli syndrome
 Guillain-Barre syndrome

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

H-ras gene mutation
 HER2 gene amplification
 HER2 protein overexpression
 HERG gene mutation
 HIV associated nephropathy
 Haematotoxicity
 Haemochromatosis trait
 Haemoglobin C disease
 Haemoglobin C trait
 Haemoglobin D disease
 Haemoglobin D trait
 Haemoglobin E disease
 Haemoglobin E trait
 Haemoglobin E-thalassaemia disease
 Haemoglobinopathy
 Haemophilia
 Haemophilia A with anti factor VIII
 Haemophilia A without inhibitors
 Haemophilia B with anti factor IX
 Haemophilia B without inhibitors
 Haemophilia carrier
 Haemorrhagic arteriovenous malformation
 Hand-foot-genital syndrome
 Harlequin foetus
 Hartnup disease
 Heart disease congenital
 Hemihypertrophy
 Hemimegalencephaly
 Hemivertebra
 Hepatic arteriovenous malformation
 Hepatitis virus-associated nephropathy
 Hepato-lenticular degeneration
 Hereditary angioedema with normal C1 esterase inhibitor
 Hereditary areflexic dystasia
 Hereditary ataxia
 Hereditary cerebral degeneration
 Hereditary choroidal dystrophy
 Hereditary disorder
 Hereditary fructose intolerance
 Hereditary haemochromatosis
 Hereditary haemolytic anaemia
 Hereditary haemorrhagic telangiectasia

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Hereditary hypophosphataemic rickets
 Hereditary motor and sensory neuropathy
 Hereditary motor neuron disease
 Hereditary neuropathic amyloidosis
 Hereditary neuropathy with liability to pressure paises
 Hereditary optic atrophy
 Hereditary palmoplantar keratoderma
 Hereditary renal microhaematuria
 Hereditary retinal dystrophy
 Hereditary sideroblastic anaemia
 Hereditary spastic paraplegia
 Hereditary spherocytosis
 Hereditary stomatocytosis
 Hermansky-Pudlak syndrome
 Hermaphroditism
 Hernia congenital
 Heterochromia iridis
 Heterotaxia
 Hexokinase deficiency anaemia
 High arched palate
 Hollow visceral myopathy
 Holoprosencephaly
 Holt-Oram syndrome
 Homocystinaemia
 Homocystinuria
 Hooded prepuce
 Huntington's disease
 Hydrancephaly
 Hydrocele
 Hydronephrosis
 Hydroureter
 Hydroxyprolinaemia
 Hyper IgD syndrome
 Hyper IgE syndrome
 Hyper IGM syndrome
 Hyperplexia
 Hyperglycinaemia
 Hyperlycinaemia
 Hypermethioninaemia
 Hypermethioninuria
 Hypermutation
 Hyperphenylalaninaemia

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Hyperpepicolic acidaemia
 Hyperprolinaemia
 Hypersplenism congenital
 Hypertelorism of orbit
 Hyperthermia malignant
 Hypocalvaria
 Hypochondroplasia
 Hypodontia
 Hypomelanosis of Ito
 Hypophosphatasia
 Hypopituitarism foetal
 Hypoplastic left heart syndrome
 Hypoplastic nasal cartilage
 Hypoplastic right heart syndrome
 Hypospadias
 Hypotelorism of orbit
 Hypotonia-cystinuria syndrome
 Hypoxanthine-guanine phosphoribosyl transferase deficiency
 IPFX syndrome
 Ichthyosis
 Idiopathic interstitial pneumonia
 Idiopathic neutropenia
 Idiopathic pneumonia syndrome
 Idiopathic pulmonary fibrosis
 IGA nephropathy
 IgM nephropathy
 Ileal atresia
 Immune-mediated nephritis
 Immune-mediated pancytopenia
 Immune-mediated pneumonitis
 Immunodeficiency congenital
 Immunotactoid glomerulonephritis
 Imperforate hymen
 Imperforate oesophagus
 Inborn error in primary bile acid synthesis
 Inborn error of amino acid metabolism
 Inborn error of bilirubin metabolism
 Inborn error of lipid metabolism
 Inborn error of metabolism
 Infantile cortical hyperostosis
 Infantile genetic agranulocytosis
 Inherited cardiac conduction disorder

