What’s New with MedDRA Version 22.1 and the MSSO

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Medical Officer, MedDRA MSSO
28 & 29 August 2019

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Topics

- What’s New with Version 22.1
  - Summary of Changes (including SMQs)
- MedDRA Translations
- Proactive Maintenance
- Update on Points to Consider (PtC) Documents
- New MSSO Staff
- Social Media Initiatives
- Update on MedDRA IT Tools
- MedDRA Training
- Upcoming Meetings
- Other Topics
What's New with MedDRA Version 22.1

- Release on 1 September 2019
- A simple release
- Change request summary:
  - MSSO considered 1,533 change requests, including SMQ requests (not including translation updates)
    - Approved: 1,358
    - Not approved: 174
    - Suspended: 1
- Changes reflect the differences between v22.0 and v22.1
### Net Change of Terms per SOC

<table>
<thead>
<tr>
<th>Medical System Disorder</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast and Lymphatic System Disorders</td>
<td>31</td>
</tr>
<tr>
<td>Cardiac Disorders</td>
<td>11</td>
</tr>
<tr>
<td>Congenital, Familial, and Genetic Disorders</td>
<td>68</td>
</tr>
<tr>
<td>Ear and Labyrinth Disorders</td>
<td>6</td>
</tr>
<tr>
<td>Endocrine Disorders</td>
<td>22</td>
</tr>
<tr>
<td>Eye Disorders</td>
<td>52</td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
<td>52</td>
</tr>
<tr>
<td>General Disorders and Administration Site Conditions</td>
<td>71</td>
</tr>
<tr>
<td>Haematopoietic and Lymphatic Disorders</td>
<td>7</td>
</tr>
<tr>
<td>Immune system Disorders</td>
<td>61</td>
</tr>
<tr>
<td>Injury, Poisoning, and Procedural Complications</td>
<td>70</td>
</tr>
<tr>
<td>Infectious and Parasitic Conditions</td>
<td>132</td>
</tr>
<tr>
<td>Investigational</td>
<td>190</td>
</tr>
<tr>
<td>Metabolic and Nutritional Disorders</td>
<td>31</td>
</tr>
<tr>
<td>Musculoskeletal and Connective Tissue Disorders</td>
<td>58</td>
</tr>
<tr>
<td>Neoplasms Benign, Malignant and Unclassified</td>
<td>24</td>
</tr>
<tr>
<td>Nervous System Disorders</td>
<td>115</td>
</tr>
<tr>
<td>Pregnancy, Puerperium, and Perinatal Conditions</td>
<td>31</td>
</tr>
<tr>
<td>Product Issues</td>
<td>18</td>
</tr>
<tr>
<td>Psychiatric Disorders</td>
<td>21</td>
</tr>
<tr>
<td>Renal and Urinary Disorders</td>
<td>16</td>
</tr>
<tr>
<td>Reproductive and Breast Disorders</td>
<td>89</td>
</tr>
<tr>
<td>Respiratory, Thoracic, and Mediastinal Disorders</td>
<td>55</td>
</tr>
<tr>
<td>Skin and Subcutaneous Tissue Disorders</td>
<td>101</td>
</tr>
<tr>
<td>Social Circumstances</td>
<td>6</td>
</tr>
<tr>
<td>Surgical and Medical Procedures</td>
<td>92</td>
</tr>
<tr>
<td>Vascular Disorders</td>
<td>67</td>
</tr>
</tbody>
</table>

### Version Report

- List of various types of changes in MedDRA

<table>
<thead>
<tr>
<th>Report Category</th>
<th>Total Unique Terms between selected versions</th>
</tr>
</thead>
<tbody>
<tr>
<td>New LLTs including New PTs</td>
<td>622</td>
</tr>
<tr>
<td>New PTs</td>
<td>581</td>
</tr>
<tr>
<td>Promotions</td>
<td>20</td>
</tr>
<tr>
<td>Direct mapping</td>
<td>33</td>
</tr>
<tr>
<td>LLTs under different PTs</td>
<td>200</td>
</tr>
<tr>
<td>LLTs and PTs Primary SOC CLng</td>
<td>45</td>
</tr>
<tr>
<td>PT Primary SOC Changes</td>
<td>13</td>
</tr>
<tr>
<td>MedDRA Terms Name Changes</td>
<td>5</td>
</tr>
<tr>
<td>MedDRA Code Switches</td>
<td>0</td>
</tr>
<tr>
<td>Currency Changes</td>
<td>6</td>
</tr>
<tr>
<td>Complex Changes</td>
<td>0</td>
</tr>
<tr>
<td>SNOM Changes</td>
<td>8</td>
</tr>
<tr>
<td>PT Changes in SNOMs</td>
<td>408</td>
</tr>
<tr>
<td>LLT Changes in SNOMs</td>
<td>1003</td>
</tr>
</tbody>
</table>
Summary of SMQ Changes

