



Role of MedDRA in Pharmacovigilance

Dr Anamika Dutta
Medical Officer, MedDRA MSSO

Disclaimer and Copyright Notice



- This presentation is protected by copyright and may, with the exception of the MedDRA and ICH logos, be used, reproduced, incorporated into other works, adapted, modified, translated or distributed under a public license provided that ICH's copyright in the presentation is acknowledged at all times. In case of any adaption, modification or translation of the presentation, reasonable steps must be taken to clearly label, demarcate or otherwise identify that changes were made to or based on the original presentation. Any impression that the adaption, modification or translation of the original presentation is endorsed or sponsored by the ICH must be avoided.
- The presentation is provided "as is" without warranty of any kind. In no event shall the ICH or the authors of the original presentation be liable for any claim, damages or other liability arising from the use of the presentation.
- The above-mentioned permissions do not apply to content supplied by third parties. Therefore, for documents where the copyright vests in a third party, permission for reproduction must be obtained from this copyright holder.



MedDRA

Why code the data?

Unstructured Data



- Free format, no defined format
- Little or not at all organized
- Requires advanced techniques for analysis, e.g. NLP

Structured Data



- Predefined, rigid format
- Highly organized
- Easy analysis



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.



MSSO

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



Governance

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



Educational offerings

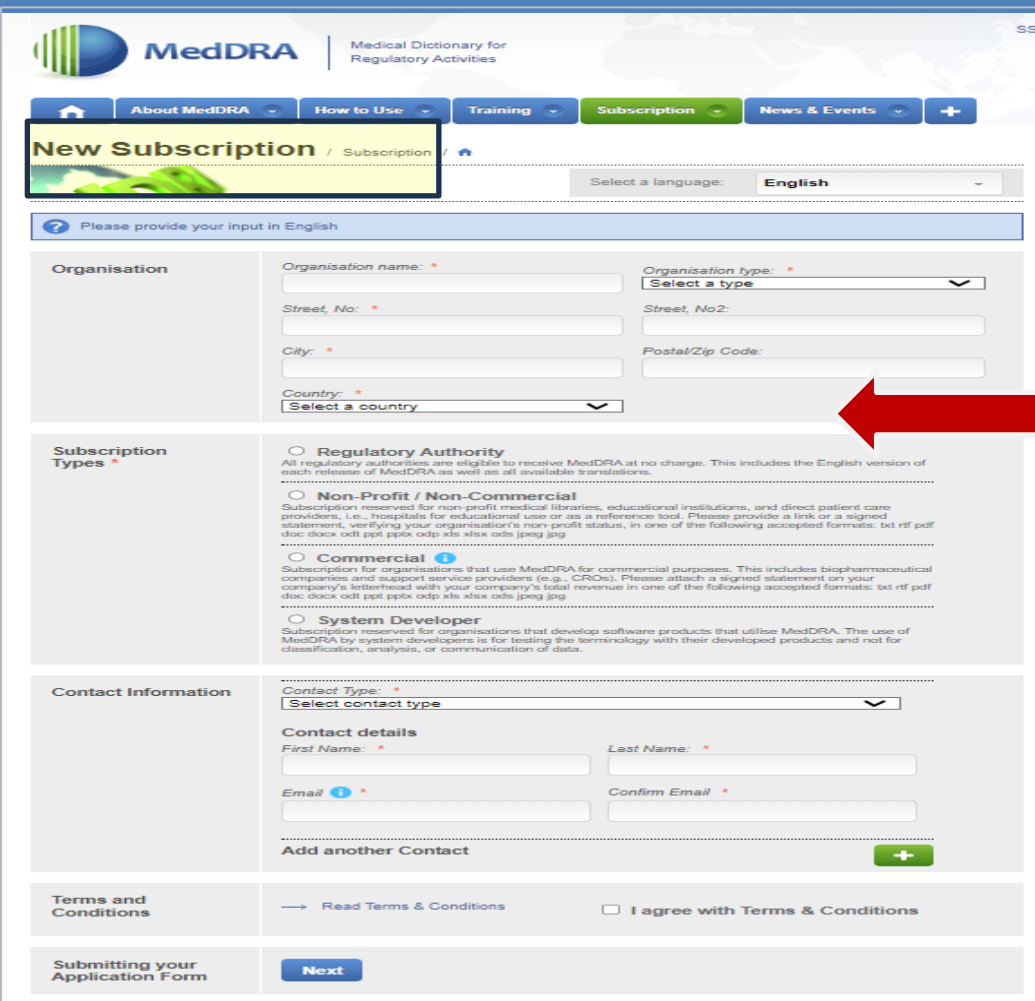
Foster use of MedDRA through communications and educational offerings



JMO

Partner organization for Japanese-language MedDRA

How to subscribe?



New Subscription / Subscription /

Select a language: **English**

Please provide your input in English

Organisation

Organisation name: *
 Organisation type: *
 Street, No: *
 Street, No2:
 City: *
 Postal/Zip Code:
 Country: *
 Select a country

Subscription Types *

☐ **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.

☐ **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. Please provide a link or a signed statement, verifying your organisation's non-profit status, in one of the following accepted formats: txt rtf pdf doc docx odt ppt ppox odp xls xlsx ods jpeg jpg

☐ **Commercial** ⓘ
 Subscription for organisations that use MedDRA for commercial purposes. This includes biopharmaceutical companies and support service providers (e.g., CROs). Please attach a signed statement on your company's letterhead with your company's total revenue in one of the following accepted formats: txt rtf pdf doc docx odt ppt ppox odp xls xlsx ods jpeg jpg

☐ **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

Contact Type: *
 Select contact type

Contact details

First Name: *
 Last Name: *
 Email ⓘ *
 Confirm Email *

Add another Contact

Terms and Conditions

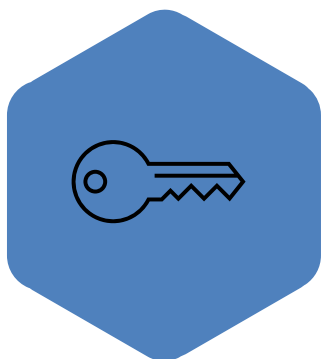
→ Read Terms & Conditions ☐ I agree with Terms & Conditions

Submitting your Application Form

Next

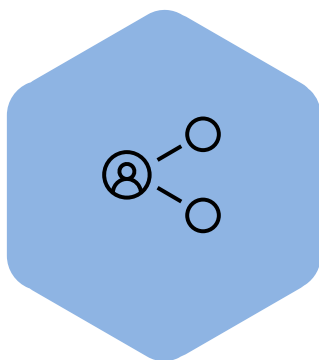
To subscribe to MedDRA, complete the online "New Subscription" form on the MedDRA website

MedDRA Data Sharing



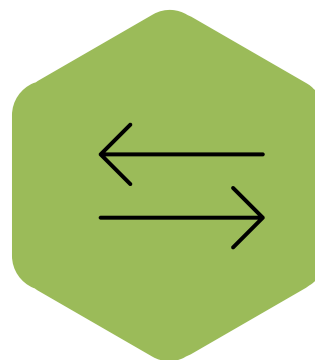
Access

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



Why MedDRA?



