



Introduction to MedDRA

Anamika Dutta
Medical Officer, MedDRA MSSO
Pharmacovigilance for Medical Products (PvM)
Skill Development Programme-2019
Indian Pharmacopoeia Commission, Ghaziabad





MedDRA

What is Coding? Why code??





MedDRA

What do you see?





MedDRA

How many cases of Headache??

Head Pain

His head started paining after he woke up from sleep

Cephalgia

Headache recurrent

Hammering pain in Head

Pounding in head

Pain in Head

Hedache

Pain head

My temples are hurting

Dull Headache

Headache

Throbbing pain in head





What Happens when we code?

- A standard code is assigned to each verbatim
- 8 digit MedDRA code gets assigned to the verbatim term

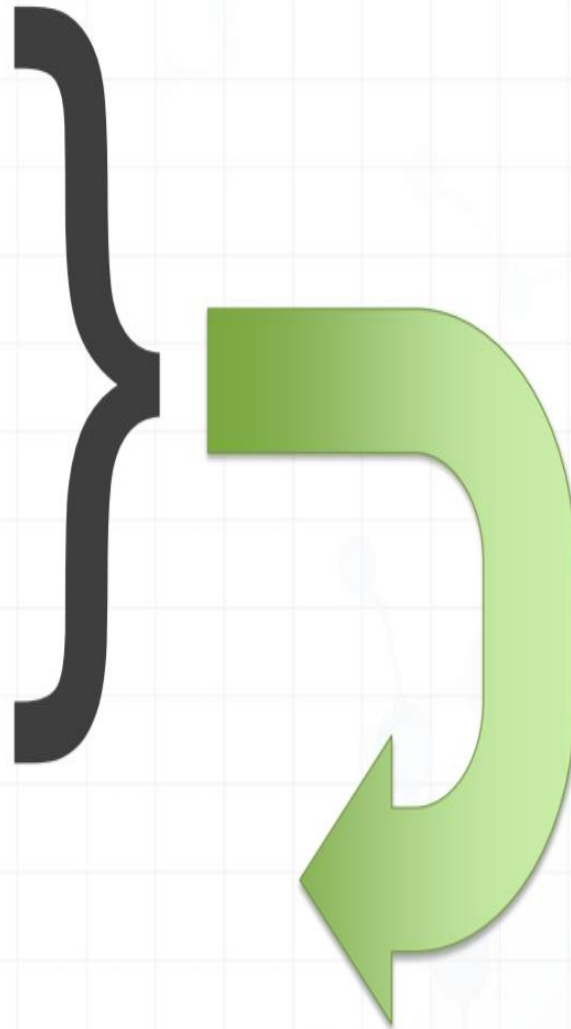
Verbatim text	Low Level Term (LLT)	LLTCode	Preferred Term (PT)	PTCode	System Organ Class (SOC)	SOC Code
Pain in eye	Pain in eyes	10033426	Eye pain	10015958	Eye disorders	10015919
Sore eyes	Sore eyes	10041357	Eye pain	10015958	Eye disorders	10015919
Pyrexia	Pyrexia	10037660	Pyrexia	10037660	General disorders and administration site conditions	10018065
Spiking temperature	Spiking temperature	10041523	Pyrexia	10037661	General disorders and administration site conditions	10018066
Suffering from Fever	Fever	10016558	Pyrexia	10037662	General disorders and administration site conditions	10018067



MedDRA

Importance of “Coding”

- ▶ Accuracy
 - ▶ Consistency
 - ▶ Transparency
 - ▶ Standardisation
 - ▶ Analysis
 - ▶ Evaluation
-
- ▶ Patient Safety



MedDRA





MedDRA

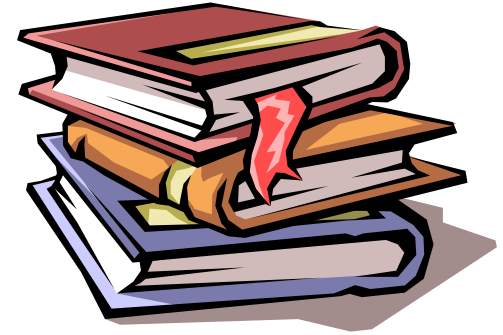
What is MedDRA?

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

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

Why MedDRA?

ICH initiative (M1)

- An international terminology for coding of medical information throughout the regulatory cycle (clinical trials Phase I-IV and post-marketing)
- Enables standardized communication of coded data between regulators and manufacturers/sponsors
 - Example: MedDRA used is a standard terminology in electronic transmission of Individual Case Safety Reports (ICSRs) following ICH E2B standards
 - Use of MedDRA in Vigibase [WHO global database of individual case safety reports (ICSRs)]
 - SDTM is one of the required standards for data submission to FDA (U.S.) and PMDA (Japan)



MedDRA

Why MedDRA?