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Iniencephaly
 Interferon gamma receptor deficiency
 Interleukin 28B polymorphism
 Interruption of aortic arch
 Interstitial lung disease
 Intestinal atresia
 Intestinal malrotation
 Intestinal neuronal dysplasia
 Intestinal transposition
 Intracranial arterial fenestration
 Intracranial lipoma
 Iris coloboma
 Isodicentric chromosome 15 syndrome
 Isovaleric acidaemia
 Janus kinase 2 mutation
 Johanson-Blizzard syndrome
 Joubert syndrome
 Juvenile Paget's disease
 K-ras gene mutation
 Kabuki make-up syndrome
 Kaufman-McKusick syndrome
 Kearns-Sayre syndrome
 Kenny-Caffey syndrome
 Keratitis-ichthyosis-deafness syndrome
 Keratolysis exfoliativa congenital
 Keratosis follicular
 Kidney duplex
 Kidney malformation
 Kidney malrotation
 Kimmelie's anomaly
 Kinematic imbalances due to suboccipital strain
 Kleeftstra syndrome
 Klinefelter's syndrome
 Klippel-Feil syndrome
 Klippel-Trenaunay syndrome
 Kniest dysplasia
 Kommerell's diverticulum
 Kosaki overgrowth syndrome
 Krabbe's disease
 Kyphosis congenital
 LDLR mutation
 Laband syndrome
 Labial tie

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search Preferred term

Rare events

- Lacrimal punctum agenesis
- Laevocardia
- Lafora's myoclonic epilepsy
- Lamin A/C gene mutation
- Langer-Giedion syndrome
- Laron syndrome
- Larsen syndrome
- Laryngeal cleft
- Laryngeal web
- Laryngo-onycho-cutaneous syndrome
- Laryngocele
- Laryngomalacia
- Laurence-Moon-Bardet-Biedl syndrome
- Leber's congenital amaurosis
- Lecithin-cholesterol acyltransferase deficiency
- Left ventricle outflow tract obstruction
- Left ventricular false tendon
- Left-to-right cardiac shunt
- Lens abnormality, congenital
- Leptin receptor deficiency
- Leukocyte adhesion deficiency type I
- Leukodystrophy
- Leukopenia
- Leukopenia neonatal
- Li-Fraumeni syndrome
- Lichen spinulosus
- Liddle's syndrome
- Limb hypoplasia congenital
- Limb malformation
- Limb reduction defect
- Lipid proteinosis
- Lipidosis
- Lipomeningocele
- Lissencephaly
- Loeys-Dietz syndrome
- Long-chain acyl-coenzyme A dehydrogenase deficiency
- Low set ears
- Lowry-Wood syndrome
- Lumbarisation
- Lung infiltration
- Lupus nephritis
- Lymphangiectasia intestinal congenital

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Lymphocyte count abnormal
 Lymphocyte count decreased
 Lymphocyte percentage abnormal
 Lymphocyte percentage decreased
 Lymphocytopenia neonatal
 Lymphopenia
 Lysinuric protein intolerance
 Lysosomal acid lipase deficiency
 MELAS syndrome
 MLASA syndrome
 MYH9-related disease
 Macrocephaly
 Macrocheilia
 Macrocornea
 Macrodactyly
 Macrogenia
 Macroglossia
 Macrognothia
 Macrostomia
 Macrotonia
 Macular dystrophy congenital
 Majeed's syndrome
 Malformation biliary
 Malformation venous
 Mandibulofacial dysostosis
 Mannose-binding lectin deficiency
 Maple syrup disease
 Marcus Gunn syndrome
 Marfan's syndrome
 Maxillofacial dysplasia
 Mayer-Rokitansky-Kuster-Hauser syndrome
 McLeod neuroacanthocytosis syndrome
 Medium-chain acyl-coenzyme A dehydrogenase deficiency
 Megakaryocytes decreased
 Meier-Gorlin syndrome
 Melkersson-Rosenthal syndrome
 Membranous lipodystrophy
 Membranous-like glomerulopathy with masked IGG-kappa deposits
 Meningocele
 Meningocelele
 Menkes' syndrome

