MedDRA Structure and Scope

MedDRA (Medical Dictionary for Regulatory Activities)
MedDRA was developed under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The activities of the MedDRA Maintenance and Support Services Organization (MSSO) are overseen by an ICH MedDRA Management Board, which is composed of the six ICH parties, the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, and the World Health Organization (as an observer).
Disclaimer and Copyright Notice

This presentation is protected by copyright and may 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.
Scope of MedDRA

**IN**
- Diseases
- Diagnoses
- Signs
- Symptoms
- Therapeutic indications
- Investigation names & qualitative results
- Medical & surgical procedures
- Medical, social, family history
- Medication errors
- Product quality, device issues
- Terms from other terminologies

**OUT**
- Frequency qualifiers
- Numerical values for results
- Severity descriptors
- Not an equipment, device, diagnostic product dictionary
- Patient demographic terms
- Clinical trial study design terms
- Not a drug dictionary
MedDRA Structure

- System Organ Class (SOC) (26)
  - High Level Group Term (HLGT) (>300)
    - High Level Term (HLT) (>1,700)
      - Preferred Term (PT) (>19,000)
    - Lowest Level Term (LLT) (>70,000)
MedDRA Term Level Definitions

- **SOC** - Highest level of the terminology, and distinguished by anatomical or physiological system, etiology, or purpose
- **HLGT** - Subordinate to SOC, superordinate descriptor for one or more HLTs
- **HLT** - Subordinate to HLGT, superordinate descriptor for one or more PTs
- **PT** - Represents a single medical concept
- **LLT** - Lowest level of the terminology, related to a single PT as a synonym, lexical variant, or quasi-synonym (Note: All PTs have an identical LLT)
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
- 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
Examples of LLTs

SOC = Cardiac disorders

HLGT = Cardiac arrhythmias

HLT = Rate and rhythm disorders NEC

PT = Arrhythmia

LLT (Non-current) Other specified cardiac dysrhythmias

LLT
Arrhythmia NOS

LLT
Arrhythmia

LLT
Dysrhythmias
Non-Current Terms

• Non-current terms are flagged at the LLT level within MedDRA
• Not recommended for continued use
• Retained within the terminology to preserve historical data for retrieval and analysis
• Terms that are vague, ambiguous, outdated, truncated, or misspelled
• Terms derived from other terminologies that do not fit MedDRA rules
MedDRA Codes

• Each MedDRA term assigned an 8-digit numeric code

• The code is non-expressive

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

• Initially assigned alphabetically by term starting with 10000001
  – New terms are assigned sequentially

• Supplemental terms are assigned codes
A Multi-Axial Terminology

• Multi-axial = the representation of a medical concept in multiple SOCs
  – Allows grouping by different classifications
  – Allows retrieval and presentation via different data sets

• Purpose of Primary SOC
  – Determines which SOC will represent a PT during cumulative data outputs
  – Is used to support consistent data presentation for reporting to regulators
A Multi-Axial Terminology (cont)

SOC = Respiratory, thoracic and mediastinal disorders

HLGT = Respiratory tract infections

HLT = Viral upper respiratory tract infections

PT = Influenza

SOC = Infections and infestations

HLGT = Viral infectious disorders

HLT = Influenza viral infections

PT = Influenza
A Multi-Axial Terminology (cont)

PTs in the following SOCs only appear in that particular SOC and not in others, i.e., they are not multi-axial

- Investigations
- Surgical and medical procedures
- Social circumstances
Rules for Primary SOC Allocation

- PTs for diseases, signs and symptoms are assigned to prime manifestation site SOC
- Congenital and hereditary anomalies terms have SOC *Congenital, familial and genetic disorders* as Primary SOC
- Neoplasms terms have SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* as Primary SOC
  - **Exception:** Cysts and polyps have prime manifestation site SOC as Primary SOC
- Infections and infestations terms have SOC *Infections and infestations* as Primary SOC
Primary SOC Priority

If a PT links to more than one of the exceptions, the following priority will be used to determine primary SOC:

1st: Congenital, familial and genetic disorders
2nd: Neoplasms benign, malignant and unspecified (incl cysts and polyps)
3rd: Infections and infestations
MSSO’s MedDRA Browsers

- MedDRA Desktop Browser
  - Download from MSSO Web site
  - View/search MedDRA and SMQs
  - Export functionality

- MedDRA Web-Based Browser
  - [https://www.meddrabrowser.org/dsnavigator/](https://www.meddrabrowser.org/dsnavigator/)
  - Requires specific user ID and password
  - Access to all MedDRA versions in English and available EU languages (and Chinese, if subscribed)
  - View/search MedDRA and SMQs
  - Export functionality
MedDRA Desktop Browser

Cardiac disorders
- Cardiac arrhythmias
  - Rate and rhythm disorders NEC
  - Arrhythmia

- Cardiac conduction disorders
- Rate and rhythm disorders NEC
- Agonal rhythm
- Anomalous atrioventricular excitation
- Arrhythmia
  - Arrhythmia
  - Arrhythmia (NOS)
  - Arrhythmia cardiac (NOS)
  - Arrhythmia exertional
  - Arrhythmia NOS
  - Cardiac arrhythmia
  - Cardiac arrhythmia (NOS)
  - Cardiac arrhythmia NOS
  - Cardiac compensatory pause
  - Cardiac dysrhythmia, unspecified
  - Cardiac dysrhythmias
  - Dysrhythmias
  - Other specified cardiac dysrhythmia
  - Other specified cardiac dysrhythmias
  - Proarrhythmia
  - Proarrhythmic effect
  - Arrhythmia neonatal
MSSO Contacts

• Web site
  • www.meddramsso.com

• Help Desk
  – Phone
    • International AT&T Toll Free: 877.258.8280
    • Direct Dial (USA): +1 571.313.2574
  – E-mail
    • mssohelp@mssotoools.com