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Topics

- What’s New with Version 22.0
  - Summary of Changes (including SMQs)
- MedDRA Translations
- Proactive Maintenance
- Update on Points to Consider (PtC) Documents and MedDRA Best Practices Document
- New MSSO Staff
- WEB-RADR 2
- Update on MedDRA IT Tools
- MedDRA Training
- Upcoming Meetings
What's New with MedDRA Version 22.0

• Release on 1 March 2019
• A complex release
• Change request summary:
  – MSSO considered 1,541 change requests, including SMQ requests (not including translation updates)
    • Approved: 1,333
    • Not approved: 207
    • Suspended: 1
• Changes reflect the differences between v21.1 and v22.0
### Net Change of Terms per SOC

<table>
<thead>
<tr>
<th>SOC</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood and lymphatic system disorders</td>
<td>51</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>37</td>
</tr>
<tr>
<td>Congenital, familial and genetic disorders</td>
<td>1</td>
</tr>
<tr>
<td>Ear and labyrinth disorders</td>
<td>4</td>
</tr>
<tr>
<td>Endocrine disorders</td>
<td>2</td>
</tr>
<tr>
<td>Eye disorders</td>
<td>1</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>1</td>
</tr>
<tr>
<td>General disorders and administration site</td>
<td>1</td>
</tr>
<tr>
<td>Haematopoietic and immunological disorders</td>
<td>1</td>
</tr>
<tr>
<td>Immune system disorders</td>
<td>51</td>
</tr>
<tr>
<td>Injury, poisoning and procedural complications</td>
<td>4</td>
</tr>
<tr>
<td>Investigations</td>
<td>13</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>11</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue</td>
<td>1</td>
</tr>
<tr>
<td>Neoplasms benign, malignant and...</td>
<td>130</td>
</tr>
<tr>
<td>Pregnancy, puerperium and perinatal...</td>
<td>133</td>
</tr>
<tr>
<td>Product issues</td>
<td>49</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td>26</td>
</tr>
<tr>
<td>Reproductive system and breast disorders</td>
<td>21</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal...</td>
<td>120</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>1</td>
</tr>
<tr>
<td>Social circumstances</td>
<td>132</td>
</tr>
<tr>
<td>Surgical and medical procedures</td>
<td>152</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>133</td>
</tr>
</tbody>
</table>

### Version Report

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

• No changes at SOC level
• Includes new/merged HLG Ts (2 of each) and new/merged HLTs (6 of each)
• Changes summarized in What’s New v22.0 document and link on Change Requests page of meddra.org website

Summary of SMQ Changes

• One new SMQ added
• See MedDRA Version 22.0 SMQ Introductory Guide for detailed information on new SMQ Hypokalaemia
• 104 level 1 SMQs in production
• 389 changes made in existing SMQs, see the Version Report
• “Active PT Codes” page added to SMQ spreadsheet
  – Allows users to quickly copy PT codes to include them in a query
MedDRA Translations

- Currently MedDRA is available in 12 languages
  - Chinese, Czech, Dutch, English, French, German, Hungarian, Italian, Japanese, Portuguese, Russian, and Spanish
  - Translation includes all terms and documentation
- Currently working on Korean and Brazilian Portuguese translation
  - Release dates to be determined
2019 MedDRA Subscription Rates

- Effective 1 January 2019, additional $850 subscription fee for the Japanese translation of MedDRA has been eliminated
- MSSO subscribers receive all MedDRA languages with their subscription at no additional cost
- All 2019 MedDRA subscription rates have been reduced 5% from 2018 levels

2019 MedDRA Subscription Rates (cont)

<table>
<thead>
<tr>
<th>MedDRA Subscription Types</th>
<th>2019 Annual Subscription Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Authority</td>
<td>$0 USD</td>
</tr>
<tr>
<td>Non-Commercial / Non-Profit</td>
<td>$0 USD</td>
</tr>
<tr>
<td>Commercial (Parent Company Annual Revenue or Turnover)</td>
<td></td>
</tr>
<tr>
<td>Level 0 (Annual Revenue &lt; $1 Million)</td>
<td>$154 USD</td>
</tr>
<tr>
<td>Level 1 (Annual Revenue $1-$10 Million)</td>
<td>$654 USD</td>
</tr>
<tr>
<td>Level 2 (Annual Revenue $10-$20 Million)</td>
<td>$2,496 USD</td>
</tr>
<tr>
<td>Level 3 (Annual Revenue $20-$500 Million)</td>
<td>$4,737 USD</td>
</tr>
<tr>
<td>Level 4 (Annual Revenue $500 Million-$1 Billion)</td>
<td>$9,918 USD</td>
</tr>
<tr>
<td>Level 5 (Annual Revenue $1-$5 Billion)</td>
<td>$41,150 USD</td>
</tr>
<tr>
<td>Level 6 (Annual Revenue $5-$20 Billion)</td>
<td>$54,354 USD</td>
</tr>
<tr>
<td>Level 7 (Annual Revenue &gt; $20 Billion)</td>
<td>$70,889 USD</td>
</tr>
</tbody>
</table>

