



What is MedDRA and How is it Used?



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MedDRA was developed under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The activities of the MedDRA Maintenance and Support Services Organization (MSSO) are overseen by an ICH MedDRA Steering Committee. The MedDRA SC is composed of the EC, Europe; EFPIA; FDA, United States; Health Canada, Canada; JPMA; MHLW/PMDA, Japan; MHRA UK; PhRMA; and WHO (as Observer). In addition, since May 2025, the following representatives have been appointed by the ICH MC to join the MedDRA SC and will serve until the next appointment in 2028: NMPA, China; SFDA, Saudi Arabia; and IFPMA (as Observer).

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Course Overview

- Present background information about MedDRA and its governance
- Review MedDRA's scope, structure, and characteristics
- Describe the maintenance of MedDRA
- Describe MedDRA tools (browsers, MVAT)
- Discuss principles of coding with MedDRA
- Introduce the MedDRA Points to Consider documents
- Describe Standardised MedDRA Queries (SMQs)
- Conclude with a question-and-answer session

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MedDRA Background and Governance



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What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities



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MedDRA

MedDRA Definition

- 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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MedDRA

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

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Governance Structure for MedDRA

- ICH MedDRA Steering Committee appointed by the ICH Assembly to provide oversight of MedDRA related activities and the Maintenance and Support Services Organization (MSSO)

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Steering Committee and MSSO Relationship

- ICH owns MedDRA
- ICH MedDRA Steering Committee
 - Contracts with MSSO to maintain it
 - Has oversight of all operations of the MSSO
 - Meets regularly with MSSO
 - Sets subscription rates
 - Approves developmental plans and services
 - Membership includes ICH regulatory authorities and industry associations



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MedDRA

MedDRA and the MSSO



MSSO

- International support and development of terminology
- “Custodians”, not owners, of the terminology



Governance

- Governed by a Steering Committee (industry, regulators, multi-national, other interested parties)



Educational offerings

- Foster use of MedDRA through communications and educational offerings



JMO

- Partner organization for Japanese-language MedDRA

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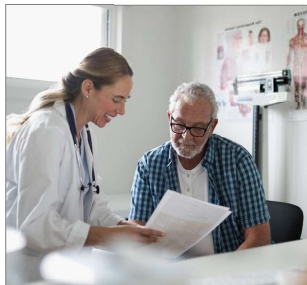
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MedDRA

Where MedDRA is Used



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Regulatory Authority and Industry Databases
 ICSRs and Safety Summaries
 Clinical Study Reports
 Investigators' Brochures
 Core Company Safety Information
 Marketing Applications
 Publications
 Prescribing Information
 Advertising

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MedDRA's Scope, Structure, and Characteristics

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Scope of MedDRA

OUT

- Not a drug dictionary
- Patient demographic terms
- Clinical trial/study design terms
- Frequency qualifiers

