Role of MedDRA in Pharmacovigilance

Dr Anamika Dutta
Medical Officer, MedDRA MSSO

ICH
harmonisation for better health

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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

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 and the MSSO

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)

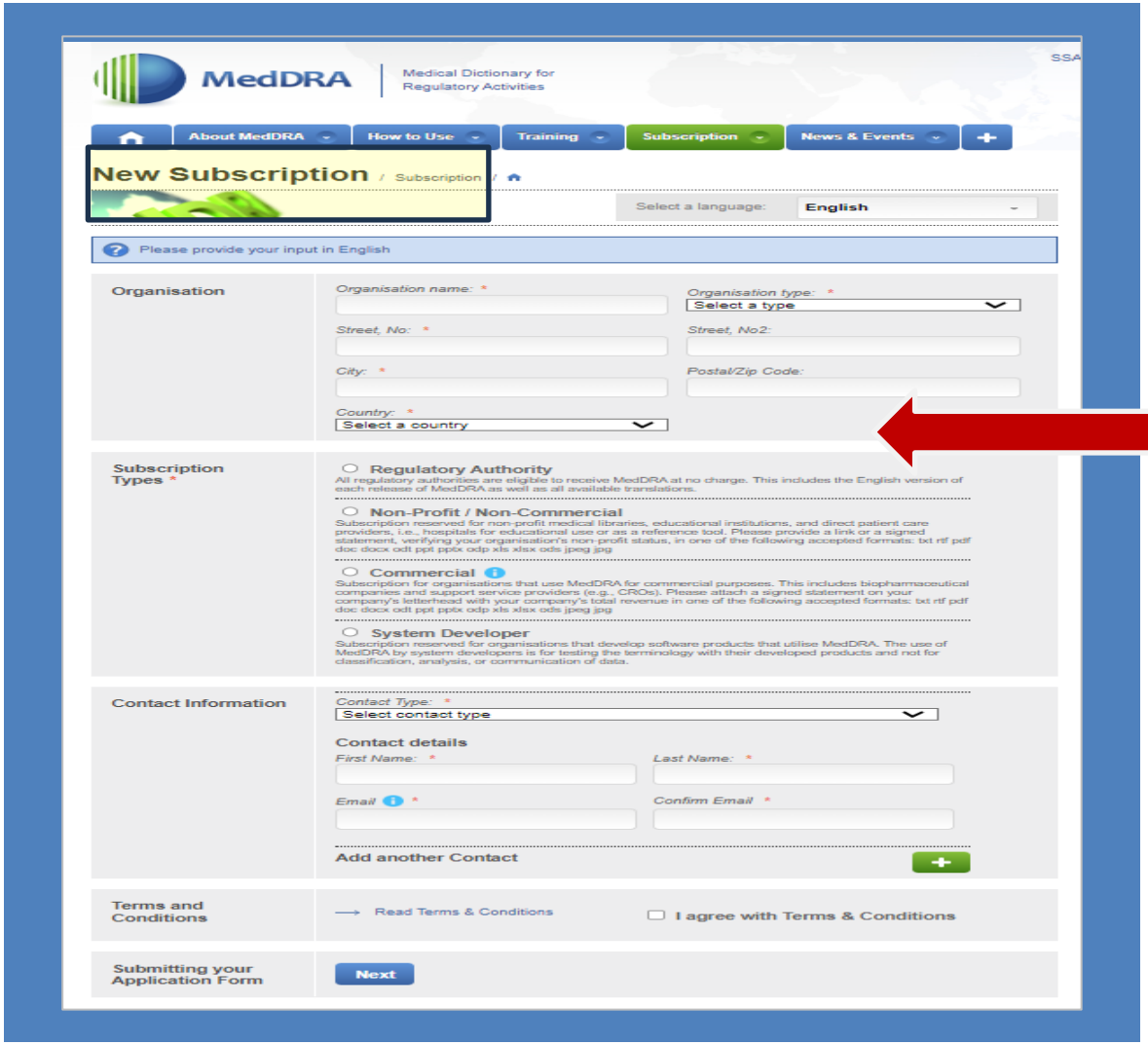
Educational offerings

Foster use of MedDRA through communications and educational offerings

JMO

Partner organization for Japanese-language MedDRA

How to subscribe?



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MedDRA Data Sharing

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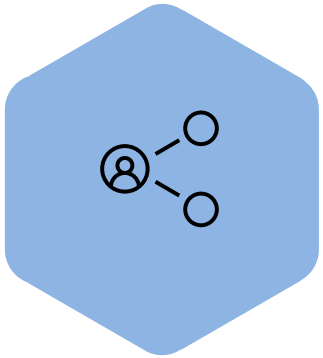

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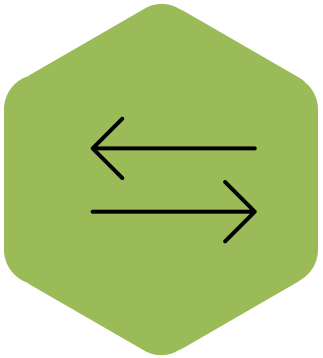

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Data may be freely exchanged between current MedDRA subscribers

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

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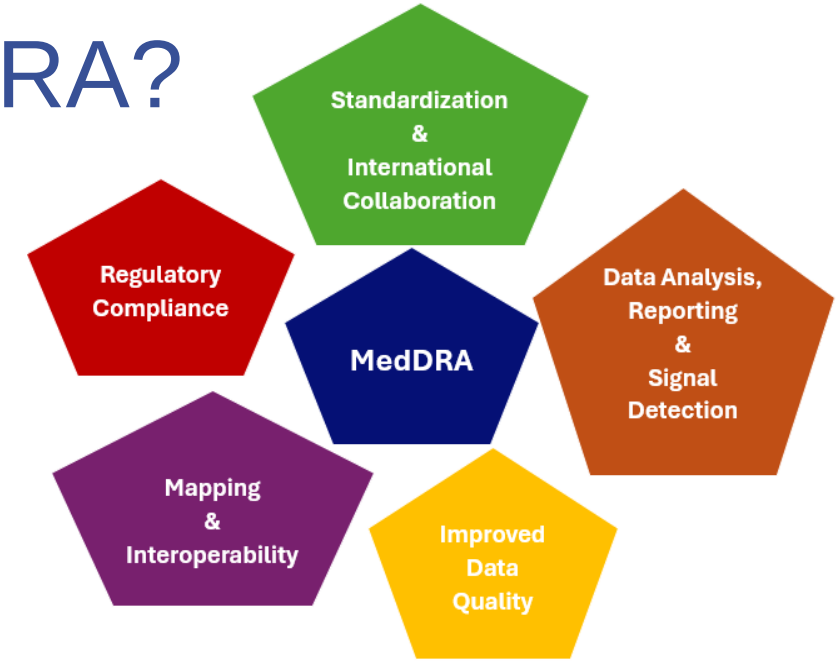


