



MedDRA

MedDRA simplified: Coding for clinical excellence

Dr Anamika Dutta
Medical Officer, MedDRA MSSO
ISCR's Medical Coding Workshop
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MedDRA

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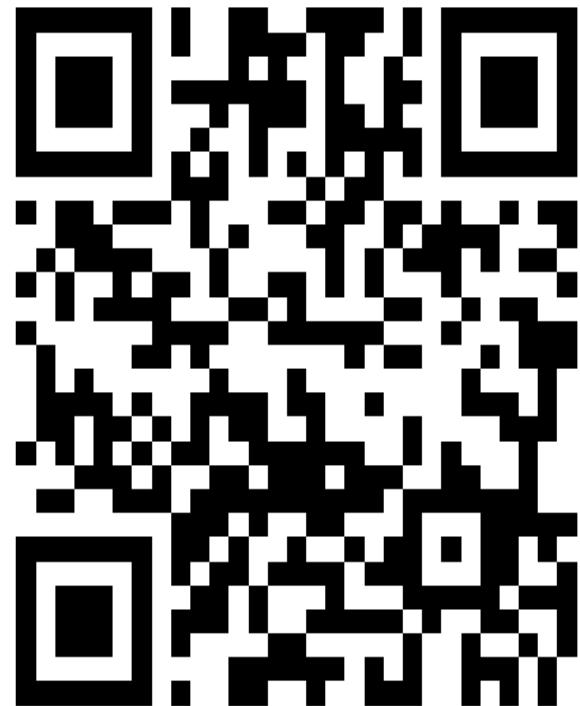
MedDRA

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What is coding?

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MedDRA

Coding in daily life?





MedDRA

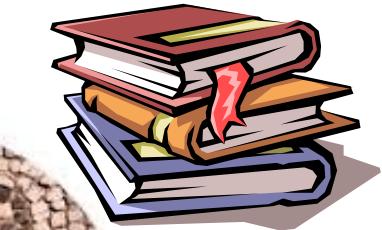
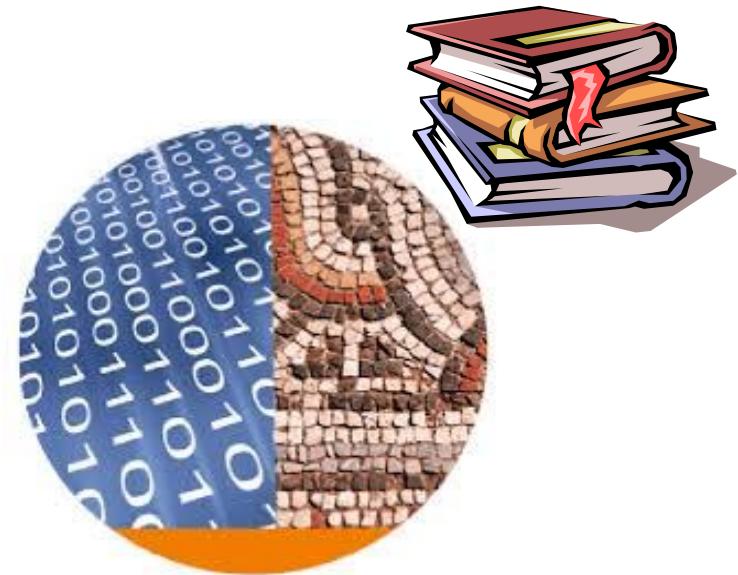
What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities



MedDRA is a clinically-validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry. The terminology is used through the entire regulatory process, from pre-marketing to post-marketing, and for data entry, retrieval, evaluation, and presentation.



MedDRA's Purpose

- Facilitate the exchange of clinical information through standardization
- Important tool for product evaluation, monitoring, communication, electronic records exchange, and oversight
- Supports coding (data entry) and retrieval and analysis of clinical information about human medical products including pharmaceuticals, biologics, vaccines, and drug-device combination products



MedDRA

MedDRA and the MSSO



International support & development terminology

“Custodians” of the terminology

Foster use of MedDRA

Governed by a Management committee

JMO for MedDRA Japanese



Types of Subscription

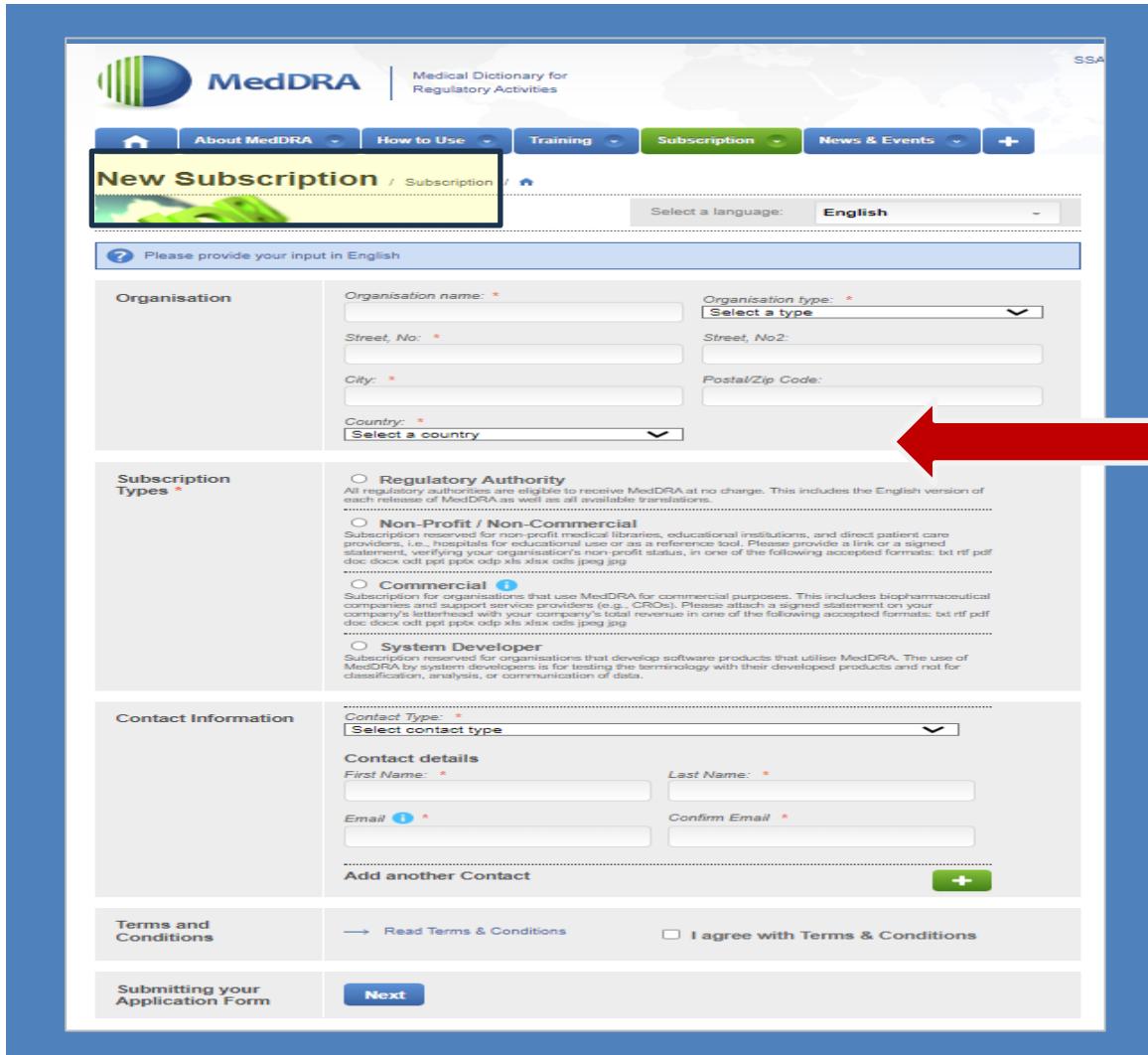
Four types of subscription are available from the MSSO:

