What’s New with MedDRA Version 21.0 and the MSSO

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Medical Officer, MedDRA MSSO
27 & 28 February 2018

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Topics

• What’s New with Version 21.0
  – Summary of Changes (including SMQs)
  – Translation Review
• MedDRA Mapping Initiatives
• MedDRA Concept Descriptions
• Proactive Maintenance
• Update on Points to Consider (PtC) Documents
• Update on MedDRA IT Tools
• Patient-Friendly Term List
• MedDRA Training
• Meetings
What's New with MedDRA Version 21.0

- Release on 1 March 2018
- A complex release
- Change request summary:
  - MSSO considered 1,575 change requests, including SMQ requests (not including translation updates)
    - Approved: 1,360
    - Rejected: 203
    - Suspended: 12
- Changes reflect the differences between v20.1 and v21.0
## Net Change of Terms per SOC

<table>
<thead>
<tr>
<th>Category</th>
<th>Change</th>
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</thead>
<tbody>
<tr>
<td>Blood and lymphatic system disorders</td>
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<tr>
<td>Cardiac disorders</td>
<td>14</td>
</tr>
<tr>
<td>Congenital, familial and genetic disorders</td>
<td>75</td>
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<tr>
<td>Ear and labyrinth disorders</td>
<td>16</td>
</tr>
<tr>
<td>Endocrine disorders</td>
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</tr>
<tr>
<td>Eye disorders</td>
<td>18</td>
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<tr>
<td>Gastrointestinal disorders</td>
<td>73</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
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<tr>
<td>Haematopoietic disorders</td>
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<tr>
<td>Immune system disorders</td>
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<tr>
<td>Infections and infestations</td>
<td>150</td>
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<tr>
<td>Injury, poisoning and procedural complications</td>
<td>14</td>
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<tr>
<td>Metabolic and nutrition disorders</td>
<td>213</td>
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<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>62</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>70</td>
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<tr>
<td>Nephron, benign, malignant and unspecified (incl cysts and polyps)</td>
<td>101</td>
</tr>
<tr>
<td>Neurologic disorders</td>
<td>40</td>
</tr>
<tr>
<td>Pregnancy, puerperium and perinatal conditions</td>
<td>99</td>
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<tr>
<td>Psychiatric disorders</td>
<td>27</td>
</tr>
<tr>
<td>Renal and urinary disorders</td>
<td>25</td>
</tr>
<tr>
<td>Reproductive system and breast disorders</td>
<td>41</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>53</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>83</td>
</tr>
<tr>
<td>Social circumstances</td>
<td>24</td>
</tr>
<tr>
<td>Surgical and medical procedures</td>
<td>145</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>63</td>
</tr>
</tbody>
</table>

## Version Report

- List of various types of changes in MedDRA

<table>
<thead>
<tr>
<th>Report Title</th>
<th>Total Changes</th>
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</thead>
<tbody>
<tr>
<td>New LTTs Including New PTs</td>
<td>762</td>
</tr>
<tr>
<td>New PTs</td>
<td>342</td>
</tr>
<tr>
<td>Promotions</td>
<td>35</td>
</tr>
<tr>
<td>Demotions</td>
<td>53</td>
</tr>
<tr>
<td>LTTs under different PTs</td>
<td>173</td>
</tr>
<tr>
<td>LTT (not PT) Primary SOC Ogm</td>
<td>21</td>
</tr>
<tr>
<td>PT Primary SOC Changes</td>
<td>8</td>
</tr>
<tr>
<td>MedDRA Term Name Changes</td>
<td>46</td>
</tr>
<tr>
<td>MedDRA Code Switches</td>
<td>0</td>
</tr>
<tr>
<td>Currency Changes</td>
<td>8</td>
</tr>
<tr>
<td>Complex Changes</td>
<td>10</td>
</tr>
<tr>
<td>13M Changes</td>
<td>6</td>
</tr>
<tr>
<td>PT Changes in SMQu</td>
<td>351</td>
</tr>
</tbody>
</table>
Summary of Complex Changes

• No changes at SOC or HLGT levels
• Includes new/merged/moved HLTs
• Changes summarized in What’s New v21.0 document and link on Change Requests page of meddra.org website

Summary of SMQ Changes

• One new SMQ added
• See MedDRA Version 21.0 SMQ Introductory Guide for detailed information on new SMQ *Dehydration*
• 103 level 1 SMQs in production
• 295 changes made in existing SMQs, see the Version Report
Translation Review

• As part of a standard quality process, MSSO reviewing MedDRA translation from English into supported languages (except Japanese)
• Ongoing effort expected to last until MedDRA Version 21.1 (September 2018)
• List of updated terms available in version reports found in download for each supported language
• As usual, users may submit requests for improvements to any translation using WebCR

