Introduction to MedDRA for Coding and Analysis in Pharmacovigilance

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Outline of the Presentation

- MedDRA Definition, Governance, and Background (Panel Discussion)
- MedDRA Use and Benefits in Pharmacovigilance (Panel Discussion)
- MedDRA Scope, Structure, and Characteristics
- Support Documentation
- Retrieval, Presentation, and Analysis of MedDRA-Coded Data
- Summary



What Benefits Does MedDRA Offer for Pharmacovigilance?

What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities



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 (coding) , retrieval, evaluation, and presentation.

MedDRA Is 25 Years Old!



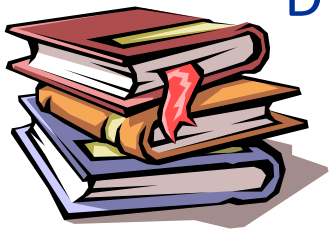
- First official release – 1 March 1999 (V2.1)
- Most recent release – 1 Sep 2024 (V27.1)
- A total of 57 releases

Med = Medical

D = Dictionary for

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ICH harmonisation for better health

MedDRA and the MSSO

MSSO

International support and development of terminology
"Custodians", not owners, of the terminology

Governance

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

Educational offerings

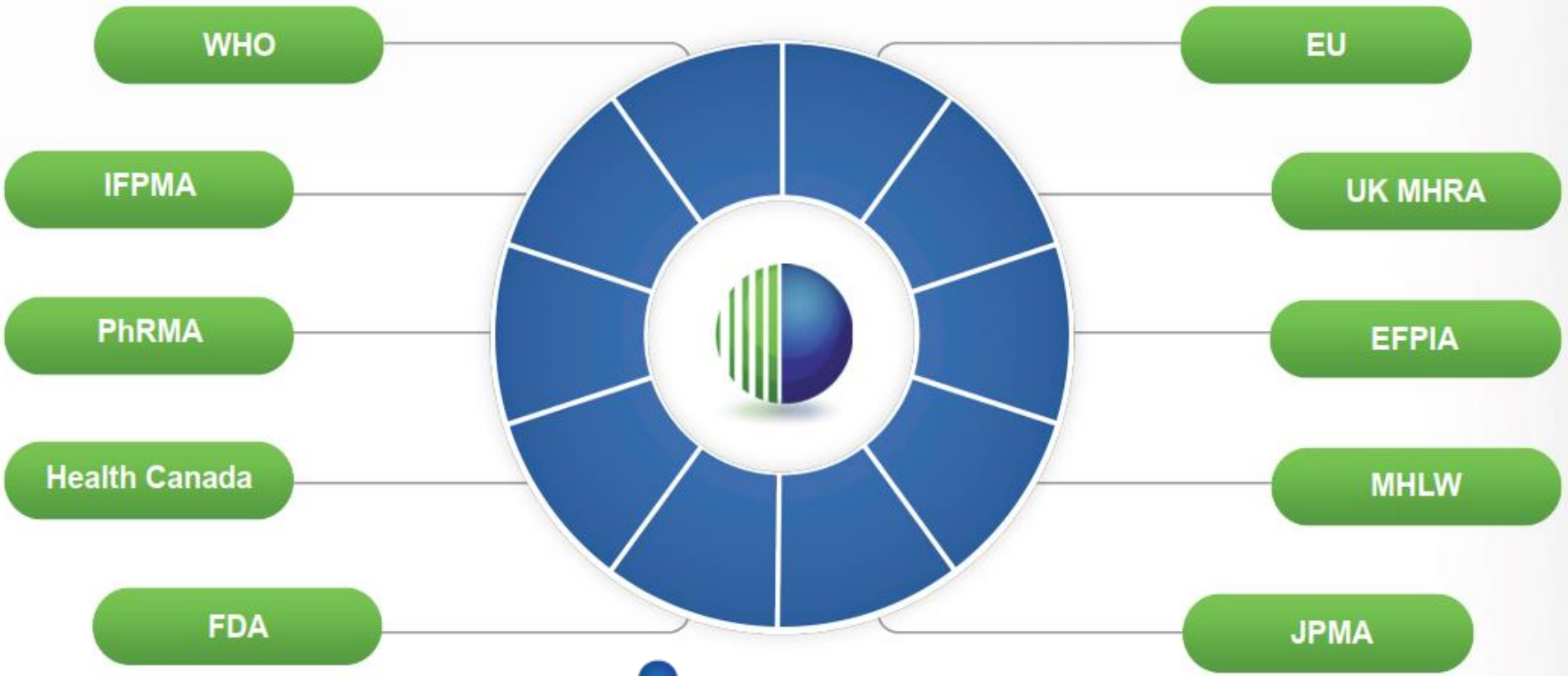
Foster use of MedDRA through communications and educational offerings