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Mesangioproliferative glomerulonephritis
 Metabolic myopathy
 Metachromatic leukodystrophy
 Metamyelocyte count decreased
 Metaphyseal dysplasia
 Metatarsus primus varus
 Metatropic dysplasia
 Methylenetetrahydrofolate reductase deficiency
 Methylenetetrahydrofolate reductase gene mutation
 Methylenetetrahydrofolate reductase polymorphism
 Methylmalonic aciduria
 Mevalonate kinase deficiency
 Mevalonic aciduria
 Microcephaly
 Microcheilia
 Microcolon
 Microcornea
 Microencephaly
 Microgenia
 Microglossia
 Micrognathia
 Microorchidism
 Micropenis
 Microphthalmos
 Microstomia
 Microtia
 Microvillous inclusion disease
 Miller Fisher syndrome
 Mitochondrial DNA deletion
 Mitochondrial DNA depletion
 Mitochondrial DNA duplication
 Mitochondrial DNA mutation
 Mitochondrial encephalomyopathy
 Mitochondrial enzyme deficiency
 Mitochondrial hepatopathy
 Mitochondrial myopathy
 Mitochondrial neurogastrointestinal encephalopathy
 Mitral valve atresia
 Mitral valve hypoplasia
 Mittendorf dot
 Mobile caecum syndrome
 Moebius II syndrome
 Molybdenum cofactor deficiency

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Monoblast count decreased
 Monocyte count abnormal
 Monocyte count decreased
 Monocyte percentage decreased
 Monocytopenia
 Monolid eyes
 Mononuclear cell count decreased
 Monopodia
 Morgagni-Stewart-Morel syndrome
 Morning glory syndrome
 Morton's syndrome
 Mosaicism
 Mount-Reback syndrome
 Muckle-Wells syndrome
 Mucopolidosis
 Mucopolidosis type I
 Mucopolidosis type II
 Mucopolidosis type III
 Mucopolidosis type IV
 Mucopolysaccharidosis
 Mucopolysaccharidosis I
 Mucopolysaccharidosis II
 Mucopolysaccharidosis III
 Mucopolysaccharidosis IV
 Mucopolysaccharidosis IX
 Mucopolysaccharidosis V
 Mucopolysaccharidosis VI
 Mucopolysaccharidosis VII
 Multiple carboxylase deficiency
 Multiple cardiac defects
 Multiple congenital abnormalities
 Multiple epiphyseal dysplasia
 Multiple gastrointestinal atresias
 Multiple lentiginos syndrome
 Muscular dystrophy
 Mutagenic effect
 Myeloblast count decreased
 Myeloblast percentage decreased
 Myelocyte count decreased
 Myelocyte percentage decreased
 Myeloid maturation arrest
 Myeloperoxidase deficiency
 Myocardial bridging

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Myoclonic epilepsy and ragged-red fibres
 Myotonia congenita
 Myotonic dystrophy
 N-acetylglutamate synthase deficiency
 N-ras gene mutation
 NAT1 polymorphism
 NAT2 polymorphism
 NTRK gene fusion overexpression
 NUT gene mutation
 Naevus anaemicus
 Naevus flammeus
 Naevus spider congenital
 Nail aplasia
 Nail-patella syndrome
 Nasopharyngeal atresia
 Necrotising bronchiolitis
 Neonatal alloimmune thrombocytopenia
 Neonatal haemochromatosis
 Neonatal lupus erythematosus
 Nephritic syndrome
 Nephritis
 Nephritis haemorrhagic
 Nephritis radiation
 Nephrotic syndrome
 Netherton's syndrome
 Neural tube defect
 Neuroacanthocytosis
 Neurodegeneration with brain iron accumulation disorder
 Neuroleptic malignant syndrome
 Neuronal ceroid lipofuscinosis
 Neuronal migration disorder
 Neuropathy, ataxia, retinitis pigmentosa syndrome
 Neutropenia
 Neutropenia neonatal
 Neutropenic infection
 Neutropenic sepsis
 Neutrophil Fc gamma RIIb deficiency
 Neutrophil count abnormal
 Neutrophil count decreased
 Neutrophil percentage decreased
 Newborn persistent pulmonary hypertension
 Niemann-Pick disease

