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Topics

• What’s New with Version 20.1
  – Summary of Changes (including SMQs)
  – Revision of “Drug Use Disorder” Terms
  – Translation Review
• Proactive Maintenance
• Update on Points to Consider Documents
• MedDRA v21.0 Complex Change Proposals
• Self-Service Application
• New Videocast about MedDRA Website
• MedDRA Training
• Upcoming Meetings
What's New with MedDRA Version 20.1

- Release on 1 September 2017
- A simple release
- Change request summary:
  - MSSO considered 1,764 change requests, including SMQ requests (not including translation updates)
    - Approved: 1,476
    - Rejected: 272
    - Suspended: 16
- Changes reflect the differences between v20.0 and v20.1
Net Change of Terms per SOC

<table>
<thead>
<tr>
<th>Category</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood and lymphatic system disorders</td>
<td>81</td>
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<tr>
<td>Cardiac disorders</td>
<td>34</td>
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<tr>
<td>Congenital, familial and genetic disorders</td>
<td>78</td>
</tr>
<tr>
<td>Ear and labyrinth disorders</td>
<td>8</td>
</tr>
<tr>
<td>Endocrine disorders</td>
<td>35</td>
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<tr>
<td>Eye disorders</td>
<td>66</td>
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<tr>
<td>Gastrointestinal disorders</td>
<td>92</td>
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<tr>
<td>General disorders and administration site</td>
<td>61</td>
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<tr>
<td>Hepatobiliary disorders</td>
<td>21</td>
</tr>
<tr>
<td>Immune system disorders</td>
<td>40</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>40</td>
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<tr>
<td>Injury, poisoning and procedural complications</td>
<td>100</td>
</tr>
<tr>
<td>Investigations</td>
<td>130</td>
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<tr>
<td>Metabolism and nutrition disorders</td>
<td>43</td>
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<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>139</td>
</tr>
<tr>
<td>Neoplasms benign, malignant and unspecified</td>
<td>87</td>
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<tr>
<td>Nervous system disorders</td>
<td>84</td>
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<tr>
<td>Pregnancy, puerperium and perinatal</td>
<td>38</td>
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<tr>
<td>Product issues</td>
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<tr>
<td>Psychiatric disorders</td>
<td>42</td>
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<tr>
<td>Renal and urinary disorders</td>
<td>38</td>
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<tr>
<td>Reproducive system and breast disorders</td>
<td>42</td>
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<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>67</td>
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<td>Skin and subcutaneous tissue disorders</td>
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<tr>
<td>Social circumstances</td>
<td>9</td>
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<tr>
<td>Surgical and medical procedures</td>
<td>104</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>104</td>
</tr>
</tbody>
</table>

Version Report

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

- One new SMQ added
- See MedDRA Version 20.1 SMQ Introductory Guide for detailed information on new SMQ *Infective pneumonia*
- 102 level 1 SMQs in production
- 297 changes made in existing SMQs, see the Version Report

Revision of “Drug Use Disorder” Terms

- Based on user feedback, several previously demoted drug/substance abuse and dependence terms were re-promoted from under “use disorder” PTs
- Abuse and dependence are distinct and important concepts in pharmacovigilance
- Warrant separate representation at PT level
- See What’s New Version 20.1 document for detailed information
Revision of “Drug Use Disorder” Terms (cont)

- Substance related and addictive disorders
  - Alcohol abuse
  - Alcohol problem
  - Alcohol use disorder
  - Alcohol withdrawal syndrome
  - Alcoholic hangover
  - Alcoholism
  - Behavioral addiction
  - Binge drinking
  - Dependence
  - Dopamine dysregulation syndrome
  - Drug abuse
  - Drug dependence
  - Drug dependence, antepartum
  - Drug dependence, postpartum
  - Drug use disorder
  - Drug use disorder, antepartum
  - Drug use disorder, postpartum
  - Drug withdrawal syndrome
  - Drug withdrawal syndrome neonatal
  - Gambling disorder
  - Neonatal complications of substance abuse
  - Nicotine dependence
  - Substance abuse
  - Substance dependence
  - Substance use disorder
  - Tobacco abuse
  - Tobacco withdrawal symptoms
  - Withdrawal syndrome

Red arrows identify promoted terms

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 21.0 (March 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
Test Your MedDRA Knowledge

According to the recommendation of the ICH, when should MedDRA Version 20.1 become the reporting version used for Individual Case Safety Reports?

A. Monday, 6 November 2017  
B. There is no such recommendation  
C. Friday, 1 September 2017  
D. Monday, 2 October 2017

Proactive Maintenance
Proactivity Request Review

- Proactive maintenance process allows users to address inconsistencies, make corrections or suggest improvements
- 1 of 3 proactivity proposals implemented in MedDRA v20.1
  - Review of foreign body terms
- Details of implementation changes in What’s New Version 20.1 document

Update on Points to Consider Documents
MedDRA Term Selection: PtC Updates

- Revised examples in Section 3.10
  Exposures during Pregnancy and Breast Feeding

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 2018

- English and Japanese PtC documents will remain as full documents updated with each MedDRA release
Companion PtC Document Update