- Enables medical accuracy and transparency in coding, since many and specific MedDRA terms
- MedDRA Hierarchy and other concept groupings (such as SMQs) allow for useful data retrieval and presentation
- Global ICH-endorsed guides for coding and data retrieval (ICH Points to Consider documents)
- Global version synchronization



MedDRA

MedDRA and the MSSO

- International support and development of terminology
- Foster use of MedDRA through communications and educational offerings
- “Custodians”, not owners, of the terminology
- JMO (partner organization for Japanese-language MedDRA)
- Governed by a Management Committee (industry, regulators, multi-national, other interested parties)



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

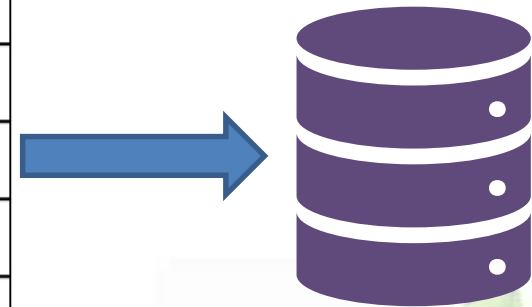


Where MedDRA is Used (Contd)

Individual Case Safety Reports (ICSRs) - ICH E2B (R3) Data Elements in MedDRA

Element id	Element Name
D.7.1.r.1b	Medical History (disease / surgical procedure / etc.) (MedDRA code)
D.8.r.6b	Indication (MedDRA code)
D.8.r.7b	Reaction (MedDRA code)
D.9.2.r.1b	Reported Cause(s) of Death (MedDRA code)
D.9.4.r.1b	Autopsy-determined Cause(s) of Death (MedDRA code)
D.10.7.1.r.1b	Medical History (disease / surgical procedure / etc.) (MedDRA code)
D.10.8.r.6b	Indication (MedDRA code)
D.10.8.r.7b	Reactions (MedDRA code)
E.i.2.1b	Reactions / Event (MedDRA code)
F.r.2.2b	Test Name (MedDRA code)
G.k.7.r.2b	Indication (MedDRA code)
H.3.r.1b	Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event (MedDRA code)

Regulator Database





Where MedDRA is Used (Contd)

- Regulatory Safety Databases Coded in MedDRA (examples)
 - US FDA
 - FAERS: drugs and biologics
 - VAERS: vaccines
 - CAERS: foods, dietary supplements, cosmetics
 - EMA
 - EudraVigilance Database
 - Health Canada
 - Canada Vigilance Database
 - MHLW/PMDA
 - Safety database



