

# **UNIT-II**

## **DRUG DICTIONARIES AND CODING IN PHARMACOVIGILANCE**



**CENTURION**  
**UNIVERSITY**  
*Shaping Lives...  
Empowering Communities!*

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- **WHO adverse reaction terminologies**
- **MedDRA and Standardized MedDRA queries**
  - **WHO drug dictionary**
- **Eudravigilance medicinal product dictionary**

What is MedDRA?

**Med**=Medical

**D**=Dictionary

**R**=Regulatory

**A**=Activities

**Definition:**

- The MedDRA is a **medical terminology** used to **classify adverse event information** associated with the use of **biopharmaceuticals** and other **medical products** (e.g. **medical devices** and **vaccines**).
- It is used to **classify the adverse drug events (ADEs)** data from **clinical trials**, **spontaneous adverse event reports** by **healthcare professionals**, **patients** and others; and from other sources of the **ADEs**.

- ✦ **MedDRA has been developed by an ICH Working Group to provide:**
  - **An international, multi-lingual, medical terminology %o**
    - Medical personnel can code ADR data in their native language
    - Safer – less likely to miscode data
  - **Standardized communication between regulators and industry/sponsors of clinical trials%o**
    - Within regions and between regions
- ✦ **A single terminology for use through all phases of development cycle (both pre- and post-marketing)**
  - **Clinical Trials (medical information, adverse events)**
  - **Registration (study reports, analyses, summary of product characteristics/labeling – undesirable effects section)**
  - **Post-authorization (adverse events)**

## ✦ Support for electronic submissions

- Each MedDRA term is assigned a unique 8-digit numeric code
- Codes can fill certain data fields in e-submission types (**E2B: ICSR- Individual Case Safety Reports, eCTD: e-Common Technical Document**)
- Codes easier to transmit as no language boundaries

## SCOPE of MedDRA



## **Who develop MedDRA?**

- It is developed by the International Council for Harmonization (ICH) of Technical Requirements for Pharmaceuticals for Human use.
- ICH has created a governance structure to nature and protects the integrity of MedDRA.
- ICH Med DRA committee oversees all the activities of the MedDRA maintenance and support services organization.

## **The Maintenance and Support Service Organization (MSSO)**

- MSSO is the management Board appointed by ICH steering committee.
- Maintain and upgrades MedDRA.
- Releases updated MedDRA versions twice a year (in March and September).

## MedDRA MSSO

- ✦ MedDRA is actively developed and maintained
  - Two releases per year
  - Evolves to meet needs of regulators, industry, other users
  - Success depends on these activities
- ✦ ICH contracted MSSO for this purpose
- ✦ MSSO activities are governed by ICH MedDRA Management Board

## ICH MedDRA Management Board

**Six Parties: EU, EFPIA, FDA, MHLW, JPMA, PhRMA,**

**Three Observers: WHO, EFTA, Canada European**

1. **Commission - European Union (EU)**
2. **European Federation of Pharmaceutical Industries and Associations (EFPIA)**
3. **US Food and Drug Administration (FDA)**
4. **Pharmaceutical Research and Manufacturers of America (PhRMA)**
5. **Ministry of Health, Labor and Welfare, Japan (MHLW)**
6. **Japan Pharmaceutical Manufacturers Association (JPMA)**

## MedDRA Governance: ICH MedDRA Management Board





## Objectives of MedDRA's Development

- + International multi-lingual terminology
  - Used in 60 countries
  - Available in 11 languages
- + Standardised communication between industry and regulators
- + Application throughout all phases of development
- + Classification of a wide range of clinical information
- + Support multiple medical product areas
- + Support electronic submissions
  - Unique 8-digits codes for all terms
  - For data fields in e- submission types (e.g. E2B)



## WHO Drug Dictionary

The WHO Drug Dictionary is an international classification of the medicines created by the WHO Programme for International Drug Monitoring (IDM) and managed by Uppsala Monitoring Centre (UMC).

- A database with information about medical products from all over the world.
- It contains medicinal products and information related to the main relational database system.
- Information is provided in a consistent and structured way
- It provides useful groupings of data useful for both data input and output.
- It is continuously updated.

