MedDRA® Overview – A Standardized Terminology

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Topics

- MedDRA overview
- Applications in coding and analysis
- Type and scope of data related to product recalls
- Use of MedDRA to prevent recalls
- Dealing with recalls

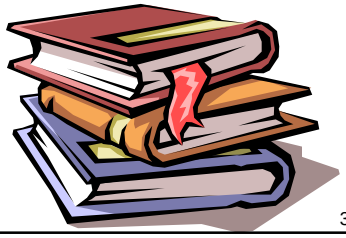
What is MedDRA?

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, retrieval, evaluation, and presentation.

Features of MedDRA

- Provides standardized communication between industry and regulators
- Supports electronic submissions
- Classification of wide range of clinical information
- Supports multiple product areas (drugs, biologics, vaccines, devices, foods, dietary supplements, etc.)
- Twice yearly version updates

MedDRA and the MSSO

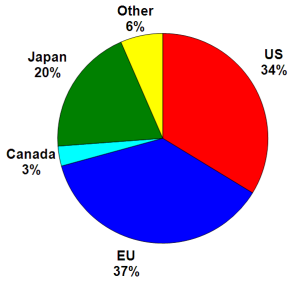
- International support and development of terminology
- Foster use of MedDRA through communications and educational offerings
- "Custodians", not owners, of the terminology
- JMO (partner organization for Japanese-language MedDRA)
- Governed by a Management Board (industry, regulators, multi-national, other interested parties)

MedDRA and CFSAN

- Center for Food Safety and Applied Nutrition (CFSAN)
  - CFSAN Adverse Event Reporting System (CAERS)database coded in MedDRA since 2002
  - MedDRA coding performed by CFSAN
  - MSSO recently added Product Quality terms

MedDRA Subscriptions

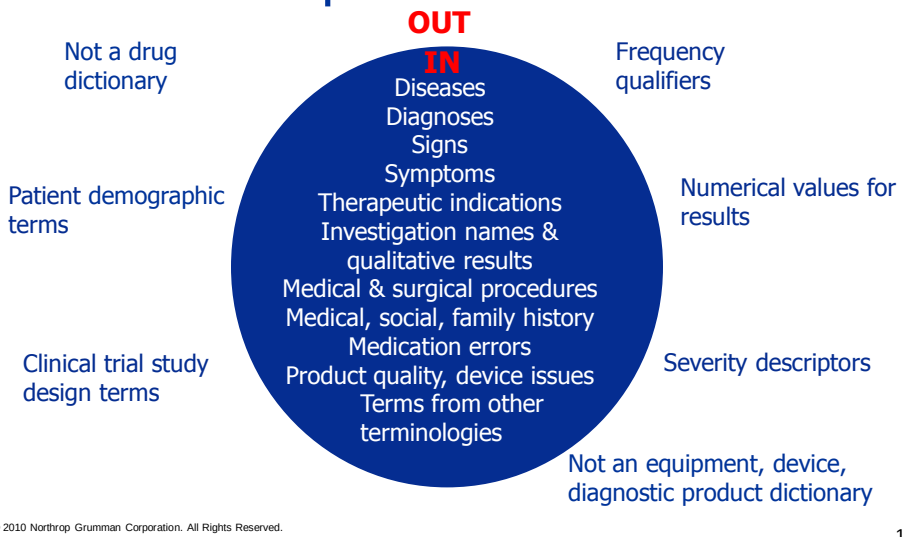
- Over 2,600 subscribing organizations around the world
  - Regulatory Authorities, Pharma companies, Device companies, CROs and other service providers, Academics, Hospitals, Software Developers



MedDRA Subscriptions (cont)

- MedDRA subscription types
  - Regulatory Authorities, Non-profits, Academics – No Fee
  - Commercial users – sliding scale based on annual revenue
    - $180/year for small organizations
    - $62K/year for the largest organizations

Scope of MedDRA



MedDRA Structure

System Organ Class (SOC) (26)

High Level Group Term (HLGT) (335)

High Level Term (HLT) (1,709)

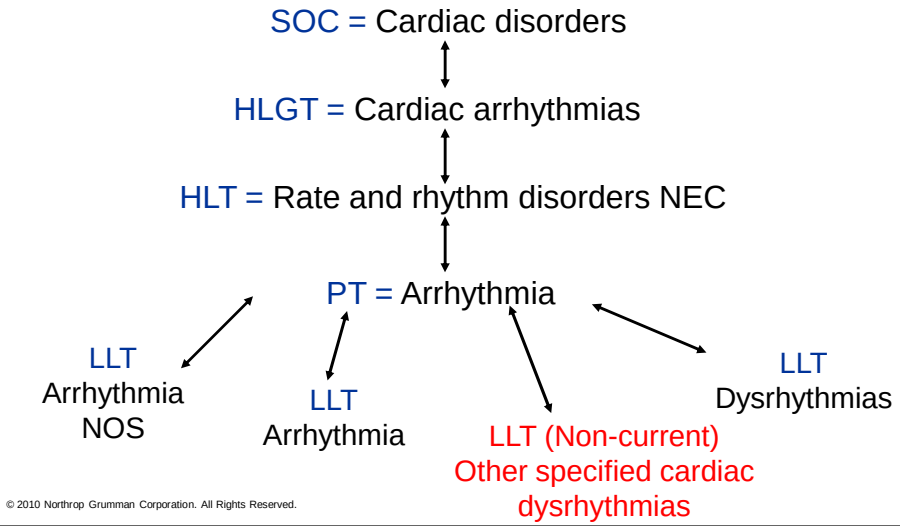
Preferred Term (PT) (18,786)