E2A - E2F Pharmacovigilance

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

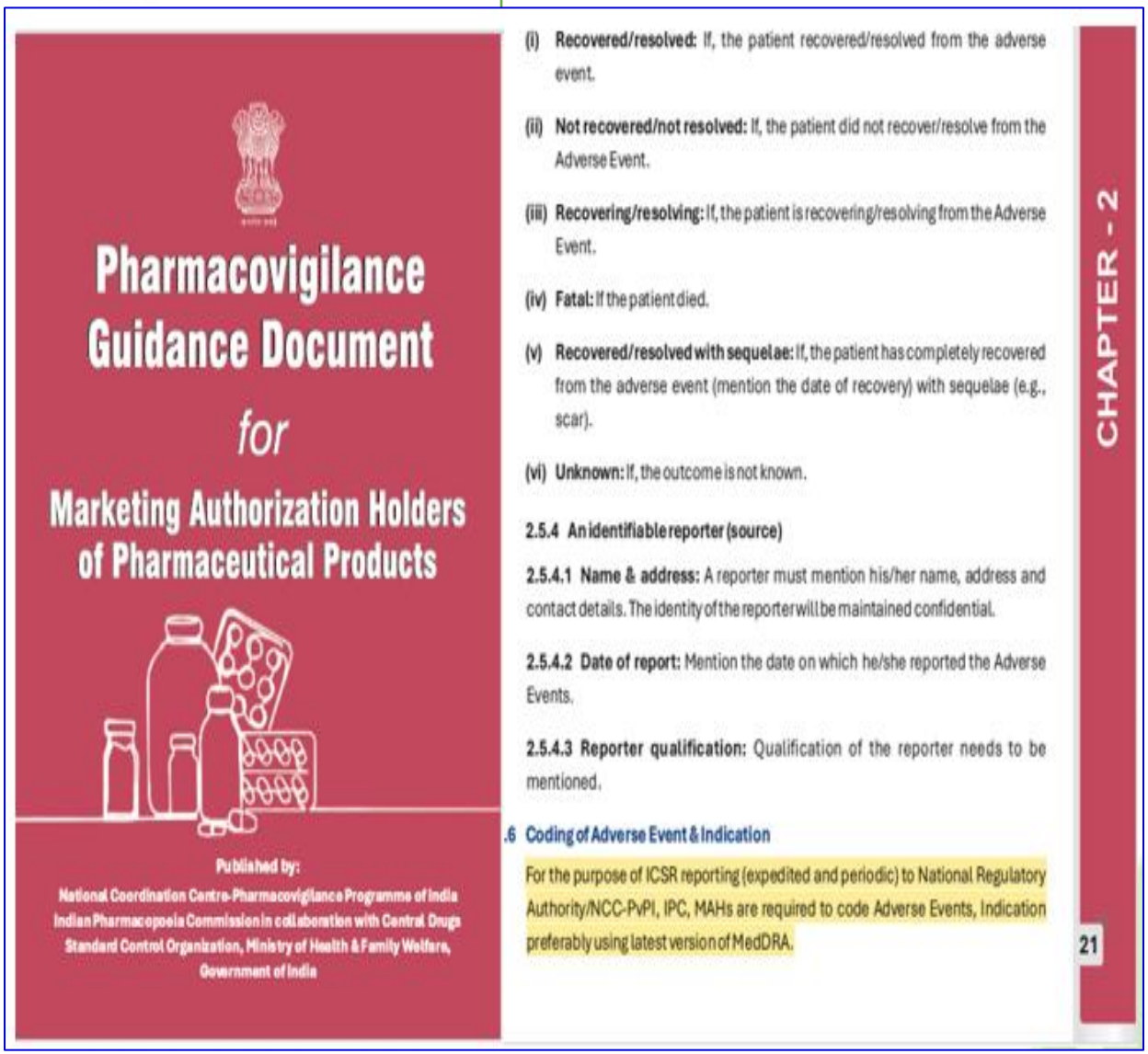
M1 MedDRA Terminology

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.

.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.