E2A - E2F Pharmacovigilance

- > E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
- > E2B(R3) Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (ICSRs)
- > E2B(R3) Q&As Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports
- > E2B(R3) EWG/IWG Electronic Transmission of Individual Case Safety Reports (ICSRs)
- > E2C(R2) Periodic Benefit-Risk Evaluation Report
- > E2C(R2) Q&As Questions & Answers: Periodic Benefit-Risk Evaluation Report
- > E2D Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting
- > E2D(R1) EWG Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports
- > E2E Pharmacovigilance Planning
- > E2F Development Safety Update Report

M1 MedDRA Terminology

- > M1 MedDRA - Medical Dictionary for Regulatory Activities
- > M1 PTC WG MedDRA Points to Consider

E2B (R3) data elements and 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)

Why MedDRA?



Pharmacovigilance Guidance Document

for

Marketing Authorization Holders of Pharmaceutical Products



Published by:

National Coordination Centre-Pharmacovigilance Programme of India
Indian Pharmacopoeia Commission in collaboration with Central Drugs
Standard Control Organization, Ministry of Health & Family Welfare,
Government of India

- (i) **Recovered/resolved:** If, the patient recovered/resolved from the adverse event.
- (ii) **Not recovered/not resolved:** If, the patient did not recover/resolve from the Adverse Event.
- (iii) **Recovering/resolving:** If, the patient is recovering/resolving from the Adverse Event.
- (iv) **Fatal:** If the patient died.
- (v) **Recovered/resolved with sequelae:** If, the patient has completely recovered from the adverse event (mention the date of recovery) with sequelae (e.g., scar).
- (vi) **Unknown:** If, the outcome is not known.

2.5.4 An identifiable reporter (source)

2.5.4.1 Name & address: A reporter must mention his/her name, address and contact details. The identity of the reporter will be maintained confidential.

2.5.4.2 Date of report: Mention the date on which he/she reported the Adverse Events.

2.5.4.3 Reporter qualification: Qualification of the reporter needs to be mentioned.

2.6 Coding of Adverse Event & Indication

For the purpose of ICSR reporting (expedited and periodic) to National Regulatory Authority/NCC-PvPI, IPC, MAHs are required to code Adverse Events, Indication preferably using latest version of MedDRA.

CHAPTER - 2

21

What is new in this document?

- This guidance document is updated in the light of New Drugs and Clinical Trials Rules, 2019 and revised Schedule M of Drugs and Cosmetics Rules, 1945.
- The terminology for PVOI is replaced with PVOIC.
- The "Module" is replaced with "Chapter"
- Definition of New Drug is updated in accordance with NDCT Rules, 2019
- The Marketing Authorization Holders should maintain records in Excel/Electronic sheets.
- All Non-Serious Adverse Events should be reported by MAHs within 90 calendar days.
- The International Classification of Diseases (ICD) is replaced with MedDRA dictionary for coding of "Indication" during entry of Individual Case Safety Reports (ICSRs).

