MedDRA® Version Updates
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, J PMA, FDA, PhRMA), the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, the Health Canada, and the WHO (as Observer).
Disclaimer and Copyright Notice

This presentation is protected by copyright and may be used, reproduced, incorporated into other works, adapted, modified, translated or distributed under a public license provided that ICH's copyright in the presentation is acknowledged at all times. In case of any adaptation, modification or translation of the presentation, reasonable steps must be taken to clearly label, demarcate or otherwise identify that changes were made to or based on the original presentation. Any impression that the adaptation, modification or translation of the original presentation is endorsed or sponsored by the ICH must be avoided.

The presentation is provided "as is" without warranty of any kind. In no event shall the ICH or the authors of the original presentation be liable for any claim, damages or other liability arising from the use of the presentation.

The above-mentioned permissions do not apply to content supplied by third parties. Therefore, for documents where the copyright vests in a third party, permission for reproduction must be obtained from this copyright holder.
Objectives

To provide an understanding of:

• Where to find information on practical approaches to MedDRA versioning
• Extent of versioning
• Impact of MedDRA versioning in your organization
• Timing of updates
• MSSO provided resources to assist with version updates
Background and Information on Approaches
MedDRA Maintenance

• MedDRA is a user responsive terminology
• Subscribers may submit change requests
  – 100 change requests maximum per month
• Twice yearly official updates
  – 1 March X.0 release (all levels)
  – 1 September X.1 release (LLT and PT levels only)
MedDRA Growth Trend

Number of Implemented Changes per Release

![Bar chart showing the number of implemented changes per MedDRA release from 6.0 to 15.1. The x-axis represents the release versions, and the y-axis represents the number of changes. The chart indicates a trend with peaks at 6.1 and 14.0, and a general decrease in changes as the version number increases.]
Goals of Version Updates

• Goals of versioning
  – Implement current version of MedDRA
  – Stay current with regulatory authorities and partners
  – Harmonize use of MedDRA to optimize communication of data
Version Update Approaches

• MSSO “Best Practice” document
  - “Recommendations for MedDRA Implementation and Versioning in Clinical Trials”
    (http://meddramsso.com/files_acrobat/clinicaltrialversioning.pdf)
  - Six options involving either “freezing” a version or re-coding at various points
  - MSSO recommends Options 5 or 6
Extent of Version Updates
Extent of Update

• What does it mean to implement latest version of MedDRA?
  – Since coding terms in MedDRA (LLTs) are not deleted, an organization could simply apply latest version with no data changes
  – What does your organization do?
    • Data coded to LLTs that become non-current
    • Data that have direct matches to new terms
    • Medically “better” terms available in new version
Extent of Update (cont)

• Many approaches to versioning by industry and regulators
• No real regulatory mandate
• Issue is addressed in *MedDRA Term Selection: Points to Consider* document (MTS:PTC)
Versioning “Best Practice” (cont)

- **Implementation methods described in MTS: PTC**

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
<th>Resource Intensity</th>
<th>Data Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Begin to use new version for coding new data; no recoding of existing data</td>
<td>Least</td>
<td>Least</td>
</tr>
<tr>
<td>2</td>
<td>Identify verbatim terms linked to non-current LLTs and recode existing data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Identify verbatim terms linked to non-current LLTs and recode existing data and Recode verbatim terms to new LLTs that are direct or lexical matches</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Identify verbatim terms linked to non-current LLTs and recode existing data and Recode verbatim terms to new LLTs that are direct or lexical matches and Recode verbatim terms to new LLTs that are more accurate concepts</td>
<td>Most</td>
<td>Most</td>
</tr>
</tbody>
</table>
Impact of Version Updates
Impacts of New Versions

- Key point – LLTs/PTs are never deleted in MedDRA

<table>
<thead>
<tr>
<th>Type of Change</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>LLT/PTs are moved</td>
<td>Be aware of change, not necessary to change coding</td>
</tr>
<tr>
<td>LLTs change currency</td>
<td>Probably need to re-code</td>
</tr>
<tr>
<td>LLT/PTs change primary SOC</td>
<td>Be aware of change, not necessary to change coding</td>
</tr>
<tr>
<td></td>
<td>Understand impact on summary reporting</td>
</tr>
<tr>
<td>LLT/PTs are added</td>
<td>May cause re-coding</td>
</tr>
</tbody>
</table>
## Impacts of New Versions (cont)

<table>
<thead>
<tr>
<th>Type of Change</th>
<th>Impact</th>
</tr>
</thead>
</table>
| Revisions, additions to hierarchy | Be aware of change, not necessary to change coding  
understand impact on summary reporting |
| Addition of new SMQs | No impact on coding  
useful information for data analysis and reporting |
| Changes to existing SMQs. PTs added or made inactive | No change to coding but be aware of impact on data analysis |
Impact of Version Updates on Data Analysis

• Version used in data retrieval and presentation should be documented

• Terms used for queries should be in same version as data being queried
# MedDRA Versioning - Effect of PT Demotion

<table>
<thead>
<tr>
<th>MedDRA Version 13.1</th>
<th>Number of Events at PT Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malignant neoplasm progression (PT)</td>
<td>15</td>
</tr>
<tr>
<td>Neoplasm malignant</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MedDRA Version 14.0</th>
<th>Number of Events at PT Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malignant neoplasm progression (no longer a PT)</td>
<td>0</td>
</tr>
<tr>
<td>Neoplasm malignant</td>
<td>20</td>
</tr>
</tbody>
</table>
## MedDRA Versioning (cont) - Effect of Primary SOC Change

