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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Topics

• What’s new with Version 17.1
  – Summary of changes (including SMQs)
  – Enhancing translations at the LLT Level

• Proactive Maintenance

• Updates to "Points to Consider" documents

• Update on Blue Ribbon Panel 8 – Scope of MedDRA

• Update on the Web-based browser

• MedDRA training

• Upcoming meetings
What's New with MedDRA Version 17.1

MedDRA Release 17.1

• Released on 1 September 2014
• A simple release
• Change request summary:
  – MSSO considered 1614 change requests, including SMQ requests (not including translation change requests)
    • Approved: 1214
    • Rejected: 290
    • Suspended: 110
Net Change of Terms per SOC

| MedDRA | Version Report |

- List of various types of changes in MedDRA
Summary of SMQ Changes

- Two new SMQs added
  - SMQ Proteinuria
  - SMQ Tubulointerstitial diseases
- Changes to Description or Notes of three SMQs
  - SMQ Pulmonary hypertension, SMQ Lacrimal disorders – minor text changes
  - SMQ Drug abuse and dependence – Modified Note to provide rationale for exclusion of signs and symptoms from the SMQ

PT Changes to SMQs

- 253 PTs were added to existing and new SMQs

<table>
<thead>
<tr>
<th>SMQ</th>
<th>PT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute pancreatitis (SMQ)</td>
<td>Grey Turner’s sign</td>
</tr>
<tr>
<td>Convulsions (SMQ)</td>
<td>Tonic posturing</td>
</tr>
<tr>
<td>Proteinuria (SMQ)*</td>
<td>Bence Jones proteinuria</td>
</tr>
<tr>
<td>Tubulointerstitial diseases (SMQ)*</td>
<td>Crystal nephropathy</td>
</tr>
</tbody>
</table>

*New SMQs
PT Changes to SMQs (cont)

- Three PTs had scope change

<table>
<thead>
<tr>
<th>SMQ</th>
<th>PT</th>
<th>V17.0</th>
<th>V17.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal premalignant disorders (SMQ)</td>
<td>Cervix warts</td>
<td>Broad</td>
<td>Narrow</td>
</tr>
<tr>
<td>Vulvovaginal warts</td>
<td>Broad</td>
<td>Narrow</td>
<td></td>
</tr>
<tr>
<td>Hearing impairment (SMQ)</td>
<td>Bone anchored hearing aid implantation</td>
<td>Broad</td>
<td>Narrow</td>
</tr>
</tbody>
</table>

- Two PTs were made inactive

<table>
<thead>
<tr>
<th>SMQ</th>
<th>PT</th>
<th>V17.0</th>
<th>V17.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital, familial and genetic disorders (SMQ)</td>
<td>Sickle cell anaemia with crisis</td>
<td>Active</td>
<td>Inactive</td>
</tr>
<tr>
<td>Retinal disorders (SMQ)</td>
<td>Haemangioma of retina</td>
<td>Active</td>
<td>Inactive</td>
</tr>
</tbody>
</table>

Enhancing Translations at the LLT level

Background:
- Duplicate translations are permitted at the LLT level under the same PT
  - Not every English LLT has a unique translation in other languages (e.g., British/American spellings, lexical variants)
  - Synonymous LLTs may not have a unique translation in every language (e.g., LLT *Dry heaves* and LLT *Gagging*)
• Current approach helpful for consistency but not optimal because this may reduce the number of terms in a translation
• MedDRA Management Board approved a modification of the translation maintenance rules:
  – Allow the use of language specific synonyms at the LLT level under the same PT

<table>
<thead>
<tr>
<th>Code</th>
<th>English Term</th>
<th>French Term v17.0</th>
<th>French Term v17.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>10063056</td>
<td>Faecal disimpaction</td>
<td>Désimpaction fécale</td>
<td>Evacuation d’un fécalome</td>
</tr>
<tr>
<td>10063058</td>
<td>Fecal disimpaction</td>
<td>Désimpaction fécale</td>
<td>Désimpaction fécale</td>
</tr>
</tbody>
</table>

• Synonym translations must enhance the utility of the translation
• Retain the meaning of the original term
Proactive Maintenance

Proactivity Request - “Hernia” Term Review

• Incarcerated, strangulated, and obstructive hernias are medically distinct concepts
• Review term placement consistency
• Identify placements where hernia concepts are not grouped optimally
• 3 new terms and 19 changes to existing terms in v17.1
Proactivity Request – “Hernia” Term Review (cont)