JMO

Partner organization for Japanese-language MedDRA



Governance Structure for MedDRA MSSO – ICH MMC



ICH
harmonisation for better health

Global View – MedDRA Growth





MedDRA is in ~ 140 countries

Over 8500 subscribing organizations worldwide

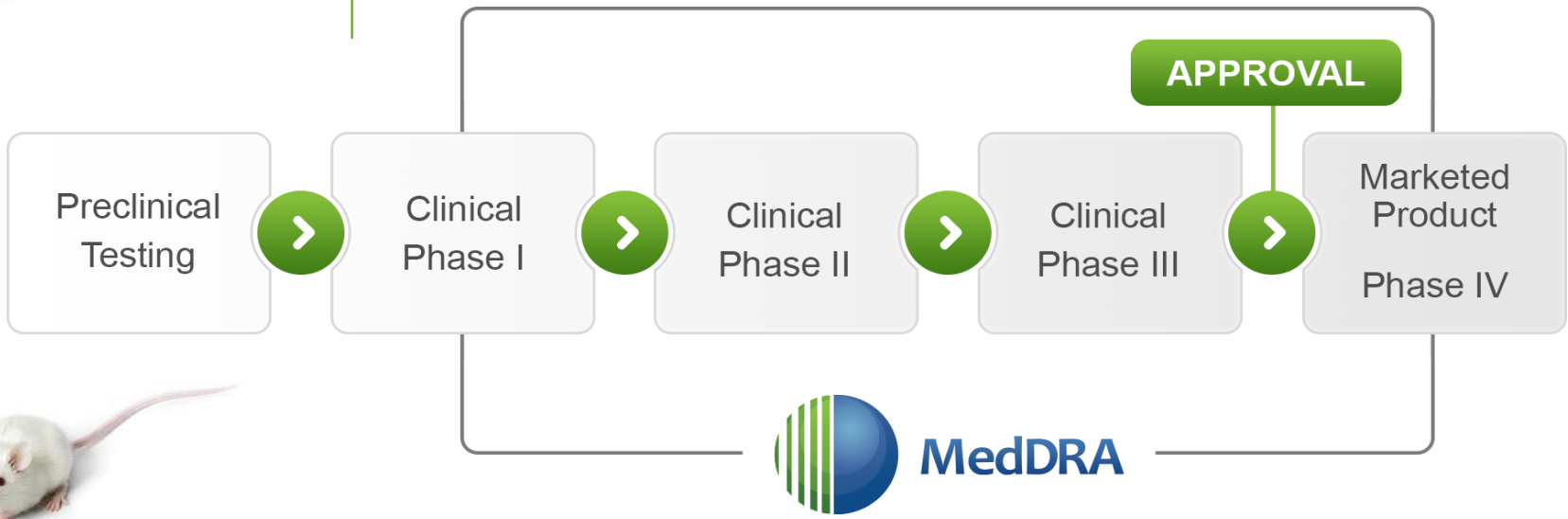
Multilingual MedDRA to Maximize Data Sharing

