



MedDRA Structure and Scope

MedDRA (Medical Dictionary for Regulatory Activities)

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Scope of MedDRA

OUT

Not a drug
dictionary

Frequency
qualifiers

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

Numerical values for
results

Severity descriptors

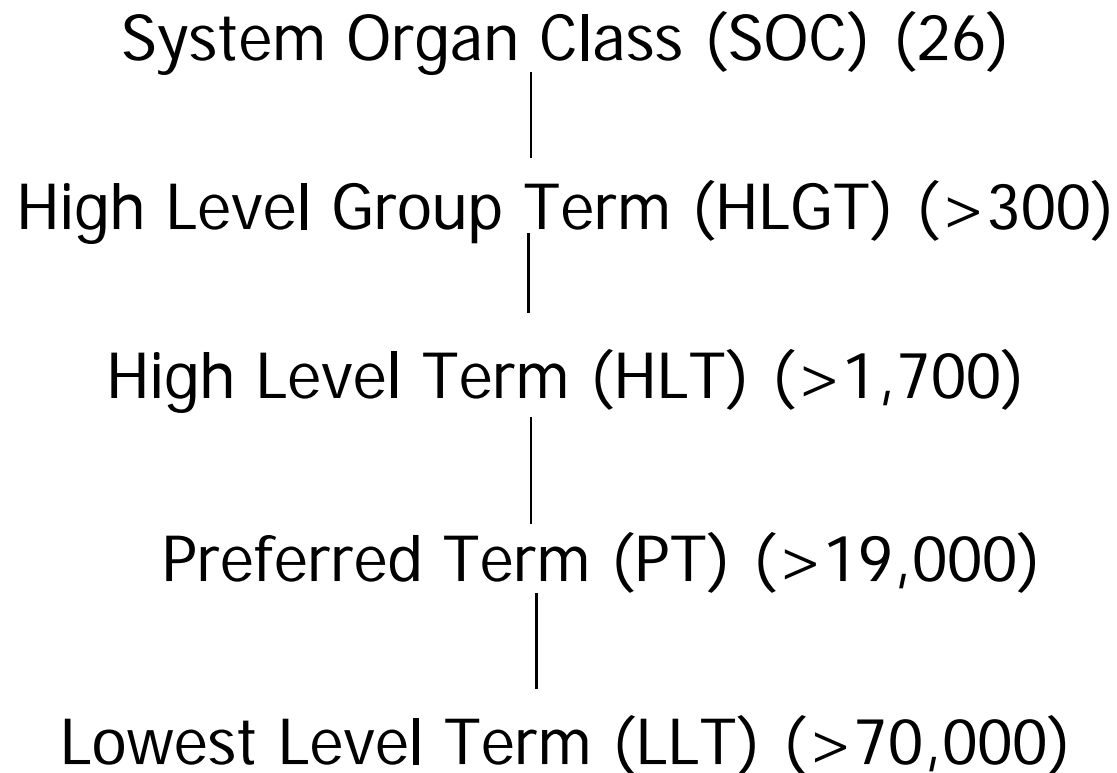
Patient demographic
terms

Clinical trial study
design terms

Not an equipment, device,
diagnostic product dictionary



MedDRA Structure





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)