IN

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

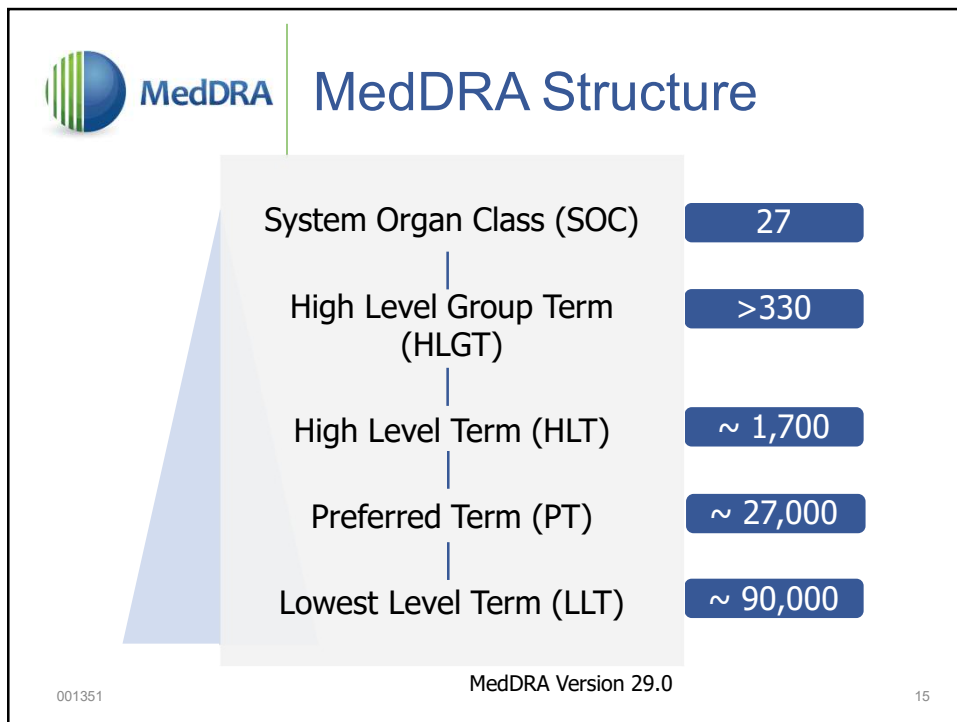
OUT

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

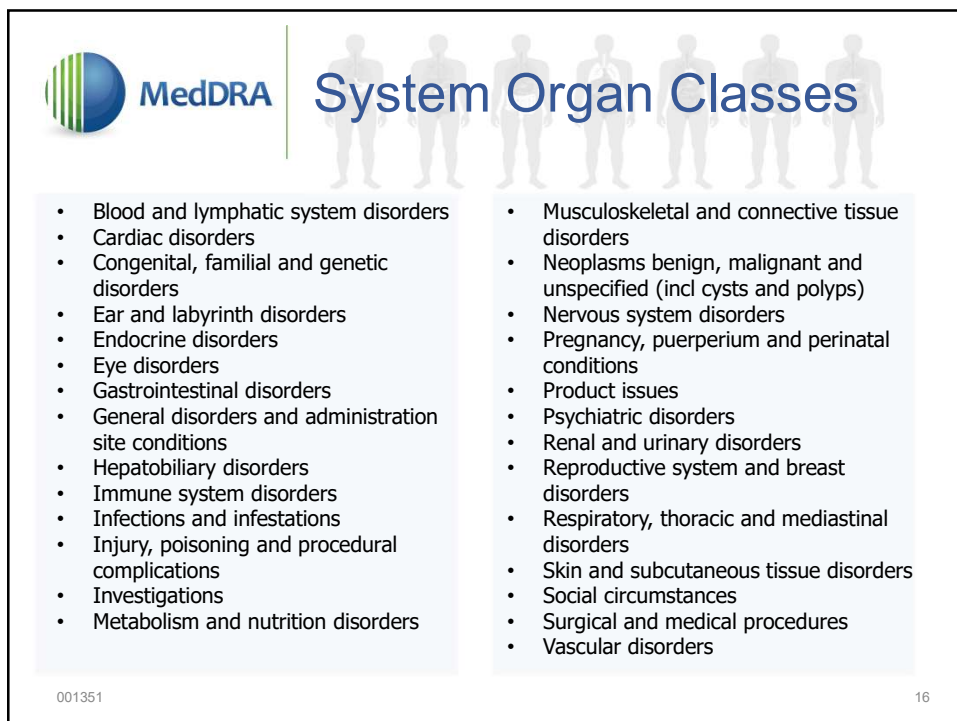
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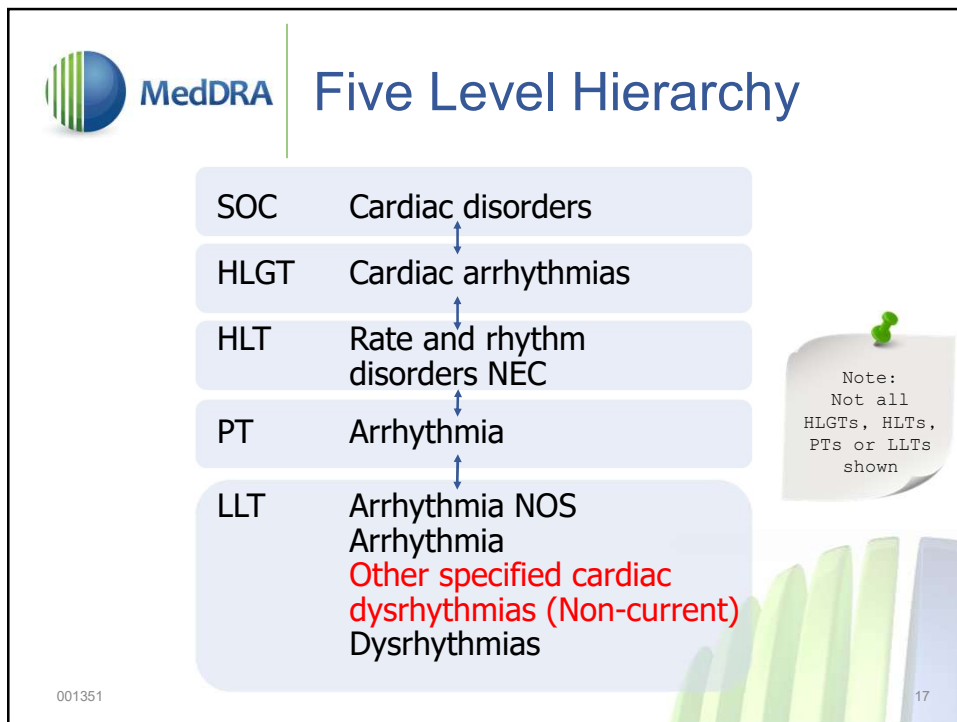
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MedDRA Non-Current Terms LLT

