Scope of MedDRA – Update on Blue Ribbon Panel Meeting

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Overview

- BRP 8 recommendations
- MedDRA Management Board review and outcome
- 27th SOC
What is a Blue Ribbon Panel?

- Provides a forum for MedDRA experts to make recommendations on challenging MedDRA issues
- Panelists include experts from all ICH regions and parties
- Observers play an important role
- Panel produces recommendations for MedDRA Management Board (MMB) consideration

Details on MedDRA website: www.meddra.org/blue-ribbon-panels

Blue Ribbon Panel 8: Purpose

- Discuss and define the scope of MedDRA as an international medical and regulatory terminology and to address its possible expansion into new topic areas
- Discuss general criteria for potential new topic areas and placement considerations
Meeting Details

- Held at MedImmune, Gaithersburg, MD USA on 29 April 2014
- Panelists
  - Mr. Barry Hammond (Terminologieze)
  - Dr. Norbert Paeschke (BfArM)
  - Dr. Stewart Geary (Eisai)
  - Mr. Daisuke Sato (PMDA)
  - Dr. Sonja Brajovic (FDA)
  - Ms. Lisa Lawrence-Miyasaki (Santen)
- MSSO Facilitators
  - Mr. Patrick Revelle
  - Dr. Judy Harrison
- Approx. 35 observers in attendance
- Approx. 80 connections for webcast

Questions for BRP

1. Scope of MedDRA as a medical and regulatory terminology
2. General criteria when considering new topic areas for expansion. Consider examples:
   - Manufacturing product quality terms
   - Additional device-related terms
   - Drug utilization terms
   - Labeling qualifiers
3. Criteria for terms that include human use factors or causality related concepts
4. Placement of new concepts/topics in MedDRA
**BRP Recommendations**

- Scope is medical/health-related and regulatory concepts
- Manufacturing product quality terms
  - Harmonization of quality and safety is a benefit
- Device-related terms
  - Coordinate with stakeholders on reporting requirements and terminologies
- Identify use cases for drug utilization terms and labeling qualifiers
- Consider human use factor terms to identify root causes; avoid identifying individual human errors
- 27th SOC is favored option for non-clinical/non-patient concepts

**MedDRA MB Review**

- Endorsed scope recommendation
  - Medical/health-related and regulatory concepts
  - Wording for MedDRA Introductory Guide Version 18.0
    “Furthermore, the terminology may also support other types of products which are regulated in at least one region such as food or cosmetics”
  - Monitor direct patient reporting and social media programs
- Supported MSSO review of drug utilization terms
  - Most concepts already in MedDRA; 4 change requests processed
  - Drug supply/availability concepts – future consideration
MedDRA MB Review (cont)

- Supported harmonization of device reporting requirements and terminologies
  - Contacted International Medical Device Regulators Forum (IMDRF)
  - IMDRF working group to develop common terminology and codes related to adverse events of medical devices
  - Seeking opportunities for collaboration

27th SOC

- MMB endorsed BRP recommendation for 27th SOC
- Product quality concepts
- Planned implementation date March 2016 (MedDRA Version 19.0)
- MSSO to engage in discussions with users
Concept Description

Product quality issues are abnormalities that may be introduced during the manufacturing/labeling, packaging, shipping, handling or storage of the products.

Mockup of 27th SOC

Structure and contents for specific manufacturing product quality terms to be determined

Expect overlap with concepts in existing HLGT

Product quality issues
27th SOC Features

- Multi-axial links to aid in retrieval and preserve links to patient safety
  - PT Transmission of an infectious agent via product (link to SOC Infections and infestations)
- Same 100 character limit for terms
- Terms must be unambiguous at all levels
- Need clear concept descriptions (view in WBB)

MedDRA Files

- MedDRA files distributed with each release
  - Detail of SOC file displayed

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<th>Name</th>
<th>Abbreviation</th>
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New Name New SOC Name Abbrev
Impact on Data Summaries

- No major impact on AE data summaries or subsequent conclusions
  - If no terms are reported, SOC is not displayed, e.g., SOC Social circumstances
  - Versioning impact (pre- to post-27th SOC) similar to primary SOC changes
  - Programming of standard tables/listings

- Impact on International Order of SOCs
  - Recommend to add as last on list

- Minimal impact on organizations not involved in product quality

Two Levels of IT Systems

**Commercial systems**
- Clinical, Safety, and Electronic Data Capture
- Validated by developer and end user organization
- MedDRA loading based on contents of MedDRA files

**Locally developed**
- Varying levels of validation
- MedDRA loading could be “hard coded”
- Some developers less familiar with MedDRA and not receiving MedDRA information
- End-users will need to be made aware of new SOC
Anticipated IT Impact of 27th SOC

▲ Commercial systems
  • Very low (if any)
  • Initial discussions with vendors confirm
  • Loading based on content of files, not a fixed number
  • Revisions to IT SOPs and other documentation possible
    • Related to the use of the new SOC

▲ Local systems
  • Higher impact
  • Too many to reach individually
  • Need a plan to communicate the change

▲ No formal IT system
  • Low (using spreadsheets, simple databases, MSSO tools)
  • Need to communicate change

Mitigation of IT Impact

▲ Provide at least one year of notification
▲ Deliver message in as many forums as possible
  • Produce a Developer focused webinar
▲ Develop technical document describing
  • Technical change
  • Scope and use of new SOC
  • Available from MedDRA.org and MSSO Help Desk
Impact on Documentation and Processes

- MSSO documents, e.g., Introductory Guide
- SOPs, procedures documentation
- In-house coding and retrieval guidelines
- Points to Consider documents
- Regulatory data standards, guidances, and rules
- Need careful consideration of SOC name

Communication and Collaboration

- Communicate plans to users early
  - Webinars, MedDRA website, broadcast emails, What’s New, User Group meetings, training sessions, videocasts, etc.
- Collaborative effort
  - MedDRA experts
  - Quality experts
- Contact the MSSO if you’re interested!
Thank you

Questions?