MedDRA - Terminologies & Coding

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• What is Coding?

• Why code?
How does this look to you?
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.
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<th>MedDRA Subscription Types</th>
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77% of all MedDRA users pay no fee or $654 (or less)
# How to subscribe?

**Organisation**

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**Subscription Type** *

- **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**
  Subscription reserved for organisations that develop software products that utilise MedDRA. The use of MedDRA by system developers is for testing the terminology with their developed products and not for classification, analysis, or communication of data.

**Contact Information**

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<th>Main point of contact</th>
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Scope of MedDRA

- Medical conditions
- Indications
- Investigations (tests, results)
- Medical and surgical procedures
- Medical, social, family history
- Medication errors
- Product quality issues
- Device-related issues
- Product use issues
- Pharmacogenetic terms
- Toxicologic issues
- Standardized queries

- Frequency qualifiers
- Numerical values for results
- Severity descriptors
- Not a drug dictionary
- Not an equipment, device, diagnostic product dictionary
- Patient demographic terms
- Clinical trial study design terms
MedDRA Structure

System Organ Class (SOC) (27)

High Level Group Term (HLGT) (337)

High Level Term (HLT) (1,737)

Preferred Term (PT) (23,708)

Lowest Level Term (LLT) (80,262)
System Organ Classes

- 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
- Investigations
- Metabolism and nutrition disorders
- Musculoskeletal and connective tissue disorders
- Neoplasms benign, malignant and unspecified (incl cysts and polyps)
- Nervous system disorders
- Pregnancy, puerperium and perinatal conditions
- Product issues
- Psychiatric disorders
- Renal and urinary disorders
- Reproductive system and breast disorders
- Respiratory, thoracic and mediastinal disorders
- Skin and subcutaneous tissue disorders
- Social circumstances
- Surgical and medical procedures
- Vascular disorders
**HLT =** Rate and rhythm disorders NEC

**HLGT =** Cardiac arrhythmias

**SOC =** Cardiac disorders

**PT =** Arrhythmia

**LLT =** Arrhythmia

**LLT (Non-current)**

Other specified cardiac dysrhythmias

Not all LLTs shown
Non-Current Terms

• 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
Codes and Languages

- Hoofdpijn Dutch
- Headache English
- Céphalée French
- Bolest hlavy Czech
- Kopfschmerz German
- Fejfájás Hungarian
- Cefalea Italian
- 頭痛 Japanese
- Cefalea Spanish

Electronic Submission

10019211
A Multi-Axial Terminology

• Multi-axial = the representation of a medical concept in multiple SOCs
  – Allows grouping by different classifications
  – Allows retrieval and presentation via different data sets

• All PTs assigned a primary SOC
  – Determines which SOC will represent a PT during cumulative data outputs
  – Prevents “double counting”
  – Supports standardized data presentation
  – Pre-defined allocations should not be changed by users
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
What are coding conventions?
MedDRA Term Selection: Points to Consider (MTS:PTC)

MedDRA® TERM SELECTION: POINTS TO CONSIDER
ICH-Endorsed Guide for MedDRA Users

Release 4.17
Based on MedDRA Version 22.0

1 March 2019

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• Provides term selection advice for industry and regulatory purposes

• Objective is to 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
General Term Selection Principles

• Quality of Source Data
• Quality Assurance
• Do Not Alter MedDRA
• Always Select a Lowest Level Term
• Select Only Current Lowest Level Terms
• When to Request a Term
• Use of Medical Judgment in Term Selection
• Selecting More than One Term
• Check the Hierarchy
• Select Terms for All Reported Information, Do Not Add Information
Term Selection Points

- Diagnoses and Provisional Diagnoses with or without Signs and Symptoms
- Death and Other Patient Outcomes
- Suicide and Self-Harm
- Conflicting/Ambiguous/Vague Information
- Combination Terms
- Age vs. Event Specificity
- Body Site vs. Event Specificity
- Location-Specific vs. Microorganism-Specific Information
- Modification of Pre-existing Conditions
- Exposures During Pregnancy and Breast Feeding
- Congenital Terms
- Neoplasms
- Medical and Surgical Procedures
- Investigations
Term Selection Points (cont)

- Medication Errors, Accidental Exposures and Occupational Exposures
- Misuse, Abuse and Addiction
- Transmission of Infectious Agent via Product
- Overdose, Toxicity and Poisoning
- Device-related Terms
- Drug Interactions
- No Adverse Effect and “Normal” Terms
- Unexpected Therapeutic Effect
- Modification of Effect
- Social Circumstances
- Medical and Social History
- Indication for Product Use
- Off Label Use
- Product Quality Issues
Some Points to consider

• Obtain clarification of data that are ambiguous, confusing, or unintelligible

• Do Not Alter MedDRA : Users must not make ad hoc structural alterations, including changing the primary SOC allocation

• Avoid company-specific “work-arounds” for MedDRA deficiencies, submit change request to MSSO

• Select current LLTs only
  – Non-current terms for legacy conversion/historical purposes
Some Points to consider

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

• Degree of specificity may be challenging
  – Example: “Abscess on face” → select “Facial abscess,” not simply “Abscess”

• If no exact match in MedDRA, use medical judgment to match to an existing term that adequately represents the concept

• Check the hierarchy above a selected LLT (PT, HLT, HLGT, SOC) to ensure placement accurately reflects meaning of reported term
Some Points to consider

• Can select more than one LLT to represent reported information. Document procedures.