- More detailed guidance, examples, and “Questions and Answers”
- PtC Working Group drafting first two sections
  - Data quality
  - Medication errors
- Available in English and Japanese only
- Initial version planned for release in 2018

MedDRA v21.0 Complex Changes Proposals
MedDRA v21.0 Complex Changes

• Proposed MedDRA Version 21.0 Complex Changes are available for comments:
  http://www.meddra.org/how-to-use/change-requests
• Complex changes are changes to HLTs, HLGTs, or SOCs
• Proposed changes involve addition of four new HLTs:
  – Visual impairment and blindness (excl colour blindness)
  – Anaesthetic and allied procedural complications
  – Chest and respiratory tract injuries NEC
  – Musculoskeletal and connective tissue conditions NEC
• Encourage comments both for and against proposed changes
• Deadline for comments is 22 September 2017 – mssorequest@meddra.org

Self-Service Application
Features of Self-Service Application

- 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

- Available as of April 2017

https://apps.meddra.org/selfservice
Those with a valid email domain can obtain their MedDRA ID to register for training and UG meetings.

**Obtain MedDRA ID (cont)**

Email sent instructing how to get your MedDRA ID

---

Dear MedDRA User,

Your one time authorization code is:

b644de15-879e-4bdc-a35f-7d8aee52c25f

Please use the following URL to retrieve your MedDRA ID:

https://apps.meddra.org/selfservice/get_help.aspx

You have to use this authorization code within 20 minutes, otherwise, it will become invalid.

Sincerely,

MSO Help Desk

msohelp@meddra.org
Points of contact may obtain their MedDRA Password, CRID and Unzip passwords.

Email sent instructing how to get your MedDRA Password:

Dear MedDRA User,

Your one-time authorization code is: 5da4f91b-8bb1-4959-a1ab-3f0e5aebf1cc

Please use the following URL to retrieve your MedDRA Password:

https://apps.meddra.org/selfservice/get_help.aspx

You have to use this authorization code within 20 minutes; otherwise, it will become invalid.

Sincerely,
MS50 Help Desk
ms50help@meddra.org
Self-Service Application (cont)

• The MSSO plans to refer users to the Self-Service Application for:
  – Distributing unzip passwords
  – Obtaining password information for new subscriptions and subscription renewal
Links on the Self-Service Application Page

The MedDRA Self-Service Application provides uninterrupted support to frequently asked questions and has the following features:

- Retrieve your organization's MedDRA ID
- Retrieve your organization's MedDRA Password and PIN
- Retrieve your organization's Primary Point of Contact
- Retrieve your organization's MedDRA ID and PIN
- Check the MedDRA subscription status of business partners
- Retrieve your organization's MedDRA ID and PIN
- MedDRA website training materials
- MedDRA training materials
- MedDRA Training Materials
- MedDRA Training Materials
- MedDRA Training Materials

To access the Self-Service application, simply click this link and enter the appropriate credentials.

The MedDRA has developed a video tutorial on how to use this new application. The tutorial is available for download at <https://www.meddra.com/trainingmaterials>.

The MedDRA is interested in your feedback, so please send the MedDRA Help Desk with any questions or comments.

MedDRA Website Training Materials Page

MedDRA training materials are provided as presentations and videos for enhancing your knowledge of MedDRA coding and terminology.
New Videocast about MedDRA Website
New MedDRA Videocast

- Entitled “The Top 12 Things to Know about the MedDRA Website”
- Fast-paced tour of website including location of:
  - MedDRA release package files
  - Support documentation
  - MedDRA tools
  - Access to electronic Change Request submission tool
  - Registration for training courses/User Group Meetings
  - Frequently asked questions
- Link is on MedDRA website “Training Materials” page
- Please give us your feedback!
MedDRA Website Training Materials Page (cont)

- The Top 12 Things to Know about the MedDRA Website
  - VideoCast
    - Streaming - English
    - Download - English

MedDRA Training
MSSO Free Training Program

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

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

• Locations
  – North and South America, Europe, Asia and “virtual”

Training Tab Screenshot
Upcoming Meetings

Chinese MedDRA and WHODrug Meeting

- Date: Wednesday, 6 September 2017
- Time: 8:45 am – 16:30 pm
- Location:
  - 14 floor, No. 77
  - Jianguo Road
  - China Central Place, Tower 3
  - Chaoyang District
  - Beijing 100025, China
- Open to all MedDRA users
- MSSO will attend
- Agenda is posted to User Group page on MedDRA website
- Registration is now closed
US Industry MedDRA User Group Meeting

- Date: Friday, 29 September 2017
- Time: 8:00 am – 3:00 pm EST
- Hosted by Medimmune
- Location:
  - 1 Medimmune Way
  - Gaithersburg, Maryland 20878
- Open to all MedDRA users
- MSSO will attend
- Agenda is posted to User Group page on MedDRA website
- Registration for this meeting is now open

European Industry MedDRA User Group Webinar

- Topic: Safety Analysis
- Date: Wednesday, 4 October 2017
- Time: 14:00 - 15:30 pm CET/ 8:00 -9:30 am US EST
- Open to all MedDRA users
- Agenda and registration information are posted to User Group page on MedDRA website
Thank You

Questions?

David W. Richardson, M.D.

Email: mssohelp@meddra.org