8-digit Numeric Code
/
each MedDRA term

- Non-expressive
- Assigned sequentially



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

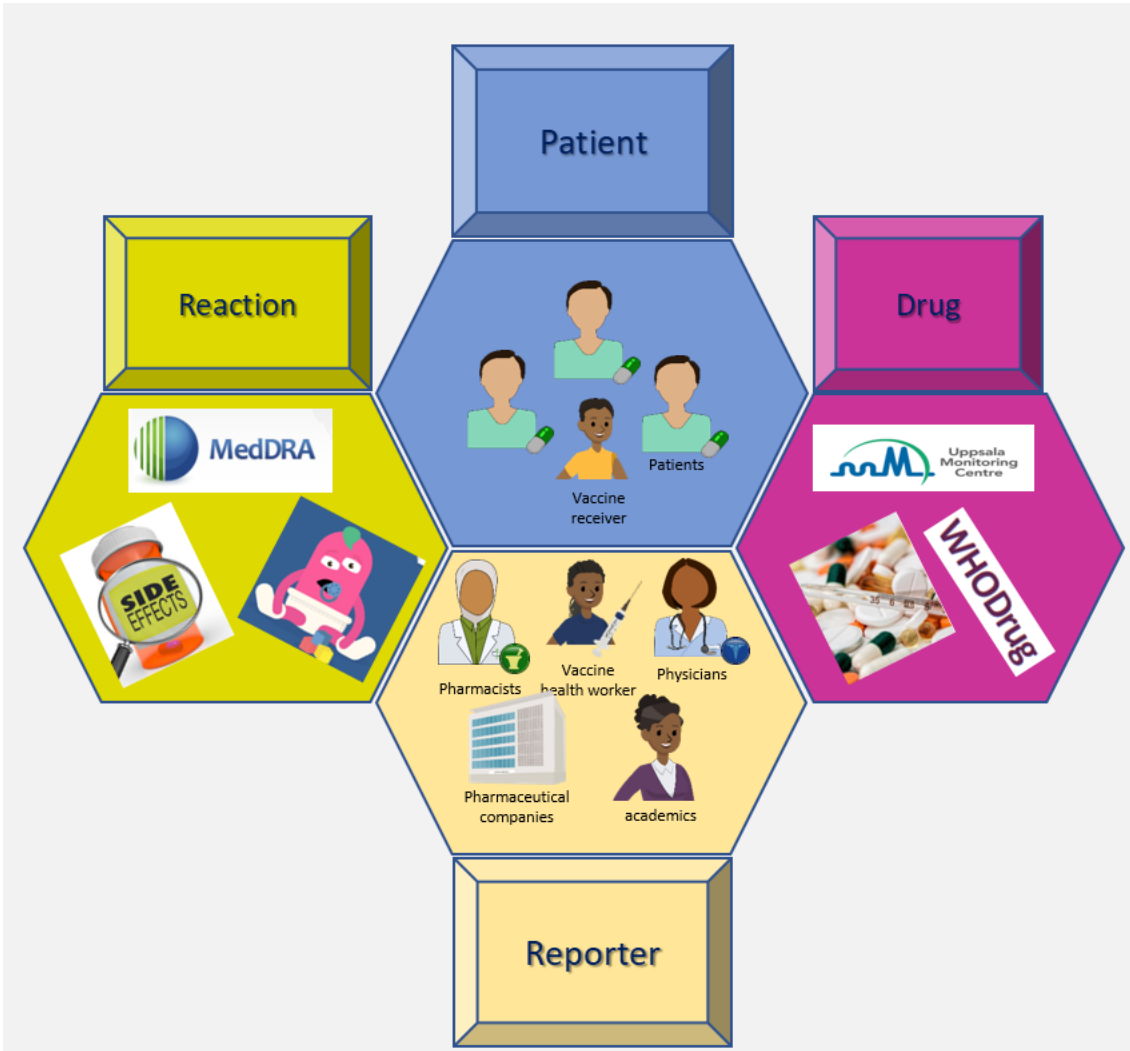
Advertising

Pillars of Individual Case Safety Report (ICSR)



ICSRs

4 Pillars



Pharmacovigilance Stakeholders versus MedDRA Stakeholders





MedDRA Benefits in Pharmacovigilance

Standardization

MedDRA provides a standard medical terminology to various PV stakeholders for coding and categorizing medical information related to adverse events, medical conditions, product use issues (e.g. Medication Errors, Off label use, Drug abuse, Overdose, Misuse), and manufacturing & quality system issues.

International Collaboration

MedDRA simplifies international collaboration and information sharing. It eases communication and data exchange between different regulatory agencies and organizations, fostering a more connected and effective approach to drug safety.

Consistent Data Collection & Aggregation

MedDRA helps collect PV data from various sources and regions. It also ensures consistent coding of medical terms and concepts across different databases and systems.

It also ensures consistency which is essential for aggregating, analyzing, and comparing PV data, allowing for the identification of national/regional/global safety concerns.

Data Analysis and Reporting

Integrating MedDRA simplifies the generation of standardized reports and data analyses. These reports are invaluable for presenting findings to regulatory authorities, stakeholders, and the public, enabling them to make informed decisions about drug safety.

MedDRA Benefits in Pharmacovigilance (cont.)

Signal Detection

Early detection of safety signals is paramount in pharmacovigilance. MedDRA integration facilitates the systematic analysis of data related to specific AEs, making it easier to identify potential safety concerns. This early detection can lead to timely risk mitigation.

Improved Data Quality

By reducing data errors, inconsistencies, and ambiguities, MedDRA integration contributes to higher data quality. This not only enhances the reliability of pharmacovigilance data but also ensures the integrity of safety assessments and subsequent actions.

Mapping and Interoperability

MedDRA includes cross-referencing capabilities, allowing for the mapping of different medical terminologies and coding systems. MedDRA features promote interoperability between various PV databases, ensuring seamless data exchange and collaboration.

Regulatory Compliance

Numerous regulatory authorities worldwide, including EPVC/EDA, mandate the use of MedDRA for reporting AEs and conducting PV activities. So, MedDRA integration is the means to achieve it.

MedDRA's Scope, Structure, and Characteristics

Scope of MedDRA

OUT

Not a drug dictionary

Frequency qualifiers

IN

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

Patient demographic terms

Numerical values for results

Clinical trial study design terms

Severity descriptors

Not an equipment, device, diagnostic product dictionary

MedDRA Hierarchical Structure

System Organ Class (SOC)	27
High Level Group Term (HLGT)	337
High Level Term (HLT)	1738
Preferred Term (PT)	26409
Lowest Level Term (LLT)	88345