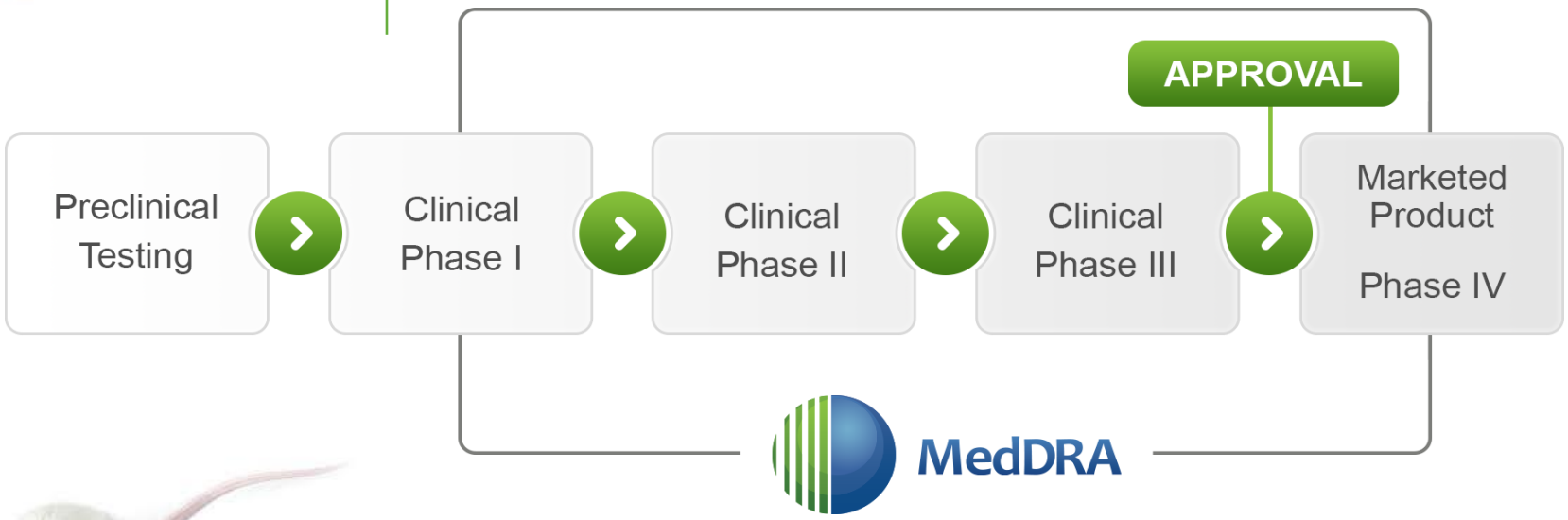
CHAPTER - 2

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

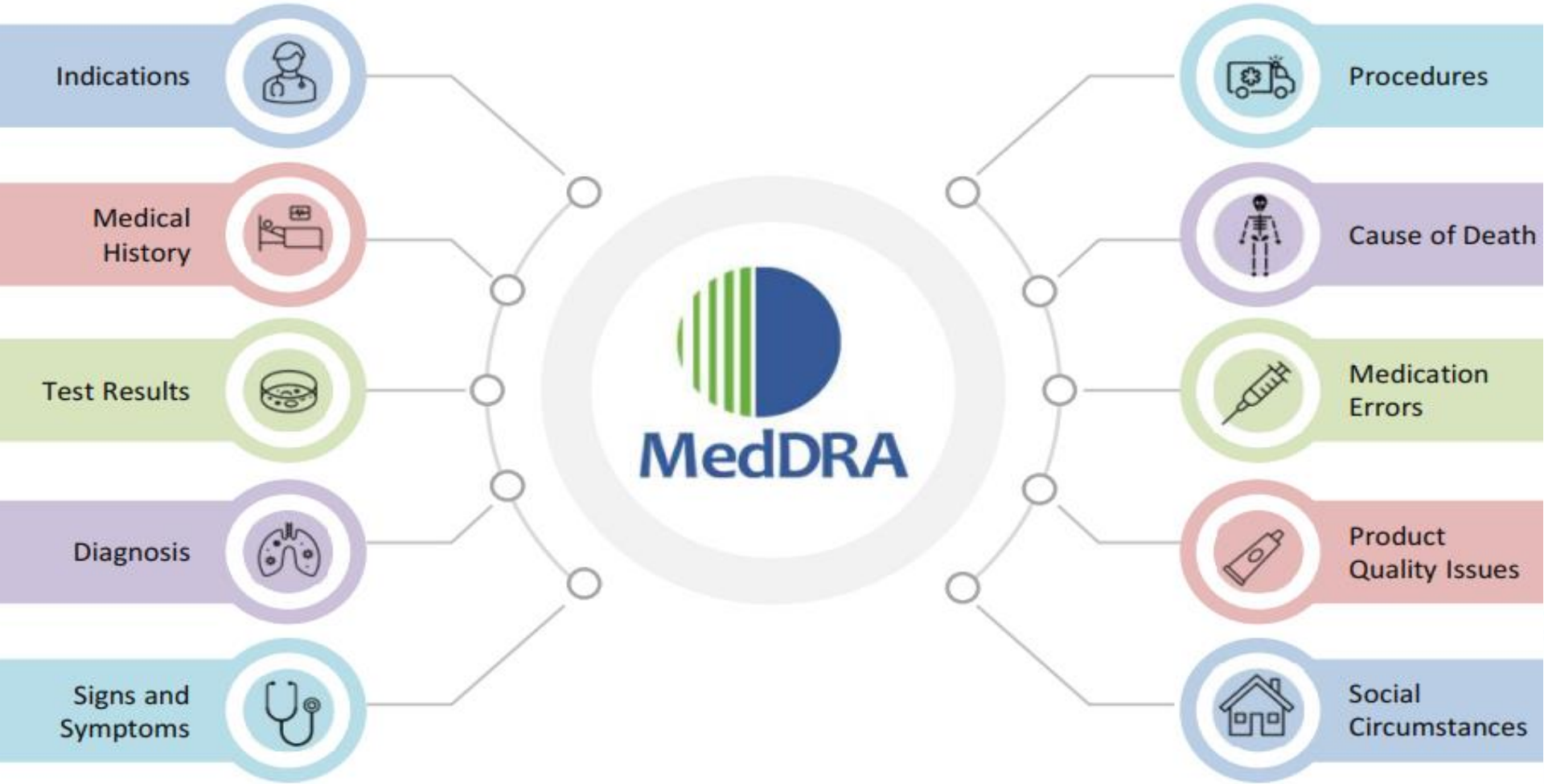
Advertising

Multilingual MedDRA

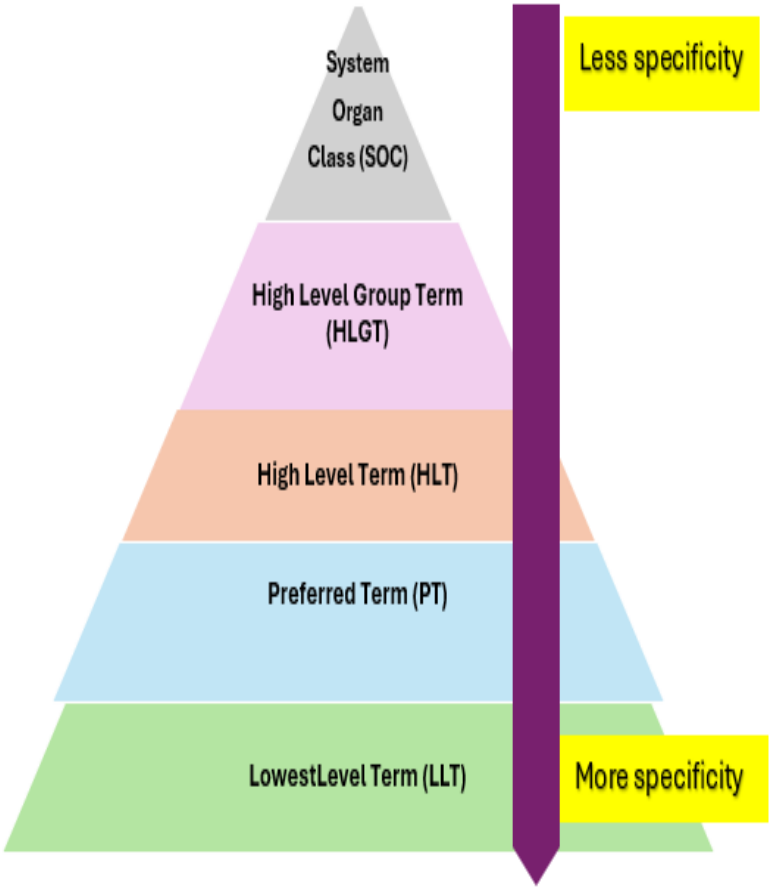
صداع **Arabic**	Cefaleia **Brazilian Portuguese**	главоболие **Bulgarian**	头痛 **Chinese**	Glavobolja **Croatian**
Bolest hlavy **Czech**	Hovedpine **Danish**	Hoofdpijn **Dutch**	Headache **English**	Peavalu **Estonian**
Päänsärky **Finnish**	Céphalée **French**		Kopfschmerzen **German**	Κεφαλαλγία **Greek**
Fejfájás **Hungarian**	Höfuðverkur **Icelandic**		Cefalea **Italian**	頭痛 **Japanese**
두통 **Korean**	Galvassāpes **Latvian**	10019211	Galvos skausmas **Lithuanian**	Uġigħ ta' ras **Maltese**
Hodepine **Norwegian**	Ból głowy **Polish**	Cefaleia **Portuguese**	Durere de cap **Romanian**	Головная боль **Russian**
Bolesť hlavy **Slovak**	Glavobol **Slovenian**	Cefalea **Spanish**	Huvudvärk **Swedish**	