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Nievergelt-Pearlman syndrome
 Nijmegen breakage syndrome
 Non-compaction cardiomyopathy
 Noonan syndrome
 Norrie's disease
 OHVIRA syndrome
 Obliterative bronchiolitis
 Ocular albinism
 Oculoauriculovertebral dysplasia
 Oculocerebrorenal syndrome
 Oculodentodigital dysplasia
 Oculopharyngeal dystrophy
 Oesophageal atresia
 Oestrogen receptor gene overexpression
 Ogden syndrome
 Olfacto genital dysplasia
 Olfactory nerve agenesis
 Olfactory syndrome
 Olmsted syndrome
 Opitz trigonocephaly syndrome
 Opitz-G/BBB syndrome
 Optic disc pit
 Optic nerve hypoplasia
 Oral-facial-digital syndrome type II
 Ornithine transcarbamoylase deficiency
 Oroticaciduria congenital
 Os trigonum
 Osteogenesis imperfecta
 Osteopathia striata
 Osteopetrosis
 Osteopoikilosis
 Osteoporosis-pseudoglioma syndrome
 Otocephaly
 Ovarian agenesis
 Ovarian hypoplasia
 Oxycephaly
 PAES2 gene mutation
 PIK3CA related overgrowth spectrum
 PIK3CA-activated mutation
 PSTPIP1-associated myeloid-related proteinemia
 inflammatory syndrome
 PTEN gene mutation
 Pachydermoperiostosis
 Pachygyria

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

- Pachyonychia congenita
- Pallister-Killian syndrome
- Pancreas divisum
- Pancytopenia
- Panniculopathy
- Papillon-LeFebvre syndrome
- Parachute mitral valve
- Paranasal sinus aplasia
- Paranasal sinus hypoplasia
- Parkes-Weber syndrome
- Paroxysmal extreme pain disorder
- Patent ductus arteriosus
- Pearson's syndrome
- Pectus carinatum
- Pectus excavatum
- Pelizaeus-Merzbacher disease
- Pelvi-ureteric obstruction
- Pelvic fibrosis
- Pelvic kidney
- Pendred syndrome
- Penile torsion
- Penoscrotal fusion
- Penoscrotal transposition
- Penta X syndrome
- Perinephritis
- Periodontal congenital anomaly
- Perry syndrome
- Persistent Muellerian duct syndrome
- Persistent cloaca
- Persistent foetal circulation
- Persistent left superior vena cava
- Persistent pupillary membrane
- Persistent urogenital sinus
- Pfeiffer syndrome
- Phalangeal agenesis
- Phalangeal hypoplasia
- Phelan-McDermid syndrome
- Phenylketonuria
- Phimosi
- Phyosterolaemia
- Pierre Robin syndrome
- Pilonidal cyst congenital
- Plagiocephaly