5% Reduction from 2018 rates

77% of all MedDRA users pay no fee or $688 (or less)
Proactive Maintenance

Proactivity Request Review

- Proactive maintenance process allows users to address inconsistencies, make corrections or suggest improvements
- 2 proactivity proposals implemented in MedDRA v22.0
  - Review of optimal placement of anesthesia terms
  - Review of placement of chemical burn and corrosive injury terms
- Details of implemented changes in What’s New Version 22.0 document
Update on Points to Consider (PtC) Documents and MedDRA Best Practices Document

<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>Term Selection</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>Data Retrieval and Presentation</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>General</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 Updates v22.0

• Mention availability of Condensed Versions of PtC documents
• Term Selection document
  – Minor text changes in Exposures during Pregnancy and Breast Feeding section 3.10
• Data Retrieval and Presentation document
  – Added references to new Hierarchy Analysis and SMQ Analysis functions in MSSO browsers

PtC Companion Document

• Reviewing feedback from users on medication errors section
• Plan to update in first half of 2019
• Initial draft of new product quality section underway
Support Documentation

- Condensed PtC documents available in all MedDRA languages except English and Japanese
- MedDRA Best Practices document available in all MedDRA languages
- Russian now available in v22.0

MedDRA Best Practices Document

- Objective is to promote accurate and consistent use of MedDRA
- Sections on primary SOC allocation, versioning, supplemental terms
- Endorsed by MMC
New MSSO Staff

• MSSO has hired new US-based staff for program development
  – They will support MedDRA mapping initiatives and terminology maintenance
• MSSO has hired locally-based support staff for the Republic of Korea and Argentina (supporting Latin America)
  – They will provide support (e.g., Help Desk, training) for local MedDRA users
• MSSO has also hired a part-time trainer based in Germany
• Additional locally-based support staff hires are planned for China and India by the end of 2019
New MSSO Staff

Dr. Amanda Saunders

Dr. Carol Ann Wilson

Ana García Rubio

Dr. Ali Awan

Yun Hui Do

WEB-RADR 2

(WEB Recognising Adverse Drug Reactions)
WEB-RADR 2

- WEB-RADR 2 project funded by Innovative Medicines Initiative (IMI)
  - Seeks to build on mobile application technology
- ICH is a partner
  - MSSO participating as ICH’s subcontractor
- 18 month project (Sep 2018 – Feb 2020)
- Work Package 4 “Terminology Mapping and Maintenance”
  - Goal is to develop a bi-directional mapping between SNOMED CT and MedDRA
  - Develop licensing and distribution agreements
  - Develop ongoing maintenance processes

Consortium members
WEB-RADR 2
Consortium Meeting

2 November 2018 at MHRA, UK

Update on MedDRA IT Tools
Major Web-Based Browser 3.0 Features

• Ability to view supplemental changes
• Upload terms to extract primary and secondary links
  – Option to export secondary SOC links from the Research Bin and Search results
• Upload terms to run against SMQs
  – Options to use algorithmic and hierarchical SMQs
• Available as of October 2018
• MedDRA Desktop Browser update expected in second quarter 2019
Web-Based Browser 3.0

• Purpose of Supplemental view in WBB 3.0:
  – Displays changes to MedDRA for the next release immediately after approval
  – Improves transparency vs. current supplemental posting

• Not the default view

WBB 3.0 Secondary SOC Information

• Option to extract Secondary SOC* information:
  – Separate feature to upload MedDRA terms and extract hierarchy in formation
  – Exporting from the research bin

*Primary SOC is the default
WBB 3.0 Secondary SOC Information (cont)

• Example export with Secondary SOC information*  

*Primary SOC hierarchy information is included by default

SMQ Analysis

• Purpose – assist MedDRA users in applying SMQs to their coded data

• Input:

<table>
<thead>
<tr>
<th>Row ID</th>
<th>Term Name</th>
<th>MedDRA Code</th>
<th>Case ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Allergic cystitis</td>
<td>10051394</td>
<td>A2346</td>
</tr>
<tr>
<td>2</td>
<td>Anaplastic thyroid cancer</td>
<td>10002240</td>
<td>A2347</td>
</tr>
<tr>
<td>3</td>
<td>Angiomixuendoelastic T-cell lymphoma stage III</td>
<td>10002456</td>
<td>A2348</td>
</tr>
<tr>
<td>4</td>
<td>Brachytherapy to liver</td>
<td>10052870</td>
<td>C2064</td>
</tr>
<tr>
<td>5</td>
<td>Central nervous system melanoma</td>
<td>10077160</td>
<td>A2345</td>
</tr>
<tr>
<td>6</td>
<td>Congenital nipple inversion</td>
<td>10080355</td>
<td>B4587</td>
</tr>
<tr>
<td>7</td>
<td>Conjoined twins</td>
<td>10010688</td>
<td>B4588</td>
</tr>
<tr>
<td>8</td>
<td>Dosage calculation error</td>
<td>10076874</td>
<td>B4599</td>
</tr>
<tr>
<td>9</td>
<td>Erythropoiesis of lip</td>
<td>10052826</td>
<td>B4590</td>
</tr>
<tr>
<td>10</td>
<td>Extragonadal primary seminoma (pure) stage IV</td>
<td>10015816</td>
<td>B4591</td>
</tr>
<tr>
<td>11</td>
<td>Foetal malnutrition</td>
<td>10010682</td>
<td>B4592</td>
</tr>
<tr>
<td>12</td>
<td>Gastritis erosive</td>
<td>10017865</td>
<td>B4593</td>
</tr>
<tr>
<td>13</td>
<td>High grade B-cell lymphoma Burkitt-like lymphoma refractory</td>
<td>10020071</td>
<td>C2057</td>
</tr>
<tr>
<td>14</td>
<td>Interverbral disc injury</td>
<td>10050400</td>
<td>C2058</td>
</tr>
</tbody>
</table>
SMQ Analysis (cont)

- Output:

<table>
<thead>
<tr>
<th>Row ID</th>
<th>LTT/PT Term</th>
<th>LTT/PT Code</th>
<th>PT Term</th>
<th>SMQ Matched</th>
<th>Scope</th>
<th>Category</th>
<th>Weight</th>
<th>Status</th>
<th>Case ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Allergic cystitis</td>
<td>A0001394</td>
<td>Allergic cystitis</td>
<td>Hypersensitivity (SMQ)</td>
<td>Narrow</td>
<td>A</td>
<td>0</td>
<td>Active</td>
<td>A2347</td>
</tr>
<tr>
<td>2</td>
<td>Anaplastic thyroid cancer</td>
<td>A0002240</td>
<td>Anaplastic thyroid cancer</td>
<td>Non-hematological malignant tumours (SMQ)</td>
<td>Narrow</td>
<td>A</td>
<td>0</td>
<td>Active</td>
<td>A2348</td>
</tr>
<tr>
<td>3</td>
<td>Angiomyolipoma T-cell lymphoma stage III</td>
<td>A0002356</td>
<td>Angiomyolipoma T-cell lymphoma stage III</td>
<td>Malignant lymphomas (SMQ)</td>
<td>Narrow</td>
<td>A</td>
<td>0</td>
<td>Active</td>
<td>A2348</td>
</tr>
<tr>
<td>4</td>
<td>Brachytherapy to liver</td>
<td>B0052670</td>
<td>Brachytherapy to liver</td>
<td>NO MATCH</td>
<td>Narrow</td>
<td>A</td>
<td>0</td>
<td>Active</td>
<td>A2349</td>
</tr>
<tr>
<td>5</td>
<td>Central nervous system melanoma</td>
<td>A00073160</td>
<td>Central nervous system melanoma</td>
<td>Non-hematological malignant tumours (SMQ)</td>
<td>Narrow</td>
<td>A</td>
<td>0</td>
<td>Active</td>
<td>A2349</td>
</tr>
<tr>
<td>6</td>
<td>Congenital rhabdomyosarcoma</td>
<td>A0085355</td>
<td>Congenital rhabdomyosarcoma</td>
<td>Congenital, familial and genetic disorders (SMQ)</td>
<td>Narrow</td>
<td>A</td>
<td>0</td>
<td>Active</td>
<td>A2349</td>
</tr>
<tr>
<td>7</td>
<td>Congenital twins</td>
<td>A0010688</td>
<td>Congenital twins</td>
<td>Congenital, familial and genetic disorders (SMQ)</td>
<td>Narrow</td>
<td>A</td>
<td>0</td>
<td>Active</td>
<td>A2349</td>
</tr>
<tr>
<td>8</td>
<td>Dose calculation error</td>
<td>A00787487</td>
<td>Dose calculation error</td>
<td>Medication errors (SMQ)</td>
<td>Narrow</td>
<td>A</td>
<td>0</td>
<td>Active</td>
<td>A2349</td>
</tr>
<tr>
<td>9</td>
<td>Erythropoiesis of lip</td>
<td>A0052826</td>
<td>Erythropoiesis of lip</td>
<td>Gastrointestinal premalignant disorders (SMQ)</td>
<td>Narrow</td>
<td>A</td>
<td>0</td>
<td>Active</td>
<td>A2349</td>
</tr>
<tr>
<td>10</td>
<td>Extragonadal primary seminoma stage IV</td>
<td>A0015816</td>
<td>Extragonadal primary seminoma stage IV</td>
<td>Non-hematological malignant tumours (SMQ)</td>
<td>Narrow</td>
<td>A</td>
<td>0</td>
<td>Active</td>
<td>A2349</td>
</tr>
</tbody>
</table>
Planned MVAT 3.0 Updates