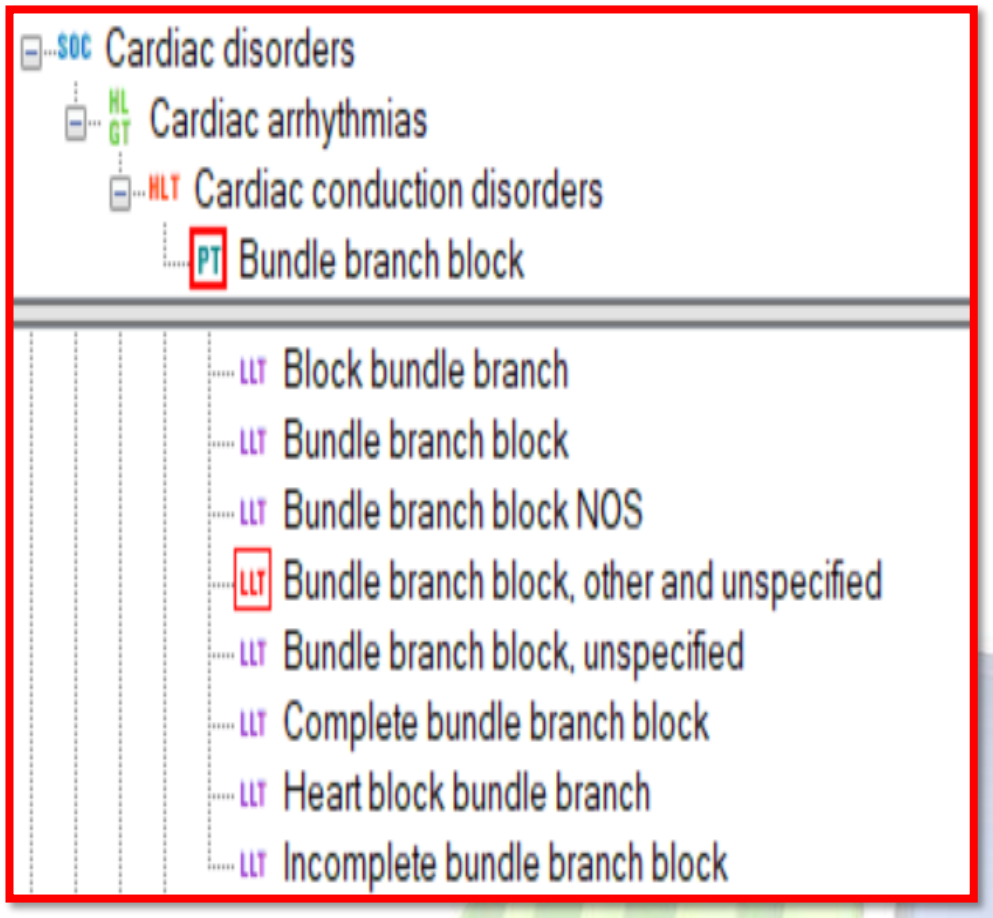
- Each MedDRA term assigned an 8-digit numeric code starting with "1"
- Codes can fulfill a data field in various electronic submission types (e.g., E2B)
- New terms are assigned sequentially

Types of Information Coded with MedDRA



MedDRA Structure





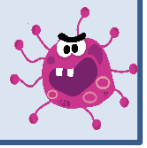
A Multi-Axial Terminology

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

HLGT = Respiratory tract infections

HLT = Viral upper respiratory tract infections

SOC = Infections and infestations (Primary SOC)



HLGT = Viral infectious disorders

HLT = Influenza viral infections

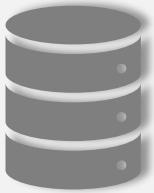
PT = Influenza

Coding: Translating into MedDRA

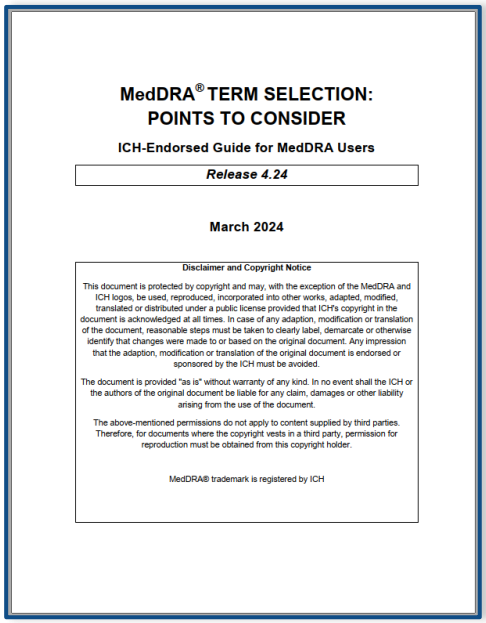
Reported Information	MedDRA Coding Term (LLT)
Throbbing above temple Aching all over head Pulsing pain in head Really bad headache Headache	Headache
Infection in lungs	Lung infection
Patient took Drug A instead of Drug B and experienced hypertension	Wrong drug administered Hypertension

Support Documentation

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

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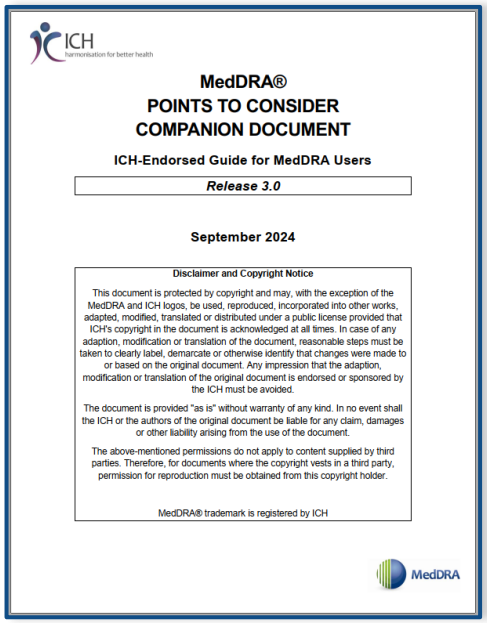

ICH harmonisation for better health

MedDRA® POINTS TO CONSIDER COMPANION DOCUMENT

ICH-Endorsed Guide for MedDRA Users

Release 3.0

September 2024

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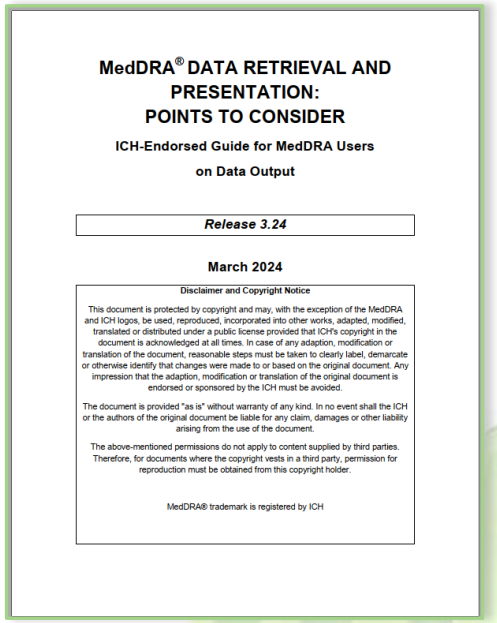
MedDRA

