Getting Started with MedDRA

ICH
harmonisation for better health

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 (EU, EFPIA, MHLW, JPMA, FDA, PhRMA), the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, and the WHO (as Observer).

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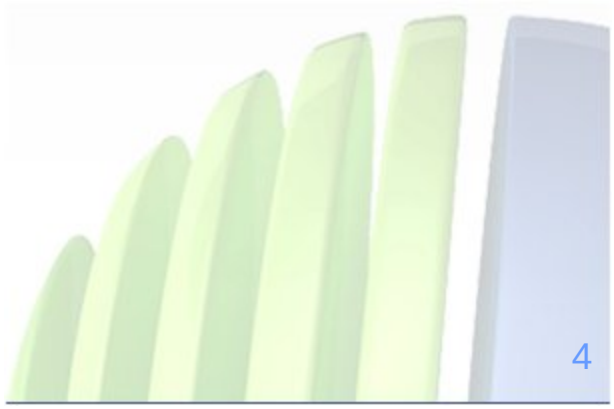
Governance Structure for MedDRA

- ICH MedDRA Management Board appointed by the ICH Steering Committee to provide oversight of MedDRA related activities and the Maintenance and Support Services Organization (MSSO)



ICH MedDRA Management Board Members

MedDRA's Purpose

- Facilitate the exchange of clinical information through standardization
- Important tool for product evaluation, monitoring, communication, electronic records exchange, and oversight
- Supports coding (data entry) and retrieval and analysis of clinical information about human medical products including pharmaceuticals, biologics, vaccines, and drug-device combination products

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

Electronic Transmission of Data

INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH E2B Expert Working Group

Implementation Guide for

Electronic Transmission of Individual Case Safety Reports (ICSRs)

E2B(R3) Data Elements and Message Specification

Version 5.01, 12 April 2013

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?

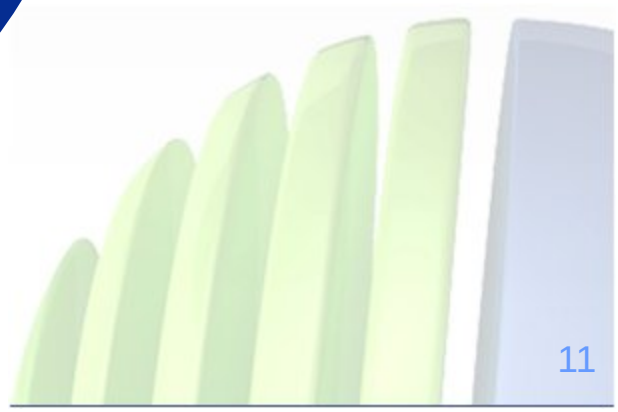
- Countries beyond the ICH regions
- WHO's international drug monitoring center (Uppsala Monitoring Centre)
- Academic researchers
- Toxicologists
- Others

More than 3,700 organizations worldwide in more than 60 countries

What Is In MedDRA?

IN

Medical conditions
Indications
Investigations (tests, results)
Medical and surgical procedures
Medical, social, family history
Medication errors
Product quality issues
Device-related issues
Pharmacogenetic terms
Toxicologic issues
Standardized queries



MedDRA Structure

System Organ Class (SOC) (26)