- Regulatory Authority
- Non-Profit/Non-Commercial (such as medical library, educational institution, organisation engaged in not-for-profit activities)
- Commercial
- System Developer (developer of software products that utilise MedDRA).





How to subscribe?



The screenshot shows the "New Subscription" form on the MedDRA website. The form is divided into several sections: "Organisation" (with fields for name, type, address, city, postal code, and country), "Subscription Types" (with options for Regulatory Authority, Non-Profit / Non-Commercial, Commercial, and System Developer), "Contact Information" (with fields for contact type, details, and email), and "Terms and Conditions" (with a link to read terms and a checkbox for agreeing). A red arrow points from the text in the blue box on the right to the "Subscription Types" section of the form.

Medical Dictionary for Regulatory Activities

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Select a language: English

Please provide your input in English

Organisation

Organisation name: *

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Regulatory Authority
All regulatory authorities are eligible to receive MedDRA at no charge. This includes the English version of each release of MedDRA as well as all available translations.

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System Developer
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Contact Information

Contact Type: *

Contact details

First Name: *

Last Name: *

Email: *

Confirm Email: *

Add another Contact

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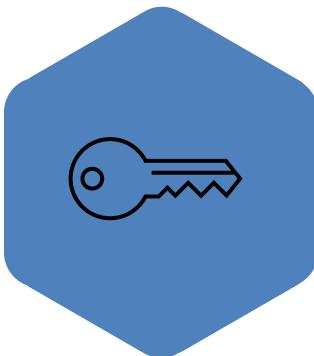
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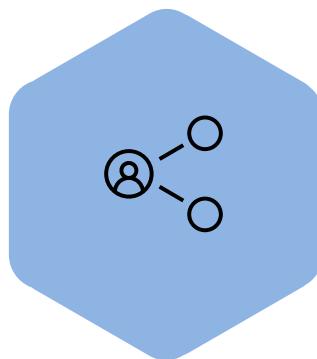


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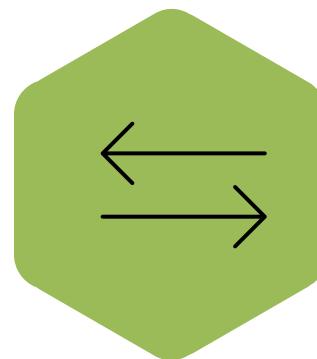
Access

Subscription grants access to MedDRA for one year



3rd Party Distribution

Subscriber cannot grant any sublicense, publish or otherwise distribute MedDRA to a third party



Free Exchange

Data may be freely exchanged between current MedDRA subscribers



Violation

Sharing MedDRA with a non-subscribing organization is a violation of the MedDRA license



MedDRA

Where MedDRA is Used



Regulatory Authority and Industry Databases
Individual Case Safety Reports and Safety Summaries

Clinical Study Reports

Investigators' Brochures

Core Company Safety Information

Marketing Applications

Publications

Prescribing Information

Advertising



Scope of MedDRA

Not a drug dictionary
Patient demographic terms
Clinical trial study design terms