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

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MedDRA

MedDRA Codes

PT *Anaemia*

[10002034]

- Each MedDRA term is assigned an 8-digit numeric code
 - Non-expressive, assigned sequentially
 - Each term has a unique code
 - Codes link terms across versions and translations
- Codes can fulfill a data field in various electronic submission types (e.g., E2B (R3))

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MedDRA

A Multi-Axial Terminology

Multi-axial = the representation of a medical concept in multiple SOC's

- ✓ Allows grouping by different classifications
- ✓ Allows retrieval and presentation via different data sets

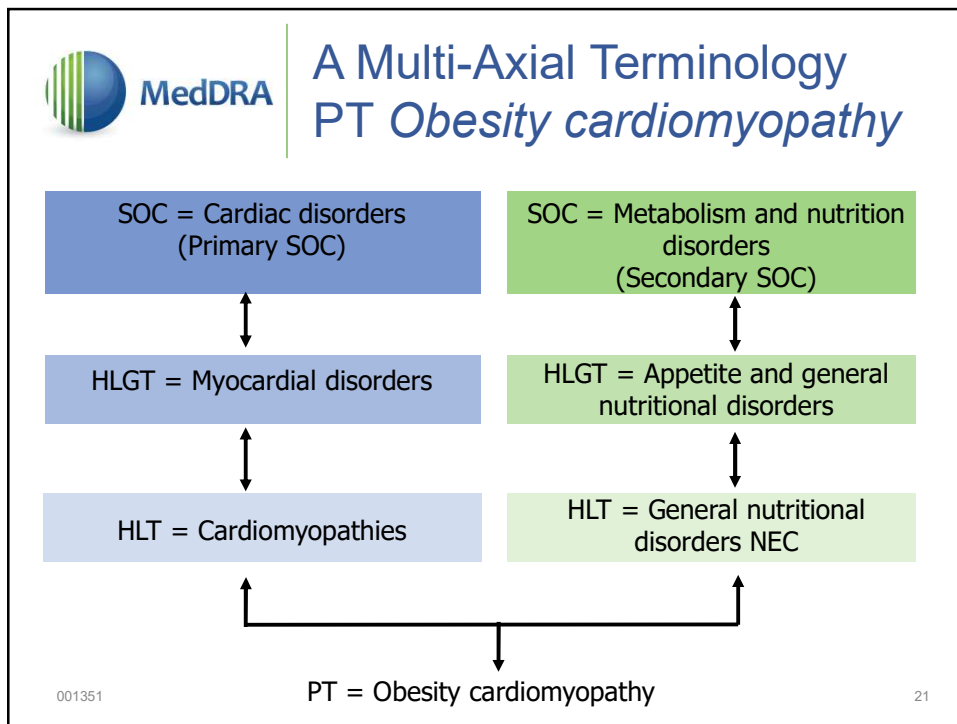
All PTs assigned a primary SOC

- ✓ 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

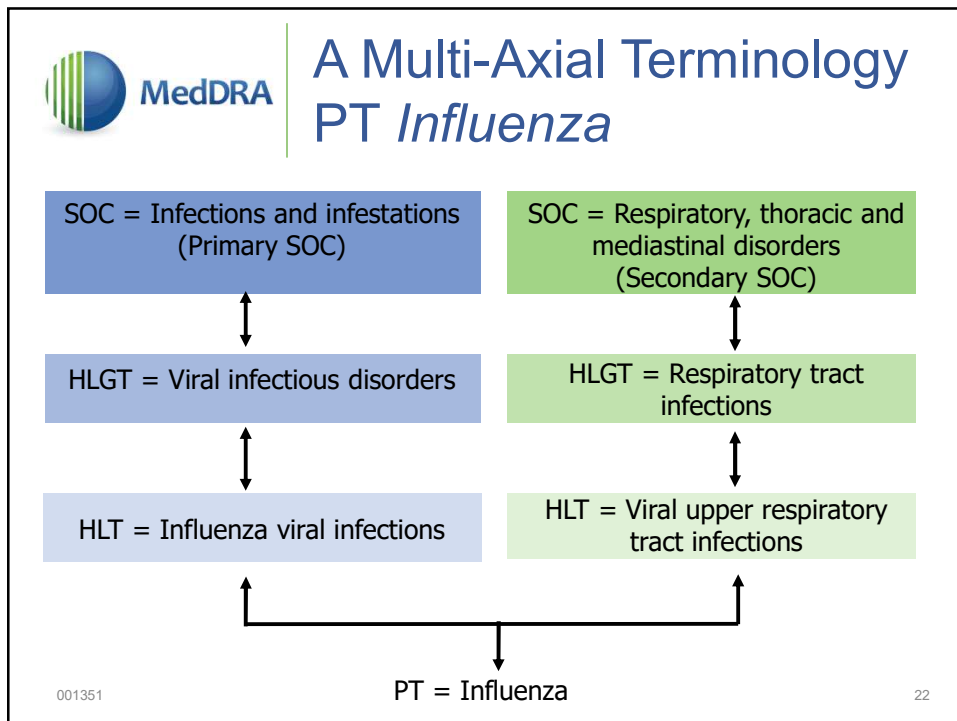
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MedDRA Maintenance

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MedDRA Maintenance

- Long-term maintenance in response to
 - Medical and scientific advances
 - Changes in the regulatory environment
- Users can send change requests (CRs) to MSSO for consideration
 - Organizations allowed 100 CRs/month
 - Rigorous medical review by MSSO physicians
 - Response within 7-10 working days (PT/LLT level changes)
 - Complex changes (above PT level) posted for user community comments mid-year
- Two MedDRA updates/year
 - 1 March X.0 (Complex release)
 - 1 September X.1 (Simple release)

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MedDRA

WebCR

- Web-based tool for Change Requests (CR)
 - URL: <https://webcr.meddra.org/>
 - Via the Change Request Information page
- Requests must be in English
- Users may propose Term, SMQ and Translation change requests
- Immediate confirmation
- Ability to export change requests
- Ability to query CR history for requests back to v5.1

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MedDRA

Submitting Changes

- MedDRA ID and Change Request password