## Eudravigilance medicinal product dictionary

### Glossary

- EudraVigilance: European Union Drug Regulating Authority  
Pharmacovigilance
- ATC: Anatomical Therapeutic Chemical
- CIOMS: Council for International Organisations of Medical Sciences
- EEA: European Economic Area
- EMA: European Medicines Agency
- ESTRIM: Electronic Standards for the Transfer of Regulatory Information
- EVDAS: Eudravigilance Data Analysis System
- EVCTM: Eudravigilance Eudravigilance Clinical Trial Module
- EVPM: Eudravigilance Post-Authorisation Module
- ICH: International Conference of Harmonisation

**EUDRAVIGILANCE:** (European Union Drug Regulating Authority Pharmacovigilance) is the European data processing network and management system for reporting and evaluation of suspected adverse reactions to medicines which have been authorized or being studied in clinical trials in the European Economic Area (EEA). The European Medicines Agency (EMA) operates the system on behalf of the European Union (EU) medicines regulatory network.

The European Eudravigilance system deals with the :

- Electronic exchange of individual case safety reports (ICSR, based on the [ICH E2B](#) specification):
  - ✦ Eudravigilance Clinical Trials Module (EVCTM) for reporting Suspected Unexpected Serious Adverse Reactions ([SUSARs](#)).
  - ✦ Eudravigilance Post-Authorisation Module (EVPAM) for post-authorization ICSRs.
- Early detection of possible safety signals from marketed drug for human use.
- Continuous monitoring and evaluation of potential safety issues in relation to reported adverse reactions.
- Decision-making process, based on broader knowledge of the adverse reaction profile of drugs.
- The first operating version was launched by EMA in December 2001

## **Eudravigilance medicinal product dictionary (EVMPD):**

The EudraVigilance Medicinal Product Dictionary (EVMPD) has been designed to support in a standardised and structured way the collection, reporting, coding and evaluation of data on authorised medicinal products and investigational medicinal products.

The EVMPD offers:

- A distributed and common approach for data collection through user-friendly and easy accessible software solutions available free of charge for pharmaceutical companies
- Integrated standard terminology to code e.g. active ingredients, excipients, pharmaceutical forms, routes of administrations, concentration ranges and units, country codes, marketing authorisation holders and sponsors.
- A hierarchical data structure accommodating coding requirements in pharmacovigilance to reliably capture product information in safety reports taking into account the possible vagueness of the reported data by the primary source .

- A hierarchical, multi-axial data structure to support scientific data analysis of medicinal product data and grouping of data based on ingredients, strengths and pharmaceutical forms.
- Automated data import and systematic workflow with integrated quality control and audit checks.
- A standardised XML schema to support the collection and exchange of structured medicinal product information.
- Defined data ownership ensuring controlled data update through the respective product owner.
- A standardised approach to support updates, variations and withdrawals to medicinal product through the defined responsible product owner.
- Traceable and auditable regulatory changes to product information (recording of medicinal product history).

**EudraVigilance contains other dictionaries:**

**MedDRA:**

MedDRA is the Medical Dictionary for Regulatory Activities. It was developed in the frame of the ICH M1 activities as a clinically validated international medical terminology for regulatory authorities, and is maintained by the MedDRA's Maintenance and Support Services Organisation (MSSO). MedDRA is used by regulators and pharmaceutical industry for data entry, retrieval, evaluation and presentation during all phases of the drug regulatory process i.e. the pre- and post-authorisation phase. These processes include clinical studies, reports of spontaneous adverse reactions, events, regulatory submissions and regulated product information.

- VEDDRA
- Routes of Administration
- Dosage Units
- Pharmaceutical forms
- ATC



## **Purpose of Eudravigilance**

- To support the public health of EU citizens by collecting safety information on medicines and making this available for scientific assessment.
- This assessment is carried out by regulatory authorities in the EU that supervise and monitor the correct use of the medicines in all EU countries on a continuous basis.
- Medicinal product authorization information.
- Pharmacovigilance information.

## Eudravigilance support

- Electronic exchange of suspected adverse reaction reports (referred to as Individual Case Safety Reports) between European Medicines Agency (EMA), National Competent Authorities (NCA's), Marketing Authorization holders, and sponsors of clinical trials in the EEA.
- Early detection of possible safety signals from marketed drug for human use.
- Continuous monitoring and evaluation of potential safety issues in relation to reported adverse reactions.
- Decision-making process, based on broader knowledge of the adverse reaction profile of medicinal products especially in the frame of risk Management.

## Conclusion

- EudraVigilance is a powerful tool for monitoring the safety of medicinal products
- Once the complete feed of data has been established, it will be the largest database of its kind in the world.
- It will become an extremely useful resource for academic and commercial research once full access to data mining and statistical evaluation can be provided.