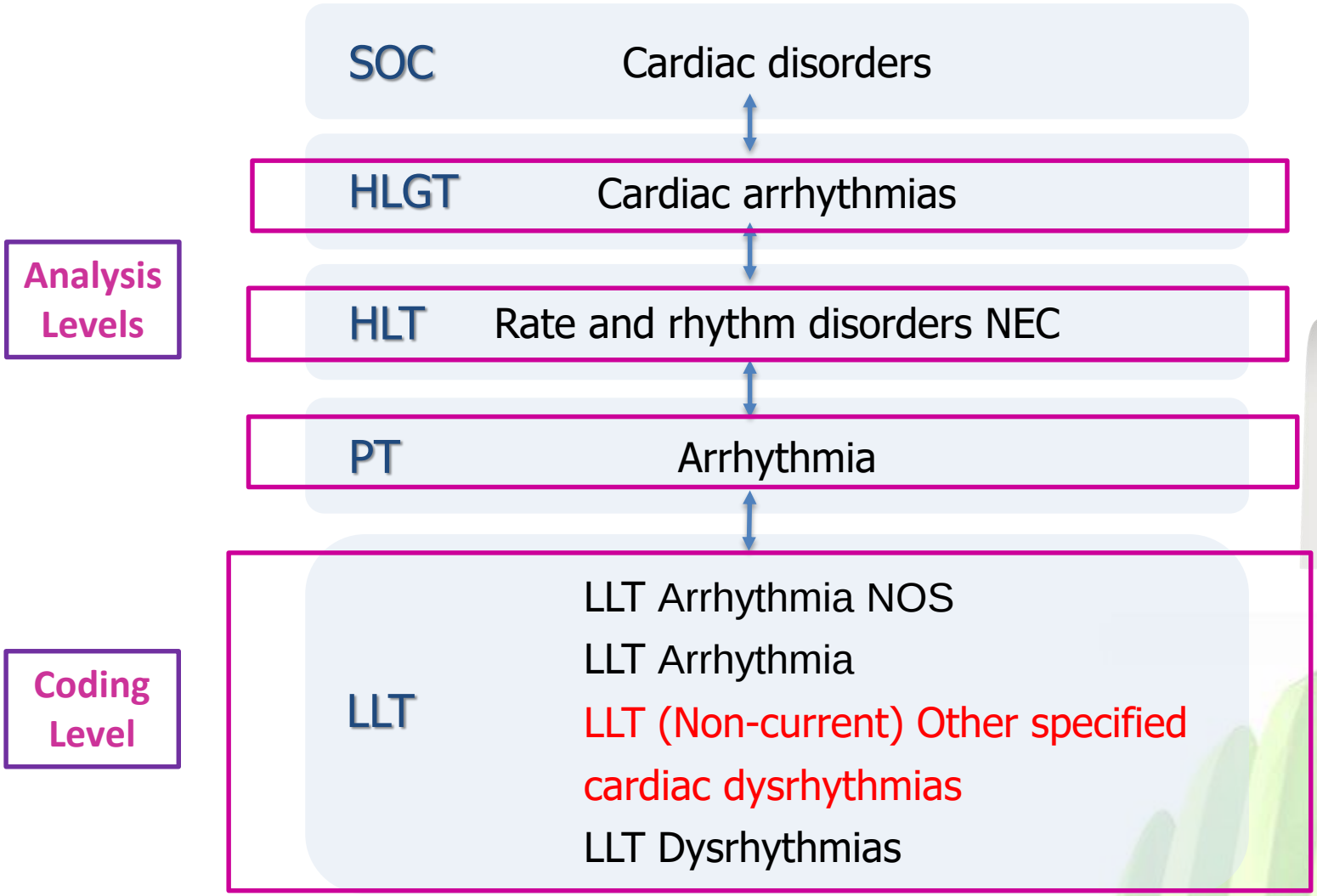


MedDRA Version 27.0

System Organ Classes

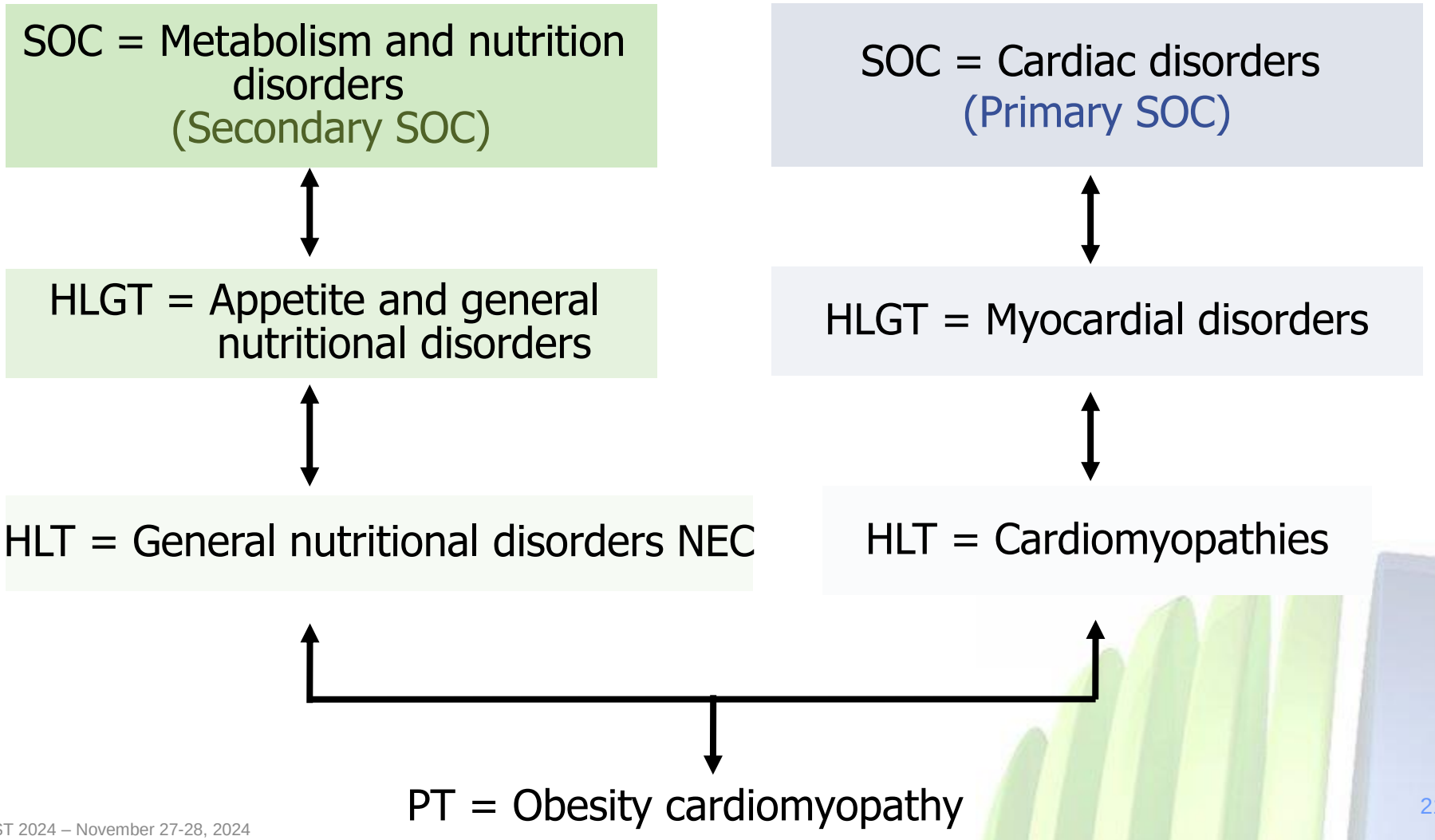
- Blood and lymphatic system disorders
- Cardiac disorders
- **Congenital, familial and genetic disorders**
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders and administration site conditions
- Hepatobiliary disorders
- Immune system 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 Hierarchy - Granularity