 - Term and SMQ changes to English MedDRA version
- MedDRA ID and password
 - Translation change requests
- Online change request submission tool guides user to enter all needed information
- User guide available within the "Support" section of the application or on the Change Request Information page

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MedDRA

Submitting Changes (cont)

- Sample entry for a new LLT in WebCR
- Justification and supporting documentation is important to help MSSO understand the need

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MedDRA

Proactive MedDRA Maintenance

- What is the proactive approach?
 - Corrections/improvements made internally by the MSSO
 - General changes suggested by users
- Submitting ideas
 - Send to MSSO Help Desk. Justification is helpful.
 - Example: Review placement of bruise and contusion terms to facilitate coding and analysis
- Evaluation of proposals
 - Final disposition is not time limited; MSSO may take time to review
 - Proactive approach does not replace usual CR process

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MedDRA Tools



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MSSO's MedDRA Browsers



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

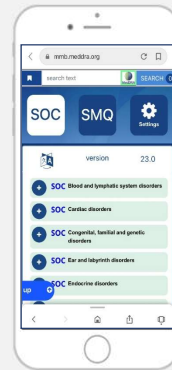
MedDRA Web-Based Browsers (WBB)

New WBB:

<https://wbb.meddra.org>

Legacy WBB:

<https://tools.meddra.org/wbb/>



Mobile MedDRA Browser
<https://mmb.meddra.org>

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MSSO's MedDRA Browsers - Features

- Each 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 (MDB and WBB only)



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MDB and WBB Special Features

- View primary and secondary link information
- Upload terms to run against SMQs
- Advanced search options (e.g., NOT, OR)
- Preview upcoming (supplemental) changes in next release*
- For more information:
 - Instructional videos: <https://www.meddra.org/instructional-videos>