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Plasma cell disorder
 Plasma cells absent
 Plasmablast count decreased
 Plasminogen activator inhibitor polymorphism
 Plasminogen activator inhibitor type 1 deficiency
 Platelet count decreased
 Platelet glycoprotein gene mutation
 Platelet maturation arrest
 Platelet production decreased
 Platelet toxicity
 Platelet-derived growth factor receptor gene mutation
 Platelet-derived growth factor receptor overexpression
 Platynechia
 Platybasia
 Platypondylia
 Pneumonitis
 Poland's syndrome
 Polycystic liver disease
 Polydactyly
 Polymicrogyria
 Polyorchidism
 Popteal pterygium syndrome
 Porencephaly
 Porokeratosis
 Porphyria
 Porphyria acute
 Porphyria non-acute
 Porphyrin metabolism disorder
 Porphyrinuria
 Portal venous system anomaly
 Post infection glomerulonephritis
 Post streptococcal glomerulonephritis
 Postauricular fistula
 Posterior segment of eye anomaly congenital
 Potter's syndrome
 Prader-Willi syndrome
 Preauricular cyst
 Preduodenal portal vein
 Preternatural anus
 Primary cerebellar degeneration
 Primary ciliary dyskinesia

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Primary coenzyme Q10 deficiency
 Primary familial hypomagnesaemia
 Primary hypercholesterolaemia
 Primary hyperoxaluria
 Primary immunodeficiency syndrome
 Primary insulin like growth factor-1 deficiency
 Pro-opiomelanocortin deficiency
 Progeria
 Progesterone receptor gene overexpression
 Progressive cerebellar degeneration
 Progressive external ophthalmoplegia
 Progressive familial intrahepatic cholestasis
 Progressive massive fibrosis
 Prominent epicanthal folds
 Promyelocyte count decreased
 Protein C deficiency
 Protein S deficiency
 Proteus syndrome
 Protuberant ear
 Proximal focal femoral deficiency
 Pseudocholesterase deficiency
 Pseudohermaphroditism
 Pseudohermaphroditism female
 Pseudohermaphroditism male
 Pseudohypoadosteronism
 Pseudohyppoparathyroidism
 Pseudomembranous colitis
 Pseudotruncus arteriosus
 Pseudoxanthoma elasticum
 Pterygium colli
 Pulmonary aplasia
 Pulmonary arteriovenous fistula
 Pulmonary artery atresia
 Pulmonary artery stenosis congenital
 Pulmonary fibrosis
 Pulmonary hypoplasia
 Pulmonary lymphangiectasia
 Pulmonary malformation
 Pulmonary necrosis
 Pulmonary radiation injury
 Pulmonary renal syndrome
 Pulmonary sequestration
 Pulmonary toxicity

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Pulmonary valve stenosis congenital
 Pure white cell aplasia
 Pycnodysostosis
 Pyloric stenosis
 Pyogenic sterile arthritis pyoderma gangrenosum
 and acne syndrome
 Pyruvate carboxylase deficiency
 Pyruvate dehydrogenase complex deficiency
 Pyruvate kinase deficiency anaemia
 RET gene mutation
 ROS1 gene rearrangement
 RPE65 gene mutation
 Radiation alveolitis
 Radiation fibrosis - lung
 Radiation leukopenia
 Radiation pneumonitis
 Rapid-onset dystonia-parkinsonism
 Rathke's cleft cyst
 Rectal atresia
 Red blood cell enzymes abnormal
 Refsum's disease
 Renal aplasia
 Renal arteriovenous malformation
 Renal dysplasia
 Renal fusion anomaly
 Renal hypoplasia
 Renal malposition
 Renal vessel congenital anomaly
 Reproductive tract hypoplasia, male
 Respiratory tract malformation
 Retinal anomaly congenital
 Retinal arteriovenous malformation
 Retinal coloboma
 Retinitis pigmentosa
 Retinopathy congenital
 Retinoschisis congenital
 Retroperitonitis
 Rett syndrome
 Rhesus haemolytic disease of newborn
 Rib hypoplasia
 Rib synostosis
 Right aortic arch
 Right ventricular false tendon