Note:
Not all HLGTs, HLTs, PTs or LLTs shown

MedDRA Hierarchy - Multi-Axial Terminology



Types of Information to be Coded with MedDRA



MedDRA Coding - General Principles

MedDRA® TERM SELECTION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users



Exercise

A 75-year-old male receiving Drug X **for** rheumatoid arthritis **developed** symptomatic aortic valve stenosis. The patient's **medical history** is significant for colon cancer and cigarette smoking. He **underwent** an aortic valve replacement and developed a sternal wound infection three days post-surgery.



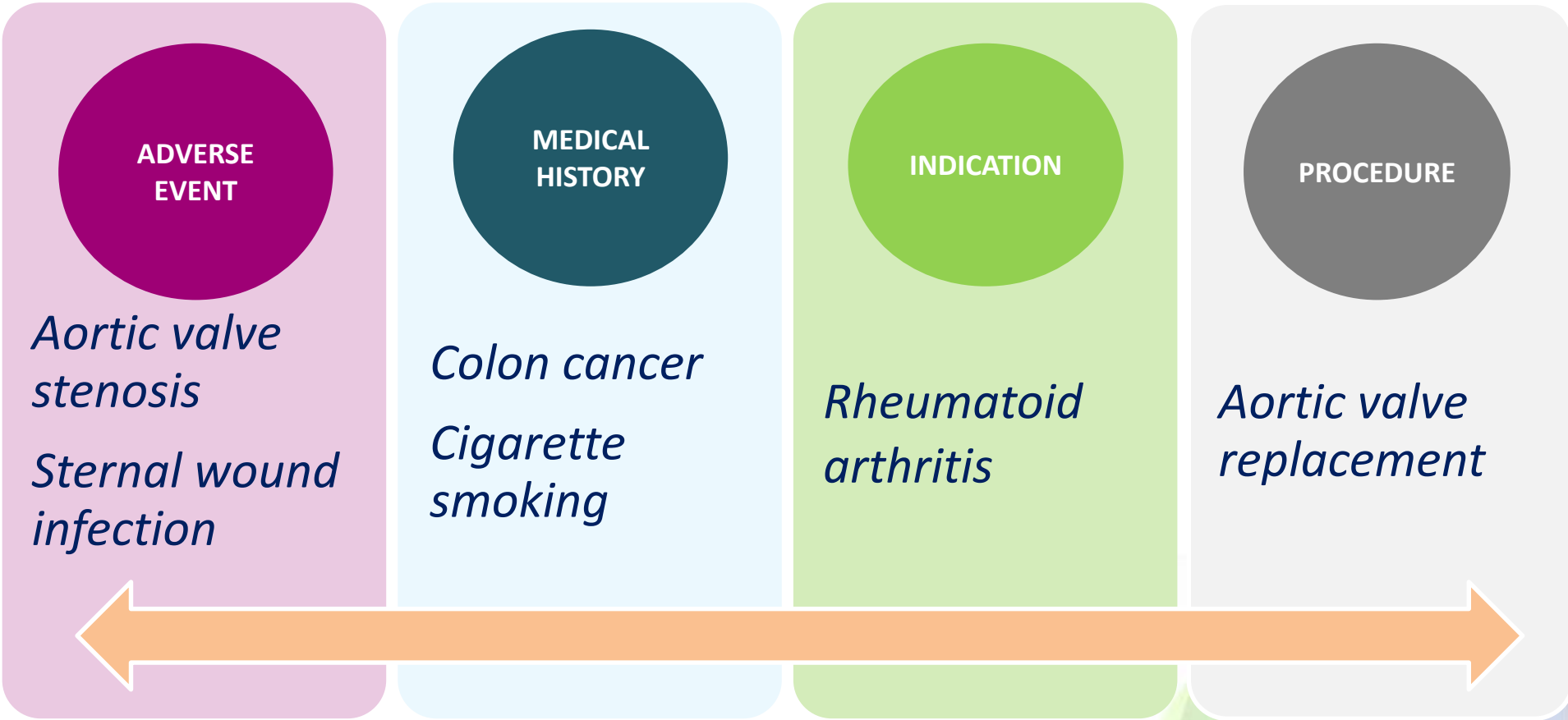
What type of information in this CASE NARRATIVE could be coded using MedDRA?