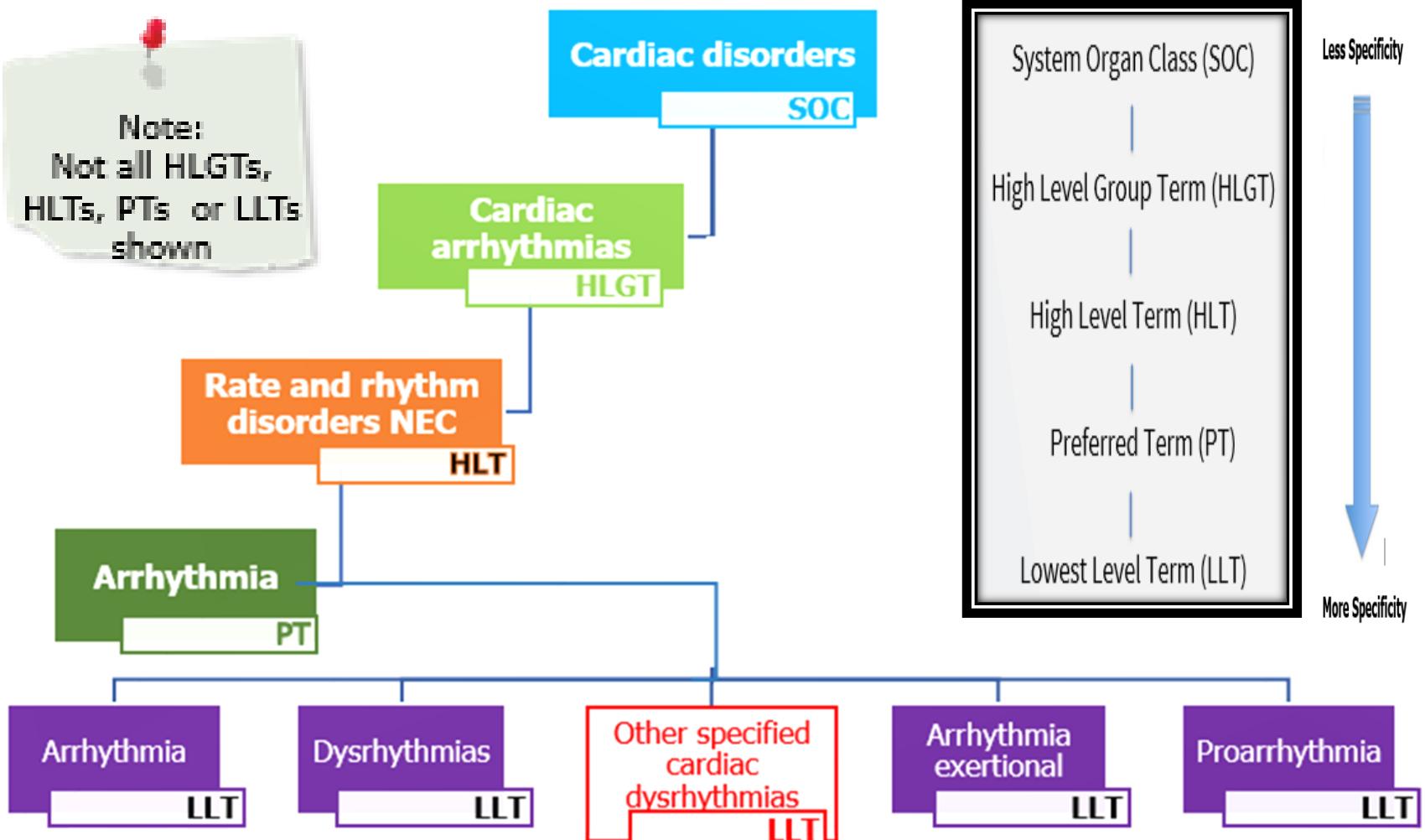
Frequency qualifiers
Numerical values for results
Severity descriptors
Not an equipment, device, diagnostic product dictionary



MedDRA

Structure of MedDRA

 Note:
Not all HLGTs,
HLTs, PTs or LLTs
shown





System Organ Classes

- + **SOC** Blood and lymphatic system disorders
- + **SOC** Cardiac disorders
- + **SOC** Congenital, familial and genetic disorders
- + **SOC** Ear and labyrinth disorders
- + **SOC** Endocrine disorders
- + **SOC** Eye disorders
- + **SOC** Gastrointestinal disorders
- + **SOC** General disorders and administration site conditions
- + **SOC** Hepatobiliary disorders
- + **SOC** Immune system disorders
- + **SOC** Infections and infestations
- + **SOC** Injury, poisoning and procedural complications
- + **SOC** Investigations
- + **SOC** Metabolism and nutrition disorders
- + **SOC** Musculoskeletal and connective tissue disorders
- + **SOC** Neoplasms benign, malignant and unspecified (incl cysts and polyps)
- + **SOC** Nervous system disorders
- + **SOC** Pregnancy, puerperium and perinatal conditions
- + **SOC** Product issues
- + **SOC** Psychiatric disorders
- + **SOC** Renal and urinary disorders
- + **SOC** Reproductive system and breast disorders
- + **SOC** Respiratory, thoracic and mediastinal disorders
- + **SOC** Skin and subcutaneous tissue disorders
- + **SOC** Social circumstances
- + **SOC** Surgical and medical procedures
- + **SOC** Vascular disorders





MedDRA

Non-Current Terms

LLT

- Flagged at the LLT level in MedDRA
- Not recommended for continued use
- Retained to preserve historical data for retrieval and analysis
- Terms that are vague, ambiguous, outdated, truncated, or misspelled
- Terms derived from other terminologies that do not fit MedDRA rules





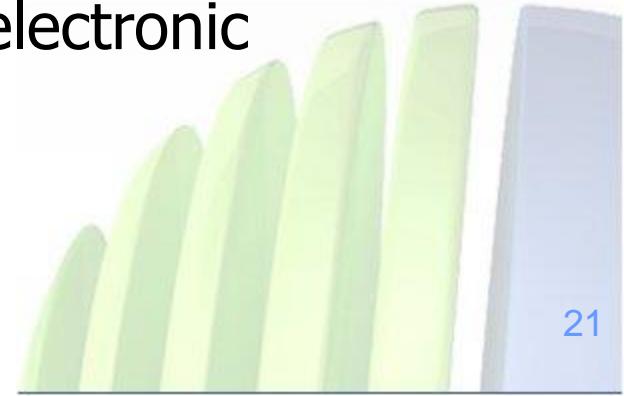
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MedDRA Codes

PT Anaemia

[10002034]

- Each MedDRA term is assigned an 8-digit numeric code
 - Non-expressive
 - Assigned sequentially
- Codes can fulfill a data field in various electronic submission types (e.g., E2B (R3))





MedDRA

A Multi-Axial Terminology

SOC = Respiratory, thoracic and mediastinal disorders
(Secondary SOC)

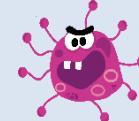


HLGT = Respiratory tract infections

HLT = Viral upper respiratory tract infections

PT = Influenza

SOC = Infections and infestations
(Primary SOC)