MedDRA

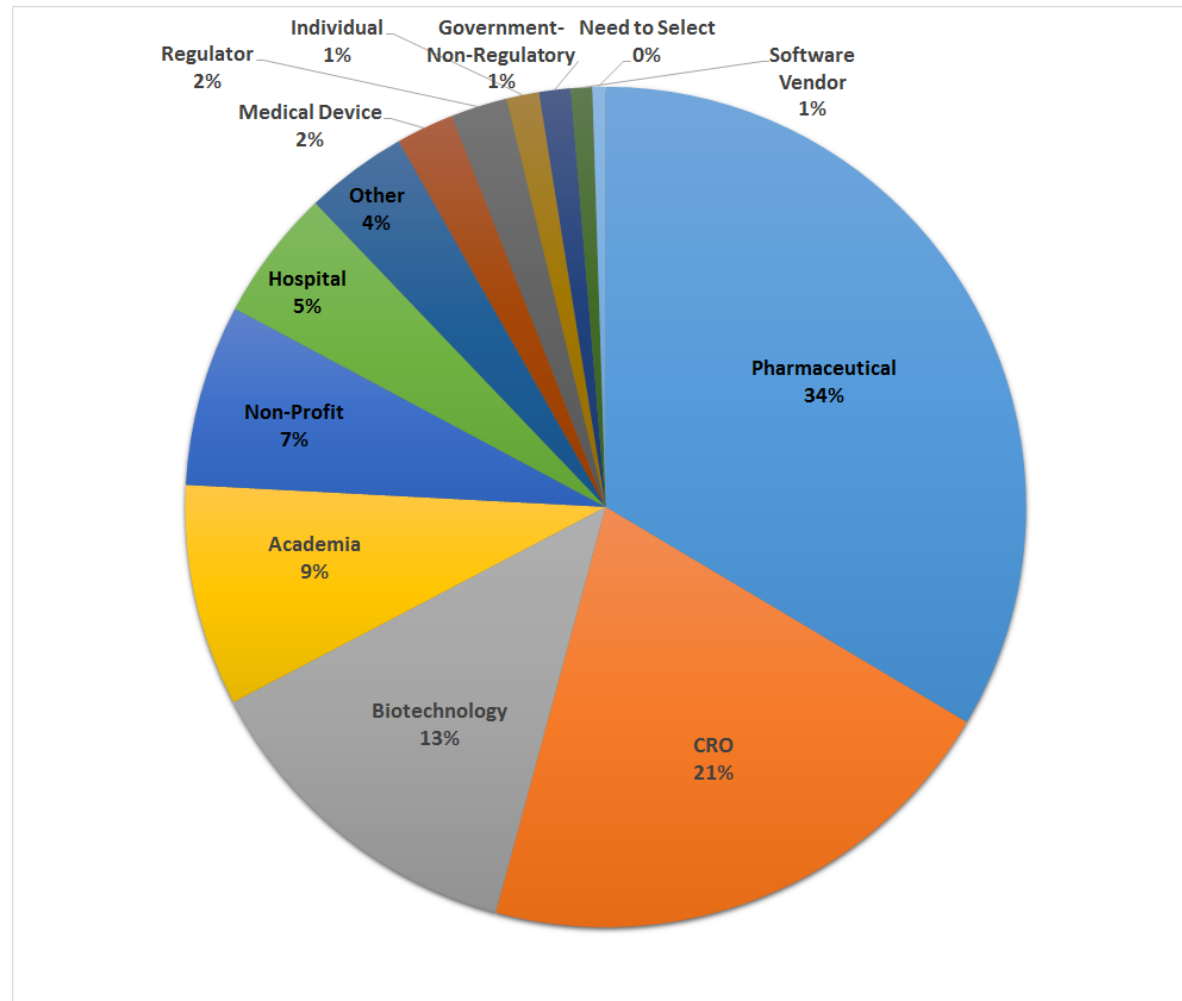
Where MedDRA is Used (Contd)

- e-Marketing Applications – ICH eCTD, for example
 - US FDA
 - NDAs: New Drug Applications, including Integrated Summary of Safety (ISS) – adverse event dataset
 - ANDAs: Abbreviated New Drug Applications
 - INDs: Investigational New Drugs
 - BLAs: Biologics License Applications
 - EMA
 - MAAs: Marketing Authorisation Applications
 - Health Canada
 - New Drug Submissions (NDSs)
 - MHLW/PMDA
 - NDAs: New Drug Applications



MedDRA Users Profile

- As of March 2019
 - 5,800 Subscribing organizations (MSSO+JMO)
 - 125 Countries
- Graph shows types of subscribing organizations





MedDRA

MedDRA Data Sharing

- Subscription grants access to MedDRA for one year
- Subscriber cannot grant any sublicense, publish or otherwise distribute MedDRA to a third party
- Data may be freely exchanged between current MedDRA subscribers
 - Sponsor-sponsor, sponsor-CRO, vendor-user, etc.
 - Use Self-Service Application to check organization's subscription status
- Sharing MedDRA with a non-subscribing organization is a violation of the MedDRA license



2019 MedDRA Subscription Rate Table

MedDRA Subscription Types	2019 Annual Subscription Rates
Regulatory Authority	\$0 USD
Non-Commercial / Non-Profit	\$0 USD
Commercial (Parent Company Annual Revenue or Turnover)	
Level 0 (Annual Revenue < \$1 Million)	\$154 USD
Level 1 (Annual Revenue \$1-\$10 Million)	\$654 USD
Level 2 (Annual Revenue \$10-\$20 Million)	\$2,496 USD
Level 3 (Annual Revenue \$20-\$500 Million)	\$4,727 USD
Level 4 (Annual Revenue \$500 Million-\$1 Billion)	\$9,918 USD
Level 5 (Annual Revenue \$1-\$5 Billion)	\$41,150 USD
Level 6 (Annual Revenue \$5-\$20 Billion)	\$54,334 USD
Level 7 (Annual Revenue > \$20 Billion)	\$70,889 USD
System Developer	\$2,556 USD

77% of all MedDRA users pay no fee or \$654 (or less)