**Supplemental view not available on MDB*

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MedDRA

New WBB Screenshot

MedDRA Version / Language 29.0 SOC SMQ

English myringosclerosis

Search Export

Total Search Results: 2

PT - 1 LLT - 1

Exact Match - 1

LLT Myringosclerosis

Lexical Variant - 0

Synonym - 0

Contains - 0

- HLGT Inner ear and VIIIth cranial nerve disorders
- HLGT Middle ear disorders (excl congenital)
- HLT Eustachian tube disorders
- HLT Mastoid disorders
- HLT Middle ear disorders NEC
- HLT Middle ear infections and inflammations
- HLT Tympanic membrane disorders (excl infections)
- PT Myringosclerosis
- LLT Myringosclerosis
- LLT Tympanic membrane scarring
- PT Tympanic membrane atrophic
- PT Tympanic membrane disorder
- PT Tympanic membrane hyperaemia
- PT Tympanic membrane perforation
- PT Tympanic membrane retraction
- PT Tympanosclerosis
- SOC Endocrine disorders

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MedDRA

Legacy WBB Screenshot

MedDRA browser B

Preferred Language English MedDRA Concept Occurrences English About Search History New Browser Window MedDRA Documentation User Guide Query Analysis Hierarchy Analysis Logout

Language and Version Options English English 29.0 Browser View SOC

Search Options

English Myringosclerosis

Use Synonym List

Ignore Diacritical Marks

Show PT/LLT with categories

Search Clear Search Cancel Advanced Search

Total Search Results: 2

Details: PT (1) LLT (1)

PT LLT

Exact Match - 1

LLT Myringosclerosis

Lexical Variant - 0

Synonym Search Results - 0

Contains Search Results - 0

Select SOC to Search (default is all SOC)

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

Clear Selection

Term Details in Primary Language

PT - Preferred Term

MedDRA Code	MedDRA Term	Primary SOC
10081592	Myringosclerosis	
10013993	Ear and labyrinth disorders	Y
10022117	Injury, poisoning and procedural complications	N

SMQ Code	SMQ Name	SMQ Status	Category	Weight	Additional Version	Last Modified Version
20000173	Hearing impairment (SMQ)	Harmon	Active	3	25.1	25.1

PT Occurrences in MedDRA

- Myringosclerosis
- Tympanic membrane disorders (excl infections)
- Middle ear disorders (excl congenital)
- Ear and labyrinth disorders
- Myringosclerosis
- Eye and ear procedural complications
- Procedural related injuries and complications NEC
- Injury, poisoning and procedural complications

PT Occurrences in SMQ

- Myringosclerosis
- Hearing impairment (SMQ)
- Hearing and vestibular disorders (SMQ)

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MedDRA Version Analysis Tool (MVAT)

- Web-based (<https://tools.meddra.org/mvat>)
- Free to all users
- Features
 - Version Report Generator:
Produces exportable report comparing any two versions
 - Data Impact Report:
Identifies changes to a specific set of MedDRA terms or codes uploaded to MVAT

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MedDRA Version Analysis Tool (MVAT) (cont)

- User interface and report output available in all MedDRA languages
- Ability to run reports on supplemental changes
- Option to run reports on secondary SOC changes
- Watch the two-part webinar on the use of MVAT under "Tools" tab on the "Training Materials" page of MedDRA website
<https://www.meddra.org/training-materials>

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MedDRA Version Analysis Tool (New WBB)

Version / Language 29.0
SMQ

Version Report
Version Data Impact
Hierarchy Analysis
SMQ Analysis

Close

Select Different Versions

1. Language: English

2. Starting Version: 28.1

3. Ending Version: 29.0

4. ☐ 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

Run Version Report
Clear Selection

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Legacy MedDRA Version Analysis Tool


MVAT
 MedDRA Version Analysis Tool

MW092114
 Tuesday, March 24, 2020 1:14 PM
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Version Report Description

Select Different Versions to Compare

Language: English

Starting Version: MedDRA 28.1 English

Ending Version: MedDRA 29.0 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

Run Version Report

Preferred Language
English
 Release/Supplemental View
Release

MVAT Home
 Search Term Change
 Data Input Report
 Logout

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MVAT Demonstration (Optional)

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Coding with MedDRA

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What are Coding Conventions?