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



MedDRA

Multilingual MedDRA

صداع

Arabic

Cefaleia

Brazilian Portuguese

главоболие

Bulgarian

头痛

Chinese

Glavobolja

Croatian

Bolest hlavy
Czech

Hovedpine
Danish

Hoofdpijn
Dutch

Headache
English

Peavalu
Estonian

Päänsärky
Finnish

Céphalée
French



Kopfschmerzen
German

Κεφαλαλγία
Greek

Fejfájás
Hungarian

Höfuðverkur
Icelandic

Cefalea
Italian

頭痛
Japanese

두통
Korean

Galvassāpes
Latvian

10019211

Galvos skausmas
Lithuanian

Ugigh ta' ras
Maltese

Hodepine
Norwegian

Ból głowy
Polish

Cefaleia
Portuguese

Durere de cap
Romanian

Головная боль
Russian

Bolest' hlavy
Slovak

Glavobol
Slovenian

Cefalea
Spanish

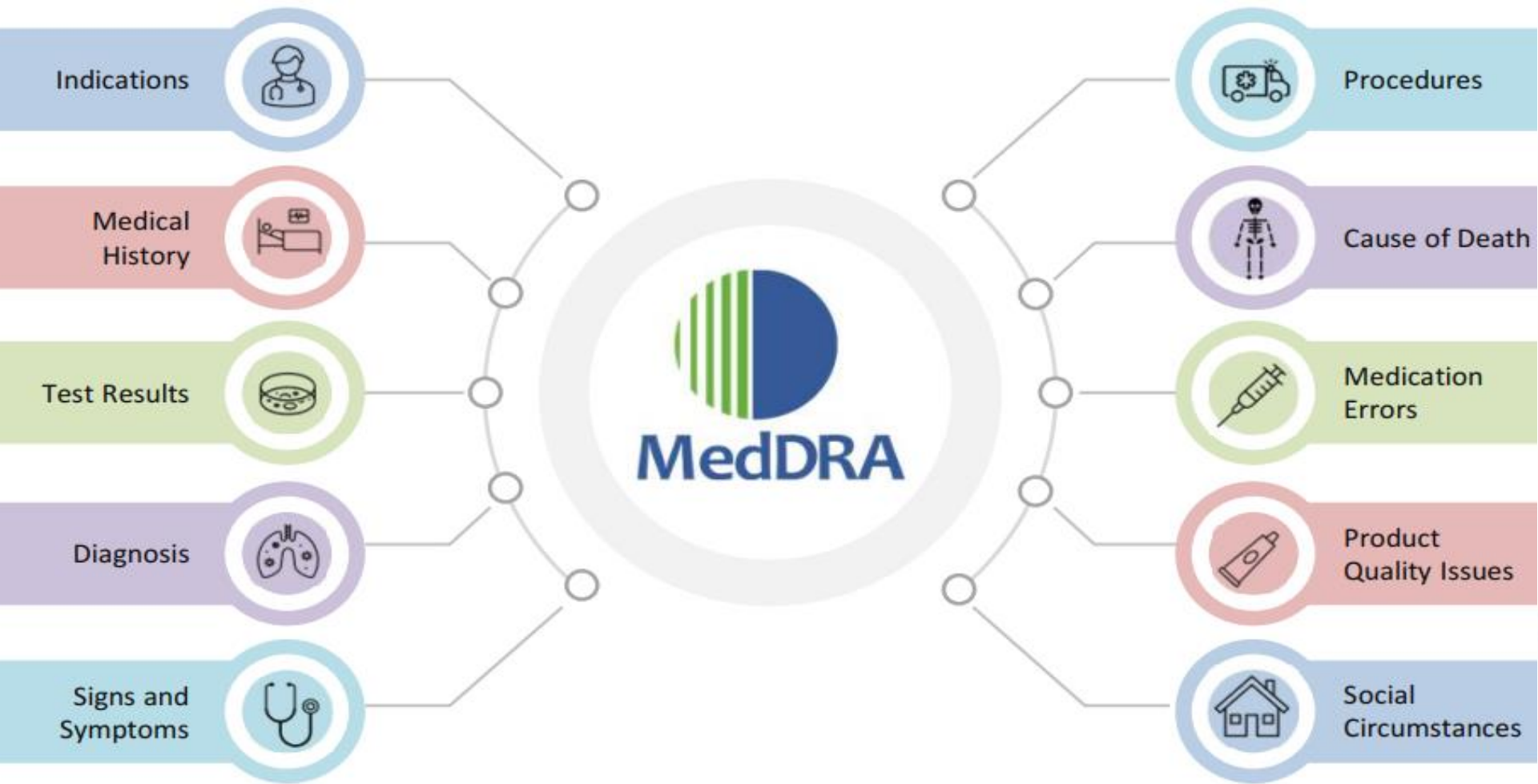
Huvudvärk
Swedish

Each MedDRA term assigned an 8-digit numeric code starting with "1"

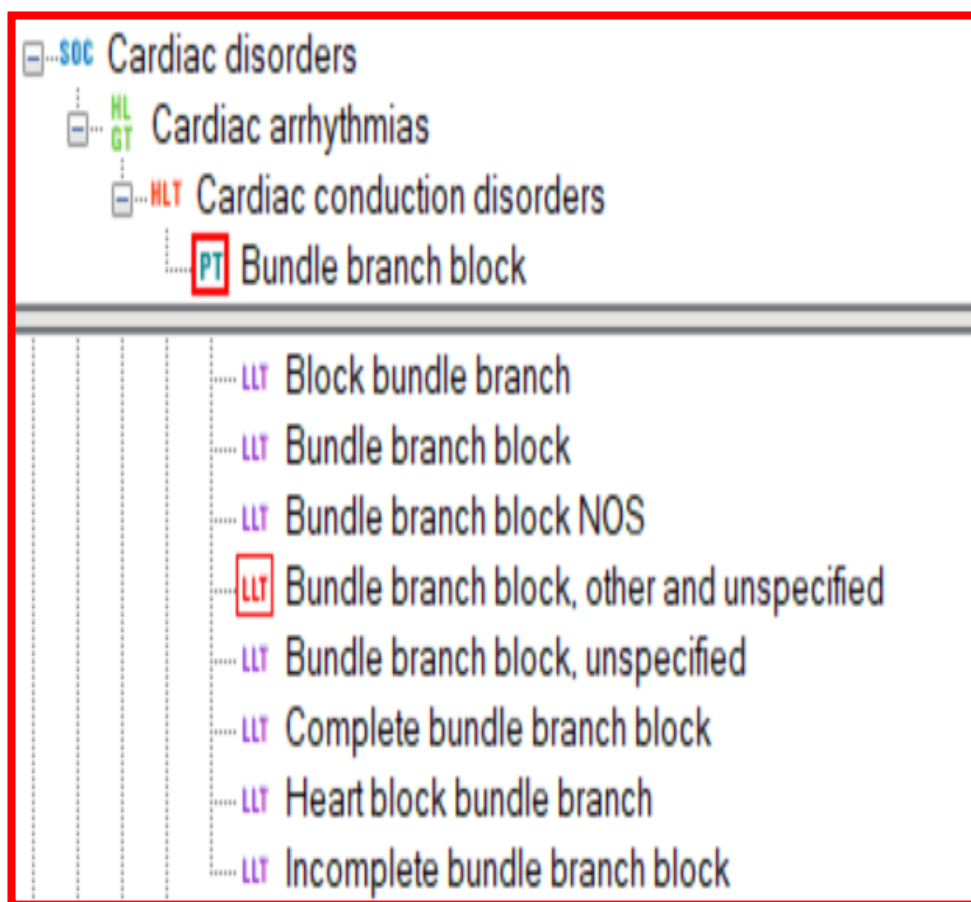
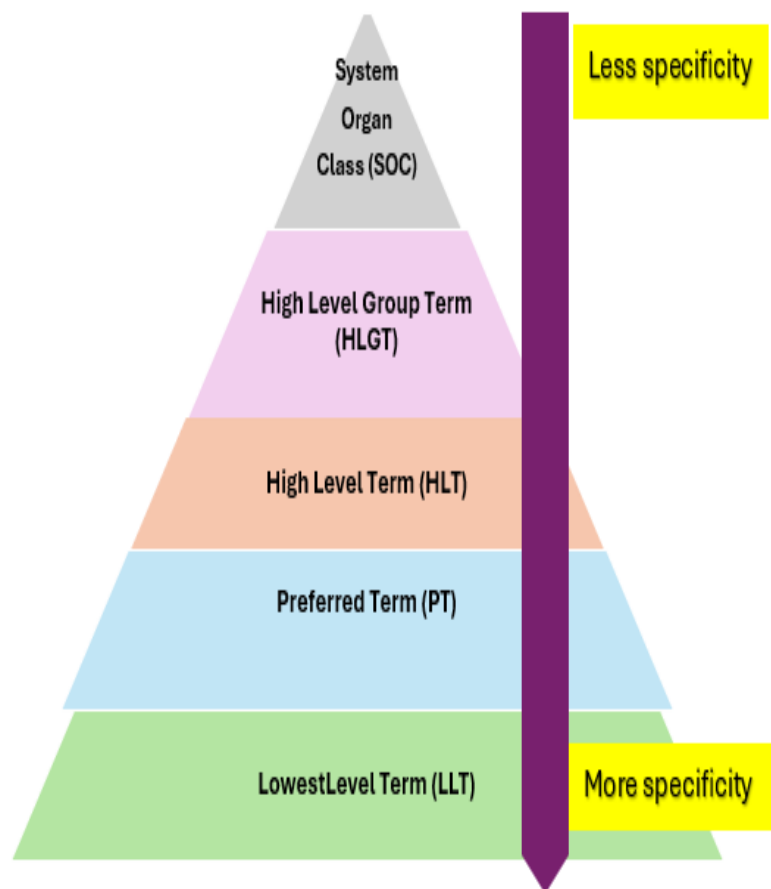
Codes can fulfill a data field in various electronic submission types (e.g., E2B)

