Highlights of MedDRA and the Developmental Activities

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MedDRA was designed as an evolving terminology
- Intended to grow and develop based on the needs of the users

MedDRA has evolved significantly since the initial launch in 1999

Goal of presentation is to provide an overview of the major developmental initiatives in MedDRA
MedDRA was first made available in March 1999
  – MedDRA 2.1
MedDRA has its roots in earlier terminologies
  – COSTART, WHO-ART, ICD, HARTS, J-ART
Since 1999 MedDRA has continued to evolve to meet expanding needs
Brief History (cont.)

MedDRA 2.1
March 1999

- SOC: 26
- HLGT: 334
- HLT: 1663
- PT: 11,193
- LLT: 35,065

MedDRA 16.1
September 2013

- SOC: 26
- HLGT: 334
- HLT: 1717
- PT: 20,307
- LLT: 51,765

Growth of ~26K terms in 14 years
March 1999

- Distributed on CD or Diskette
- No regulatory requirements
- No coding or analysis guidance available
- 9 Special Search Categories
- Big effort to convert people, systems and databases

September 2013

- Web distribution
- Mandated by law or practice
- Points to Consider documents for coding and analysis
- 94 SMQs are available
- MedDRA is an international standard
• MedDRA Version 8.0 (March 2005)
• Standardised MedDRA Queries (SMQs) were first made available
  – Rhabdomyolysis/myopathy
  – Torsade de pointes/QT prolongation
• Currently 94 SMQ topics are available
• MedDRA Version 12.0 (March 2009)
• Regulatory need to use a single coding system for both adverse events and product quality issues
• New HLGT *Product quality issues in General disorders and administration site conditions SOC*
• Examples
  – *Product label counterfeit*
  – *Product contamination microbial*
Vaccine Terms

• MedDRA Version 12.1 (September 2009)
• In collaboration with the CIOMS/WHO Working Group on Vaccine Pharmacovigilance
• Examples
  – Vaccination site bruising
  – Vaccination site exfoliation
Device Related Terms

- MedDRA Version 13.0 (March 2010)
- Expansion of device related terms with improved hierarchical groupings (~280 changes)
MedDRA Version 13.0 (March 2010)

Regulatory authority proposed a set of microorganism terms to capture identification (by a test) of an organism when there is no documented infection

~400 new terms and 200 changes to existing terms

Example
  – *Brucella test positive*
Toxic Chemical Terms

• MedDRA Version 13.1 (September 2010)
• MedDRA selected by the Alerting System for Chemical Health Threats (ASHT II) to improve information sharing, analysis and reporting of events between health professionals from poison centers and national public health officials

• Examples
  – Chemical burn of larynx
  – Delayed blistering
Pharmacogenetic Terms

- MedDRA Version 15.0 (March 2012)
- Based on subscriber input, the MSSO added an initial group of pharmacogenetic and pharmacogenomic terms
  - Focused on genetic concepts and factors that have a potential impact on drug therapy
- Examples
  - BRCA1 gene mutation
  - EGFR gene overexpression
Neoplasm Terms

- MedDRA Version 16.0 (March 2013)
- Extensive changes to *Neoplasms benign, malignant and unspecified (incl cysts and polyps) SOC*
  - Improve histologic specificity at the PT level
  - Reference standard tumor classifications when adding new terms
Expansion of Medication Error Terms

• Prior to MedDRA Version 8.0, only one term existed - PT Medication error
• Medication error section expanded in v8.0 (March 2005)
  – Added HLGT Medication errors in Injury, poisoning and procedural complications SOC
    • HLT Maladministrations
    • HLT Medication errors due to accidental exposures
    • HLT Medication monitoring errors
    • HLT Overdoses
    • HLT Medication errors NEC
Medication Errors – Terms in MedDRA

• Approx. 160 LLTs under HLGT *Medication errors*

- Examples
  • LLT Intramuscular formulation administered by other route
  • LLT Wrong drug dispensed
• Developed along with MedDRA
• Key tools to support consistent and accurate coding and analysis
• MedDRA is a user responsive terminology
• Subscribers may submit change requests to the MSSO for consideration
  – MSSO provides responses within 10 working days
  – Weekly supplemental changes posted on MedDRA Web site
  – Hierarchical changes received all year round. Posted for subscribers’ comments mid-year
• Web-based tool for Change Requests
  – URL: https://mssotools.com/webcr/
  – Via the Change Request Information page
• Ability to submit change requests online
• Immediate confirmation
• Review unsubmitted change requests online
• Ability to query CR history back to v5.1
• What is the proactive approach?
  – Corrections/improvements made internally by the MSSO
  – General changes suggested by users

• Submitting ideas
  – Send to MSSO Help Desk. Justification is helpful.

• Evaluation of proposals
  – Done within MSSO, may contact submitter for follow-up
  – Proactive approach does not replace usual change request process
MSSO has received requests that test the boundaries of MedDRA’s scope

- Manufacturing product quality terms
  - Testing, out of specification issues, process control issues, shipping and packaging issues
- Additional device related terms
  - Represents growing development of devices
- Drug utilization terms
  - Stopping or changing medication and the reasons for which these occur (compliance, adverse events, patient decision)
- Labeling qualifiers
  - e.g., age groups, response to other therapies, low vs. high risk, stage of disease, first-, second-, third-line treatment, etc.
MSSO to propose a BRP in early 2014
  – Meeting with MedDRA Board in November

BRP to discuss and provide recommendations on:
  – What should be the scope of MedDRA as a medical and regulatory terminology?
  – What are the general criteria when considering new topic areas for expansion?
  – Where should new topics be placed in MedDRA?
    • Within the existing MedDRA structure?
    • Within a separate area for “product related” topics?
    • For certain topics, within maintained lists with a different structure instead of MedDRA’s five level hierarchy?
• MedDRA has grown to meet the needs of users
  – Original scope included various categories of terms classified as “medical”, i.e., not only adverse reactions
  – Developmental efforts have tended to focus on areas of medical and regulatory relevance

• PTC Working group has kept the PTC documents current with MedDRA developments