<table>
<thead>
<tr>
<th>MedDRA Version 13.1</th>
<th>Number of Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOC Injury, poisoning and procedural</td>
<td>20</td>
</tr>
<tr>
<td>complications</td>
<td></td>
</tr>
<tr>
<td>PT Retinal scar</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MedDRA Version 14.0</th>
<th>Number of Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOC Injury, poisoning and procedural</td>
<td>0</td>
</tr>
<tr>
<td>complications</td>
<td></td>
</tr>
<tr>
<td>SOC Eye disorders</td>
<td>20</td>
</tr>
<tr>
<td>PT Retinal scar</td>
<td></td>
</tr>
</tbody>
</table>
Timing of Version Updates
Timing of Update (cont)

From the MSSO “Best Practice” recommendations

Transition Date for the Next MedDRA Version

Per the MedDRA Management Board endorsed, "best practice" on MedDRA versioning for single case reporting, the implementation (change-over) date for a new version of MedDRA is the first Monday of the second month following the release, at midnight GMT (Sunday to Monday), as follows:

<table>
<thead>
<tr>
<th>MedDRA v</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>v15.1</td>
<td>Monday 5 November 2012</td>
</tr>
<tr>
<td>v16.0</td>
<td>Monday 6 May 2013</td>
</tr>
<tr>
<td>v16.1</td>
<td>Monday 4 November 2013</td>
</tr>
</tbody>
</table>
Timing of Update (cont)

- Impact limited to data that are being transmitted
  - Internal data (i.e., some clinical trial data) could follow a different schedule
- EMA and MHLW will accept current version plus previous version for ICSRs and SUSARs
- FDA has no version requirement
  - Follows MSSO recommendation for versioning
Issues with Timing

- Currently, organizations may be implementing on different dates
  1. On release date
  2. During implementation period
  3. At end of implementation period

March 1  

Implementation Period

May 6
Issues with Timing (cont)

• Differences in implementation date negatively impact communication of ICSRs
• EMA issued letter supporting original MSSO recommendation
• MSSO is working with regulatory authorities to coordinate implementation for all MedDRA users
• MSSO recommendation is to transition **on** transition date
  - Not by transition date
Resources for Version Updates
Resources for Version Updates

- What’s New document
- MSSO “What’s New” webinars – now free
- Sequence files
- MedDRA Version Reports
- MedDRA Version Analysis Tool (MVAT)
MedDRA Version Reports

- Developed by MSSO to provide list of changes between latest version and previous version
- Detailed record-by-record report
- Included in the MedDRA terminology download
MedDRA Version Reports

<table>
<thead>
<tr>
<th>Tab Title</th>
<th>Record Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>New LLTs including New PTs</td>
<td>692</td>
</tr>
<tr>
<td>New PTs</td>
<td>360</td>
</tr>
<tr>
<td>Promotions</td>
<td>113</td>
</tr>
<tr>
<td>Demotions</td>
<td>153</td>
</tr>
<tr>
<td>LLTs under different PTs</td>
<td>1183</td>
</tr>
<tr>
<td>LLT (excl PT) Prim SOC Changes</td>
<td>123</td>
</tr>
<tr>
<td>PT Primary SOC Changes</td>
<td>27</td>
</tr>
<tr>
<td>MedDRA LLT PT Text Changes</td>
<td>8</td>
</tr>
<tr>
<td>MedDRA Code Switches</td>
<td>0</td>
</tr>
<tr>
<td>Currency Changes</td>
<td>33</td>
</tr>
<tr>
<td>Complex Changes</td>
<td>31</td>
</tr>
<tr>
<td>SMQ Changes</td>
<td>9</td>
</tr>
<tr>
<td>PT Changes in SMQs</td>
<td>1120</td>
</tr>
</tbody>
</table>

This report provides a listing of the new PTs added to this version and the MedDRA code and full primary path hierarchy (HLT, HLGT and SOC) for each new PT.

Move cursor over the report title above to view a description of its contents.
MVAT

• MedDRA Version Analysis Tool
• Three things that MVAT can help you do:
  – Generate MedDRA Version Report between any two versions of MedDRA (including non-consecutive ones)
  – Search a term change
  – Identify changes specific MedDRA terms of interest to the user
• Features
  – Web-based
  – Free with subscription
  – Spreadsheet export and import

• Reports are informational only
  – Will not perform autoencoding tasks
How to Access MVAT

• https://mssotools.com/mvat/ or
  – The MSSO web site under Subscriber Download

• MedDRA UserID and Password to login
MVAT Help

• MVAT training videocast
  - Videocast can also be downloaded

• MSSO Help Desk: mssohelp@mssotools.com

• MVAT FAQs:
Summary

• In this video cast, we:
  – Practical approaches to MedDRA versioning
  – Learned about the timing and extent of MedDRA version updates
  – Considered the impact of version updates on coded data, including data analysis
  – Learned about resources available to assist in version updates
MSSO Contacts

• Web site
  • www.meddramsso.com

• Help Desk
  – Phone
    • International AT&T Toll Free:  877.258.8280
    • Direct Dial (USA):  +1 571.313.2574
  – E-mail
    • mssohelp@mssotools.com