Online Subscription / Subscription / Home

Organisation	<i>Organisation Name:</i> * <input type="text"/>	<i>Organisation Type:</i> * <input type="text" value="Select a type"/>
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Subscription Type *	<p><input type="radio"/> 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.</p> <p><input type="radio"/> Non-Profit / Non-Commercial Subscription reserved for non-profit medical libraries, educational institutions, and direct patient care providers, i.e., hospitals for educational use or as a reference tool.</p> <p><input type="radio"/> Commercial Subscription for organisations that use MedDRA for commercial purposes. This includes biopharmaceutical companies and support service providers (e.g., CROs). Please provide a link to your company's financial information or attach a signed statement on your company's letterhead with your company's total revenue in PDF format.</p> <p><input type="radio"/> 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.</p>
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Contact Information	Main point of contact	
	<i>First Name:</i> *	<i>Last Name:</i> *
	<input type="text"/>	<input type="text"/>
	<i>Street, No:</i> *	<i>City:</i> *
	<input type="text"/>	<input type="text"/>
	<i>Province/State:</i> *	<i>Postal/Zip Code:</i>
	<input type="text"/>	<input type="text"/>
	<i>Country:</i> *	<i>Phone:</i> *
	<input type="text"/>	<input type="text"/>



MedDRA

Scope of MedDRA

OUT
IN

Not a drug
dictionary

Frequency
qualifiers

Patient demographic
terms

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

Numerical values for
results

Clinical trial study
design terms

Severity descriptors

Not an equipment, device,
diagnostic product dictionary



MedDRA

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)



MedDRA Structure (Cont)

SOC = Cardiac disorders

HLGT = Cardiac arrhythmias

HLT = Rate and rhythm disorders NEC

PT = Arrhythmia

LLT
Arrhythmia
NOS

LLT
Arrhythmia

LLT (Non-current)
Other specified cardiac
dysrhythmias

LLT
Dysrhythmias



MedDRA

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



MedDRA Codes

- Each MedDRA term assigned an 8-digit numeric code starting with "1"
- The code is non-expressive
- Codes can fulfill a data field in various electronic submission types (e.g., E2B)
- New terms are assigned sequentially



MedDRA

Codes and Languages



A Multi-Axial Terminology (cont)

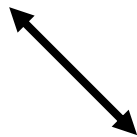
SOC = Respiratory, thoracic and
mediastinal disorders
(Secondary SOC)