- One new SMQ added
- See MedDRA Version 22.1 SMQ Introductory Guide for detailed information on new SMQ *Sepsis*
- Additional changes made to existing SMQ *Agranulocytosis*
- 105 level 1 SMQs in production
- 331 changes made in existing SMQs, see the Version Report

MedDRA Translations
MedDRA Translations

• Korean MedDRA released in v22.1
• MedDRA is available in 13 languages
  – Chinese, Czech, Dutch, English, French, German, Hungarian, Italian, Japanese, Korean, Portuguese, Russian, and Spanish
• Currently working on Brazilian Portuguese translation
  – Release anticipated for Version 23.0 (March 2020)

Proactive Maintenance
Proactivity Request Review

- Proactive maintenance process allows users to address inconsistencies, make corrections or suggest improvements
- Detailed justification needed
- No proactivity proposals implemented in MedDRA v22.1
- Please send ideas for “proactive” improvements to the MSSO Help Desk

Update on Points to Consider (PtC) Documents
### PtC Documents

<table>
<thead>
<tr>
<th>PtC Category</th>
<th>PtC Document</th>
<th>Purpose</th>
<th>Languages</th>
<th>Release Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Term Selection</strong></td>
<td>MedDRA Term Selection: Points to Consider</td>
<td>Promote accurate and consistent coding with MedDRA</td>
<td>English and Japanese</td>
<td>Updated with each MedDRA release</td>
</tr>
<tr>
<td></td>
<td>MedDRA Term Selection: Points to Consider Condensed Version</td>
<td>Shorter version focusing on general coding principles to promote accurate and consistent use of MedDRA worldwide</td>
<td>All MedDRA languages (except English and Japanese)</td>
<td>Update as needed</td>
</tr>
<tr>
<td><strong>Data Retrieval and Presentation</strong></td>
<td>MedDRA Data Retrieval and Presentation: Points to Consider</td>
<td>Demonstrate how data retrieval options impact the accuracy and consistency of data output</td>
<td>English and Japanese</td>
<td>Updated with each MedDRA release</td>
</tr>
<tr>
<td></td>
<td>MedDRA Data Retrieval and Presentation: Points to Consider Condensed Version</td>
<td>Shorter version focusing on general retrieval and analysis principles to promote accurate and consistent use of MedDRA worldwide</td>
<td>All MedDRA languages (except English and Japanese)</td>
<td>Update as needed</td>
</tr>
<tr>
<td><strong>General</strong></td>
<td>MedDRA Points to Consider Companion Document</td>
<td>More detailed information, examples, and guidance on specific topics of regulatory importance. Intended as a &quot;living&quot; document with frequent updates based on users' needs. First edition covers data quality and medication errors.</td>
<td>English and Japanese</td>
<td>Updated as needed</td>
</tr>
</tbody>
</table>

### PtC Companion Document

- Reviewing feedback from users on medication errors section
- Plan to update by Q4 2019
- Initial draft of new product quality section underway by FDA, United States
MTS: PTC Update for v22.1

- Added an example in section 3.23.1 to cover drugs that are used for prophylaxis

### 3.23.1 Lack of effect

The **preferred option** is to select only the "lack of effect" term even if consequences are also reported. However, terms may also be selected for events associated with the lack of effect.