<table>
<thead>
<tr>
<th>Term Name</th>
<th>Level</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral hernia incarcerated</td>
<td>PT</td>
<td>New PT</td>
</tr>
<tr>
<td>Hiatus hernia strangulated</td>
<td>PT</td>
<td>New PT</td>
</tr>
<tr>
<td>Incarcerated hernia</td>
<td>PT</td>
<td>Promoted LLT</td>
</tr>
<tr>
<td>Strangulated hernia</td>
<td>PT</td>
<td>Promoted LLT</td>
</tr>
</tbody>
</table>

Proactivity Request – Pressure and Pain or Discomfort Terms

- A user request to review inconsistencies in the mapping of “pressure” terms under “pain” or “discomfort” terms
- 9 changes to existing terms were made
  - Align “pressure” terms with “discomfort” vs. “pain”

<table>
<thead>
<tr>
<th></th>
<th>LLT</th>
<th>PT in v17.0</th>
<th>PT in v17.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head pressure</td>
<td>Headache</td>
<td>Head discomfort</td>
<td></td>
</tr>
<tr>
<td>Sinus pressure</td>
<td>Sinus headache</td>
<td>Paranasal sinus discomfort</td>
<td></td>
</tr>
</tbody>
</table>
Update on *Points to Consider* Documents

- ICH-endorsed guides
  - MedDRA Term Selection: Points to Consider
  - MedDRA Data Retrieval and Presentation: Points to Consider
- Now available when MedDRA is released
  - 1 March and 1 September
ICH M1 Points to Consider Working Group (PtC WG)

- Regulators and industry from EU, US, and Japan
- Health Canada
- MFDS (Korea)
- MSSO
- JMO

EU Action Plan on Medication Errors

- EU pharmacovigilance legislation requires
  - Reporting of ADRs associated with medication errors
  - Involvement of patient safety organizations
  - Facilitation of direct patient reporting
- EU regulatory network agreed on several deliverables to be completed by September 2015
  - Includes “Good practice guide on coding and reporting medication errors”
- EU requested PtC WG to provide consultation on sections of good practice guide that reference PtC documents
Summary of PtC WG Meeting

- 2-5 June 2014 in Minneapolis, USA
- Presentations from EMA, UK’s National Health Service, FDA, Japanese regulators, and Health Canada on medication error reporting
- Developed concept descriptions for “product confusion” terms for MedDRA Introductory Guide
- Discussed updates for MedDRA Term Selection: PTC document for v17.1
  - Revision of medication monitoring errors section with new examples
  - Clarifications on coding congenital and acquired conditions
  - Additional overdose examples

Future Plans

- Further PtC WG discussions on medication errors and related topics of misuse, abuse, overdoses, off label use, etc.
- Complex change proposals received by MSSO
  - Placement of HLT *Overdoses* and HLT *Underdoses* in SOC *General disorders and administration site conditions*
    - Rationale: intentional overdose/underdose concepts are not medication errors and are not appropriately placed under current HLGT *Medication errors*
  - Add new HLT *Off label uses* in SOC *General disorders and administration site conditions*
    - Rationale: Need more specificity for coding and retrieving reports of off label use; there is currently only one PT *Off label use* in SOC *Surgical and medical procedures*
- Changes to MedDRA and updated guidance in PtC documents would be in MedDRA Version 18.0 in March 2015
Update on Blue Ribbon Panel 8 – Scope of MedDRA

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 consideration
Blue Ribbon Panel 8 – Scope of MedDRA

• 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

• BRP to discuss and provide recommendations to Management Board on:
  1. What should be the scope of MedDRA as a medical and regulatory terminology?
  2. What are the general criteria when considering new topic areas for expansion?
  3. What are the criteria for terms that include human use factors or causality related concepts?
  4. Where should new concepts/topics be placed in MedDRA?
Potential Topic Areas for Expansion

• Examples
  – Manufacturing product quality terms
  – Additional device-related terms
  – Drug utilization terms
  – Labeling qualifiers

• BRP used examples to formulate general criteria for inclusion of new topics in future

BRP Recommendations and Board Considerations

• BRP discussions yielded a set of recommendations
  – See Blue Ribbon Panel page on MedDRA website

• At its latest meeting, ICH MedDRA Management Board considered Panel recommendations

• Requested the MSSO to develop impact analyses

• Board will then communicate its decisions to MedDRA user community
MedDRA Training

MSSO Free Training Program

• Formats
  – Face-to-face sessions, webinars, videocasts
• Languages
  – English, French, German, Spanish, Mandarin Chinese
• Locations
  – US, Europe, Asia, and “virtual”
Host for Free Training?