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





MedDRA

ICH MedDRA Coding Guide

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



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

- Detailed coding instructions**

SECTION 2 – GENERAL TERM SELECTION PRINCIPLES			
2.1 Quality of Source Data	3.10.2 Events in the child or foetus	3.18.1 Overdose reported with clinical consequences	
2.2 Quality Assurance	3.11 Congenital Terms	3.18.2 Overdose reported without clinical consequences	
2.3 Do Not Alter MedDRA	3.11.1 Congenital conditions	3.19 Device-related Terms	
2.4 Always Select a Lowest Level Term	3.11.2 Acquired conditions (not present at birth)	3.19.1 Device-related event reported with clinical consequences	
2.5 Select Only Current Lowest Level Terms	3.11.3 Conditions not specified as either congenital or acquired	3.19.2 Device-related event reported without clinical consequences	
2.6 When to Request a Term	3.12 Neoplasms	3.20 Drug Interactions	
2.7 Use of Medical Judgment in Term Selection	3.12.1 Do not infer malignancy	3.20.1 Reporter specifically states an interaction	
2.8 Selecting More than One Term	3.13 Medical and Surgical Procedures	3.20.2 Reporter does not specifically state an interaction	
2.9 Check the Hierarchy	3.13.1 Only the procedure is reported	3.21 No Adverse Effect and "Normal" Terms	
2.10 Select Terms for All Reported Information, Do Not Add Information	3.13.2 Procedure and diagnosis are reported	3.21.1 No adverse effect	
SECTION 3 – TERM SELECTION POINTS			
3.1 Definitive and Provisional Diagnoses with or without Signs and Symptoms	3.14 Investigations	3.21.2 Use of "normal" terms	
3.2 Death and Other Patient Outcomes	3.14.1 Results of investigations as ARs/AEs	3.22 Unexpected Therapeutic Effect	
3.2.1 Death with ARs/AEs	3.14.2 Investigation results consistent with diagnosis	3.23 Modification of Effect	
3.2.2 Death as the only reported information	3.14.3 Investigation results not consistent with diagnosis	3.23.1 Lack of effect	
3.2.3 Death terms that add important clinical information	3.14.4 Grouped investigation result terms	3.23.2 Do not infer lack of effect	
3.2.4 Other patient outcomes (non-fatal)	3.14.5 Investigation terms without qualifiers	3.23.3 Increased, decreased and prolonged effect	
3.3 Suicide and Self-Harm	3.15 Medication Errors, Accidental Exposures and Occupational Exposures	3.24 Social Circumstances	
3.3.1 If overdose is reported	3.15.1 Medication errors	3.24.1 Use of terms in this SOC	
3.3.2 If self-injury is reported	3.15.2 Accidental exposures and occupational exposures	3.24.2 Illegal acts of crime or abuse	
3.3.3 Fatal suicide attempt	3.16 Misuse, Abuse and Addiction	3.25 Medical and Social History	
3.4 Conflicting/Ambiguous/Vague Information	3.16.1 Misuse	3.26 Indication for Product Use	
3.4.1 Conflicting information	3.16.2 Abuse	3.26.1 Medical conditions	
3.4.2 Ambiguous information	3.16.3 Addiction	3.26.2 Complex indications	
3.4.3 Vague information	3.16.4 Drug diversion	3.26.3 Indications with genetic markers or abnormalities	
3.5 Combination Terms	3.17 Transmission of Infectious Agent via Product	3.26.4 Prevention and prophylaxis	
3.5.1 Diagnosis and sign/symptom	3.18 Overdose, Toxicity and Poisoning	3.26.5 Procedures and diagnostic tests as indications	
3.5.2 One reported condition is more specific than the other		3.26.6 Supplementation and replacement therapies	
3.5.3 A MedDRA combination term is available		3.26.7 Indication not reported	
3.5.4 When to "split" into more than one MedDRA term		3.27 Off Label Use	
3.5.5 Event reported with pre-existing condition		3.27.1 Off label use when reported as an indication	
3.6 Age vs. Event Specificity		3.27.2 Off label use when reported with an AR/AE	
3.6.1 MedDRA term includes age and event information		3.28 Product Quality Issues	
3.6.2 No available MedDRA term includes both age and event information		3.28.1 Product quality issue reported with clinical consequences	
3.7 Body Site vs. Event Specificity		3.28.2 Product quality issue reported without clinical consequences	
3.7.1 MedDRA term includes body site and event information		3.28.3 Product quality issue vs. medication error	
3.7.2 No available MedDRA term includes both body site and event information		SECTION 4 – APPENDIX	
3.7.3 Event occurring at multiple body sites		4.1 Versioning	
3.8 Location-Specific vs. Microorganism-Specific Infection		4.1.1 Versioning methodologies	
3.8.1 MedDRA term includes microorganism and anatomic location		4.1.2 Timing of version implementation	
3.8.2 No available MedDRA term includes both microorganism and anatomic location		4.2 Links and References	
3.9 Modification of Pre-existing Conditions			
3.10 Exposures during Pregnancy and Breast Feeding			
3.10.1 Events in the mother			



What are Coding Conventions?

Written guidelines for coding with MedDRA in your organization

Support accuracy and consistency

Common topics

- Misspellings, abbreviations and acronyms
- Combination terms and “due to” concepts
- “Always query” terms, e.g., “Chest pain”

