



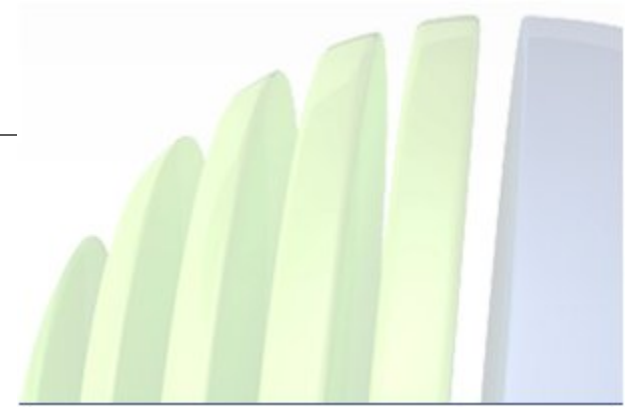
MedDRA

MedDRA and Reporting of Adverse Events

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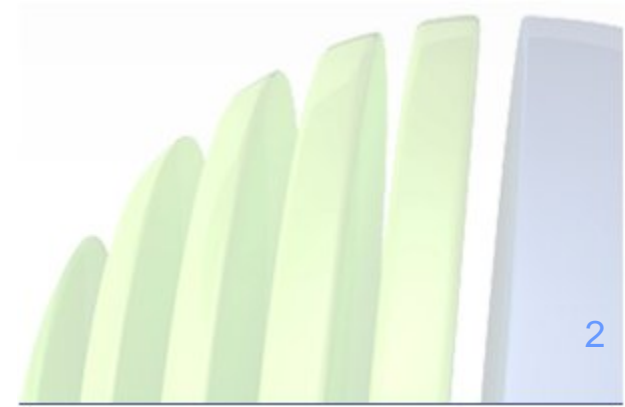




MedDRA

Topics

- MedDRA overview
 - What is MedDRA
 - Where it is used
 - Who uses it
 - Features
- Integration with other terminologies
- World SIVA AE tool and MedDRA





MedDRA

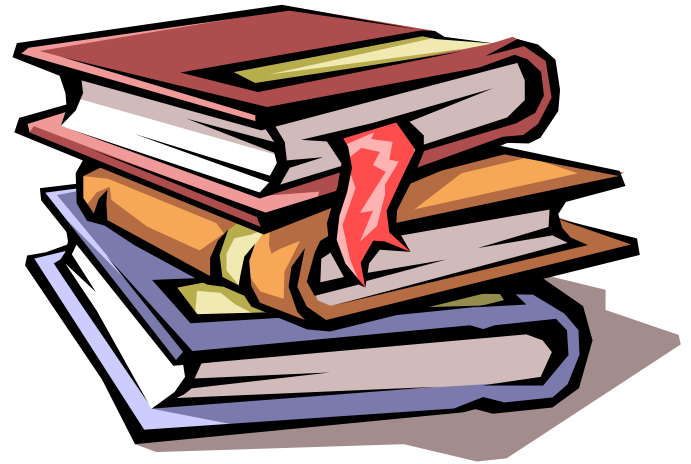
What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities





MedDRA

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, retrieval, evaluation, and presentation.





MedDRA

Where MedDRA is Used



Regulatory Authority and Industry Databases
Individual Case Safety Reports and Safety Summaries