• 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 make diagnosis if only signs/symptoms reported
MedDRA Browser & Demonstration
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/

• Features
  – Both require MedDRA ID and password
  – View/search MedDRA and SMQs
  – Support for all MedDRA languages
  – Language specific interface
  – Ability to export search results and Research Bin to local file system
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.
Specificity

The patient suffered from an allergic reaction to an antibiotic.
Symptoms

The patient states she has been experiencing cold sweats.
Investigations

Lab results indicate the patient has **increased troponin** and **increased CPK-MB**
Patient demographics

A 2 day old baby was noted to have a mild fever
A 35 year old woman was taking Drug X to prevent relapses of multiple sclerosis.
Product quality issues

It was determined that the product was counterfeit.
Social circumstances

The patient was confined to a wheelchair
Medication errors/Product use errors and issues

The pharmacist made a mistake in compounding the medication
MedDRA Coding Exercise
Which LLT Would You Select?

Verbatim: “Man with decreased fertility.”

A. Infertility
B. Fertility decreased male
C. Infertility male
D. Fertility decreased
Which LLT Would You Select?

Verbatim: “Became color blind in adolescence”

A. Color blindness
B. Blindness color
C. Colour blindness acquired
D. Color blindness acquired
Which LLT Would You Select?

Verbatim: “Turned very greasy”

A. Ill-defined disorder
B. Unevaluable event
C. Skin greasy
D. Unevaluable reaction
Which LLT Would You Select?

Verbatim: “Deliberately took an overdose”

A. Intentional overdose
B. Overdose NOS
C. Deliberate overdose
D. Overdose
Which LLT Would You Select?

Verbatim: “Toddler accidentally took her mother’s medication”

A. Accidental overdose
B. Accidental exposure to product by child
C. Accidental drug intake by child
D. Accidental ingestion
Which LLT Would You Select?

Verbatim: “Infection after surgery”

A. Infection
B. Postoperative wound infection
C. Surgical wound infection
D. Postoperative infection
Which LLT Would You Select?

Verbatim: “He sold his father’s medication”

A. Drug diversion
B. Intentional product misuse
C. Drug use for unapproved indication
D. Intentional drug misuse
Which LLT Would You Select?

Verbatim: “Had MI”

A. Myocardial infarction
B. Ill-defined disorder
C. MI
D. Unevaluable event
Verbatim:
“Hypernatraemia (Serum sodium = 115 mEq/L)”

A. Serum sodium abnormal
B. Hypernatraemia
C. Hyponatraemia
D. Serum sodium decreased
Which LLT Would You Select?

Verbatim: “Took intramuscular drug by mouth”

A. Wrong route of administration
B. Drug administered via inappropriate route
C. Medication error
D. Intramuscular formulation administered by other route
Which LLT Would You Select?

Verbatim: “The doctor mistakenly prescribed the wrong drug; the pharmacist noticed the error before dispensing the drug”

A. Wrong drug dispensed
B. Medication error
C. Intercepted drug prescribing error
D. Intercepted drug dispensing error
Verbatim: Patient attempted to commit suicide by walking into the sea; unfortunately, he could swim

A. Suicidal behaviour
B. Attempted suicide
C. Completed suicide
D. Death
Which LLT Would You Select?

Verbatim: “Dose taken was below the minimum recommended dose in the product label”

A. Underdose
B. Drug administration error
C. Accidental underdose
D. Incorrect dosage administered
Which LLT Would You Select?

Verbatim: “After taking an antihistamine along with her prescribed proton pump inhibitor, a 53-year-old woman developed vertigo.”

A. Drug interaction NOS
B. Vertigo subjective
C. Vertigo
D. Drug interaction
Which LLT Would You Select?

Verbatim: “The medication was stored at room temperature instead of in the refrigerator where it belonged.”

A. Incorrect storage of drug
B. Improper storage of unused product
C. Intercepted medication error
D. Product storage error temperature too high
Which LLTs Would You Select?

Verbatim: The 66 year old man died from a ruptured aortic aneurysm

A. Aortic aneurysm rupture
B. Ascending aortic aneurysm rupture
C. Dissecting aortic aneurysm, ruptured
D. Death
E. A & D both
Quick Guess?

- Hippo tension
- Mousy feeling in chest
- Patient recently began new job where he works around chicken wings and barbecue sauce
- Loss of brain
- Spray it in the nose as much as you want and the Septum is gone
- Medication messed up with the brain
- Adult teeth came in three different colors – yellow, green and white
- Husband had his uterus scrapped and frozen
- Death-worsened clinically by end of 4 hrs rx
- Even Need to spend more time with my wife (as the subject stated)
After Coding?
How is MedDRA Used for Analysis?

• MedDRA can be used to summarise large volumes of data
  – Standard approach is to list data at PT and SOC levels for overview

• Focused searches can be made using features of MedDRA
  – Searching for specific PTs
  – Summarising at HLT or HLGT levels
  – Using multiaxial links to group diagnoses with signs and symptoms
  – Selecting a set of relevant PTs which reflect the condition of interest
  – Using Standardised MedDRA Queries (SMQs) for signal detection
  – Customized search / Modified MedDRA Queries
More on SMQ and Data Retrieval?

- **Documentation**:
  - SMQ Introductory Guide
    [https://www.meddra.org/how-to-use/support-documentation](https://www.meddra.org/how-to-use/support-documentation)

- **Processes**:
  - MedDRA Data Retrieval and Presentation: Points to Consider
    [https://www.meddra.org/how-to-use/support-documentation](https://www.meddra.org/how-to-use/support-documentation)

- **Training**:
  - Face-to-Face Training - MedDRA: Safety Data Analysis and SMQs
  - Webinar
  - Training Videocast
    [https://www.meddra.org/training/offerings](https://www.meddra.org/training/offerings)
Thank You!!

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