Nobody has responded yet.

Hang tight! Responses are coming in.

Start the presentation to see live content. For screen share software, share the entire screen. Get help at **pollev.com/app**

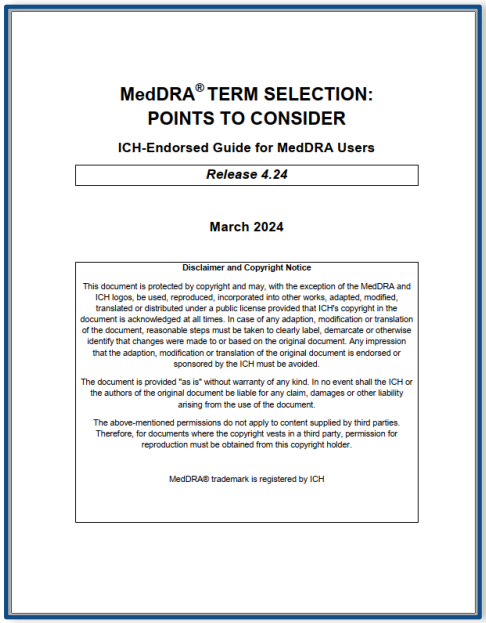
Exercise (cont.)



ICH/MSSO Support Documentation

MedDRA Term Selection (MTS:PtC) Release 4.24
&
MedDRA PtC Companion Document Release 3.0

MedDRA Data Retrieval and Presentation (DRP:PtC) Release 3.24



MedDRA® TERM SELECTION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users

Release 4.24

March 2024

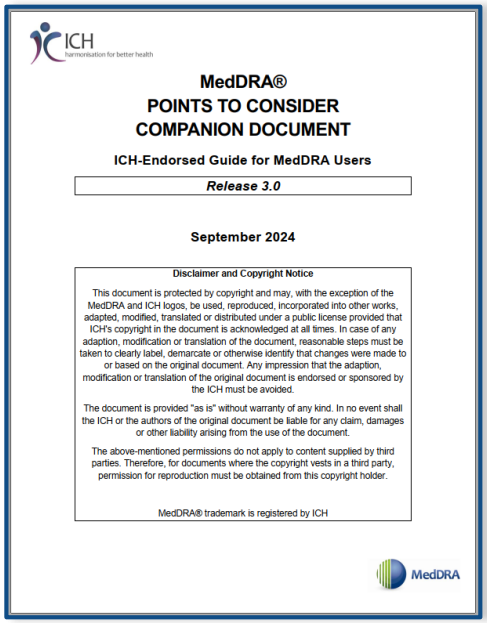
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ICH harmonisation for better health

MedDRA® POINTS TO CONSIDER COMPANION DOCUMENT

ICH-Endorsed Guide for MedDRA Users

Release 3.0

September 2024

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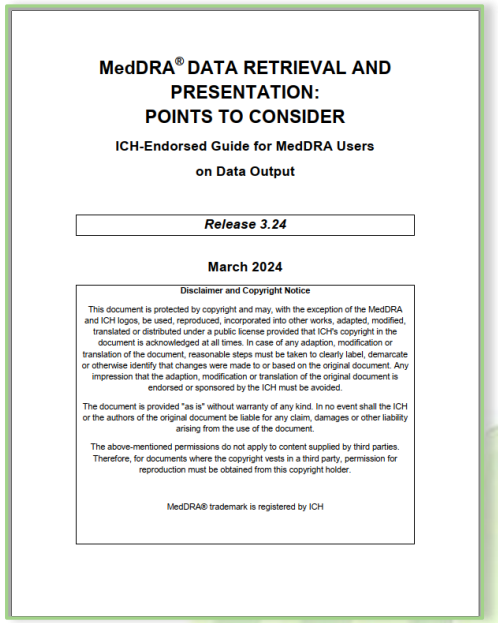
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MedDRA

MedDRA Coding Guidelines



MedDRA® DATA RETRIEVAL AND PRESENTATION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users on Data Output

Release 3.24

March 2024

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Data Retrieval & Analysis Guidelines

Retrieval, Presentation, and Analysis of MedDRA-Coded Data

Retrieval, Presentation, and Analysis in MedDRA (cont.)

Main PPTN PT/SOC

↔

Grouping HLT/HLGT

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

Retrieval, Presentation, and Analysis in MedDRA (cont.)