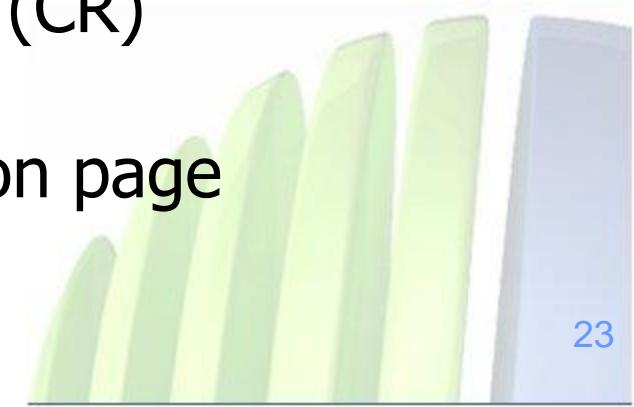


HLGT = Viral infectious disorders

HLT = Influenza viral infections



- Users can send change requests (CRs) to MSSO for consideration
 - Organizations allowed 100 CRs/month
 - Rigorous medical review by MSSO physicians
 - For simple changes (PT and LLT levels), response within 7-10 working days
 - Complex changes (above PT level) posted for comments mid-year
- Web-based tool for Change Requests (CR)
 - URL: <https://webcr.meddra.org/>
 - Via the Change Request Information page





- Two MedDRA updates/year
 - 1 March X.0 (Complex release)
 - 1 September X.1 (Simple release)
- Resources:
 - “What’s New” document
 - Version report
 - MedDRA Version Analysis Tool (MVAT)
- Version used in data retrieval and presentation should be documented
- Terms used for queries should be in same version as data being queried





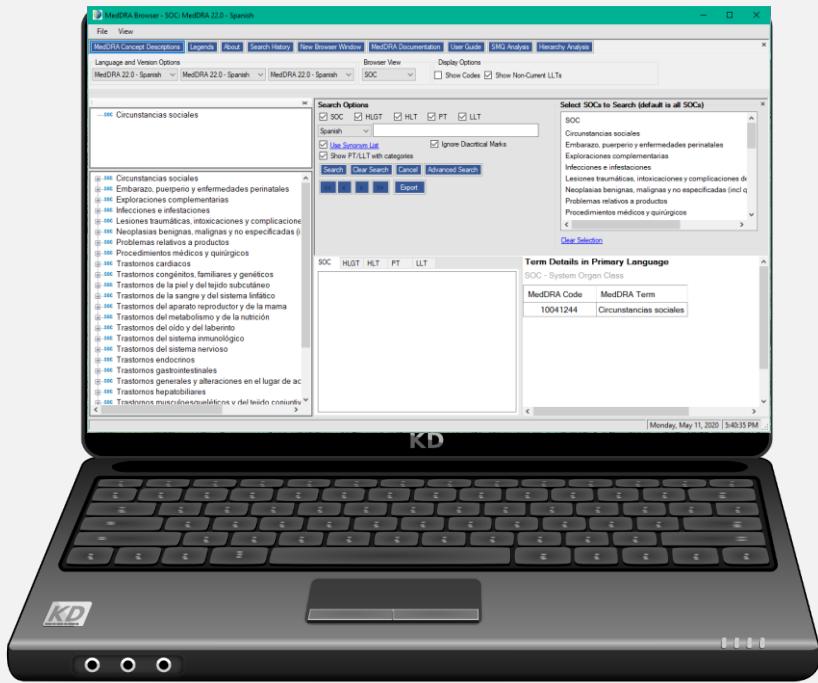
MedDRA

MedDRA Tools



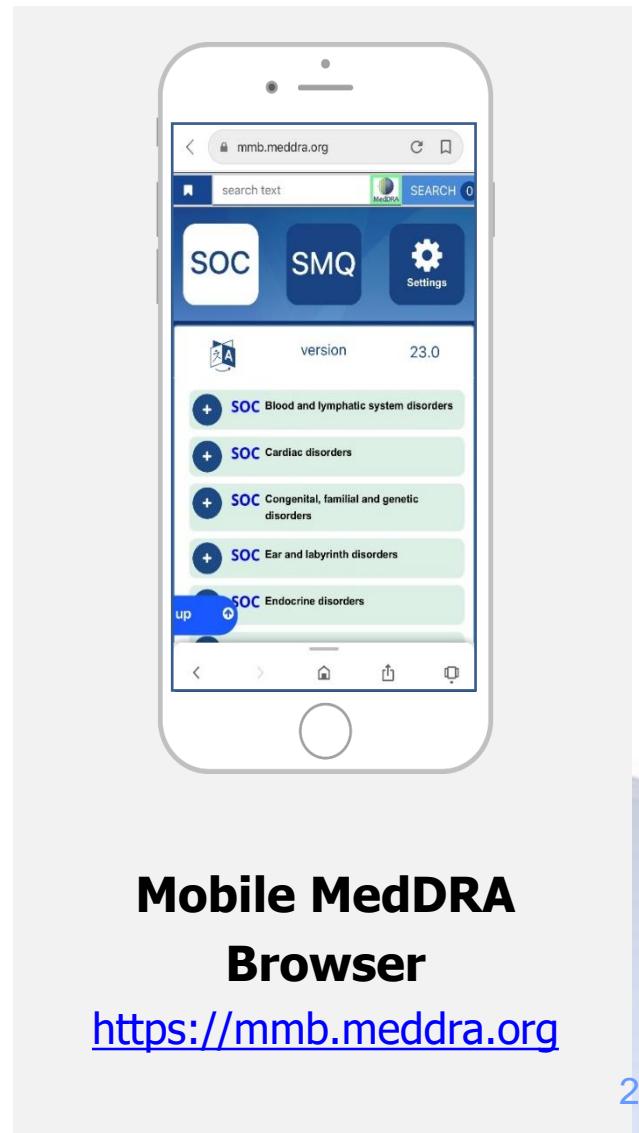


MSSO's MedDRA Browsers



MedDRA Desktop Browser (MDB)
Download MDB and release files from MedDRA website

MedDRA Web-Based Browser (WBB)
<https://tools.meddra.org/wbb/>



**Mobile MedDRA
Browser**

<https://mmb.meddra.org>



MedDRA

MedDRA Version Analysis Tool (MVAT)