- Written guides and sets of principles for using MedDRA that help achieve consistency in coding and data retrieval
- Conventions harmonize exchange of MedDRA coded data worldwide
- Common topics
 - Misspellings, abbreviations and acronyms
 - Combination terms and “due to” concepts
 - “Always query” terms, e.g., “Chest pain”

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Why Do We Need Coding Conventions?

- Differences in medical aptitude of coders
- Consistency concerns (many more “choices” in MedDRA versus older terminologies)
- Autoencoded data need human oversight and may still need manual coding



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MedDRA Support Documentation

- ICH provides a guidance document for MedDRA coding called the MedDRA Term Selection: Points to Consider (PtC) document

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

MedDRA® TERM SELECTION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users

Release X.XX

Month Year

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- Provides term selection advice for industry and regulatory purposes
- Objective is to promote accurate and consistent term selection to facilitate common understanding of shared data
- Recommended to be used as basis for individual organization's own coding conventions

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MedDRA Term Selection: PTC (cont)

- Developed by a working group of the ICH Management Committee
- Released annually in March
- Complete versions available in
 - English, Japanese, Brazilian Portuguese, Chinese, French, Korean, Spanish, and Russian
- Condensed versions available for other MedDRA languages*
- Available on MedDRA and JMO websites



*Arabic, Czech, Dutch, German, Hungarian, Italian, Portuguese

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MTS:PTC General Principle

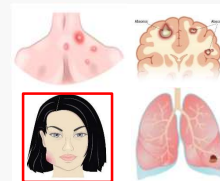


- Always Select a Lowest Level Term
Select Only Current LLTs

- ✓ Select the Lowest Level Term that **most accurately reflects the reported verbatim** information

"Abscess on face"

- Do not simply select LLT *Abscess*
- Select a term with greater specificity
LLT *Facial abscess*



- ✓ Select current LLTs only
 - Non-current terms for legacy conversion/historical purposes

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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

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Term Selection Points

Section 3

- 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 Infection
- Modification of Pre-existing Conditions
- Exposures During Pregnancy and Breast Feeding
- Congenital Terms
- Neoplasms
- Medical and Surgical Procedures
- Investigations

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Term Selection Points

Section 3

- 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

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MedDRA

PtC Documents

	PtC Document	Purpose	Languages	Release Cycle
Term Selection	MedDRA Term Selection: Points to Consider (MTS:PTC)	Promote accurate and consistent coding with MedDRA	English, Japanese, Brazilian Portuguese, Chinese, French, Korean, Russian and Spanish	Annual March release
	MTS:PTC Condensed Version	Shorter version focusing on general coding principles to promote accurate and consistent use of MedDRA worldwide	All MedDRA languages (except languages with full MTS:PTC document, and EEA languages*)	Update as needed
Data Retrieval and Presentation	MedDRA Data Retrieval and Presentation: PtC (DRP:PTC)	Demonstrate how data retrieval options impact the accuracy and consistency of data output	English, Japanese, Brazilian Portuguese, Chinese, French, Korean, Russian and Spanish	Annual March release
	DRP:PTC Condensed Version	Shorter version focusing on general retrieval and analysis principles to promote accurate and consistent use of MedDRA worldwide	All MedDRA languages (except languages with full DRP:PTC document, and EEA languages*)	Update as needed

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*The following languages do not have translations of PtC documents: Bulgarian, Croatian, Danish, Estonian, Finnish, Greek, Icelandic, Latvian, Lithuanian, Maltese, Norwegian, Polish, Romanian, Slovak, Slovenian, Swedish

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MedDRA

PtC Documents (cont)

	PtC Document	Purpose	Languages	Release Cycle
General	MedDRA Points to Consider Companion Document	• More detailed information, examples, and guidance on specific topics of regulatory importance • “Living” document with updates based on users’ needs • Data quality and medication errors (Release 1.0 and 1.1) • Product quality issues (Release 2.0 in October 2020) • Manufacturing and Quality System Issues and other updates (Release 3.0 in September 2024)	English and Japanese	Updated as needed

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MedDRA

Coding Demonstration with MedDRA Browser (Optional)

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Standardised MedDRA Queries (SMQs)

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Standardised MedDRA Queries (SMQs)

- Groupings of terms from one or more MedDRA SOC's 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

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MedDRA

MedDRA Term Inclusion

- SMQs are constructed at MedDRA PT level
- LLTs that are subordinate to an included PT are also included

System Organ Class (SOC)

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High Level Group Term (HLGT)

High Level Term (HLT)

Preferred Term (PT)

~ 27,000

Lowest Level Term (LLT)

~ 90,000

MedDRA Version 29.0

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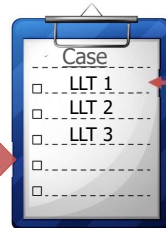
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MedDRA

What is a Query?