**Example**

<table>
<thead>
<tr>
<th>Reported</th>
<th>ILT Selected</th>
<th>Preferred Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient took drug for a headache, and her headache didn't go away</td>
<td>Drug ineffective</td>
<td>✓</td>
</tr>
<tr>
<td>Antibiotic didn't work</td>
<td>Drug ineffective Headache</td>
<td></td>
</tr>
<tr>
<td>Patient took drug for thrombosis prophylaxis but she developed a deep vein thrombosis in her left leg</td>
<td>Drug ineffective Deep vein thrombosis leg</td>
<td>✓</td>
</tr>
</tbody>
</table>

New MSSO Staff
New MSSO Staff

Dr. Amanda Saunders
Development MD

Ana Garcia Rubio
Local Support Latin America

Dr. Joy Zhu
Local Support China

Dr. Ali Awan
Development MD / Mapping Support

Dr. Anamika Dutta
Local Support India

Yun Hui Do
Local Support Republic of Korea

Dr. Carol-Ann Wilson
EU Trainer (Part-time)

Social Media Initiatives
• MSSO discovered that some users prefer methods of communication other than email
• MSSO is developing a social media plan
  – What platforms to use?
  – How will the MSSO participate (e.g., monitor, disseminate information, respond to questions)?
• Follow the MSSO on WhatsApp, WeChat, Facebook, Twitter, and LinkedIn

Update on MedDRA IT Tools
MedDRA Browser Features

- Web-Based and Desktop Browsers
- New functionality for users
  - Preview upcoming (supplemental) changes in next release*
  - View primary and secondary link information
  - Upload terms to run against SMQs
  - Advanced search options (e.g., NOT, OR)

*Supplemental view not available on MedDRA Desktop Browser

WBB Supplemental View

- Display changes color to pink
- Supplemental terms highlighted by broken green line
- Changes for the next release are displayed immediately after they are approved by the MSSO

*Supplemental view available in the Web-Based Browser only
Hierarchy Analysis Function

- Hierarchy Analysis feature
  - Upload terms in spreadsheet
  - Export with primary and secondary SOC hierarchies
  - No need for programming

Standardised MedDRA Query (SMQ) Analysis

- In my dataset, which cases are “hits” for SMQs (potential cases of interest)?
SMQ Analysis

- SMQ Analysis feature
- Apply SMQs to user’s MedDRA-coded data
  - Narrow/broad
  - Hierarchical
  - Algorithmic (separate search option to apply algorithm)

SMQ Analysis (cont)

- Results of broad search on all SMQs
  - Includes narrow search
  - Includes hierarchical SMQs
  - Algorithmic SMQ analysis not shown
**Mobile WBB**

- Mobile MedDRA Browser
  - Search MedDRA terms and codes via a mobile platform
    - Smart Phone
    - Tablet
- Similar features as the Web-Based Browser
- Simple browsing and searching functions provided
  - Deployed in April 2019

**Mobile WBB Polling Question #1**

Were you aware of the release of the Mobile WBB?

A) Yes  
B) No
Mobile WBB Polling

Question #2

Have you used the Mobile WBB?

A) Yes
B) No

MVAT 3.0 Updates

- Ability to run reports on supplemental changes
- Option to include secondary SOC changes
- Deployed in June 2019
Secondary SOC Information also available in Data Impact Report

**MedDRA APIs**

- **MedDRA Application Program Interface (API)**
  - Software building blocks to provide the best features of MSSO tools (e.g., WBB, MVAT)
  - Allows users to develop their own MedDRA tools
  - Provides a proven tool that accurately depicts MedDRA
  - Expected in 2020
  - Please contact MSSO Help Desk if your organization is interested in testing APIs
Application Program Interfaces - Examples

**Input**

*Request:*
SMQ Analysis

**Data:** List of MedDRA Terms

**Outputs**

List of SMQ matches per the inputted term list

The user does not need to know how to apply the input data against MedDRA

**Input**

*Request:*
MedDRA hierarchy

**Data:** List of MedDRA Terms

**Outputs**

MedDRA primary & Secondary SOC hierarchy information

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MedDRA Training
MSSO Free Training Program

• Formats
  – Face-to-face sessions, webinars, videocasts, YouTube Channel

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

• 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

**What’s New Webinar in Chinese and Spanish**

- What’s New with MedDRA v22.1 webinar will be offered in Chinese and Spanish in presenter’s local times zones