MVAT
MedDRA Version Analysis Tool

Tuesday, January 30, 2024 5:02 PM
[MedDRA End User License Agreement](#)
[MedDRA Privacy Statement](#)

MedDRA Version Analysis Tool (MVAT)

Version Report Description

Select Different Versions to Compare

Language: English

Starting Version: MedDRA 26.1 English

Ending Version: MedDRA 27.0 English

Include Secondary SOC Information

Select SOCs to filter (default is all SOCs):

- Blood and lymphatic system disorders
- Cardiac disorders
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders and administration site conditions
- Hepatobiliary disorders
- Immune system disorders
- Infections and infestations
- Injury, poisoning and procedural complications

Note: The starting MedDRA version must be older than the ending MedDRA version

Preferred Language: English

Release/Supplemental View: Release



MedDRA Term Selection: Points to Consider (MTS:PTC)

Provides term selection advice for industry and regulatory purposes

Promote accurate and consistent term selection to facilitate a common understanding of shared data

Recommended to be used as basis for individual organization's own coding conventions



MedDRA

MedDRA Term Selection: Points to Consider (MTS:PTC)

SECTION 2 – GENERAL TERM SELECTION PRINCIPLES

- 2.1 Quality of Source Data
- 2.2 Quality Assurance
- 2.3 Do Not Alter MedDRA
- 2.4 Always Select a Lowest Level Term
- 2.5 Select Only Current Lowest Level Terms
- 2.6 When to Request a Term
- 2.7 Use of Medical Judgment in Term Selection
- 2.8 Selecting More than One Term
- 2.9 Check the Hierarchy
- 2.10 Select Terms for All Reported Information, Do Not Add Information

SECTION 3 – TERM SELECTION POINTS

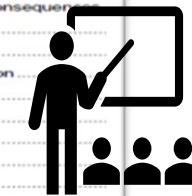
- 3.1 Definitive and Provisional Diagnoses with or without Signs and Symptoms
- 3.2 Death and Other Patient Outcomes
 - 3.2.1 Death with ARs/AEs
 - 3.2.2 Death as the only reported information
 - 3.2.3 Death terms that add important clinical information
 - 3.2.4 Other patient outcomes (non-fatal)
- 3.3 Suicide and Self-Harm
 - 3.3.1 If overdose is reported
 - 3.3.2 If self-injury is reported
 - 3.3.3 Fatal suicide attempt
- 3.4 Conflicting/Ambiguous/Vague Information
 - 3.4.1 Conflicting information
 - 3.4.2 Ambiguous information
 - 3.4.3 Vague information
- 3.5 Combination Terms
 - 3.5.1 Diagnosis and sign/symptom
 - 3.5.2 One reported condition is more specific than the other
 - 3.5.3 A MedDRA combination term is available
 - 3.5.4 When to "split" into more than one MedDRA term
 - 3.5.5 Event reported with pre-existing condition
- 3.6 Age vs. Event Specificity
 - 3.6.1 MedDRA term includes age and event information
 - 3.6.2 No available MedDRA term includes both age and event information
- 3.7 Body Site vs. Event Specificity
 - 3.7.1 MedDRA term includes body site and event information
 - 3.7.2 No available MedDRA term includes both body site and event information
 - 3.7.3 Event occurring at multiple body sites
- 3.8 Location-Specific vs. Microorganism-Specific Infection
 - 3.8.1 MedDRA term includes microorganism and anatomic location
 - 3.8.2 No available MedDRA term includes both microorganism and anatomic location
- 3.9 Modification of Pre-existing Conditions
- 3.10 Exposures during Pregnancy and Breast Feeding
 - 3.10.1 Events in the mother

Detailed coding instructions

- 3.10.2 Events in the child or foetus
- 3.11 Congenital Terms
 - 3.11.1 Congenital conditions
 - 3.11.2 Acquired conditions (not present at birth)
 - 3.11.3 Conditions not specified as either congenital or acquired
- 3.12 Neoplasms
 - 3.12.1 Do not infer malignancy
- 3.13 Medical and Surgical Procedures
 - 3.13.1 Only the procedure is reported
 - 3.13.2 Procedure and diagnosis are reported
- 3.14 Investigations
 - 3.14.1 Results of investigations as ARs/AEs
 - 3.14.2 Investigation results consistent with diagnosis
 - 3.14.3 Investigation results not consistent with diagnosis
 - 3.14.4 Grouped in with other result terms
 - 3.14.5 Investigations terms without qualifiers
- 3.15 Medication Errors, Accidental Exposures and Occupational Exposures
 - 3.15.1 Medication errors
 - 3.15.2 Accidental exposures and occupational exposures
- 3.16 Misuse, Abuse and Addiction
 - 3.16.1 Misuse
 - 3.16.2 Abuse
 - 3.16.3 Addiction
 - 3.16.4 Drug diversion
- 3.17 Transmission of Infectious Agent via Product
- 3.18 Overdose, Toxicity and Poisoning
- 3.18.1 Overdose reported with clinical consequences
- 3.18.2 Overdose reported without clinical consequences
- 3.19 Device-related Terms
 - 3.19.1 Device-related event reported with clinical consequences
 - 3.19.2 Device-related event reported without clinical consequences
- 3.20 Drug Interactions
 - 3.20.1 Reporter specifically states an interaction
 - 3.20.2 Reporter does not specifically state an interaction
- 3.21 No Adverse Effect and "Normal" Terms
 - 3.21.1 No adverse effect
 - 3.21.2 Use of "normal" terms
- 3.22 Unexpected Therapeutic Effect
- 3.23 Modification of Effect
 - 3.23.1 Lack of effect
 - 3.23.2 Do not infer lack of effect
 - 3.23.3 Increased, decreased and prolonged effect
- 3.24 Social Circumstances
 - 3.24.1 Use of terms in this SOC
 - 3.24.2 Illegal acts of crime or abuse
- 3.25 Medical and Social History
- 3.26 Indication for Product Use
 - 3.26.1 Medical conditions
 - 3.26.2 Complex indications
 - 3.26.3 Indications with genetic markers or abnormalities
 - 3.26.4 Prevention and prophylaxis
 - 3.26.5 Procedures and diagnostic tests as indications
 - 3.26.6 Supplementation and replacement therapies
 - 3.26.7 Indication not reported
- 3.27 Off Label Use
 - 3.27.1 Off label use when reported as an indication
 - 3.27.2 Off label use when reported with an AR/AE
- 3.28 Product Quality Issues
 - 3.28.1 Product quality issue reported with clinical consequences
 - 3.28.2 Product quality issue reported without clinical consequences
 - 3.28.3 Product quality issue vs. medication error

