MedDRA Implementation within the Canada Vigilance Program at Health Canada

Heather Sutcliffe
MedDRA Management Board
November, 2010
Health Canada Regulatory Reporting and MedDRA

- Established international medical terminology that is used throughout the regulatory process
  - Clinical trials
    - Medical history, adverse events
  - Labelling
    - Product Monograph
  - Post-Market Surveillance
    - Suspect Adverse Reactions (medical history, reactions, investigations, indications)
  - Safety studies
- Facilitates consistency of data coding, data assessment and data analysis
- Facilitates standardized electronic transmission of medical information
MedDRA - Canada Vigilance Database

- New pharmacovigilance information system implemented within Health Canada’s post market surveillance environment, March 2008
- Enables compliance with the ICH international Adverse Reaction (AR) reporting requirements, including MedDRA
MedDRA – Canada Vigilance Sub-Projects

- Post-Market implementation – 2008
- Pre-Market implementation – 2011
- Post-Market On-Line Database
- Electronic Reporting by Small/Medium/Large MAH/Sponsor
- Signal Detection and Data Mining
Canada Vigilance Database

- Supports MedDRA coding for the following terms:
  - Reaction terms
  - Patient history
  - Indications
  - Laboratory tests
- Stores Reported Term, Primary SOC, PT and LLT (coding level)
- Includes both French and English user interfaces
Implementation of MedDRA

• Legacy Database Conversion:
  – Canadian Adverse Drug Reaction Information System (CADRIS)
  – Contained suspected Adverse Reaction (AR) reports for Canadian marketed health products reported to Health Canada since 1965
  – Reaction terms coded in WHO-ART terminology
Terminology Conversion Strategy

• Legacy data conversion:
  – WHO-ART terminology was included in the development of MedDRA
    • Every WHO-ART term has a corresponding term in the MedDRA terminology
    • Not necessarily at the same level of the hierarchy

1. Data review:
  • Outliers were identified, documented and corrected prior to data conversion and migration
Terminology Conversion Strategy (cont’d):

2. Mapping exercise:
   • Developed conversion table of WHO-ART term to equivalent MedDRA v11.0 (current/non-current) term, (vendor mapping process) e.g.:

<table>
<thead>
<tr>
<th>WHOart Lx Id</th>
<th>Reaction Term</th>
<th>MedDRA Reaction Term version 11.0</th>
<th>MedDRA LLT Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>101002100210</td>
<td>hypertension</td>
<td>Hypertension</td>
<td>10020772</td>
</tr>
</tbody>
</table>

3. Data conversion and migration:
   • Performed by vendor

4. Testing, Quality Control and Validation
MedDRA Training

Health Canada:
• 4 training sessions, 3 modules offered at implementation, Biannual – ongoing:
  • Introductory Webinar
  • Hands-on Coding with MedDRA
  • Hands-on Safety Data Analysis and Standardized MedDRA Queries (SMQ’s)

Industry:
• Collaborated with the MSSO to offer MedDRA training to subscribers, 2 modules offered
Documentation

- Guidance Document for Industry: Reporting Adverse Reactions to Marketed Health Products
- Organization specific MedDRA Coding Conventions based on the MedDRA Term Selection: Points to Consider document (ICH endorsed guide for MedDRA users)
  - Updated biannually with each MedDRA version release
Documentation (Cont’d)

• Updated fact sheet awaiting web posting
• Quality Assurance Procedures for monitoring MedDRA coded data
• Versioning Strategy Procedure
• Submitting a Change Request to the MSSO
• Use of MedDRA terms and Standard MedDRA Queries (SMQ’s) for signal detection
Quality Assurance

- Monitor quality of MedDRA coded data
- Verify adherence to and deviation from MedDRA Coding Conventions SOP
- Compare verbatim (Reported Term) versus coded MedDRA LLT term
Departmental MedDRA Working Group

• Forum for discussion with respect to the implementation and use of MedDRA within the Department
• Ensure coordination and harmonization of the use of MedDRA terminology
• Serve as the channel to review and process MedDRA Change Requests
• Educate, promote and disseminate MedDRA information both within the department and externally e.g. academia, industry
Post MedDRA Implementation

- Versioning
  - Follow MSSO’s recommendations for semi-annual version control
    - Re-code historical data (automatic and minimal manual)
    - Synchronize with ICH regions (first Monday of the second month after its release, midnight GMT, Sunday to Monday)
  - Versioning allows Health Canada to profit from the continual enhancements that are ongoing with the MedDRA terminology
Health Canada Experience with MedDRA

- Diversity of coding provides more specificity with respect to data
- Complete terminology allows data analysis and documentation across the product life cycle
- Tools for data review and analysis has enhanced signal detection and data management
- Enables communication and management of safety issues between regulators and industry