MedDRA Mapping Initiatives
MedDRA Mapping Initiatives

- Regulatory and industry users interested in getting access to more sources of data
- MSSO is part of the Innovative Medicines Initiative (IMI) consortium of regulators, industry, and maintenance organizations which will:
  - Facilitate communication between regulatory and healthcare databases
    - e.g., SNOMED CT, ICD
  - Establish mapping protocols and distribution agreements
  - Deliver an initial mapping between a subset of key pharmacovigilance terms
  - Begin a 18 month project starting in Q2 2018

MedDRA Concept Descriptions
Concept Descriptions

- Descriptions of how a concept is interpreted, used, and classified in MedDRA
- Not a definition
- Intended to aid accurate and consistent use of MedDRA in coding and retrieval
- Overcome differences in medical practice worldwide
  - Descriptions aim to be broadly consistent with definitions across different regulatory regions
- See Appendix B of MedDRA Introductory Guide
- Accessible in MSSO’s Browsers

Concept Descriptions (cont)
Concept Descriptions (cont)

• Two changes in MedDRA v21.0
  – Product storage concept description added
  – NCC MERP* reference added to Medication Error concept description

*National Coordinating Council for Medication Error Reporting and Prevention

Product Storage Concept Description

HLT Product distribution and storage issues in SOC Product issues is intended to cover issues with the storage of products by manufacturers, distributors, wholesalers, etc.

In contrast, product storage issues by end-users such as healthcare professionals, patients, and consumers are considered to be medication errors and are represented by the appropriate medication error terms in HLT Product storage errors and issues in the product use system in SOC Injury, poisoning and procedural complications.
Proactive Maintenance

Proactivity Request Review

- Proactive maintenance process allows users to address inconsistencies, make corrections or suggest improvements.
- As follow-up to proactivity review of foreign body terms in MedDRA v20.1, one HLT replaced in v21.0 to provide better term alignment.

<table>
<thead>
<tr>
<th>New HLT</th>
<th>Old HLT</th>
<th>SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest and respiratory tract injuries NEC</td>
<td>Chest and lung injuries NEC</td>
<td>Injury, poisoning and procedural complications</td>
</tr>
</tbody>
</table>
Update on *Points to Consider (PtC) Documents*

**ICH M1 Points to Consider Working Group (PtC WG)**

- Regulators and industry from EU, US, and Japan
  - Health Canada
  - MSSO
  - JMO
  - WHO (Observer)

**New members 2017/2018**
- MFDS, Republic of Korea
- ANVISA, Brazil
- CFDA, China
PtC Updates v21.0

- No changes to content of Term Selection or Data Retrieval and Presentation PtC documents

Companion PtC Document Update

- More detailed guidance, examples, and “Questions and Answers”
- PtC Working Group drafted two sections at Geneva meeting
  - Data quality
  - Medication errors
- First edition planned for release in Q2 2018
- Available in English and Japanese
Condensed PtC Documents Update

• Condensed versions of PtC documents finalized
  – To be translated into all MedDRA languages except English and Japanese
  – Plan to make available in late 2018

• English and Japanese PtC documents will remain as full documents updated with each MedDRA release

Update on MedDRA IT Tools
Self-Service Application Update

• Available since April 2017
• Web-based application which allows:
  – Users to obtain their MedDRA ID
  – Retrieve primary Point of Contact
  – Points of contact to obtain subscription password information and MedDRA zip file passwords
  – Confirmation of MedDRA subscription with business partners
  – Download and print training certificates

Self-Service Application Update (cont)

• Beginning with MedDRA v21.1 (September 2018), MSSO will use the Self-Service Application for:
  – Distributing unzip passwords
  – Obtaining password information for new subscriptions and subscription renewal
• Unzip passwords will not be included directly in email messages
• This change will improve information security
Supplemental Files

• MSSO posts interim changes to MedDRA which will appear in next MedDRA version

• Postings include:
  – Weekly changes
  – Comprehensive change to date
  – A PDF file describing all changes considered
  – Sequential extended ASCII files that can be applied to non-production environments

Supplemental Files (cont)

MedDRA Version 21.1 Supplemental Changes

<table>
<thead>
<tr>
<th>Supplemental Changes</th>
<th>PDF format</th>
<th>SEQ ASCII format</th>
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<tr>
<td>Comprehensive changes for MedDRA 21.1</td>
<td>[link]</td>
<td>[link]</td>
<td>19 Jan 2019</td>
</tr>
<tr>
<td>Segmented changes for MedDRA 21.1</td>
<td>[link]</td>
<td>[link]</td>
<td>19 Jan 2019</td>
</tr>
<tr>
<td>Supplemental changes for MedDRA 21.1</td>
<td>[link]</td>
<td>[link]</td>
<td>12 Jan 2019</td>
</tr>
</tbody>
</table>
Planned IT Updates - Web-Based Browser 3.0