Secondary SOC

Programming a List of PTs in Primary and Secondary SOC Locations
SOC *Eye disorders*
HLGT *Vision disorders*
HLT *Visual pathway disorders*
PT *Chiasma syndrome*
PT *Optic nerve compression* (primary SOC location)
PT *Optic nerve disorder* (primary SOC location)
PT *Optic neuropathy* (primary SOC location)
PT *Toxic optic neuropathy* (primary SOC location)
PT *Visual cortex atrophy*
PT *Visual pathway disorder*
3 of 7 PTs are primary to SOC *Nervous system disorders*

What is a Query?



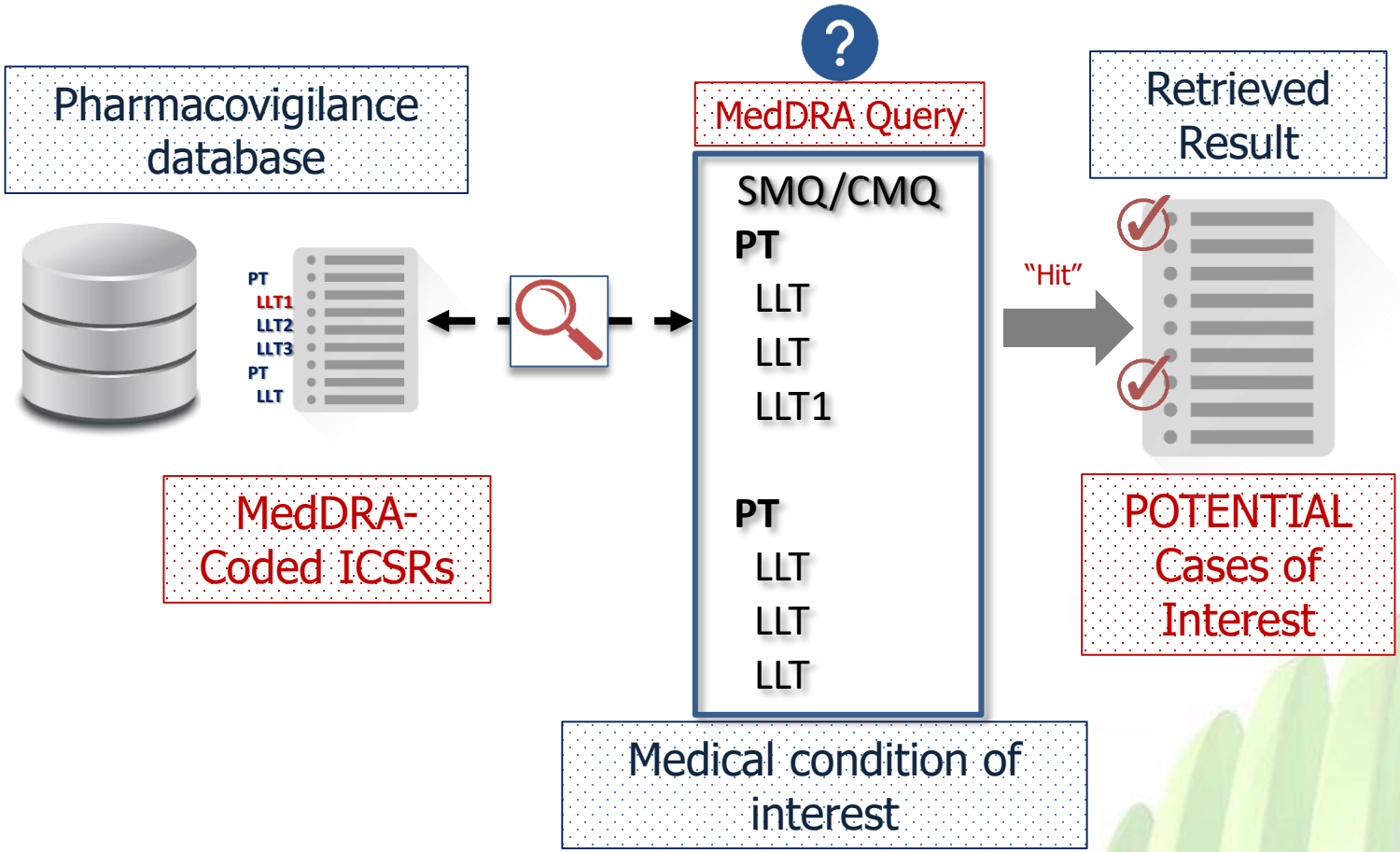
Groupings of MedDRA terms, typically at the Preferred Term (PT) level related to a defined medical condition or area of interest.

SMQ/CMQ

PT
- LLT
- LLT
- LLT1

PT
- LLT
- LLT
- LLT

What is a Query? (cont.)



Retrieval, Presentation, and Analysis in MedDRA (cont.)