Clinical Study Reports

Investigators' Brochures

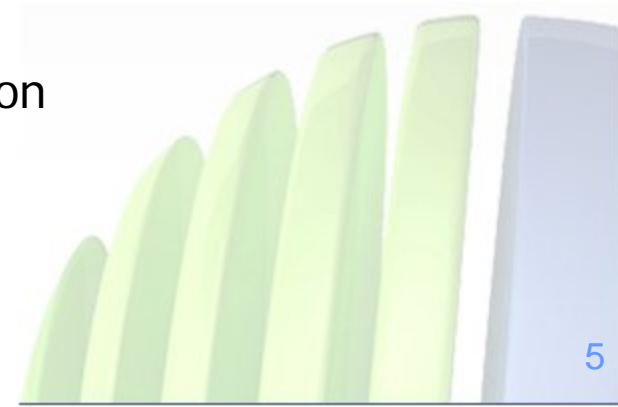
Core Company Safety Information

Marketing Applications

Publications

Prescribing Information

Advertising





Regulatory Use in ICH Regions

- US FDA
 - Not mandated but *de facto* standard in US
 - Used in several FDA databases
- Japanese Ministry of Health, Labour and Welfare
 - Mandatory use in electronic reporting
- European Union
 - Mandatory use in electronic reporting
 - EudraVigilance database
 - Good Pharmacovigilance Practices (GVP) specifically mention MedDRA
- Biopharmaceutical industry



Who Else Uses MedDRA?

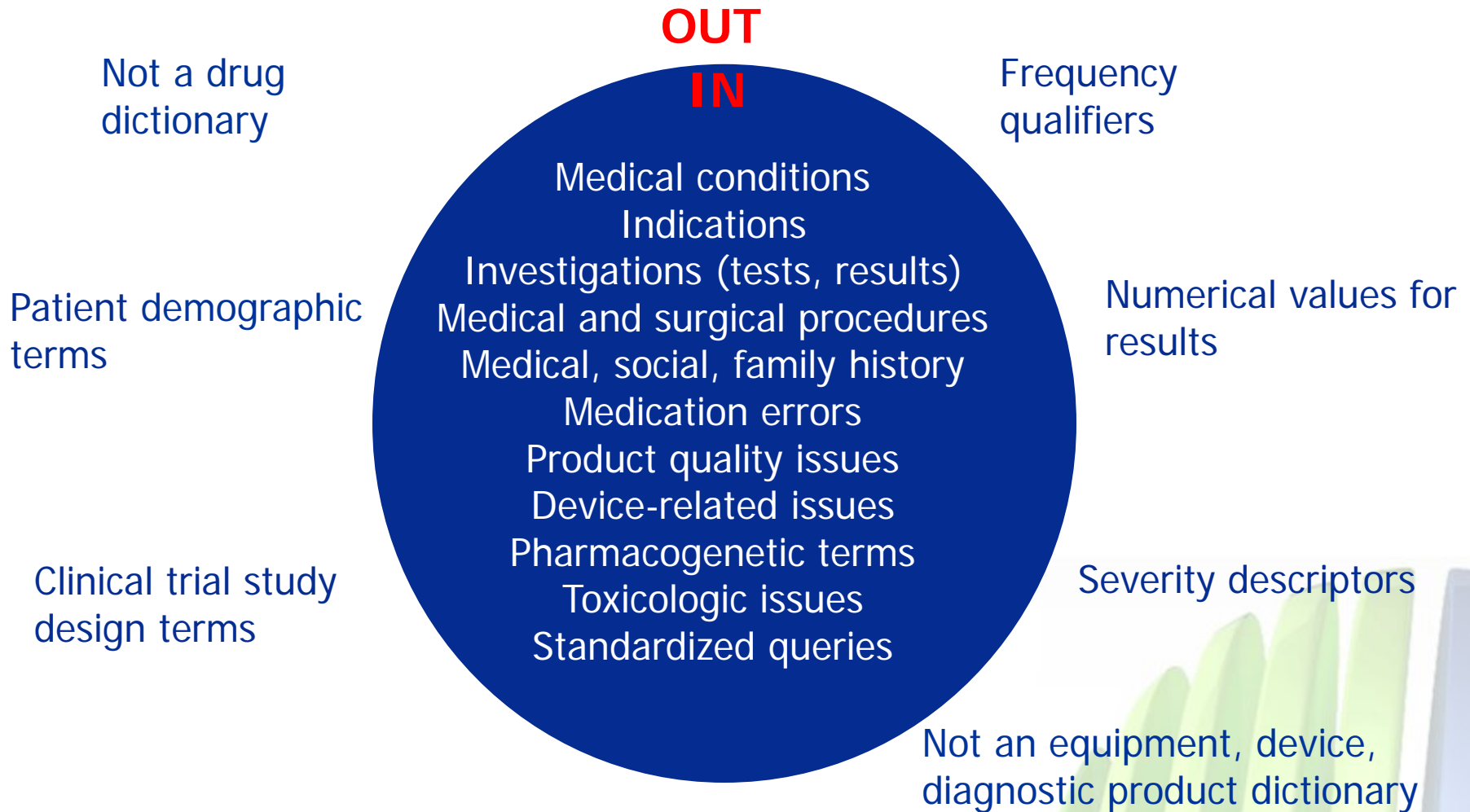
- Countries beyond the ICH regions
- WHO's international drug monitoring center (Uppsala Monitoring Centre)
- Academic researchers
- Toxicologists
- Others