Should be consistent with the MedDRA Term Selection: Points to Consider document



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

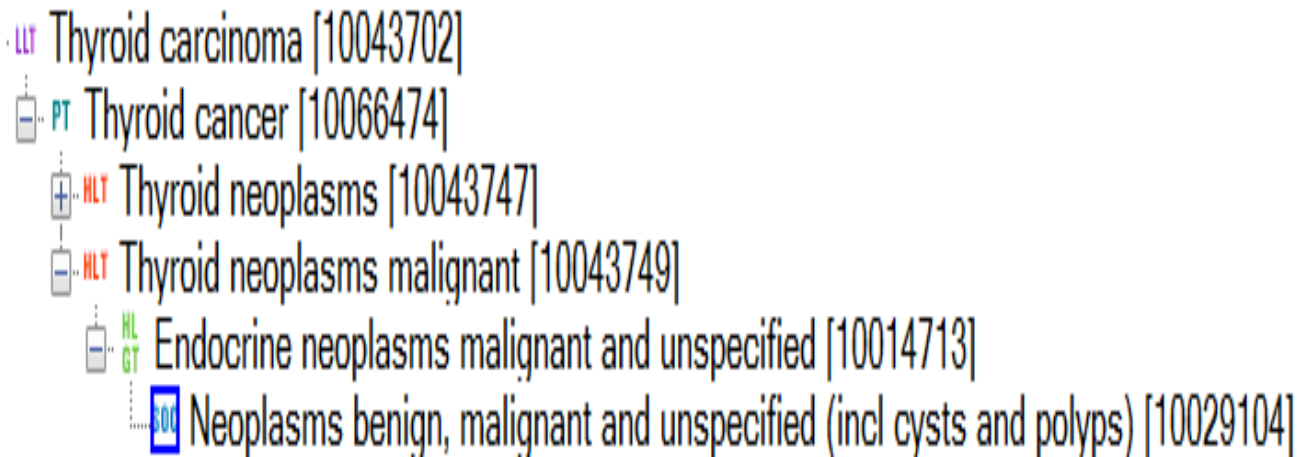


- Lowest Level Term that most accurately reflects the reported verbatim information should be selected
- Degree of specificity may be challenging
 - Example: "*Abscess on face*" → select "*Facial abscess*," not simply "*Abscess*"
- Select current LLTs only
 - Non-current terms for legacy conversion/historical purposes
- If no exact match in MedDRA, use medical judgment to match to an existing term that adequately represents the concept
- Avoid company-specific "work-arounds" for MedDRA deficiencies, submit change request to MSSO



How to code with MedDRA? Example:

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





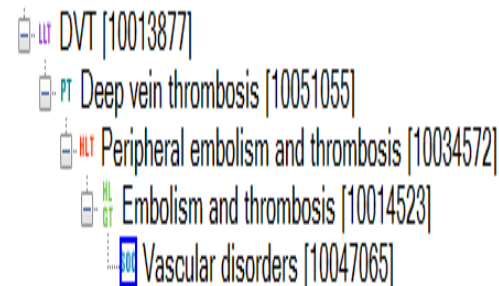
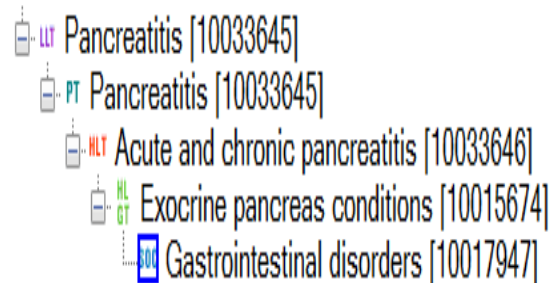
How to code with MedDRA? Example:

- 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





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.



MedDRA

How to code with MedDRA?

- Gastric Boating





What Terms to Select?

- Sepsis leading to shock from possible spontaneous bacterial peritonitis or bowel perforation

Sepsis

Shock

Septic shock

Spontaneous bacterial peritonitis

Bowel perforation



What Terms to Select?

- Hypoglycemia (blood glucose = 200 mg/dL)

Blood glucose abnormal

Blood glucose increased

Hypoglycemia





What Terms to Select?

- **Clinical complication of IUD**

IUD complication (PT Complication associated with device)

Intra-uterine death (PT Foetal death)

Unevaluatable event





What Terms to Select?

- Retinal disease from HIV with near total blindness (R and L)

Retinal damage

Retinal disorder

HIV disease

Blindness

HIV retinopathy

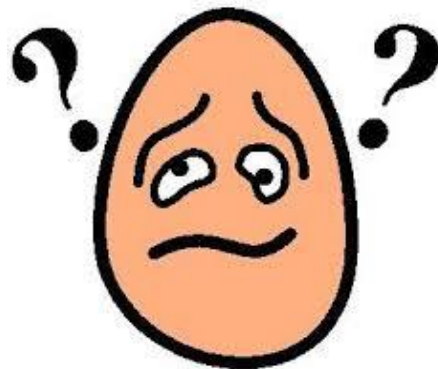
Blindness, both eyes





What Terms to Select?

- **MI**
Myocardial infarction ?
Mitral incompetence ?
Mental Illness ?





MedDRA

What Terms to Select?

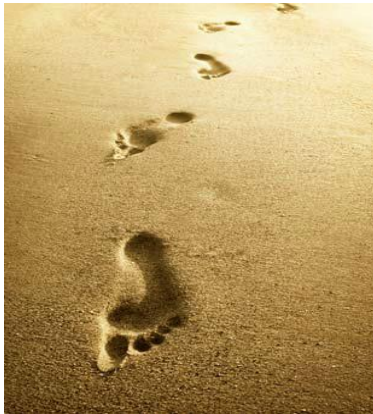
“Husband had his uterus scrapped and frozen”





What Terms to Select?