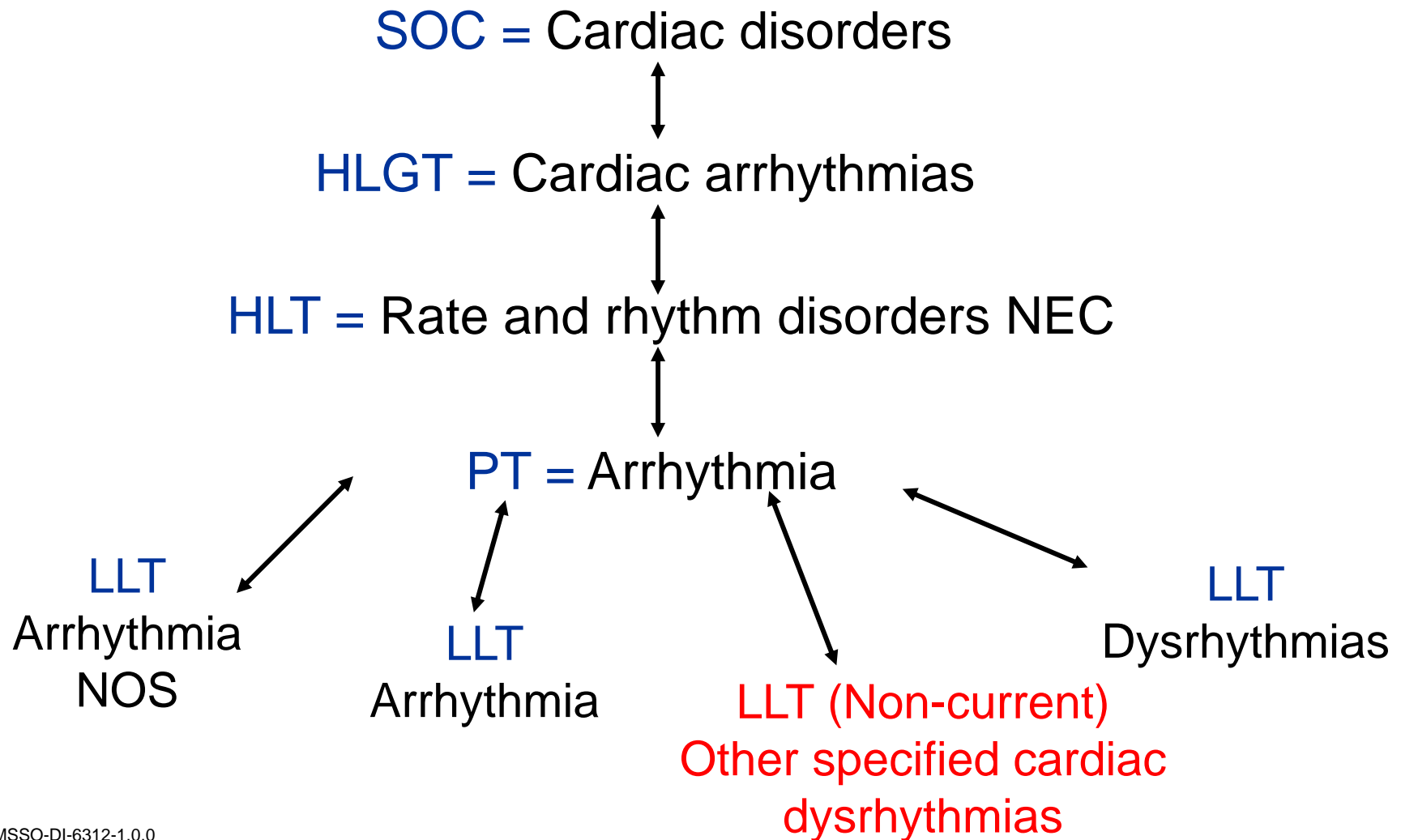


System Organ Classes

- 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





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 SOC's
 - 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)

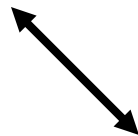
SOC = Respiratory, thoracic and mediastinal disorders



HLGT = Respiratory tract infections



HLT = Viral upper respiratory tract infections



PT = Influenza

SOC = Infections and infestations



HLGT = Viral infectious disorders



HLT = Influenza viral infections





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:

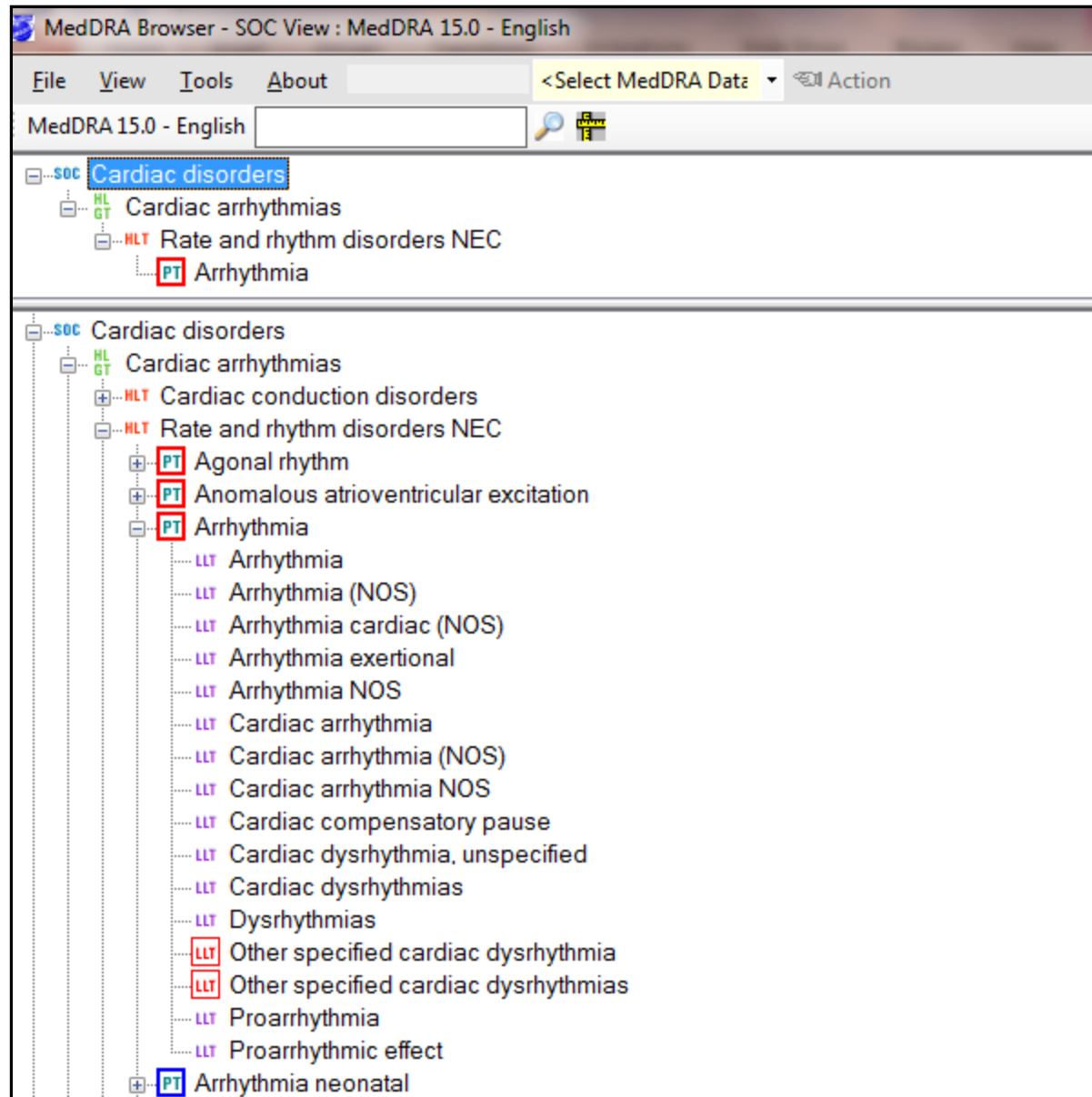
- 1st: Congenital, familial and genetic disorders*
- 2nd: Neoplasms benign, malignant and unspecified (incl cysts and polyps)*
- 3rd: Infections and infestations*



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/>
 - 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





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