Lowest Level Term (LLT) (68,258)

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



Coding with MedDRA

- Size and specificity ("granularity")
- Hierarchy/grouping terms
- "Support" SOCs widen data collection/analysis options (patient and product information)
- Up-to-date and medically rigorous
- ICH-endorsed guide for MedDRA users – *MedDRA Term Selection: Points to Consider* document
- STANDARDIZATION

MedDRA: Data Retrieval and Analysis

- Specificity presents both advantages and challenges (signal dilution)
- Hierarchy/grouping terms aggregate related concepts
- Standardised MedDRA Queries (SMQs)
  - Groupings of terms from one or more MedDRA SOCs related to defined medical condition or area of interest
- ICH-endorsed guide for MedDRA users – *MedDRA Data Retrieval and Presentation: Points to Consider* document
- STANDARDIZATION

SMQs in Production - Examples

- As of Version 13.0, a total of 82 in production (Other SMQs in development)

- Adverse pregnancy outcome/reproductive toxicity (incl neonatal disorders)
- Agranulocytosis
- Anaphylactic reaction
- Cerebrovascular disorders
- Convulsions
- Depression and suicide/self-injury
- Hepatic disorders
- Ischaemic heart disease
- Lack of efficacy/effect
- Peripheral neuropathy
- Pseudomembranous colitis
- Rhabdomyolysis/myopathy
- Severe cutaneous adverse reactions
- Systemic lupus erythematosus

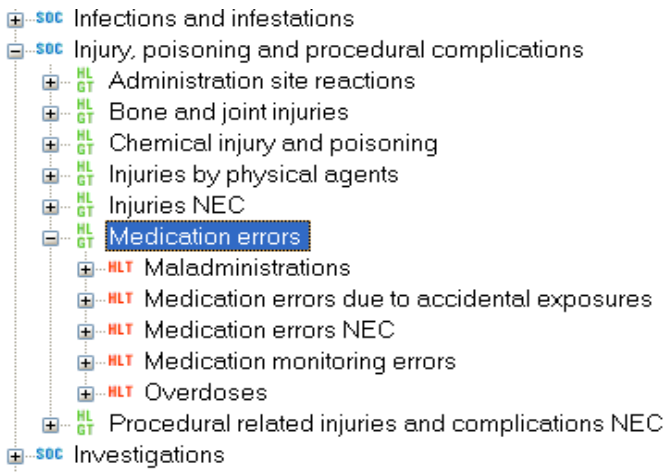
Product Recalls – Types of Data

- Adverse events affecting patient/consumer
  - Extensive clinical information in MedDRA
  - Can also code and analyze "No adverse effect"
- Product quality issues
  - Abnormalities that may be introduced during product manufacturing/labeling, packaging, shipping, handling or storage
- Medication errors
  - Any preventable event that may cause or lead to inappropriate medication use or patient harm

Product Quality Issues

- SOC Gastrointestinal disorders
- SOC General disorders and administration site conditions
  - HLGT Administration site reactions
  - HLGT Body temperature conditions
  - HLGT Complications associated with device
  - HLGT Device issues
  - HLGT Fatal outcomes
  - HLGT General system disorders NEC
  - HLGT Product quality issues
    - HLT Product contamination and sterility issues
    - HLT Product label issues
    - HLT Product packaging issues
    - HLT Product physical issues
    - HLT Product quality issues NEC
  - HLGT Therapeutic and nontherapeutic effects (excl toxicity)
  - HLGT Tissue disorders NEC
- SOC Hepatobiliary disorders

Medication Errors



Product Recall Examples

- Weight loss dietary supplement associated with serious liver injuries
- Male enhancement products containing undeclared active ingredient
  - Potential for interaction with nitrates – hypotension
- Nutrition bars potentially contaminated with *Salmonella*
  - Product quality issue: *Product contamination bacterial*
  - Potential adverse events in consumers: Salmonella infections

Preventing Product Recalls

- Coding with MedDRA enables medical accuracy
- Regular monitoring of consumer reports to identify potential problems
  - Consider using SMQs for specific safety concerns e.g., Hepatic disorders, Cardiac arrhythmias
  - Product quality issues, e.g., contamination, formulation, labeling issues
  - Medication errors, e.g., overdoses, wrong route of administration

Dealing with Product Recalls

- MedDRA provides standardized communication between regulator and industry
- SMQs provide consistent data retrieval enabling comparison of regulator and industry data
- Using a "common language" may assist in confirming or refuting product recall

Summary

- MedDRA is
  - A proven tool for coding and analyzing adverse events
  - An international standard
  - Evolves to meet the needs of its users
- MedDRA users have realized cost savings
  - Single terminology for business partners
  - Single terminology to communicate to regulatory authorities

MSSO Contact Information

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