SECTION 4 – APPENDIX

- 4.1 Versioning
 - 4.1.1 Versioning methodologies
 - 4.1.2 Timing of version implementation
- 4.2 Links and References





MedDRA

General term selection principles



Lowest Level Term that most accurately reflects the reported verbatim information should be selected



Select current LLTs only



Degree of specificity may be challenging



Use medical judgment when appropriate



Avoid company-specific “work-arounds” for MedDRA deficiencies



Submit change request to MSSO



MedDRA

General term selection principles



Select Terms for All Reported Information

Select terms for every AR/AE reported, regardless of causal association; Select terms for device-related events, product quality issues, medication errors, medical and social history, investigations, and indications as appropriate



Do Not Add Information

Do not make diagnosis if only signs/symptoms reported

| Reported | LLT Selected | Comment |
|---|-------------------------|--|
| Abdominal pain, increased serum amylase, and increased serum lipase | Abdominal pain | It is inappropriate to assign an LLT for diagnosis of "pancreatitis" |
| | Serum amylase increased | |
| | Lipase increased | |





MedDRA

Coding: Translating into MedDRA

| Reported Information | MedDRA Coding Term (LLT) |
|---|---|
| Throbbing above temple Aching all over head Pulsing pain in head Really bad headache Headache | Headache |
| Infection in lungs | Lung infection |
| Patient took Drug A instead of Drug B and experienced hypertension | Wrong drug administered Hypertension |



Data Quality

- Quality of original information impacts quality of output
- Obtain clarification of data
- Can be optimized by careful design of data collection forms and proper training of staff
- Organizations' coding guidelines should be consistent with MTS:PTC
- Review of term selection by qualified individuals
- Human oversight of automated coding results

Quality of Input = Quality of Output

IN



OUT





MedDRA

Quality Assurance (QA) Reports

- Allows reviewers to check for consistency (both auto-encoded and human-coded terms)
- Check for adherence to/deviation from coding conventions
- Check for emerging drifts/biases
- Multiple data views (verbatim to coded terms; coded term to verbatims; by SOC, etc.)





- Missed Concepts
 - All medical concepts described after the product is taken should be coded
 - Example: "*The patient took drug X and developed alopecia, increased LFTs and pancreatitis*". Manufacturer only codes alopecia and increased LFTs (missed concept of pancreatitis)
- "Soft Coding"
 - Selecting a term which is both less specific and less severe than another MedDRA term is "soft coding"
 - Example: "*Liver failure*" coded as hepatotoxicity or increased LFTs



Making the Most of MedDRA

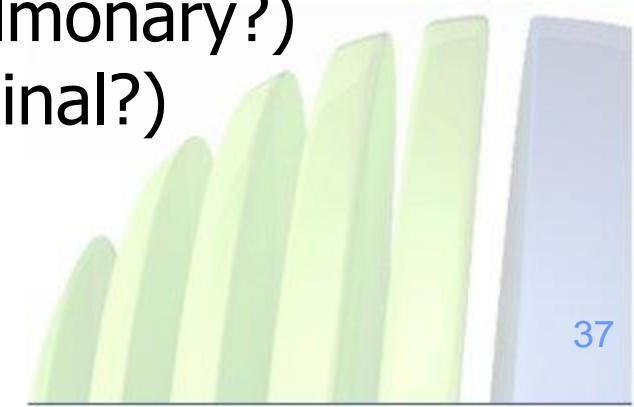
- To take advantage of MedDRA's richness and specificity, the source data should be
 - Clear
 - Concise
 - Complete
 - Accurate
- General principles apply to all clinical data





Problems With Coding Data

- Appropriate coding requires clear initial data
- What is clear to the investigator at the point of data entry may be unclear to the sponsor at the point of data coding
- Sponsor must only code reported verbatim term; not permitted to interpret or draw information from other sources
- Example: Ambiguous information
 - Congestion (nasal, liver, sinus, pulmonary?)
 - Cramp (muscle, menstrual, abdominal?)
 - Pain (pain where?)





Problems With Coding Data (cont)

- Exercise caution with abbreviations that could be misinterpreted
- Example: Ambiguous abbreviations
 - MI (myocardial infarction or mitral incompetence?)
 - Decreased BS (breath sounds, bowel sounds or blood sugar?)
- Try to avoid combination terms, they should be split
- Example: Nausea and vomiting
 - Nausea
 - Vomiting





Problems With Coding Data (cont)

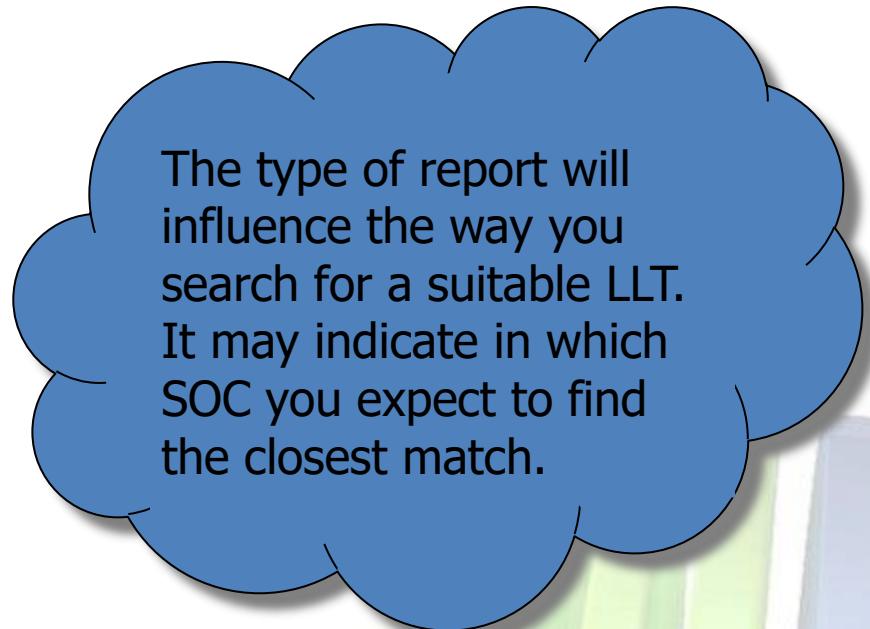
- Death, hospitalization, and disability are outcomes and are not usually considered to be adverse events
- Provide details of the underlying event, if known
- Examples:
 - “Death due to myocardial infarction” (Coded as *Myocardial infarction* with death captured as the outcome)
 - “Hospitalization due to congestive heart failure” (Coded as *Congestive heart failure* with hospitalization captured as the outcome)