More than 4,000 organizations worldwide in more than 90 countries



MedDRA

Scope of MedDRA





MedDRA

MedDRA Structure

System Organ Class (SOC) (27)



High Level Group Term (HLGT) (335)



High Level Term (HLT) (1,732)



Preferred Term (PT) (21,920)



Lowest Level Term (LLT) (75,818)



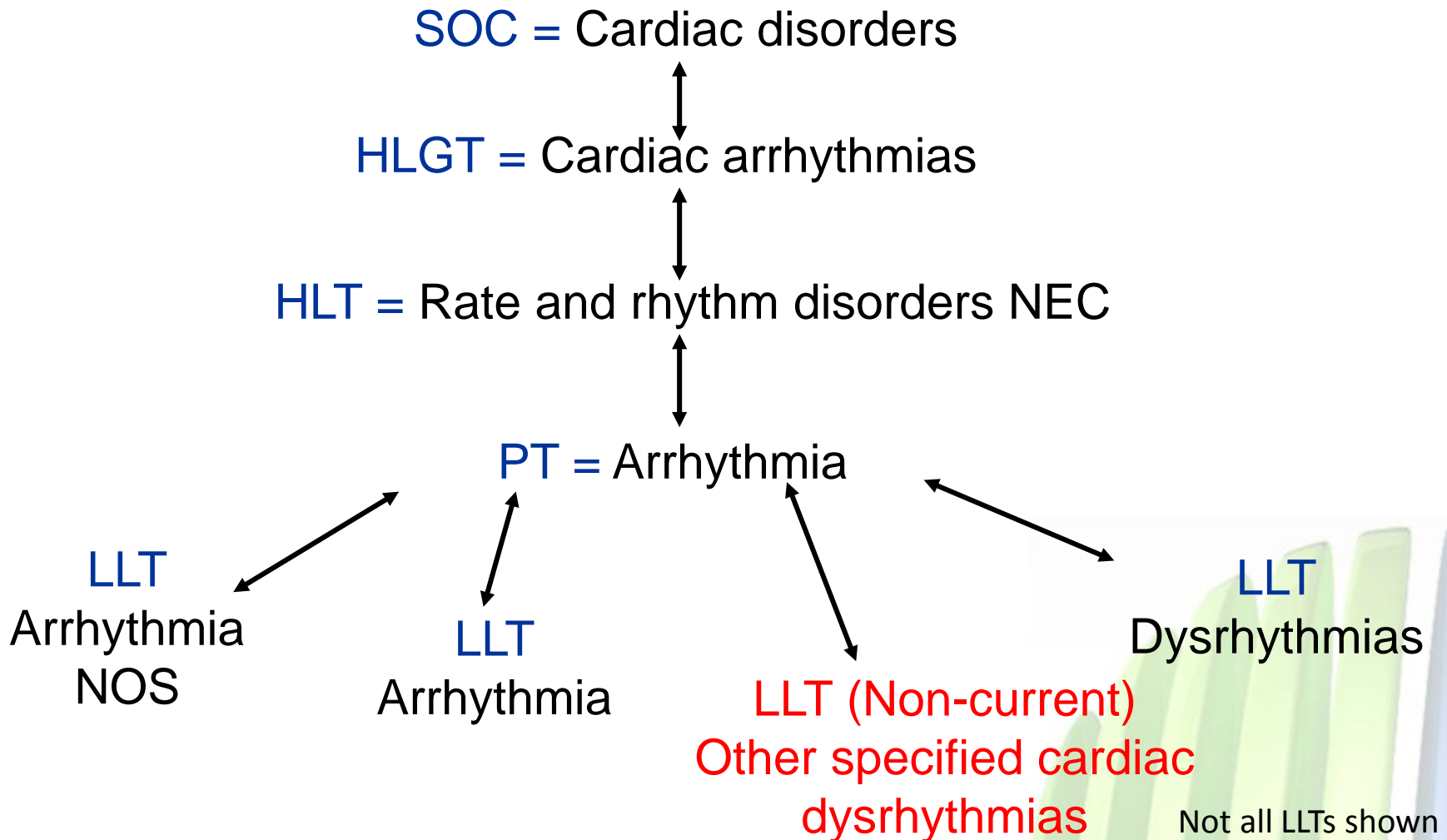
MedDRA

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 Structure (cont)



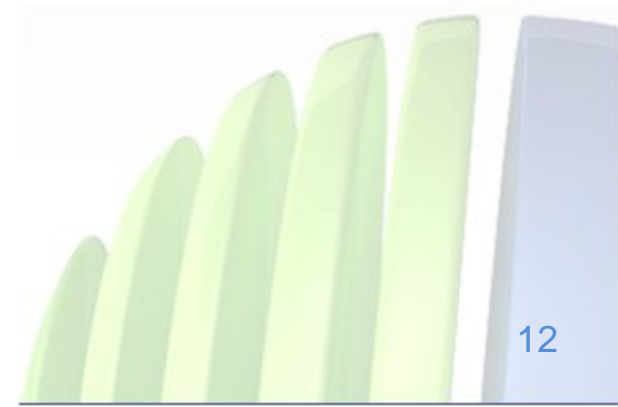


MedDRA

Codes and Languages



Electronic Submission





Integration with Other Terminologies

- Subsets of MedDRA terms used as basis for several other AE terminologies
 - NCI's Common Terminology Criteria for Adverse Events (CTCAE v4.0)
 - National Institute of Child Health and Human Development's Pediatric AE terminology
 - EVERREST project's maternal and fetal AE terminology
- Integration of MedDRA terms and codes facilitates exchange of information
- MedDRA is an international standardized terminology
 - No need to create separate terms for the other terminology
- Other terminology can incorporate its own features
 - Definitions
 - Severity rating scales

CTCAE v4.0 Example

- CTCAE v4 is a subset of MedDRA LLTs, organized by SOC, allowing seamless data exchange
- CTCAE definitions and severity scale added

Respiratory, thoracic and mediastinal disorders					
Adverse Event	Grade				
	1	2	3	4	5