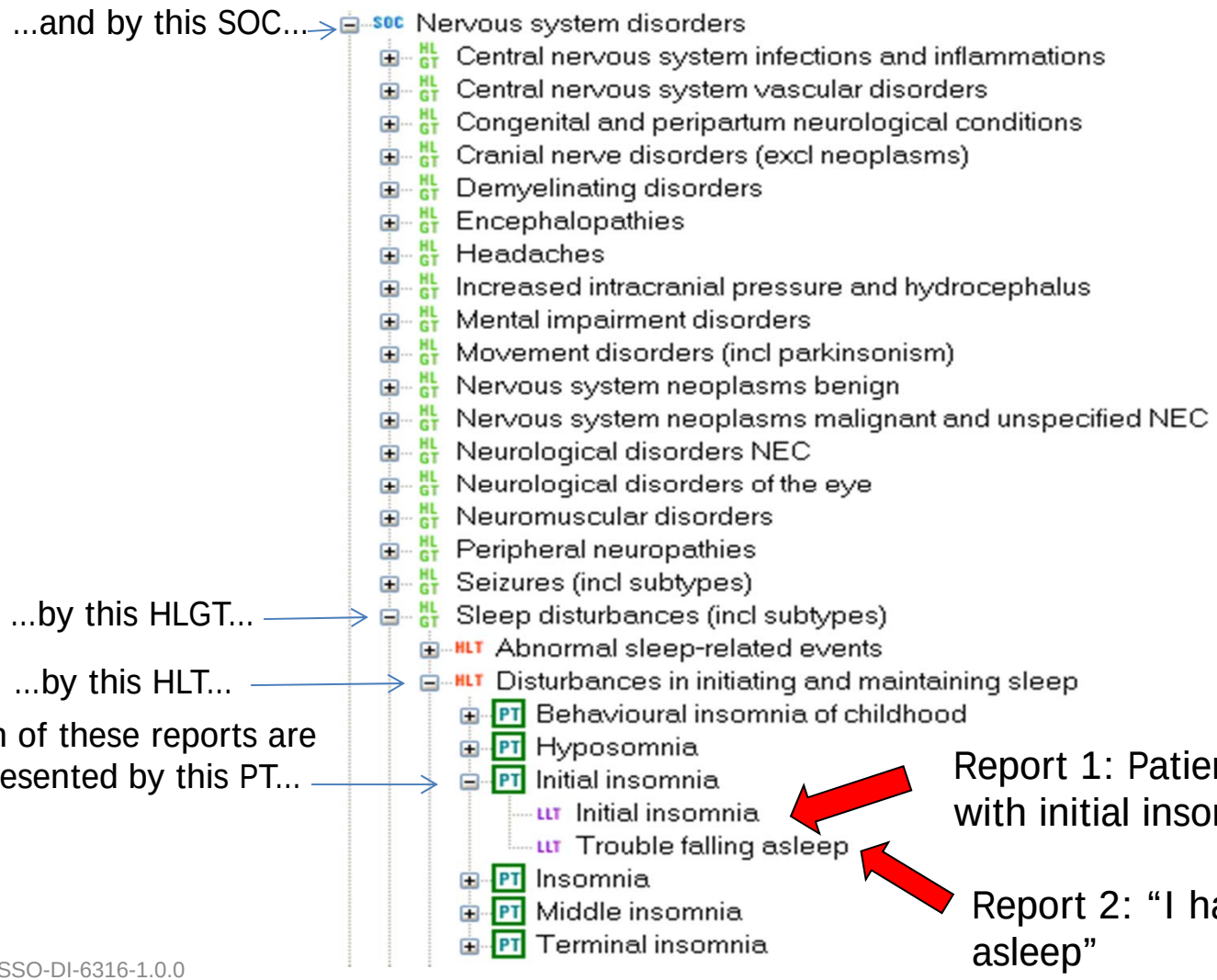
High Level Group Term (HLGT) (334)

High Level Term (HLT) (1,717)

Preferred Term (PT) (20,307)

Lowest Level Term (LLT) (>72,072)

How MedDRA is Used



Codes and Languages

MedDRA Maintenance

- MSSO processes change requests from its subscriber organizations
- Rigorous medical review by MSSO physicians
- Twice yearly official updates
  - 1 March X.0 release
  - 1 September X.1 release