Assessing the Reported Information

- Consider what is being reported. Is it a:
 - Clinical condition - Diagnosis, sign or symptom?
 - Indication?
 - Test result?
 - Injury?
 - Procedure?
 - Medication error?
 - Product use issue?
 - Product quality issue?
 - Social circumstance?
 - Device issue?
 - Procedural complication?
 - **Is it a combination of these?**

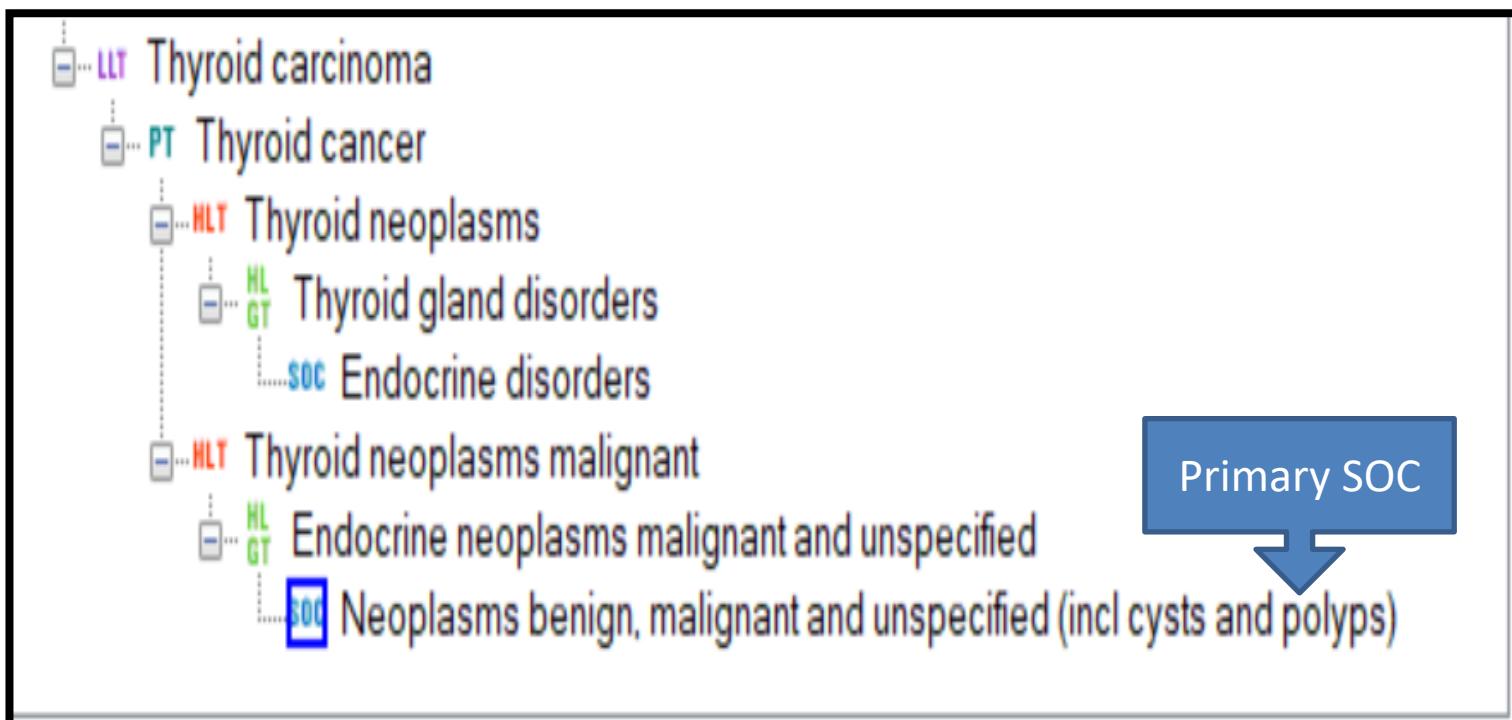


The type of report will influence the way you search for a suitable LLT. It may indicate in which SOC you expect to find the closest match.



How to code? Example:

- Verbatim: THYROID CARCINOMA
 - Coded to LLT : Thyroid carcinoma





How to code? Example:

- Verbatim: The patient suffered from an allergic reaction to an antibiotic
 - Coded to LLT : Allergic reaction to antibiotics



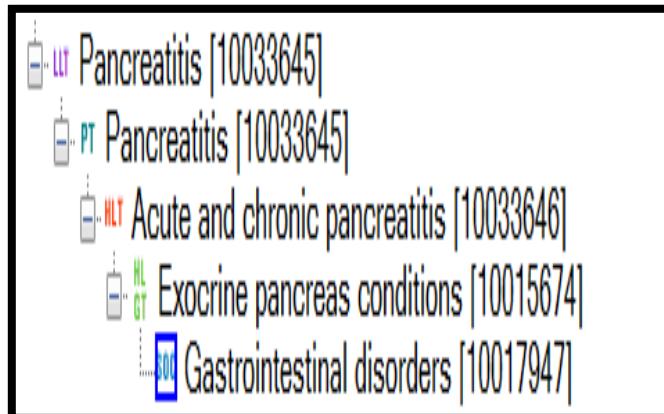


How to code? Example:

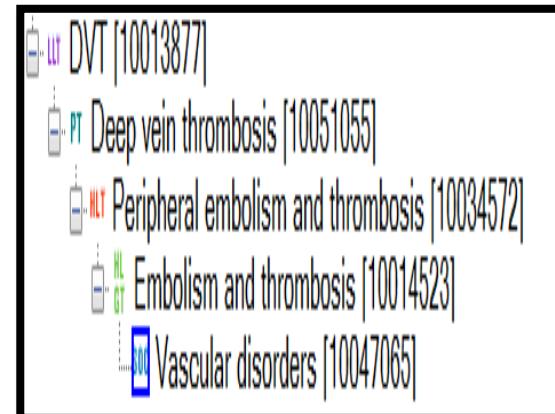
- Verbatim: 03/19/2012: Patient was hospitalized with severe upper abdominal burning pain radiating to the back, nausea, and vomiting that worsened with eating. Upon further investigation her serum amylase levels were found to be elevated and was diagnosed with Pancreatitis. During the hospitalization she was also found to have DVT.

— Coded to

1. LLT : Pancreatitis



2. LLT : DVT





MedDRA

How to code? Example:

Patient reported severe **eye irritation** after using **eye drops that had a cloudy appearance**. An investigation by the manufacturer revealed that the **batch of eye drops contained foreign material**.

- Coded to LLTs

| LLT | PT | Primary SOC |
|--|--------------------------------|----------------|
| Eye irritation | Eye irritation | Eye disorders |
| Product appearance cloudy | Liquid product physical issue | Product issues |
| Product contamination foreign material | Product contamination physical | Product issues |

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all computers you use



Reported term: 'Abuse'

ⓘ Start presenting to display the poll results on this slide.

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"Man with decreased fertility."

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**"Deliberately took an
overdose".**

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"Death from cerebral haemorrhage"

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**"Hypoglycemia (blood
glucose = 200 mg/dL)"**

ⓘ Start presenting to display the poll results on this slide.

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**"Took intramuscular
drug by mouth".**

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Infection after surgery

ⓘ Start presenting to display the poll results on this slide.



How would you handle this report?

A diabetic patient is anxious about his XXXX vaccination appointment, so he forgets that he took his morning insulin and administers a second dose. At the vaccination clinic, the diabetic patient seems confused, looks pale, and is sweaty.



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How would you handle this report?

- ① Start presenting to display the poll results on this slide.



MedDRA

What Terms to Select?

“Spray it in the nose as much as you can, and the septum is gone !! ”



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**One of this terms was
not reported for coding.
Guess which one :)**

ⓘ Start presenting to display the poll results on this slide.



MedDRA Data Retrieval and Presentation: Points to Consider (DRP:PTC)

Provides data retrieval and presentation options for industry or regulatory purposes

Most effective when used in conjunction with MedDRA Term Selection: PTC document

Recommended to be used as basis for individual organization's own data retrieval conventions



Standardised MedDRA Queries (SMQs)

Groupings of terms from one or more MedDRA SOCs related to medical condition or area of interest

- Terms relate to
 - ✓ Signs/symptoms,
 - ✓ Diagnoses,
 - ✓ Syndromes,
 - ✓ Physical findings,
 - ✓ Laboratory and other test data, etc.
- Intended to aid in case identification





SMQs in Production - Examples

As of Version 27.0, a total of 110 level 1 SMQs in production

- Agranulocytosis
- Anaphylactic reaction
- Central nervous system vascular disorders
- Convulsions
- COVID-19
- Depression and suicide/self-injury
- Hepatic disorders
- Hypersensitivity
- Ischaemic heart disease
- Lack of efficacy/effect
- Medication errors
- Osteonecrosis
- Peripheral neuropathy
- Pregnancy and neonatal topics
- Pseudomembranous colitis
- Rhabdomyolysis/myopathy
- Severe cutaneous adverse reactions
- Shock
- Systemic lupus erythematosus



Standardised MedDRA Queries (SMQs) in Pharmacovigilance

Retrieve cases for suspected or known safety issue

Signal detection

Single case alerts

Periodic reporting



MedDRA

Know more?



Medical Dictionary for Regulatory Activities

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Contact

MedDRA MSSO
7575 Colshire Drive
McLean, VA 22102
USA
E-mail: mssohelp@meddra.org or use the form below.
Direct: +1 703.556.2950

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Additional Points to Consider Documents and MedDRA Best Practices Document (click here)

- MedDRA Version 24.0 March 2021
- MedDRA Version 23.1 September 2020
- MedDRA Version 23.0 English March/April 2020
- MedDRA Version 22.1 English September 2019
- MedDRA Version 22.0 English March 2019
- MedDRA Version 21.1 English September 2018
- MedDRA Version 21.0 English March 2018
- MedDRA Version 20.1 English September 2017
- MedDRA Version 20.0 English March 2017
- MedDRA Version 19.1 English September 2016
- MedDRA Version 19.0 English March 2016
- MedDRA Version 18.1 English September 2015

Training Materials

MedDRA training materials are available as presentations and videocasts for streaming to your computer (.wmv) or for downloading (.zip).

General / Basics

| Topic | Presentation | Training Type |
|-------|--------------|---------------|
|-------|--------------|---------------|

Coding

| Topic | Presentation | Training Type |
|-------|--------------|---------------|
|-------|--------------|---------------|

Retrieval / Analysis (SMQs)

| Topic | Presentation | Training Type |
|-------|--------------|---------------|
|-------|--------------|---------------|

MedDRA Versioning

| Topic | Presentation | Training Type |
|-------|--------------|---------------|
|-------|--------------|---------------|

Tools

| Topic | Presentation | Training Type |
|-------|--------------|---------------|
|-------|--------------|---------------|

Contributions from MedDRA User Groups

A number of useful training materials (presentations and recordings) are developed for User Groups and are available for download on the User Group page.

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MedDRA

Thank You!

mssohelp@meddra.org

anamika.dutta@meddra.org