MedDRA Coding Guidelines



MedDRA® DATA RETRIEVAL AND PRESENTATION: POINTS TO CONSIDER

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Data Retrieval & Analysis Guidelines

Criteria for a valid Individual Case Safety Report (ICSR)

Reporter

Patient

Suspected Product

ICSR

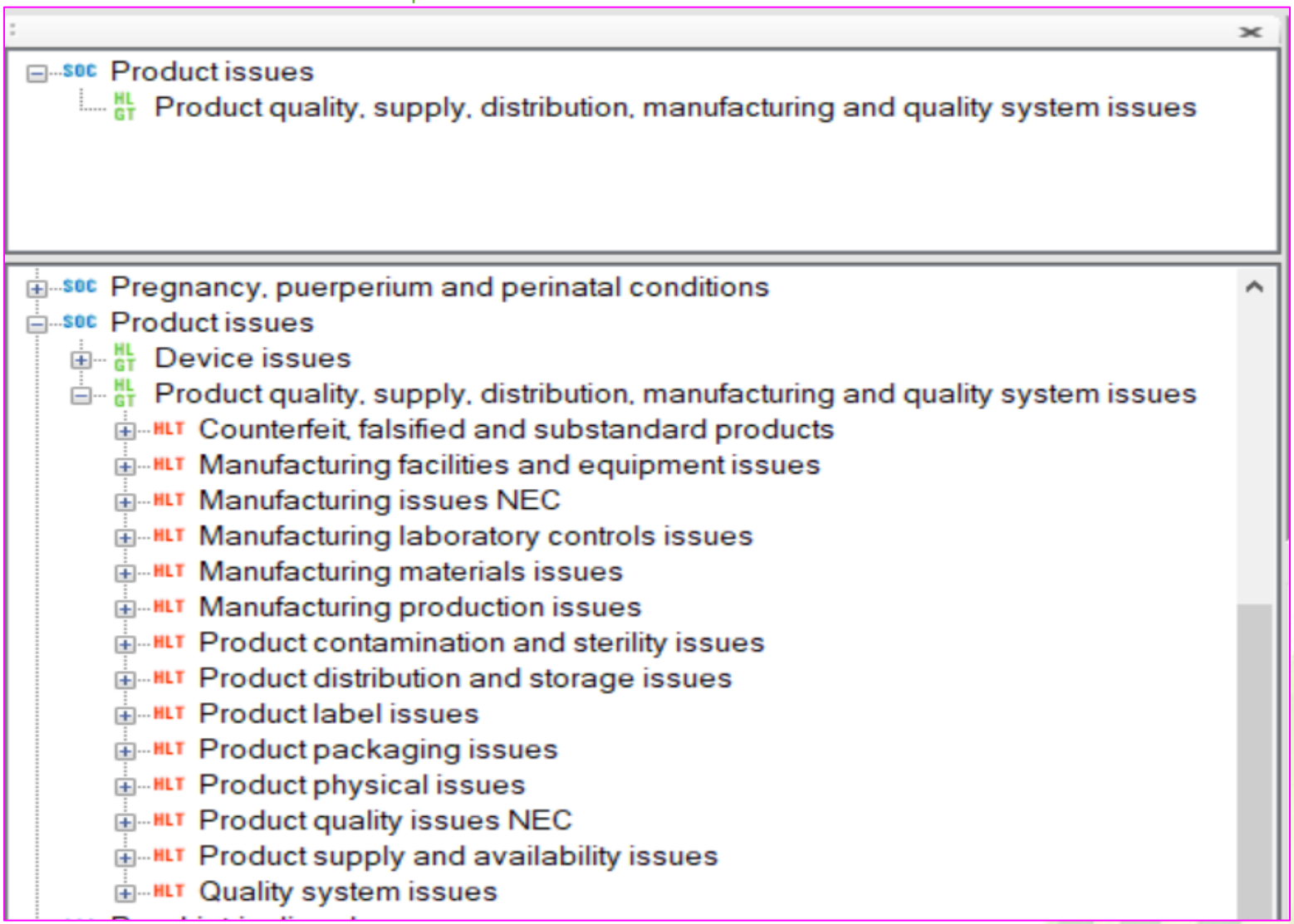