- Patient attempted to commit suicide by walking into the sea; unfortunately, he could swim

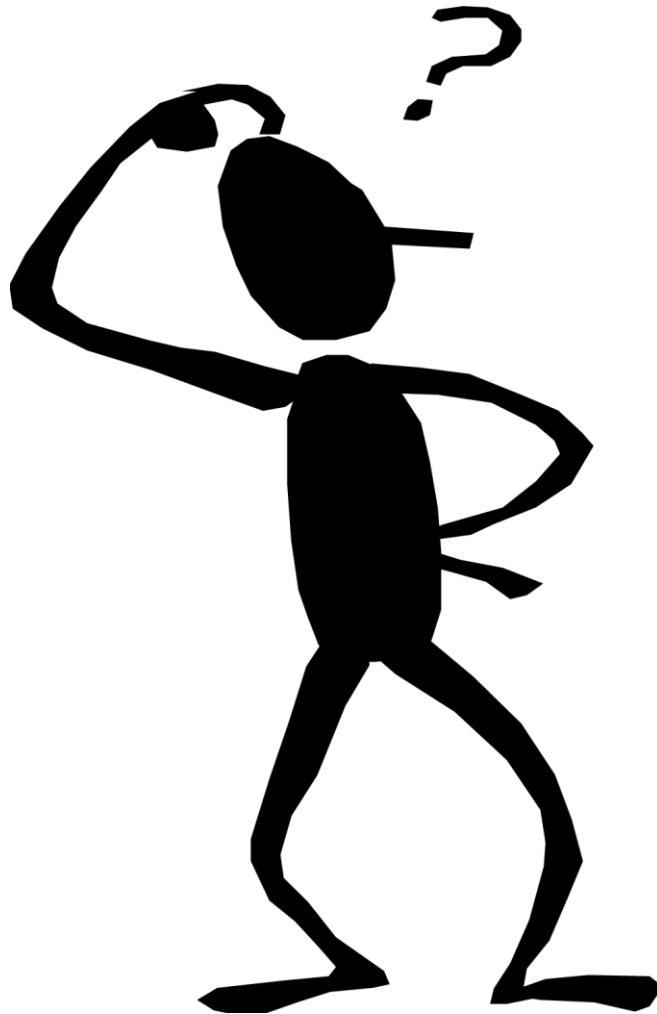


Attempted suicide



MedDRA

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 HLGTT 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

MedDRA Data Retrieval and Presentation: Points to Consider

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

Release 3.17
Based on MedDRA Version 22.0

1 March 2019

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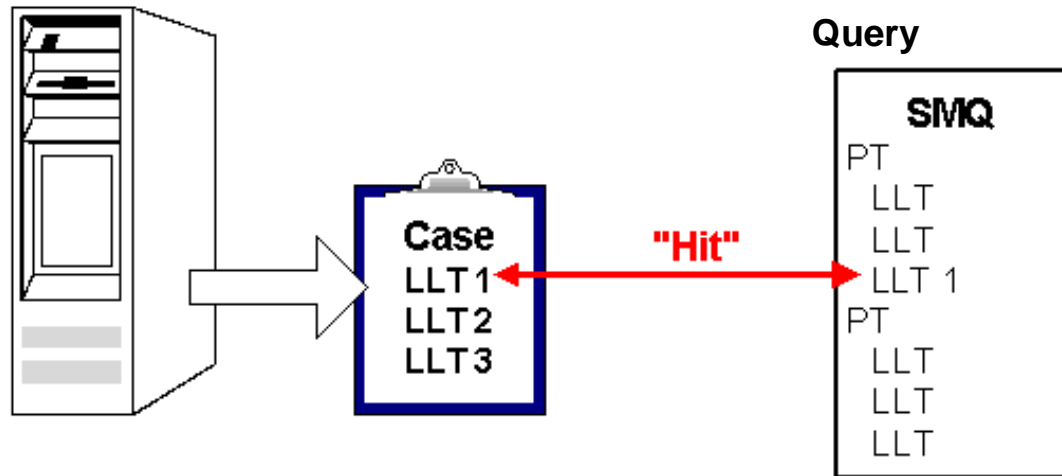
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- Provides data retrieval and presentation options for industry or regulatory purposes
- Recommended to be used as basis for individual organization's own data retrieval conventions
- Most effective when used in conjunction with MedDRA Term Selection: PTC document



What is a Query?