Adult respiratory distress syndrome	-	-	Present with radiologic findings; intubation not indicated	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by progressive and life-threatening pulmonary distress in the absence of an underlying pulmonary condition, usually following major trauma or surgery.					
Allergic rhinitis	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated	-	-	-
Definition: A disorder characterized by an inflammation of the nasal mucous membranes caused by an IgE-mediated response to external allergens. The inflammation may also involve the mucous membranes of the sinuses, eyes, middle ear, and pharynx. Symptoms include sneezing, nasal congestion, rhinorrhea and itching.					
Apnea	-	-	Present; medical intervention indicated	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Definition: A disorder characterized by cessation of breathing.					



World SIVA AE Tool and MedDRA

- Interest in collaboration to integrate MedDRA into tool
- Preliminary mapping performed

World SIVA AE tool - MedDRA v17.1 mapping					
World SIVA sedation AE term	Fotnote	LLT	PT	Primary SOC	MSSO comment
Minor risk descriptors					
Oxygen desaturation (75-90%) for <60s		Oxygen saturation decreased	Oxygen saturation decreased	Investigations	MedDRA does not include numerical values for investigation results
Apnoea, not prolonged		Apnoea	Apnoea	Respiratory, thoracic and mediastinal disorders	"Prolonged" concept for apnoea is not in MedDRA. Terms referring to duration are not generally included.

- Next steps?



MedDRA

Medical Dictionary
for Regulatory Activities

Thank you

Questions?