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Right-to-left cardiac shunt
 Riley-Day syndrome
 Ring chromosome
 Rippling muscle disease
 Rotor's syndrome
 Rubinstein-Taybi syndrome
 SADDAN syndrome
 SATB2-associated syndrome
 Sacral hypoplasia
 Sacralisation
 Saposin C deficiency
 Sarcoglycanopathy
 Sarcosinaemia
 Scaphocephaly
 Schimke immunosseous dysplasia
 Schinzel-Giedion syndrome
 Schizencephaly
 Schmid Fraccaro syndrome
 Schwartz Jampel syndrome
 Scimitar syndrome
 Sclerolyosis
 Sensory neuropathy hereditary
 Septate hymen
 Septo-optic dysplasia
 Septum pellucidum agenesis
 Serotonin syndrome
 Sertoli-cell-only syndrome
 Severe myoclonic epilepsy of infancy
 Severe primary insulin like growth factor-1
 deficiency
 Sex chromosome abnormality
 Shawl scrotum
 Shone complex
 Short stature homeobox gene mutation
 Short-chain acyl-coenzyme A dehydrogenase
 deficiency
 SPRINTZEN-Goldberg syndrome
 Shwachman-Diamond syndrome
 Sick cell anaemia
 Sick cell disease
 Sick cell trait
 Silver-Russell syndrome
 Single atrium

Pre-defined MedDRA search

Preferred term

Rare events

Single umbilical artery
 Sirenomelia
 Sjogren-Larsson syndrome
 Skeletal dysplasia
 Skin hypoplasia
 Skin malformation
 Skull malformation
 Small airways disease
 Smith-Lemli-Opitz syndrome
 Smith-Magenis syndrome
 Sotos' syndrome
 Special senses congenital anomaly
 Spherophakia
 Spina bifida
 Spina bifida cystica
 Spina bifida occulta
 Spinal muscular atrophy
 Spine malformation
 Spleen malformation
 Spondyloepiphyseal dysplasia
 Stahl's ear
 Stargardt's disease
 Stickler's syndrome
 Sticky platelet syndrome
 Strabismus congenital
 Straddling tricuspid valve
 Sturge-Weber syndrome
 Subacute inflammatory demyelinating polyneuropathy
 Sucrase-isomaltase deficiency
 Supernumerary nipple
 Supernumerary vertebra
 Syndactyly
 Synostosis
 Syringomyelia
 Systemic right ventricle
 T-lymphocyte count abnormal
 T-lymphocyte count decreased
 TORCH infection
 TRPV4 gene mutation
 Talipes
 Tangier disease
 Telangiectasia congenital
 Teratogenicity

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Testicular dysplasia
 Testotoxicosis
 Tetrahydrobiopterin deficiency
 Thalassaemia
 Thalassaemia alpha
 Thalassaemia beta
 Thalassaemia minor
 Thalassaemia sickle cell
 Thalidomide embryopathy
 Thanatophoric dwarfism
 Thiopurine methyltransferase polymorphism
 Thrombocytopenia
 Thrombocytopenia-absent radius syndrome
 Thymus hypoplasia
 Thyroglossal fistula
 Thyroid hemiagenesis
 Thyroid malformation
 Tibial agenesis
 Tibial torsion
 Tilted disc syndrome
 Timothy syndrome
 Tooth discolouration congenital
 Tooth hypoplasia
 Tooth malformation hereditary
 Tourette's disorder
 Tracheal atresia
 Tracheal web
 Tracheo-oesophageal fistula
 Tracheobronchomegaly
 Transcobalamin deficiency
 Transfusion-related acute lung injury
 Transgenerational epigenetic inheritance
 Transitional vertebrae
 Transmembrane receptor tyrosine kinase overexpression
 Transposition of the great vessels
 Trichorhinophalangeal syndrome
 Trifunctional protein deficiency
 Trimethylaminuria
 Triple A syndrome
 Trisomy 11
 Trisomy 13
 Trisomy 14