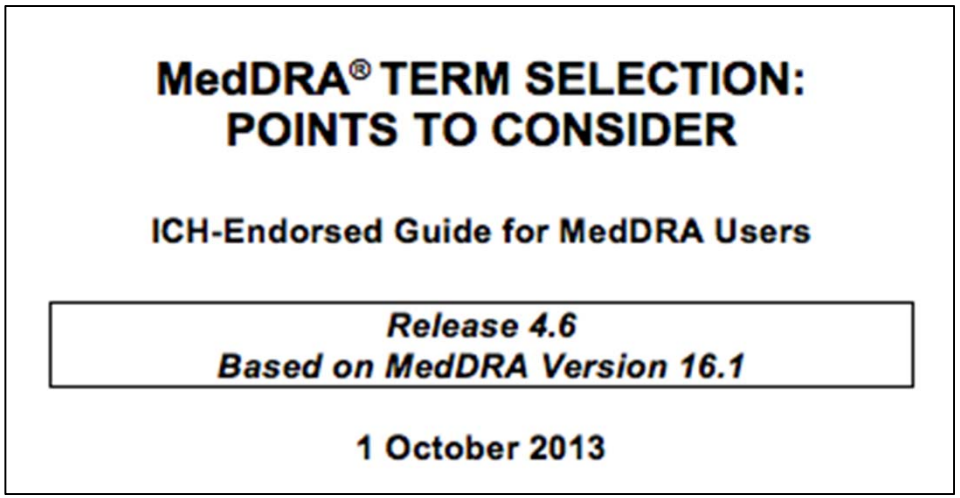
Implementing MedDRA

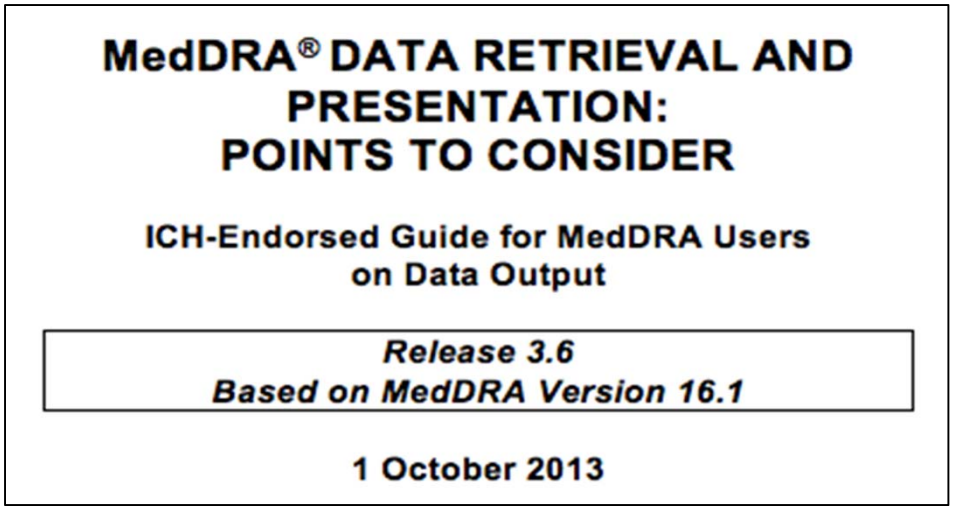
- No single method for all organizations
- Implementation approach depends on factors such as size of organization
- Topics to consider
  - Training
  - Coding and data retrieval conventions
  - Procedures documentation
  - Legacy data conversion
  - IT considerations

Training

- Free Face-to-Face training for users
  - Coding with MedDRA
  - MedDRA: Safety Data Analysis and SMQs
- Free webinars for users
  - Introduction to MedDRA
  - Coding Basics
  - Introduction to MedDRA Data Analysis and SMQs for Physicians
  - What's New with MedDRA
- Free videocasts on MedDRA website and YouTube

Coding and Data Retrieval Conventions





- ICH Working Group developed and maintains two guides for MedDRA users
- Recommended to be used as the basis for individual organizations' own guidelines

Procedures Documentation

- Documentation of procedures and processes is a best practice for all organizations
  - This includes the use of MedDRA
- Standard operating procedures and other relevant documents in an organization should address the use of MedDRA
  - Coding, dictionary management, MedDRA versioning, and analytical processes and tools (e.g., using MedDRA's hierarchy and Standardised MedDRA Queries)