- MSSO is seeking locations to host free training
  - Could be at regulator or company site
  - Host can send 5 attendees
- Qualifications
  - A conference room for 25-30 people
  - A projector and a screen
- Please contact MSSO Help Desk if you are interested in hosting training
  - mssohelp@meddra.org

New in 2014 - Training Curriculum

- Prepares trainees for face-to-face courses
  - Essential background knowledge
  - Engage in interactive exercises and discussions
- View a recommended series of videocasts
- Test knowledge with an optional MedDRA quiz
Free Training Videocasts

- Recorded short presentations on specific MedDRA topics
  - Download or stream for viewing

- Offered in 5 languages
  - English, Chinese, French, German and Spanish

- Videocast (and webinar) planned on new Web-based Browser in fourth quarter 2014
**Free Videocasts (cont.)**

Videocasts are posted on Training Materials Page: [http://www.meddra.org/training-materials](http://www.meddra.org/training-materials)

<table>
<thead>
<tr>
<th>Videocast Name</th>
<th>Chinese</th>
<th>English</th>
<th>French</th>
<th>German</th>
<th>Spanish</th>
</tr>
</thead>
<tbody>
<tr>
<td>Getting started with MedDRA (new)</td>
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<tr>
<td>Introduction to the Points to Consider documents</td>
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<tr>
<td>What's New with MedDRA Version 17.0</td>
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<tr>
<td>MedDRA Structure and Scope</td>
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<td>Standardised MedDRA Queries (SIMQs)</td>
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<td>MedDRA Version Updates</td>
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<td>MedDRA Version Analysis Tool (MVAT)</td>
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<tr>
<td>Primary System Organ Class (SOC) Allocation in MedDRA</td>
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<tr>
<td>MedDRA Desktop Browser Research Bin and Export Functions</td>
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</table>

**New in 2014 – “Getting Started with MedDRA” course**

- Free, half-day, face-to-face course
- Extension of “Getting Started with MedDRA” videocast
- Available in locations around world, upon request
- Designed for organizations preparing to implement MedDRA
- Topics include:
  - Overview of MedDRA
  - Downloading and installing
  - Versioning
  - Documentation and conventions
  - Legacy data conversion
  - IT considerations
  - Interactive exercises
- See Training section of MedDRA website for more details
Update on the Web-based browser

Current Status

- Currently two browsers are available
  - MedDRA Desktop Browser (MDB)
  - MedDRA Web-Based Browser (WBB)
- MedDRA Board tasked the MSSO to develop a new Web-based browser
Web-Based Browser

- Goals of new WBB
  - Desktop and WBB Browsers have similar “look and feel”
  - MSSO will also update the MDB to match the search algorithm and include new features introduced in the WBB
  - WBB and Desktop browsers produce identical results
  - Support for all languages (display and user interface)
    - Initial release of WBB will display all MedDRA translations
    - Next release will allow user to display user interface in any MedDRA language
  - Improve search capability compared to Desktop search

Sample Screenshot
### Sample Screenshot (cont)

![Sample Screenshot](image)

### Access to Concept Descriptions

![Access to Concept Descriptions](image)

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**MedDRA Concept Descriptions**

This document provides a list of MedDRA concept descriptions. A concept description is a description of how a concept is interpreted, used, and classified within the MedDRA terminology and is not a definition. The concept descriptions are intended to aid the consistent and accurate use of MedDRA in coding, retrieval, and analysis and to overcome the differences of medicine practice worldwide. The MSSO expects this appendix to be a working document and grow as subscribers request additional concepts to be documented.

<table>
<thead>
<tr>
<th>Concept Description</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abuse</td>
<td>Intentional, non-therapeutic use of a product – over the counter or prescription – for a perceived reward or desired non-therapeutic effect, including, but not limited to its psychotropic effects. Abuse may occur with a single use, sporadic use or persistent use of the product.</td>
</tr>
<tr>
<td>Acute</td>
<td>A condition may be interpreted as more severe than a &quot;chronic&quot; one. This was considered during the processing of proposed modified terms to assure that terms expressing only severity were not included.</td>
</tr>
</tbody>
</table>
Learn about the New Browser

• Two webinars to introduce the new WBB
  – Recording will be available on MedDRA website
• Videocast
  – Will be available for download or streaming from MedDRA website
• User Guide included within WBB

MedDRA Desktop Browser (MDB)

• Will be updated to match new features added to WBB
  – Search algorithm (single line entry)
  – Search result categories
    • Exact match, Lexical variant, Synonym search, Contains search
  – Research bin import function
• New Features
  – Language specific interface (will be added to WBB in next version)
Upcoming Meetings

US Industry MedDRA User Group Meeting

- Friday, 26 September 2014
- Hosted by Allergan
  – Newport Beach Marriott
    900 Newport Center Drive
    Newport Beach, California 92660
- MSSO will attend
- See User Group page on MedDRA website for agenda and registration
Thank You

Questions?
David W. Richardson, M.D.
Email: mssohelp@meddra.org