New terms are assigned sequentially

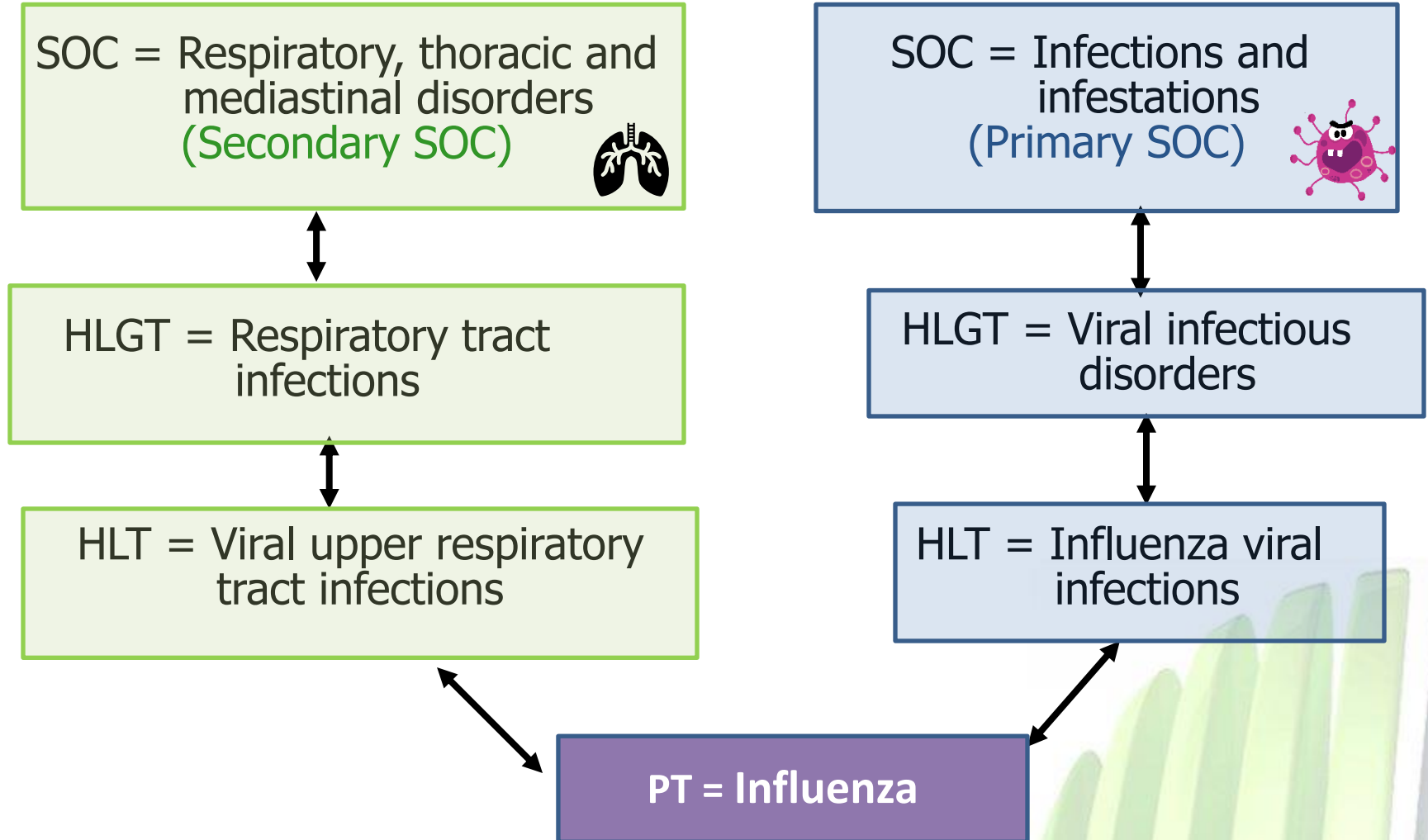
Types of Information Coded with MedDRA



MedDRA Structure



A Multi-Axial Terminology



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

MedDRA Term Selection (MTS:PtC) & MedDRA PtC Companion Document



MedDRA Data Retrieval and Presentation (DRP:PtC)

MedDRA® TERM SELECTION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users

Release 4.24

March 2024

Disclaimer and Copyright Notice

This document is protected by copyright and may, with the exception of the MedDRA and ICH logos, be used, reproduced, incorporated into other works, adapted, modified, translated or distributed under a public license provided that ICH's copyright in the document is acknowledged at all times. In case of any adaptation, modification or translation of the document, reasonable steps must be taken to clearly label, demarcate or otherwise identify that changes were made to or based on the original document. Any impression that the adaptation, modification or translation of the original document is endorsed or sponsored by the ICH must be avoided.

The document is provided "as is" without warranty of any kind. In no event shall the ICH or the authors of the original document be liable for any claim, damages or other liability arising from the use of the document.

The above-mentioned permissions do not apply to content supplied by third parties. Therefore, for documents where the copyright vests in a third party, permission for reproduction must be obtained from this copyright holder.

MedDRA® trademark is registered by ICH



MedDRA® POINTS TO CONSIDER COMPANION DOCUMENT

ICH-Endorsed Guide for MedDRA Users

Release 3.0

September 2024

Disclaimer and Copyright Notice

This document is protected by copyright and may, with the exception of the MedDRA and ICH logos, be used, reproduced, incorporated into other works, adapted, modified, translated or distributed under a public license provided that ICH's copyright in the document is acknowledged at all times. In case of any adaptation, modification or translation of the document, reasonable steps must be taken to clearly label, demarcate or otherwise identify that changes were made to or based on the original document. Any impression that the adaptation, modification or translation of the original document is endorsed or sponsored by the ICH must be avoided.

The document is provided "as is" without warranty of any kind. In no event shall the ICH or the authors of the original document be liable for any claim, damages or other liability arising from the use of the document.

The above-mentioned permissions do not apply to content supplied by third parties. Therefore, for documents where the copyright vests in a third party, permission for reproduction must be obtained from this copyright holder.