Pre-defined MedDRA search

Preferred term

Rare events

Trisomy 15
 Trisomy 16
 Trisomy 17
 Trisomy 18
 Trisomy 21
 Trisomy 22
 Trisomy 4p
 Trisomy 8
 Trisomy 9
 Truncus arteriosus persistent
 Tubulointerstitial nephritis
 Tubulointerstitial nephritis and uveitis syndrome
 Tumour necrosis factor receptor-associated
 periodic syndrome
 Turner's syndrome
 Twin reversed arterial perfusion sequence
 malformation
 Tympanomeatal fissure
 Type I hyperlipidaemia
 Type II hyperlipidaemia
 Type III hyperlipidaemia
 Type Iia hyperlipidaemia
 Type Iib hyperlipidaemia
 Type IV hyperlipidaemia
 Type V hyperlipidaemia
 Tyrosinaemia
 Tyrosine kinase mutation
 UGT1A1 gene mutation
 UGT1A1 gene polymorphism
 Uhl's anomaly
 Umbilical artery hypoplasia
 Umbilical malformation
 Unicuspid aortic valve
 Univentricular heart
 Urachal abnormality
 Urea cycle disorder
 Ureteric atresia
 Ureteric compression
 Ureteric dilatation
 Ureteric obstruction
 Ureteric stenosis
 Urethral atresia
 Urethral valves

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Urinary tract malformation
 Urinary tract obstruction
 Usher's syndrome
 Uterine aplasia
 Uterine cervix canal atresia
 Uterine cervix hypoplasia
 Uterine hypoplasia
 Uvula aplasia
 VACTERL syndrome
 VKORC1 gene polymorphism
 Vaginal atresia
 Vaginal hypoplasia
 Vaginal septum
 Vascular endothelial growth factor overexpression
 Vascular malformation
 Velo-cardio-facial syndrome
 Venolymphatic malformation
 Ventricular hypoplasia
 Ventricular septal defect
 Vertebral artery hypoplasia
 Vertical talus
 Very long-chain acyl-coenzyme A dehydrogenase deficiency
 Vestibulocerebellar syndrome
 Virilism foetal
 Vitello-intestinal duct remnant
 Von Hippel-Lindau disease
 Von Willebrand's disease
 Von Willebrand's disease gene carrier
 Waardenburg syndrome
 Wagner's disease
 Weaver syndrome
 Well-Marchesani syndrome
 Welander distal myopathy
 Werner's syndrome
 White blood cell analysis abnormal
 White blood cell count abnormal
 White blood cell count decreased
 White blood cell disorder
 Wildervanck syndrome
 Williams syndrome
 Winchester syndrome
 Wiskott-Aldrich syndrome

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Rare events

Wolf-Hirschhorn syndrome
 Wolfram syndrome
 Woodhouse-Sakati syndrome
 Wyburn Mason's syndrome
 X-linked chromosomal disorder
 X-linked intellectual disability, Siderius type
 XXX syndrome
 XXXY syndrome
 XYY syndrome
 XYY syndrome
 Xeroderma pigmentosum
 Y-linked chromosomal disorder
 Young's syndrome
 Zhu-Tokita-Takenouchi-Kim syndrome
 Zika virus associated Guillain Barre syndrome
 Zika virus associated birth defect
 Zika virus associated microcephaly
 Zika virus associated ocular birth defect

Suspected transmission of an infectious agent

Air-borne transmission
 Arthropod-borne disease
 Bacterial disease carrier
 Community acquired infection
 Diphtheria carrier
 Direct infection transmission
 Faecal-oral transmission of infection
 Fungal disease carrier
 HIV carrier
 HTLV-1 carrier
 Human immunodeficiency virus transmission
 Iatrogenic infection
 Indirect infection transmission
 Infection transmission via personal contact
 Infection via vaccine
 Infectious disease carrier
 Mycobacterial disease carrier
 Nosocomial infection
 Primary transmission
 SARS-CoV-2 carrier
 Secondary transmission
 Sexual transmission of infection
 Sexually transmitted disease
 Sexually transmitted disease carrier

Pre-defined MedDRA search - list of preferred terms

Pre-defined MedDRA search

Preferred term

Suspected transmission of an infectious agent	Suspected transmission of an infectious agent via product Transmission of an infectious agent via product Transmission of an infectious agent via transplant Typhoid carrier Vaccine bacteria shedding Vaccine virus shedding Vector-borne transmission of infection Vertical infection transmission Viral disease carrier Viral hepatitis carrier
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