Clinical Trial Database
Safety Database



"Hit"

Query

SMQ

PT

LLT

LLT

LLT1

PT

LLT

LLT

LLT

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MedDRA

MedDRA DRP:PTC

MedDRA® DATA RETRIEVAL AND PRESENTATION: POINTS TO CONSIDER ICH-Endorsed Guide for MedDRA Users on Data Output

Release X.XX

Month Year

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- Provides data retrieval and presentation options for industry or regulatory purposes
- Demonstrates how data retrieval options impact the accuracy and consistency of data output
- 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

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MedDRA

SMQs in Production - Examples

As of Version 29.0, a total of 110 level 1 SMQs in production

- Agranulocytosis
- Anaphylactic reaction
- Central nervous system vascular disorders
- Convulsions
- Embolic and thrombotic events
- Hepatic disorders
- Hypersensitivity
- Ischaemic heart disease
- Lack of efficacy/effect
- Medication errors
- Osteonecrosis
- Peripheral neuropathy
- Pregnancy and neonatal topics
- Rhabdomyolysis/myopathy
- Severe cutaneous adverse reactions
- Shock

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MedDRA

SMQ Benefits and Limitations



• Benefits

- Application across multiple therapeutic areas
- Validated reusable search logic
- Standardized communication of safety information
- Consistent data retrieval
- Maintenance by MSSO/JMO



• Limitations

- Do not cover all medical topics or safety issues
- Will evolve and undergo further refinement in the production phase

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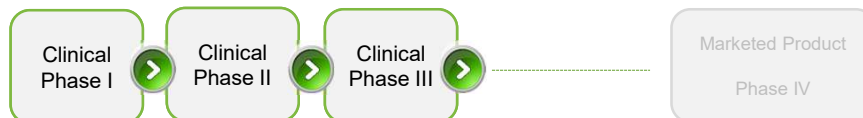
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SMQ Applications



• Clinical trials

- Where safety profile is not fully established, use multiple SMQs on routine basis as screening tool
- Selected SMQs to evaluate previously identified issue (pre-clinical data or class effect)

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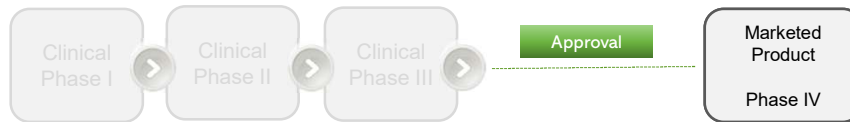
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SMQ Applications (cont)



- Post-marketing
 - Selected SMQs to retrieve cases for suspected or known safety issue
 - Signal detection (multiple SMQs employed)
 - Single case alerts
 - Periodic reporting (aggregate cases for safety and other issues, e.g., lack of efficacy)

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MedDRA

Summary

- ✓ Presented background information about MedDRA
- ✓ Reviewed MedDRA's scope, structure, and characteristics
- ✓ Described the maintenance of MedDRA
- ✓ Described MedDRA tools (browsers, MVAT)
- ✓ Discussed coding with MedDRA
- ✓ Discussed the MedDRA Points to Consider documents
- ✓ Described Standardised MedDRA Queries (SMQs)

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MedDRA

MSSO Contacts

- Website
 - www.meddra.org
- Email
 - mssohelp@meddra.org
- Frequently Asked Questions
 - www.meddra.org/faq

MedDRA Browsers

- Desktop –
 - <https://www.meddra.org/meddra-desktop-browsers>
- Web-Based
 - New WBB: <https://wbb.meddra.org>
 - Legacy WBB: <https://tools.meddra.org/wbb/>
- Mobile
 - <https://mmb.meddra.org>

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MSSO Contacts (cont)

- Change Request Submission
 - <https://www.meddra.org/how-to-use/change-requests>
- Training Schedule
 - <https://www.meddra.org/training/schedule>
- MedDRA Support Documentation
 - <https://www.meddra.org/how-to-use/support-documentation>

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Question and Answer Session

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**MedDRA**

Medical Dictionary
for Regulatory Activities

Thank you!



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