- Ability to run reports on supplemental changes
- Option to include secondary SOC changes
- Expected second quarter 2019

MVAT 3.0 – Secondary SOC Information

Secondary SOC information also available in Data Impact Report
Mobile WBB

- Mobile MedDRA Browser
  - Search MedDRA terms and codes via a mobile platform
    - Smart Phone
    - Tablet
  - Similar features as the Web-Based Browser
  - Some features may be limited due to constraints of the mobile platform
  - Expected in middle of 2019

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 end of 2019/early 2020
Application Program Interfaces - Examples

**Input**

- **Request:** SMQ Analysis
- **Data:** List of MedDRA Terms

**Outputs**

- List of SMQ matches per the inputted term list

**Input**

- **Request:** MedDRA hierarchy
- **Data:** List of MedDRA Terms

**Outputs**

- MedDRA primary & Secondary SOC hierarchy information

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

---

MedDRA Training
MSSO Free Training Program

• Formats
  – Face-to-face sessions, webinars, videocasts, YouTube Channel
• Languages
  – English, French, German, Spanish, Mandarin Chinese, Korean
• 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

Face to Face Training Tab

MedDRA Training

- FEB 26/2019: Face-to-Face Training - Coding with MedDRA, Istanbul, Turkey
- FEB 27/2019: Face-to-Face Training - MedDRA, Safety Data Analysis and SMQs, Istanbul, Turkey
- FEB 28/2019: Face-to-Face Training - Coding with MedDRA, Billerup, Denmark
- MAR 11/2019: Face-to-Face Training - MedDRA, Safety Data Analysis and SMQs, Billerup, Denmark
- MAR 12/2019: Face-to-Face Training - Coding with MedDRA, Paris, France
- MAR 13/2019: Face-to-Face Training - MedDRA, Safety Data Analysis and SMQs, Hyderabad, India
- MAR 14/2019: Face-to-Face Training - MedDRA, Safety Data Analysis and SMQs, Hyderabad, India
Summary of 2018 Training

<table>
<thead>
<tr>
<th>Attendees</th>
<th>Sessions</th>
<th>Locations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face-to-Face Training</td>
<td>2,753</td>
<td>71</td>
</tr>
<tr>
<td>Webinars</td>
<td>2,584 connections</td>
<td>27</td>
</tr>
</tbody>
</table>
Upcoming Meetings

India MedDRA User Group Meeting

• Date: Tuesday, 12 March 2019
• Time: 9:00 – 18:00
• Where:
  Westin Hyderabad Mindspace
  Raheja IT Park, Hitec City, Madhapur
  Hyderabad 500 081 India
• Given in connection with WHO-Drug User Group Meeting
• Open to all MedDRA users
• Registration form posted to User Group page on MedDRA website
European MedDRA User Group Meeting

- Date: Wednesday, 10 April 2019
- Time: 8:30 – 16:30
- Where:
  Jury’s Inn
  Sokolovska 11, Prague, 186 00 Praha
  Czech Republic
- Given in connection with WHO-Drug User Group Meeting
- Open to all MedDRA users
- Registration form posted to User Group page on MedDRA website

Other MedDRA User Group Meetings – Dates to be Determined

- Chinese MedDRA User Group Meeting
- US 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.

Email: mssohelp@meddra.org