Adverse Event

Uppsala Monitoring Centre

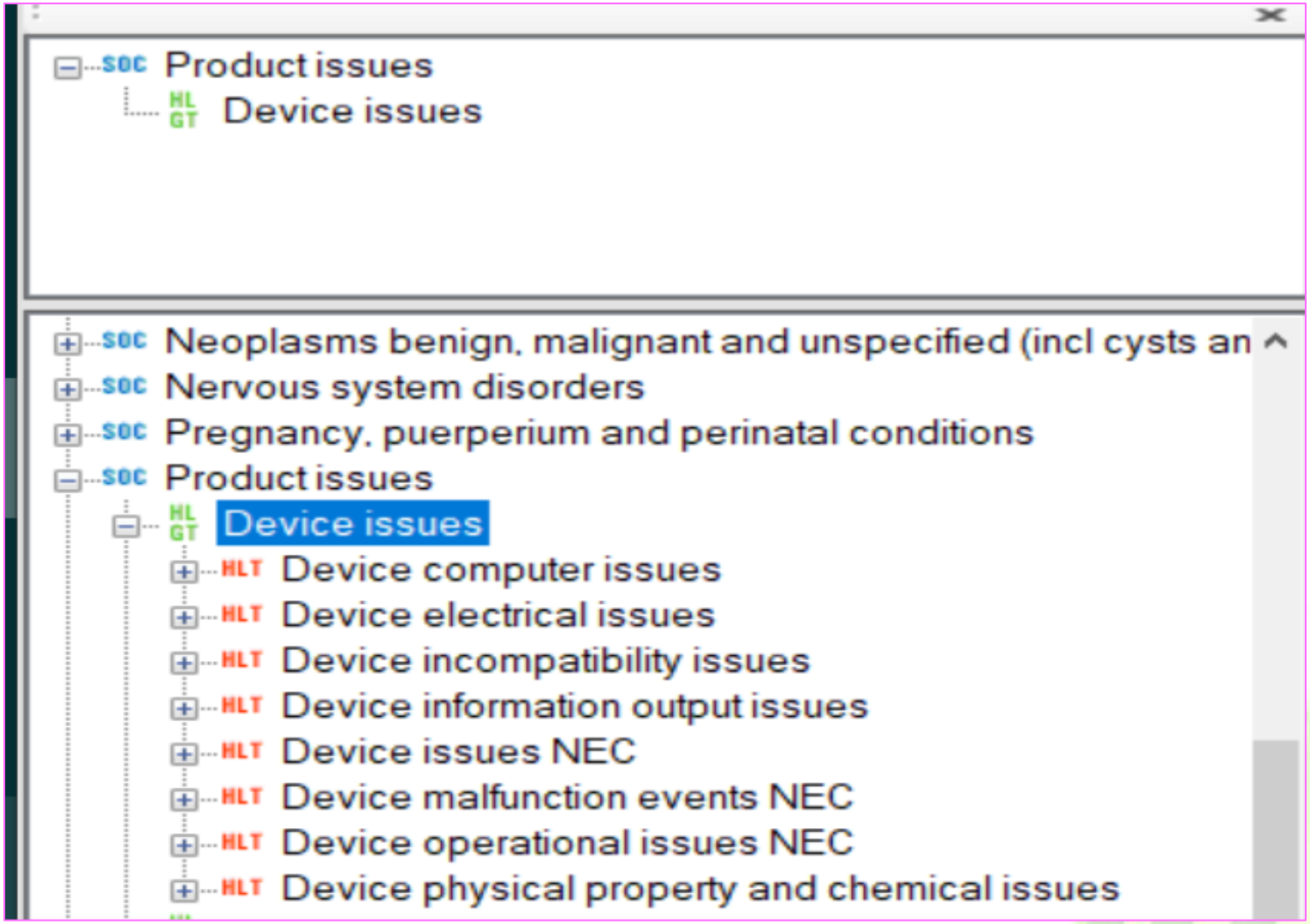
WHODrug Global

MedDRA

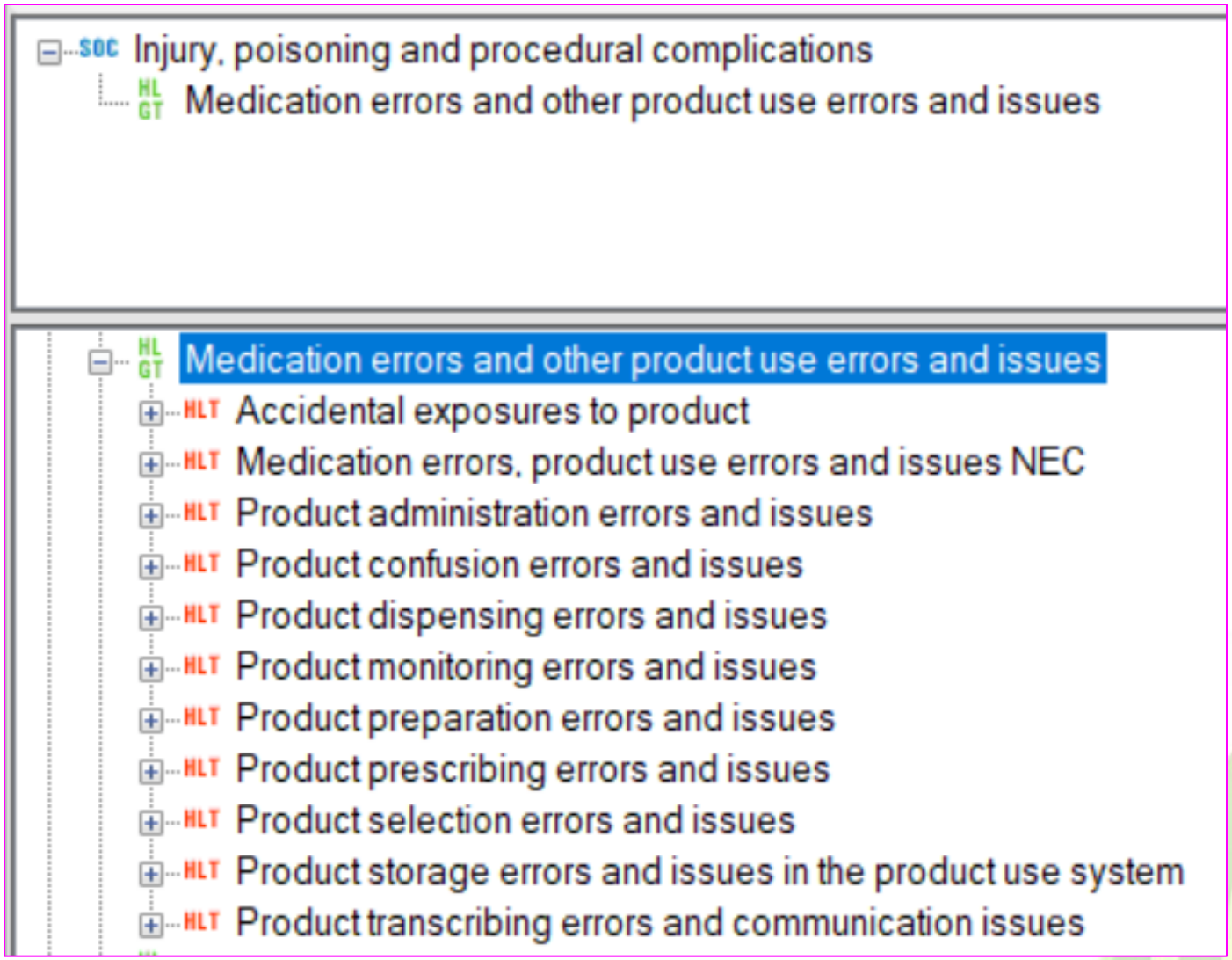
Product Issue Concepts in MedDRA



Device Issue Concepts in MedDRA



Medication Errors Concepts in MedDRA



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)