Clinical Trial Database
Safety Database





Standardised MedDRA Queries (SMQs)

- Tools developed to facilitate retrieval of MedDRA-coded
- Collaboration between CIOMS (Council for International Organizations of Medical Sciences) and ICH (MSSO)
- 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
- Broad/narrow scope
- Hierarchical SMQs
- Algorithmic SMQs



MedDRA

SMQ in Production - Examples

- As of Version 22.0, a total of 104 level 1 SMQs in production
 - Agranulocytosis
 - Anaphylactic reaction
 - Cerebrovascular disorders
 - Convulsions
 - 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
 - Systemic lupus erythematosus



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)

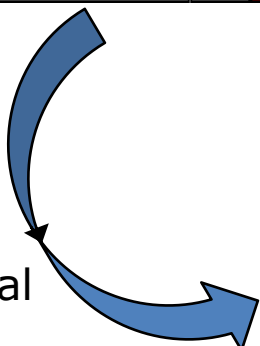
- **Post –marketing**

- 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)



EMA: Signal of Lactic Acidosis - PT vs. SMQ

Active Substances	SOCs	HLGTs	HLTs	SMQ Broad	SMQ Narrow	PTs	Tot EV	PRR (-)
Drug A	Metab	Acid-Base Disorders	Metabolic Acidoses (Excl Diabetic Acidoses)	Hyperglyc/New Onset Diab. mell -- Lactic Acidosis	Lactic Acidosis	Lactic Acidosis	63	13.74



Broad search of SMQ identifies additional ICSRs with related **signs** and symptoms where no specific diagnosis is made. These would be missed if search only conducted with PT *Lactic acidosis*.

SMQ *Lactic acidosis* (Broad search)

PT	Cases
Acidosis	2
Anion gap increased	1
Blood bicarbonate abnormal	1
Blood bicarbonate decreased	6
Blood gases abnormal	1
Blood lactic acid increased	27
Hyperlactacidaemia	22
Lactic acidosis	63
Metabolic acidosis	18
PCO2 decreased	1



Use of SMQs at FDA – Reviewing Prescribing Information

- Proposed Prescribing Information:
- Warnings & Precautions:
 - Dizziness/Somnolence
 - Withdrawal of Antiepileptic Drugs
 - Suicidal Behavior and Ideation (class labeling)

SMQ (Narrow Search)	RR
(1) Hostility/aggression	4.4
(2) Vestibular disorders	4.258
(1) Hearing and vestibular disorders	4.088
(1) Hyponatraemia/SIADH	3.832
(2) Hearing impairment	3.832
(1) Dyslipidaemia *	2.555
(1) Biliary disorders	2.135
(2) Functional, inflammatory and gallstone related biliary disorders	2.135

- Final Prescribing Information
- **Boxed Warning:**
 - **Serious Psychiatric and Behavioral Reactions**
- Warnings & Precautions:
 - Falls
 - Dizziness & somnolence
 - Withdrawal of Antiepileptic Drugs
 - Suicidal Behavior and Ideation (class labeling)



Required Skills?



➤ Coding

- Logical approach
- Ability to apply rules
- Clinical knowledge
- Research skills
- Language abilities
- Good memory
- Desire to understand
- Attention to detail
- Ability to explain to others

➤ Analysis

- Clinical knowledge
- Desire to understand
- Patience
- Lateral thinking
- Willingness to explore data
- Ability to remain unbiased





MedDRA

Who uses MedDRA?

- Coder – Codes Clinical Trials and Pharmacovigilance data
- Drug Safety Associate – Enters cases for monitoring & reporting
- Clinical Scientist – Evaluates & analyses clinical trial data
- Drug Safety Physician – Performs periodic reporting & signal detection
- Others
 - Investigator site staff
 - CRA/Monitor
 - Data Manager
 - Statistician
 - Quality & documentation
 - Software designer
 - Database programmer





MedDRA

Know more?

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The screenshot shows the MedDRA website homepage. At the top left is the MedDRA logo and the text "Medical Dictionary for Regulatory Activities". To the right are navigation links: WBB, PtC, Contact, FAQs, Downloads. Below this is a search bar and a row of menu items: Home, About MedDRA, How to Use, Training, Subscription, News & Events, RSS, and a plus sign. The main content area is divided into several sections:

- Welcome to MedDRA**: A paragraph explaining the history of MedDRA, developed in the late 1990s by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).
- Multilingual Access**: A list of languages including Chinese, Czech, Dutch, English, French, German, Hungarian, Italian, Japanese, Portuguese, Russian, and Spanish.
- Discover MedDRA**: A banner for "MedDRA Access How to subscribe" with a "Learn more" button and a green checkmark icon.
- MedDRA Training**: A section header at the bottom left.
- Help to Shape the MedDRA Terminology**: A call to action to submit change requests, accompanied by a green pen icon.
- Recent News**: A list of news items, including "Register for the MedDRA & UMC WHODrug User Group Meeting" (16 August 2019) and "MedDRA v22.1 will be" (15 August 2019).





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Medical Dictionary
for Regulatory Activities

Thank You!!

- anamika.dutta@meddra.org
- mssohelp@meddra.org