- Ability to view supplemental changes
- Boolean logic search options (e.g., Not, Or)
- Upload terms to extract primary and secondary links
  - Option to export secondary SOC links from the Research Bin and Search results
- Select which levels of the hierarchy to add to the Research Bin
- Upload terms to run against SMQs
  - Options to use algorithmic and hierarchical SMQs
- Expected by Mid 2018

Example of Supplemental view in WBB 3.0:
Planned IT Updates - Web-Based Browser 3.0

- Example of Supplemental view in WBB 3.0:

Planned MVAT 3.0 Updates

- Ability to run reports on supplemental changes
- New reports on secondary SOC changes
- Expected in 2018
MSSO and partner organizations developed a “patient-friendly” term list

- Sub-set of MedDRA Lowest Level Terms in English
- Derived from adverse events reported by patients and consumers in several pharmacovigilance databases
Use of Patient-Friendly Terms

- For adverse event reporting websites and mobile applications intended for patients and consumers
- Allows direct reporting using terms that are already in MedDRA
  - No need for additional coding into MedDRA
  - Immediately available for analysis
- List is used in YellowCard online form for the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK

List Available for Download

- Link on Support Documentation page on MedDRA website
- Spreadsheet of LLT names and codes
  - 1,440 terms in v21.0
  - Maintained by MSSO with each MedDRA release
<table>
<thead>
<tr>
<th>LLT</th>
<th>LLT code</th>
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<tbody>
<tr>
<td>Abdomen enlarged</td>
<td>10000045</td>
</tr>
<tr>
<td>Abdominal bloating</td>
<td>10048746</td>
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<tr>
<td>Abdominal cramps</td>
<td>10000057</td>
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<tr>
<td>Abdominal crampy pains</td>
<td>10000058</td>
</tr>
<tr>
<td>Abdominal discomfort</td>
<td>10000059</td>
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<tr>
<td>Abdominal hernia</td>
<td>10060954</td>
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<tr>
<td>Abdominal infection</td>
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<tr>
<td>Abdominal mass</td>
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<tr>
<td>Abdominal pain</td>
<td>10000081</td>
</tr>
<tr>
<td>Abdominal tenderness</td>
<td>10000097</td>
</tr>
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MSSO Free Training Program

• Formats
  – Face-to-face sessions
  – Webinars
  – Videocasts
  – YouTube Channel with recorded videocasts and webinars (new)

• Languages
  – English, French, German, Spanish, Mandarin Chinese

• Locations
  – Worldwide and “virtual”
Face to Face Training

Session Titles

• Coding with MedDRA
• Safety Data Analysis and Standardised MedDRA Queries (SMQs)
• Getting Started with MedDRA

Webinar Titles

• MedDRA Overview
• Getting Started with MedDRA
• MedDRA Coding Basics
• Advanced MedDRA Coding
• Data Analysis and Query Building with MedDRA
• Standardised MedDRA Queries (SMQs)
• What’s New with MedDRA and the MSSO
Summary of 2017 Training

• 63 face-to-face sessions (45 subscriber, 18 regulator):
  – 1,736 attendees
  – Central/South and North America, Europe, Asia/Eurasia, Scandinavia

• 27 webinars:
  – 2,705 connections
  – Central/South and North America, Europe, Asia/Eurasia, Africa, Australia, Scandinavia
Webinar Training Tab

MedDRA Training

<table>
<thead>
<tr>
<th>Month</th>
<th>Date</th>
<th>Event</th>
<th>Type</th>
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<tbody>
<tr>
<td>JAN</td>
<td>31/2018</td>
<td>Advanced MedDRA Coding</td>
<td>Webinar</td>
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<tr>
<td>FEB</td>
<td>22/2018</td>
<td>Data Analysis and Query Building with MedDRA</td>
<td>Webinar</td>
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<td>27/2018</td>
<td>What's New with MedDRA Version 21.0 and the IR5.0</td>
<td>Webinar</td>
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<td>28/2018</td>
<td>What's New with MedDRA Version 21.0 and the IR5.0</td>
<td>Webinar</td>
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<td>MAR</td>
<td>22/2018</td>
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<td>Webinar</td>
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<td>Standardized MedDRA Queries (SMQs)</td>
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<td>APR</td>
<td>29/2018</td>
<td>MedDRA Coding Basics</td>
<td>Webinar</td>
</tr>
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</table>

Meetings
European MedDRA User Group Meeting

• Date: Monday, 16 April 2018
• Time: 8:30 – 16:30
• Where:
  Hotel Pullman Basel Europe
  Clarastrasse 43
  4058 Basel
  Switzerland
• Open to all MedDRA users
• Preliminary agenda and registration form posted to User Group page on MedDRA website
• Registration deadline: 4 April 2018

US MedDRA User Group Meeting

• US User Group – Boston, Massachusetts, 28 June 2018
• Open to all MedDRA users
• More details to be posted to User Group page on MedDRA website when available
Chinese MedDRA User Group Meeting

• More details to be posted to User Group page on MedDRA website when available

Thank You

Questions?

David W. Richardson, M.D.

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