Standardized MedDRA Query (SMQ)

Lactic acidosis (SMQ)

Narrow search terms

- Blood lactic acid increased
- Hyperlactacidaemia
- Lactic acidosis

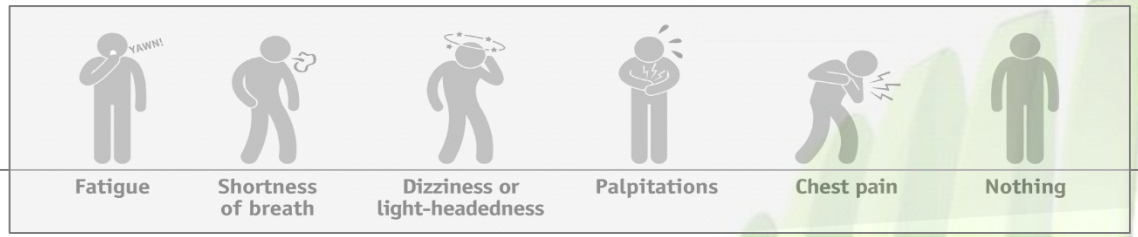
Broad Search Terms

- 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

Retrieval, Presentation, and Analysis in MedDRA (cont.)

Ad Hoc Query (CMQ)

- Because arrhythmias may produce various signs and symptoms, you may wish to review PTs subordinate to the following **HLTs**:
  - HLT *Disturbances in consciousness NEC*
  - HLT *Neurological signs and symptoms NEC*
  - HLT *Cardiac disorders NEC*
  - HLT *Cardiac signs and symptoms NEC*
  - HLT *Dyspnoeas*



Conclusion - MedDRA in Pharmacovigilance Process

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

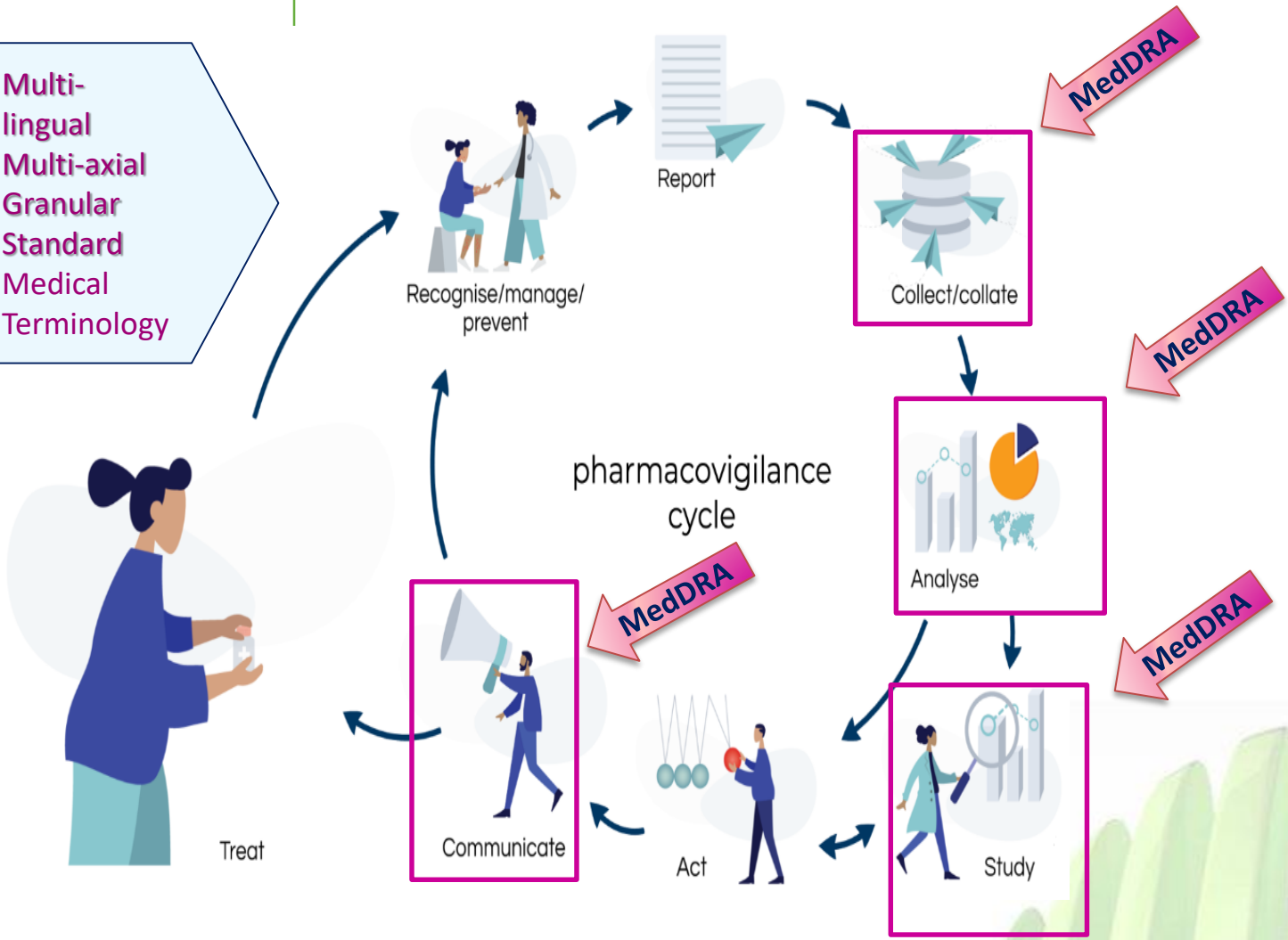


Fig. UMC's PV Cycle
https://who-umc.org/signal-work/what-is-a-signal/

MSSO Contacts





Thank You!

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