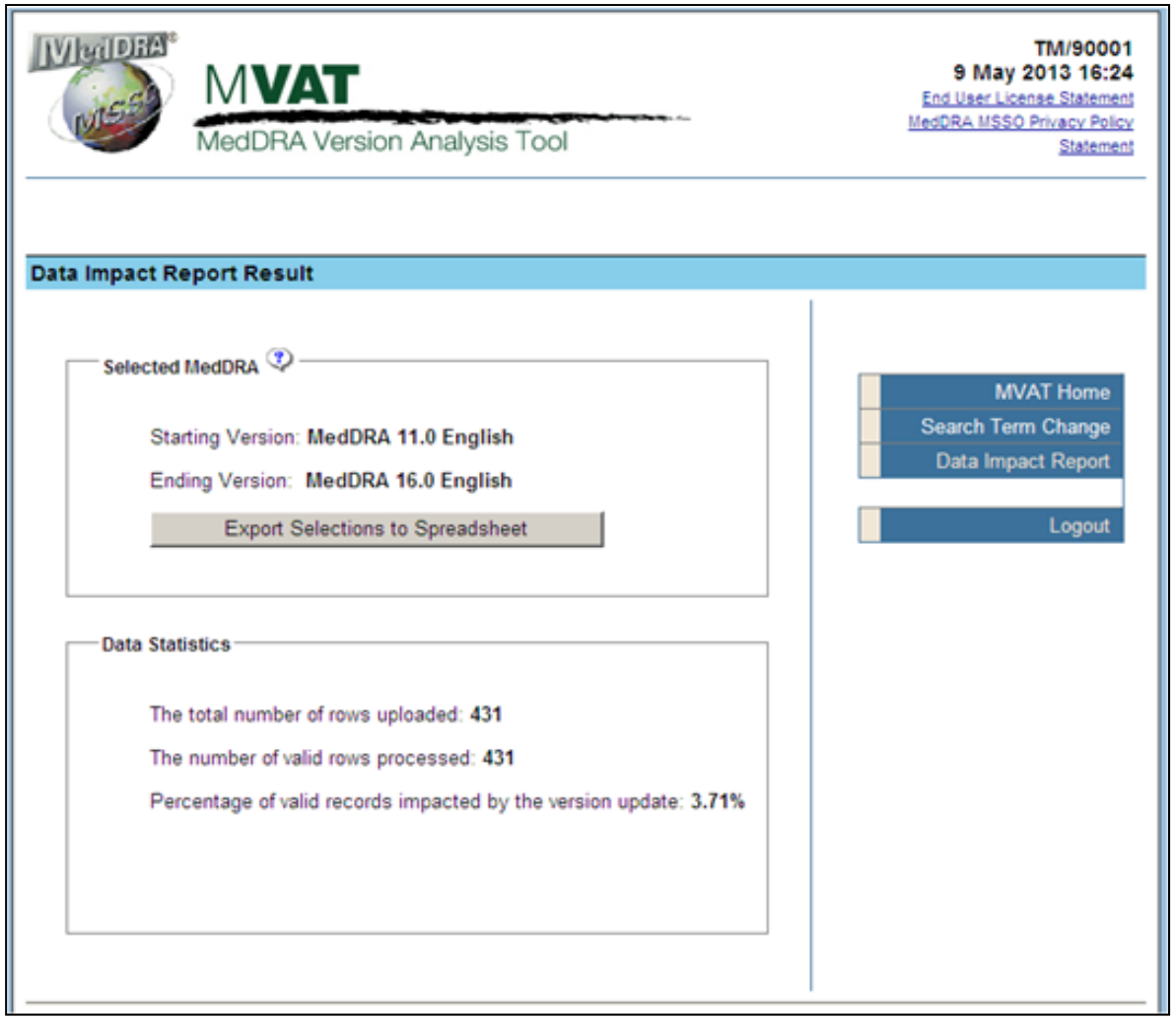
Legacy Data Conversion

- Existing data may need to be converted to MedDRA
  - Options to consider
    - Convert from the original reported verbatims (if available)
    - Convert from the coded terms of the legacy terminology
      - WHO Uppsala Monitoring Centre and the MSSO maintain a WHO-ART to MedDRA bridge to support the conversion of WHO-ART coded data to MedDRA

IT Considerations

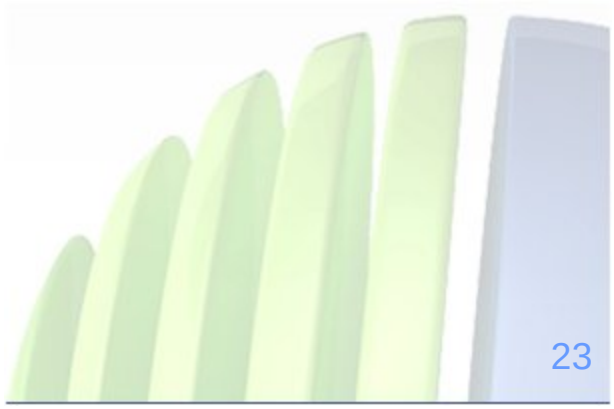
- Many software tools available to support the use of MedDRA
  - Several are provided free with the MedDRA subscription
    - Two browsers (desktop and web-based)
    - MedDRA Version Analysis Tool (MVAT)
  - Need for software tools should be driven by the volume of data to be supported
    - With small amounts of data users can use simple software tools (e.g., free MSSO browsers, spreadsheets)
    - Larger implementations should consider commercial data management software products
    - List of third-party software tools on MedDRA website

MedDRA Version Analysis Tool



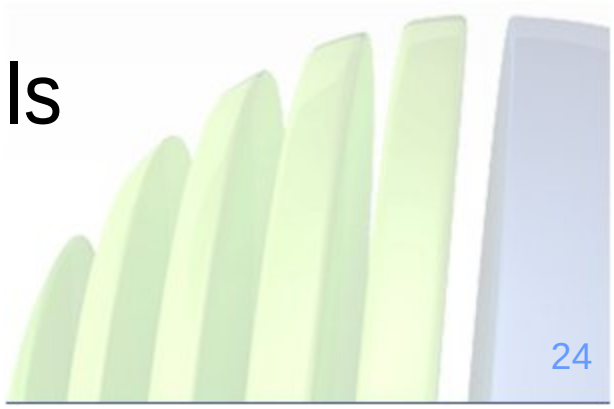
Resources for MedDRA Users

- MedDRA website
  - Help Desk
  - Subscriptions
  - News and Events
  - Points to Consider documents
  - Terminology downloads
  - Training
  - Tools
  - MedDRA publications
  - User group meetings
  - Expert meetings



How to Subscribe

- MedDRA is available as a subscription
  - Free to Regulatory Authorities and Non-profit / Non-commercial organizations
  - Commercial organizations pay an annual fee from a sliding scale based on annual revenue (turnover)
    - MedDRA Management Board reviews and approves rates annually
- See MedDRA website for details



MedDRA | Medical Dictionary for Regulatory Activities

MedDRA website: www.meddra.org
Email: mssohelp@meddra.org

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