<table>
<thead>
<tr>
<th>Language</th>
<th>Date and Time</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Spanish</strong></td>
<td>16 September 2019, 11:30AM, ART -- Argentina Time (Standard Time)</td>
</tr>
<tr>
<td><strong>Chinese</strong></td>
<td>17 September 2019, 2:00PM, China Standard Time</td>
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</tbody>
</table>
## Face to Face Training Tab

### MedDRA Training

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUG 22/2019</td>
<td>Face to Face Training, Coding with MedDRA (presented in Korean)</td>
<td>Seoul, Republic of Korea</td>
</tr>
<tr>
<td>AUG 23/2019</td>
<td>Face to Face Training, MedDRA: Safety Data Analysis and SRGs (presented in Korean)</td>
<td>Seoul, Republic of Korea</td>
</tr>
<tr>
<td>AUG 28/2019</td>
<td>Face to Face Training, Coding with MedDRA</td>
<td>Ahmedabad, Gujarat, India</td>
</tr>
<tr>
<td>SEP 10/2019</td>
<td>Face to Face Training, MedDRA: Safety Data Analysis and SRGs (presented in English and Spanish)</td>
<td>Belo Horizonte, Brazil</td>
</tr>
<tr>
<td>SEP 11/2019</td>
<td>Face to Face Training, MedDRA: Safety Data Analysis and SRGs (presented in English and Spanish)</td>
<td>Basel, Switzerland</td>
</tr>
<tr>
<td>SEP 12/2019</td>
<td>MedDRA: Safety Data Analysis and SRGs (presented in English and Spanish)</td>
<td>Athens, Greece</td>
</tr>
</tbody>
</table>

## Webinar Training Tab

### MedDRA Training

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Webinar Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUG 26/2019</td>
<td>What’s New with MedDRA, Version 22.1 and the MSSO</td>
<td>Webinar</td>
</tr>
<tr>
<td>AUG 29/2019</td>
<td>What’s New with MedDRA, Version 22.1 and the MSSO</td>
<td>Webinar</td>
</tr>
<tr>
<td>SEP 04/2019</td>
<td>Getting Started with MedDRA</td>
<td>Webinar</td>
</tr>
<tr>
<td>SEP 05/2019</td>
<td>MedDRA 22.1 (What’s New with MedDRA, Version 22.1 and the MSSO (Presented in Chinese))</td>
<td>Webinar</td>
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<tr>
<td>SEP 06/2019</td>
<td>MedDRA Coding Basics (What’s New with MedDRA, Version 22.1 and the MSSO (Presented in Spanish))</td>
<td>Webinar</td>
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<tr>
<td>SEP 07/2019</td>
<td>MedDRA Overview (presented in Spanish)</td>
<td>Webinar</td>
</tr>
<tr>
<td>OCT 02/2019</td>
<td>Standards MedDRA Queries (SRGs)</td>
<td>Webinar</td>
</tr>
<tr>
<td>OCT 03/2019</td>
<td>MedDRA Overview (presented in Chinese)</td>
<td>Webinar</td>
</tr>
<tr>
<td>OCT 04/2019</td>
<td>MedDRA Overview (presented in Spanish)</td>
<td>Webinar</td>
</tr>
</tbody>
</table>
Upcoming Meetings

U.S. Industry MedDRA and WHO-Drug User Group Meeting

- Dates: Thursday and Friday, 3 and 4 October 2019
- Time: 8:00 am – 3:00 pm each day
- Where:
  Bristol-Myers Squibb Company
  311 Pennington-Rocky Hill Road
  Pennington, New Jersey 08534

- Open to all MedDRA users
- Collaboration with WHO-Drug User Group Meeting
- Meeting agenda and registration link for both meetings posted on User Group page of MedDRA website
Other Topics

Credit Card Payment

• Paying MedDRA subscription by credit card was made available to 0-2 level commercial and developer subscribers in April 2019
• Qualified subscribers may pay their subscriptions by either wire transfer or credit card
• No additional fee is charged for credit card payment
Special Edition of
MedDRA Messenger

• September 2019 edition is dedicated to the 20th Anniversary of MedDRA
• Personal reflections from MedDRA Management Committee members on the history and future of MedDRA

Thank You

Questions?

David W. Richardson, M.D.

Email: mssohelp@meddra.org