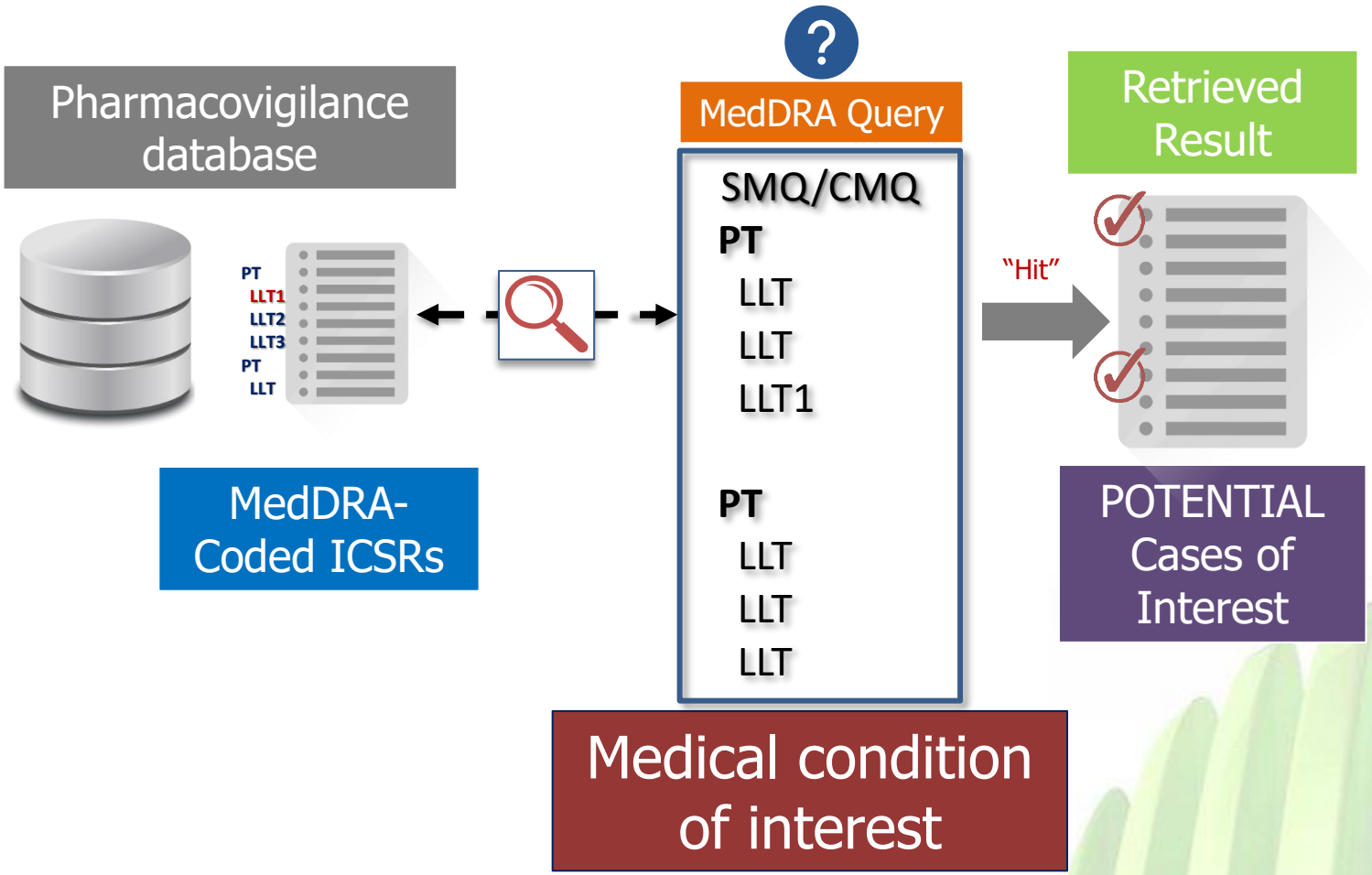
SMQ/CMQ
PT
LLT
LLT
LLT1

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 alkalinisation 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

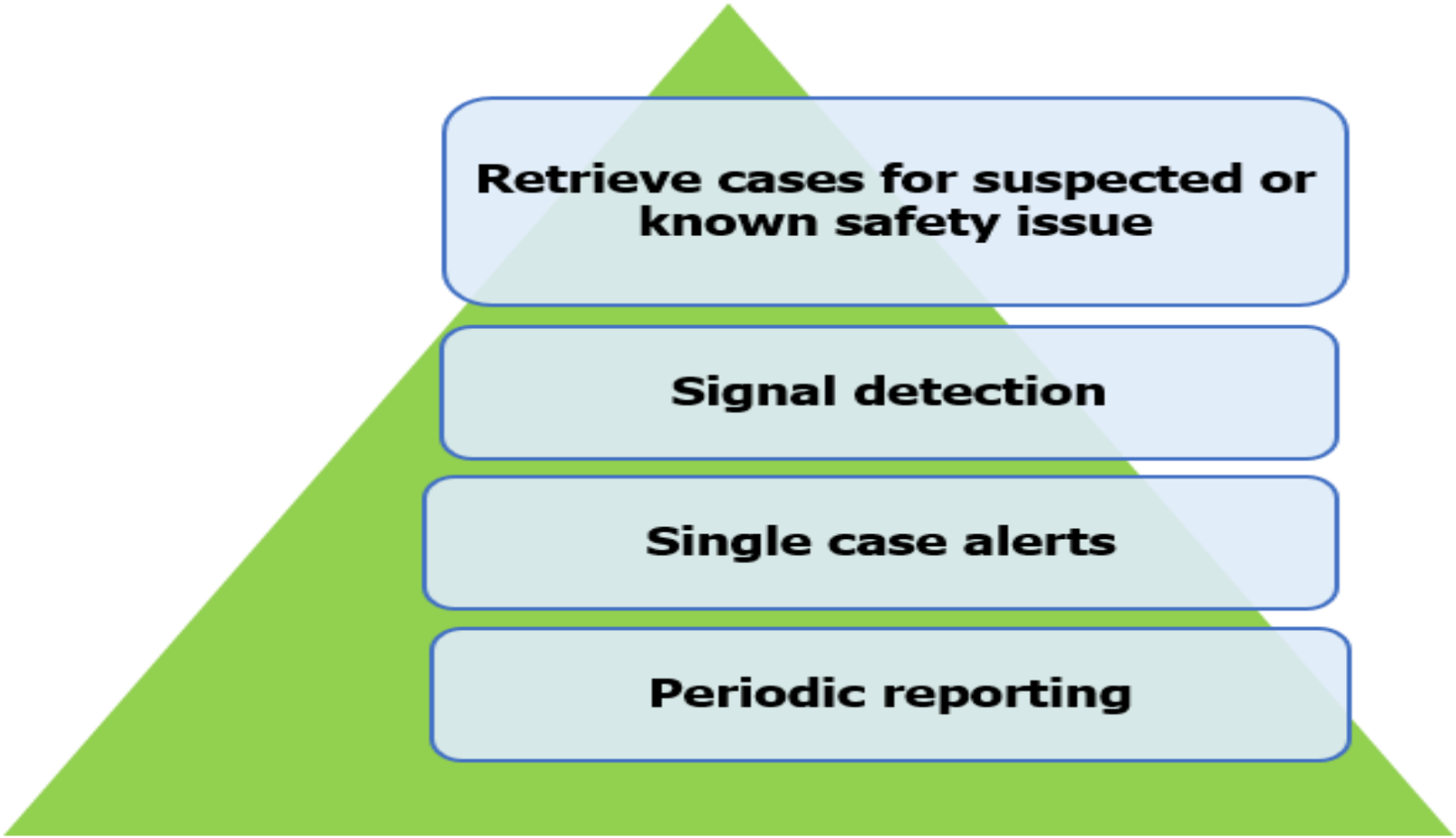
- Proposed Prescribing Information:
- Warnings & Precautions:
  - Dizziness/Somnolence
  - Withdrawal of Antiepileptic Drugs
  - Suicidal Behavior and Ideation (class labeling)

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)