MedDRA® trademark is registered by ICH



MedDRA® DATA RETRIEVAL AND PRESENTATION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users
on Data Output

Release 3.24

March 2024

Disclaimer and Copyright Notice

This document is protected by copyright and may, with the exception of the MedDRA and ICH logos, be used, reproduced, incorporated into other works, adapted, modified, translated or distributed under a public license provided that ICH's copyright in the document is acknowledged at all times. In case of any adaptation, modification or translation of the document, reasonable steps must be taken to clearly label, demarcate or otherwise identify that changes were made to or based on the original document. Any impression that the adaptation, modification or translation of the original document is endorsed or sponsored by the ICH must be avoided.

The document is provided "as is" without warranty of any kind. In no event shall the ICH or the authors of the original document be liable for any claim, damages or other liability arising from the use of the document.

The above-mentioned permissions do not apply to content supplied by third parties. Therefore, for documents where the copyright vests in a third party, permission for reproduction must be obtained from this copyright holder.

MedDRA® trademark is registered by ICH

Criteria for a valid Individual Case Safety Report (ICSR)



Reporter



Patient



Suspected Product



ICSR



Adverse Event



Product Issue Concepts in MedDRA

A screenshot of a MedDRA browser window. The window title bar is at the top. The main content area shows a hierarchical tree of concepts. The top-level concept is "SOC Product issues", which is expanded to show its sub-concepts. The sub-concepts are listed under "HL GT" (High Level Grouping Term) and include "Device issues" and "Product quality, supply, distribution, manufacturing and quality system issues". The latter is further expanded to show a list of specific issues under "HLT" (High Level Term), such as "Counterfeit, falsified and substandard products", "Manufacturing facilities and equipment issues", "Manufacturing issues NEC", "Manufacturing laboratory controls issues", "Manufacturing materials issues", "Manufacturing production issues", "Product contamination and sterility issues", "Product distribution and storage issues", "Product label issues", "Product packaging issues", "Product physical issues", "Product quality issues NEC", "Product supply and availability issues", and "Quality system issues". The window has a standard Windows-style title bar with minimize, maximize, and close buttons. A vertical scrollbar is visible on the right side of the content area.

---SOC Product issues

- HL GT Product quality, supply, distribution, manufacturing and quality system issues

---SOC Pregnancy, puerperium and perinatal conditions

---SOC Product issues

- HL GT Device issues
- HL GT Product quality, supply, distribution, manufacturing and quality system issues
 - HLT Counterfeit, falsified and substandard products
 - HLT Manufacturing facilities and equipment issues
 - HLT Manufacturing issues NEC
 - HLT Manufacturing laboratory controls issues
 - HLT Manufacturing materials issues
 - HLT Manufacturing production issues
 - HLT Product contamination and sterility issues
 - HLT Product distribution and storage issues
 - HLT Product label issues
 - HLT Product packaging issues
 - HLT Product physical issues
 - HLT Product quality issues NEC
 - HLT Product supply and availability issues
 - HLT Quality system issues



MedDRA

Device Issue Concepts in MedDRA

The screenshot shows a web browser window displaying the MedDRA hierarchy. The top section shows 'SOC Product issues' expanded, with 'HL GT Device issues' listed below it. The main content area shows a list of SOC terms: 'Neoplasms benign, malignant and unspecified (incl cysts and polyps)', 'Nervous system disorders', 'Pregnancy, puerperium and perinatal conditions', and 'Product issues'. The 'Product issues' term is expanded, showing a list of HL GT terms: 'Device issues' (highlighted in blue), 'Device computer issues', 'Device electrical issues', 'Device incompatibility issues', 'Device information output issues', 'Device issues NEC', 'Device malfunction events NEC', 'Device operational issues NEC', and 'Device physical property and chemical issues'.

- SOC Product issues
 - HL GT Device issues

- + SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) ^
- + SOC Nervous system disorders
- + SOC Pregnancy, puerperium and perinatal conditions
- SOC Product issues
 - HL GT Device issues
 - + HLT Device computer issues
 - + HLT Device electrical issues
 - + HLT Device incompatibility issues
 - + HLT Device information output issues
 - + HLT Device issues NEC
 - + HLT Device malfunction events NEC
 - + HLT Device operational issues NEC
 - + HLT Device physical property and chemical issues

Medication Errors Concepts in MedDRA

[-] SOC Injury, poisoning and procedural complications
 [+] HL Medication errors and other product use errors and issues
 [+] GT

[-] HL Medication errors and other product use errors and issues
 [+] GT
 [+] HLT Accidental exposures to product
 [+] HLT Medication errors, product use errors and issues NEC
 [+] HLT Product administration errors and issues
 [+] HLT Product confusion errors and issues
 [+] HLT Product dispensing errors and issues
 [+] HLT Product monitoring errors and issues
 [+] HLT Product preparation errors and issues
 [+] HLT Product prescribing errors and issues
 [+] HLT Product selection errors and issues
 [+] HLT Product storage errors and issues in the product use system
 [+] HLT Product transcribing errors and communication issues

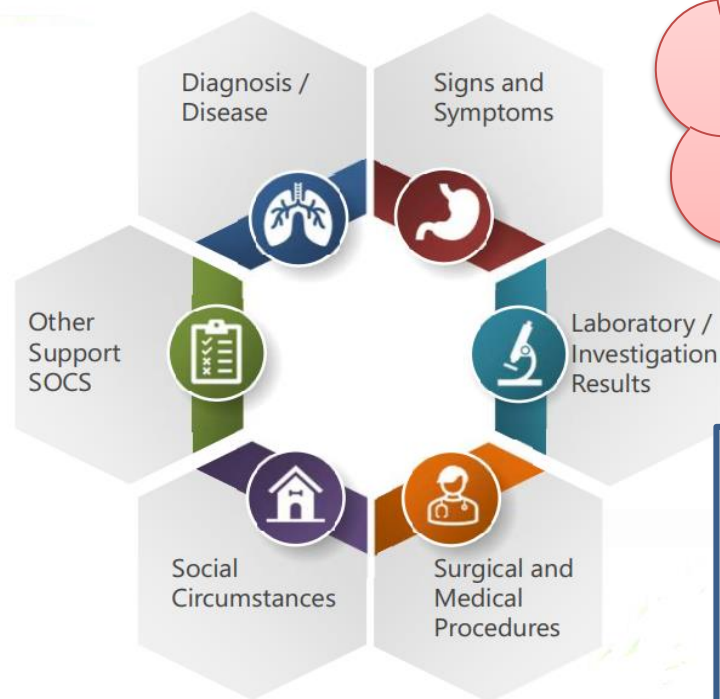
Retrieval and analysis of MedDRA-Coded Data



SMQs / MedDRA Query?

Groupings of MedDRA terms, typically at the Preferred Term (PT) level related to a defined medical condition or area of interest.

Standardised MedDRA Queries (SMQs)



SMQ/CMQ

PT

LLT

LLT

LLT1

PT

LLT

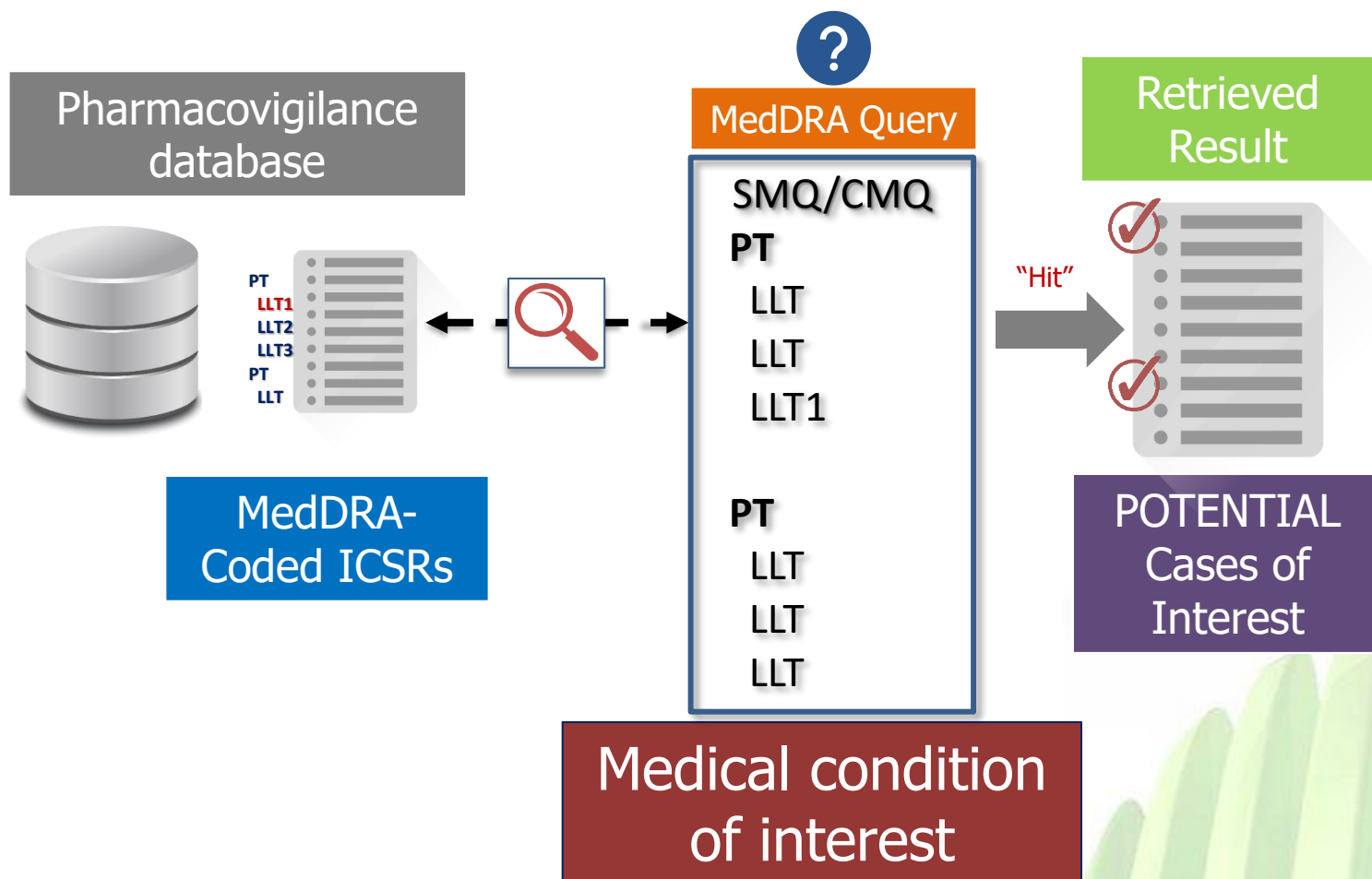
LLT

LLT

Examples of some 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

How to run a MedDRA Query?



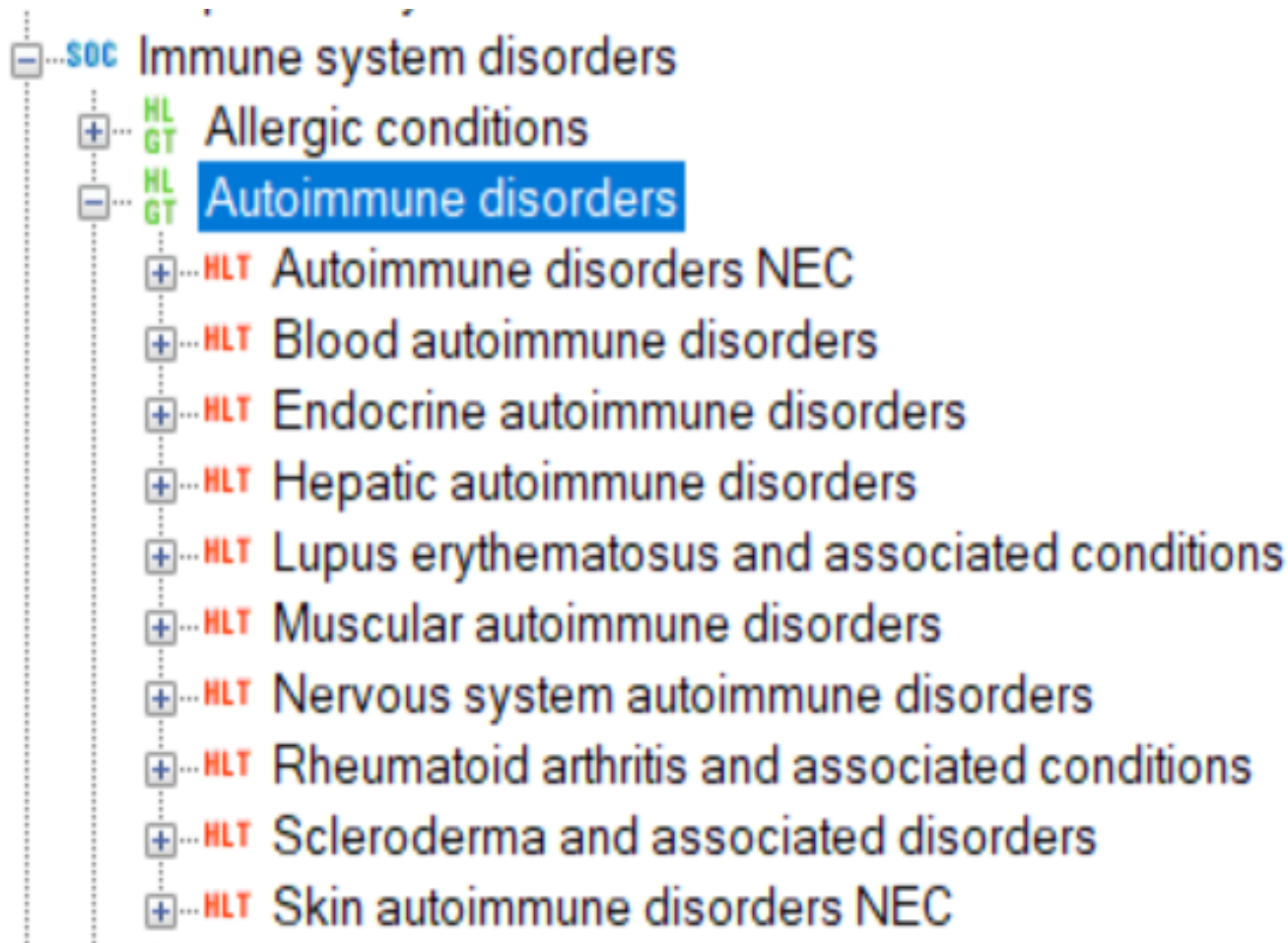
How Many Cases of Autoimmune Diseases?