Acknowledgement: Dr. Christopher Breder, Office of New Drugs, CDER, FDA

Standardised MedDRA Queries (SMQs) in Pharmacovigilance



Exercise

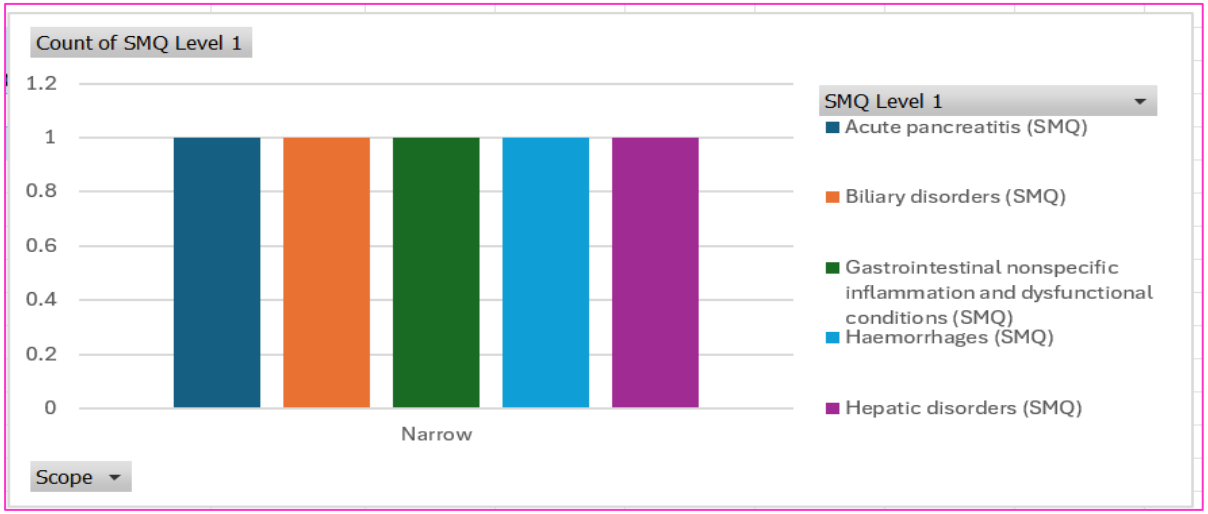
Patient ABC aged 45 years, Female, was on drug XYZ from some time. She was hospitalized with severe upper abdominal pain, nausea, projectile vomiting and Jaundice. Her Laboratory investigation revealed that her serum amylase and serum bilirubin levels were elevated. On physical examination she was also 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

Exercise…(contd).

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

MedDRA in Pharmacovigilance

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

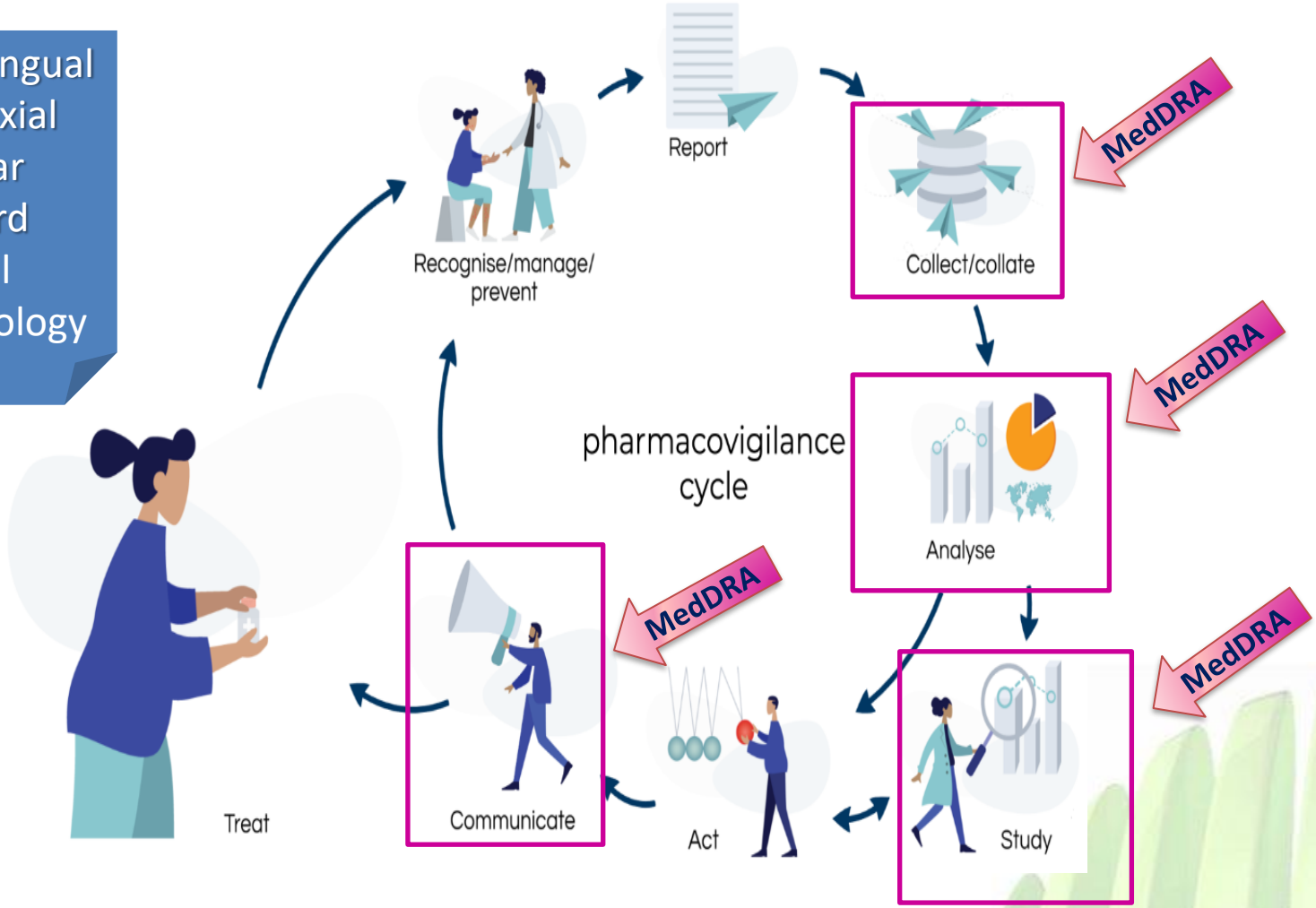


Fig. UMC's PV Cycle
https://who-umc.org/signal-work/what-is-a-signal/

Know more?

MedDRA | Medical Dictionary for Regulatory Activities

SSA WBB PtC Contact FAQs Downloads

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Support Documentation / How to Use /

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- Additional Points to Consider Documents and MedDRA Best Practices Document (click here)
- MedDRA Version 24.0 March 2021
- MedDRA Version 23.1 September 2020
- MedDRA Version 23.0 English March/April 2020
- MedDRA Version 22.1 English September 2019
- MedDRA Version 22.0 English March 2019
- MedDRA Version 21.1 English September 2018
- MedDRA Version 21.0 English March 2018
- MedDRA Version 20.1 English September 2017
- MedDRA Version 20.0 English March 2017
- MedDRA Version 19.1 English September 2016
- MedDRA Version 19.0 English March 2016
- MedDRA Version 18.1 English September 2015

Training Materials / 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.

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