Evans syndrome	Anemia	Birdshot chorioretinopathy
Encephalopathy	Vitiligo	Polymyalgia rheumatica
Systemic lupus erythematosus	Teratoma	Adams-Stokes syndrome
Rheumatoid arthritis	Type 1 diabetes mellitus	Alopecia areata
Guillain-Barre syndrome	Cholangitis sclerosing	Acute disseminated encephalomyelitis

How Many Cases of Autoimmune Diseases?

Hierarchy Analysis

Data Retrieval
with hierarchy
analysis, primary
& secondary SOC
output



How many cases of Nervous system disorders?

Preferred
Term &
System Organ
Class

Data Retrieval
example with
SOC and PT

SOC Nervous system disorders	8
HLGT Mental impairment disorders	
HLT Mental impairment (excl dementia and memory loss)	
PT Disturbance in attention	1
HLGT Movement disorders (incl Parkinsonism)	
HLT Dyskinesias and movement disorders NEC	
PT Psychomotor hyperactivity	2
HLT Tremor (excl congenital)	
PT Tremor	3
HLGT Neurological disorders NEC	
HLT Disturbances in consciousness NEC	
PT Somnolence	1
HLT Neurological signs and symptoms NEC	
PT Dizziness	1

How many cases of Lactic acidosis?

Standardized
MedDRA
Query (SMQ)

Data Retrieval
with SMQ

Verbatim Report

Acidosis
Akinaesthesia
Albumin CSF increased
Anion gap abnormal
Blood bicarbonate abnormal
Bronchiolitis
Bacteraemia
Blood pH abnormal
Drug level decreased
Hyperlactacidaemia
Miller Fisher syndrome
PCO2 decreased
Tachyphylaxis

Lactic acidosis (SMQ)

Narrow search terms

- Blood lactic acid increased
- Hyperlactacidaemia
- Lactic acidosis

Broad Search Terms

- Acid base balance abnormal
- Acidosis
- Anion gap abnormal
- Anion gap increased
- Blood alkalisation therapy
- Blood bicarbonate abnormal
- Blood bicarbonate decreased
- Blood gases abnormal
- Blood lactic acid abnormal
- Blood pH abnormal
- Blood pH decreased
- Carbon dioxide combining power abnormal
- Carbon dioxide combining power decreased
- Coma acidotic
- Kussmaul respiration
- Metabolic acidosis
- PCO2 abnormal
- PCO2 decreased
- Urine lactic acid increased

Use of SMQs for Reviewing Prescribing Information

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

<i>SMQ (Narrow Search)</i>	<i>RR</i>
(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)



MedDRA

Standardised MedDRA Queries (SMQs) in Pharmacovigilance

**Retrieve cases for suspected or
known safety issue**

Signal detection

Single case alerts

Periodic reporting

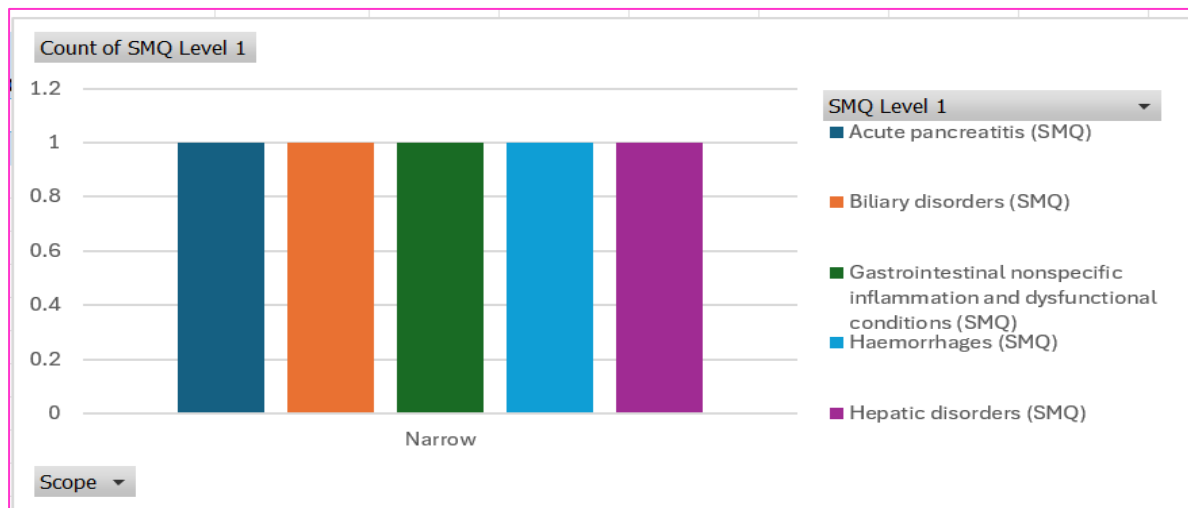
Exercise

Patient ABC aged 45 years, Female, was on drug XYZ from some time. She was hospitalized with severe upper abdominal pain, nausea, projectile vomiting and Jaundice. Her Laboratory investigation revealed that her serum amylase and serum bilirubin levels were elevated. On physical examination she was also positive for Grey Turner's sign, Cullen's sign and Abdominal rebound tenderness. She had no significant past medical history.

How to code the report?

Low Level Term	Preferred Term	System Organ Class
Upper abdominal pain	Abdominal pain upper	Gastrointestinal disorders
Nausea	Nausea	Gastrointestinal disorders
Vomiting projectile	Vomiting projectile	Gastrointestinal disorders
Jaundice	Jaundice	Hepatobiliary disorders
Serum amylase increased	Amylase increased	Investigations
Serum bilirubin increased	Blood bilirubin increased	Investigations
Grey Turner's sign	Grey Turner's sign	Skin and subcutaneous tissue disorders
Cullen's sign	Cullen's sign	Skin and subcutaneous tissue disorders
Abdominal rebound tenderness	Abdominal rebound tenderness	Gastrointestinal disorders

Possible Medical Events of interest?



English: Acute pancreatitis (SMQ)

English	Code	Level	Scope	Category
Cullen's sign	10059029	PT	Narrow	A
Grey Turner's sign	10075426	PT	Narrow	A
Amylase increased	10002016	PT	Broad	B
Blood bilirubin increased	10005364	PT	Broad	B
Abdominal pain upper	10000087	PT	Broad	C
Abdominal rebound tenderness	10052489	PT	Broad	C
Jaundice	10023126	PT	Broad	C
Nausea	10028813	PT	Broad	C
Vomiting projectile	10047708	PT	Broad	C

- Multi-lingual
- Multi-axial
- Granular
- Standard Medical Terminology

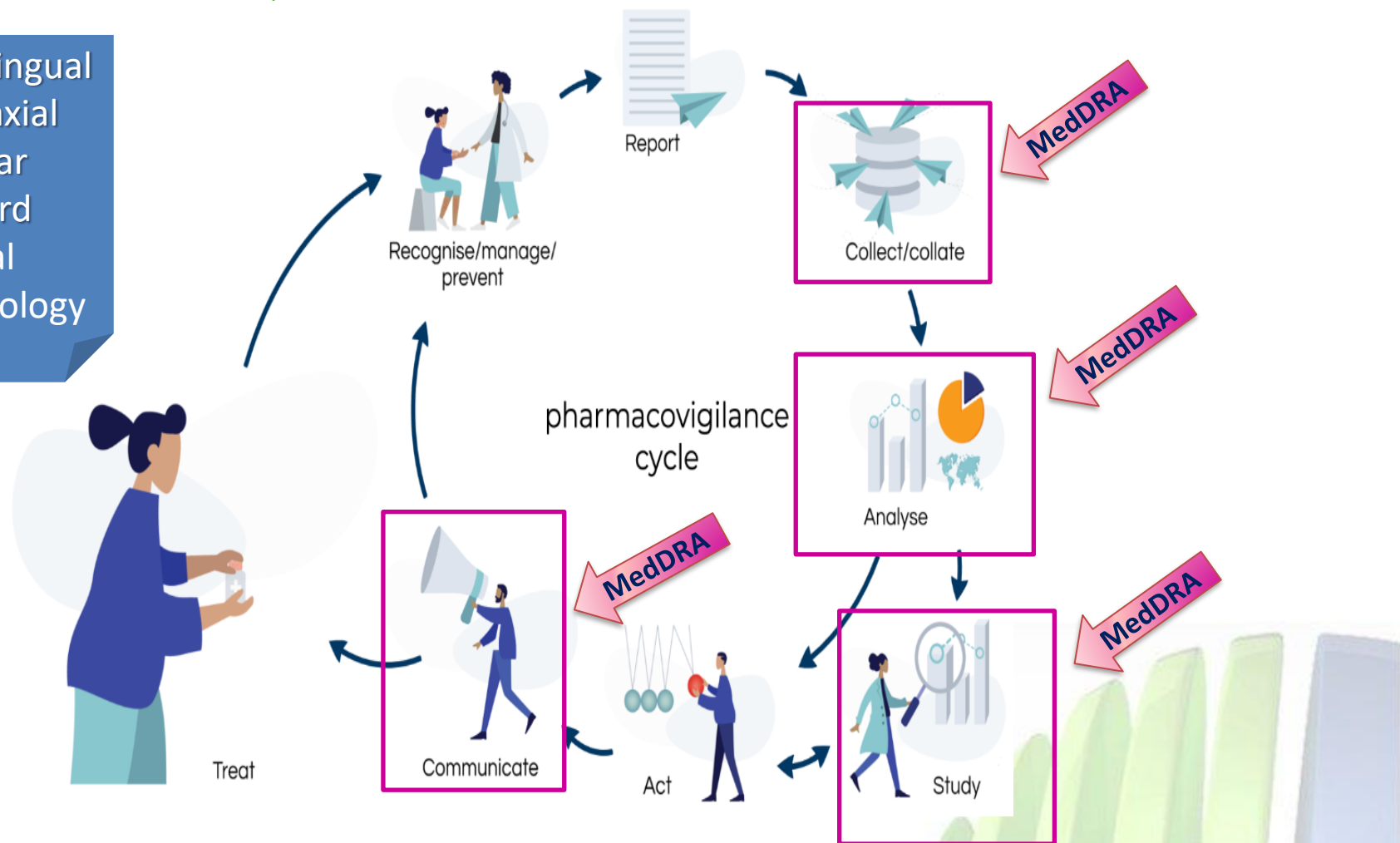


Fig. UMC's PV Cycle

<https://who-umc.org/signal-work/what-is-a-signal/>



Know more?

www.meddra.org



Medical Dictionary for
Regulatory Activities

SSA WBB PTC Contact FAQs Downloads



- Home
- About MedDRA
- How to Use
- Training
- Subscription
- News & Events
- Search the site

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

Help Yourself

Get answers to some of your immediate questions
via the MedDRA Self-Service Application

Follow us on Social Media



Social Media Channels

Connect with us in: Please scan the appropriate QR code
to join the MedDRA group on WhatsApp or WeChat.



WhatsApp

English/Spanish:
MedDRA Group



French:

MedDRA - French speakers



Russian:

MedDRA RU Users Support



WeChat

Chinese:



MedDRA MSSO

微信扫描二维码，关注我们公众号

Contact Form

Name:

Telephone:

E-mail: Confirm E-mail:

Organization:

Comment:

☒ Add me to the MSSO email list

☐ I'm not a robot

reCAPTCHA

Support Documentation / How to Use /



Select a language: English

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 / Training /

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.		

zendesk chat

Help Desk Live Chat

Type your message here



Thank You!

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