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Topics

• What’s New with Version 19.0 – Summary of changes (including SMQs)
• SOC Product issues
• Proactive Maintenance
• Update on Points to Consider Documents
• Update on MedDRA IT Tools
• MedDRA Training
• Upcoming Meetings
What's New with MedDRA Version 19.0

- Release on 1 March 2016
- A complex release
- Change request summary:
  - MSSO considered 2264 change requests, including SMQ requests (not including translation updates)
    - Approved: 1814
    - Rejected: 419
    - Suspended: 31
- Changes reflect the differences between v18.1 and v19.0
### Net Change of Terms per SOC

<table>
<thead>
<tr>
<th>Condition Category</th>
<th>Change Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood and lymphatic system disorders</td>
<td>72</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>39</td>
</tr>
<tr>
<td>Congenital, familial and genetic disorders</td>
<td>82</td>
</tr>
<tr>
<td>Ear and labyrinth disorders</td>
<td>13</td>
</tr>
<tr>
<td>Endocrine disorders</td>
<td>52</td>
</tr>
<tr>
<td>Eye disorders</td>
<td>96</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>94</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>609</td>
</tr>
<tr>
<td>Hematopoietic disorders</td>
<td>38</td>
</tr>
<tr>
<td>Innervation system disorders</td>
<td>64</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>70</td>
</tr>
<tr>
<td>Injury, poisoning and procedural complications</td>
<td>374</td>
</tr>
<tr>
<td>Investigation</td>
<td>115</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>67</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>141</td>
</tr>
<tr>
<td>Neoplastic benign, malignant and unspecified (incl cysts and polyps)</td>
<td>103</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>142</td>
</tr>
<tr>
<td>Pregnancy, puerperium and perinatal conditions</td>
<td>18</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td>86</td>
</tr>
<tr>
<td>Renal and urinary disorders</td>
<td>39</td>
</tr>
<tr>
<td>Reproductive system and breast disorders</td>
<td>26</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>78</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>75</td>
</tr>
<tr>
<td>Social circumstances</td>
<td>5</td>
</tr>
<tr>
<td>Surgical and medical procedures</td>
<td>92</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>197</td>
</tr>
</tbody>
</table>

### Version Report

- List of various types of changes in MedDRA
Complex Changes

- One new SOC

<table>
<thead>
<tr>
<th>New SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product issues</td>
</tr>
</tbody>
</table>

- Two new HLGTs

<table>
<thead>
<tr>
<th>New HLGT</th>
<th>To SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product quality, supply, distribution, manufacturing and quality system issues</td>
<td>Product issues</td>
</tr>
<tr>
<td>Somatic symptom and related disorders</td>
<td>Psychiatric disorders</td>
</tr>
</tbody>
</table>

Complex Changes (cont)

- Two merged HLGTs

<table>
<thead>
<tr>
<th>Merged HLGT</th>
<th>To HLGT</th>
<th>To SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product quality issues</td>
<td>Product quality, supply, distribution, manufacturing and quality system issues</td>
<td>Product issues</td>
</tr>
<tr>
<td>Somatoform and factitious disorders</td>
<td>Somatic symptom and related disorders</td>
<td>Psychiatric disorders</td>
</tr>
</tbody>
</table>

- One HLGT move

<table>
<thead>
<tr>
<th>HLGT</th>
<th>From SOC</th>
<th>To SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device issues</td>
<td>General disorders and administration site conditions</td>
<td>Product issues</td>
</tr>
</tbody>
</table>
### Complex Changes (cont)

#### Sixteen new HLTs

<table>
<thead>
<tr>
<th>New HLT</th>
<th>To SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaphylactic and anaphylactoid responses</td>
<td>Immune system disorders</td>
</tr>
<tr>
<td>Counterfeit, falsified and substandard products</td>
<td>Product issues</td>
</tr>
<tr>
<td>Device site reactions</td>
<td>Injury, poisoning and procedural complications</td>
</tr>
<tr>
<td>Intellectual disabilities</td>
<td>Psychiatric disorders, Nervous system disorders</td>
</tr>
<tr>
<td>Intercepted medication errors</td>
<td>Injury, poisoning and procedural complications</td>
</tr>
<tr>
<td>Manufacturing facilities and equipment issues</td>
<td>Product issues</td>
</tr>
<tr>
<td>Manufacturing issues NEC</td>
<td>Product issues</td>
</tr>
<tr>
<td>Manufacturing laboratory controls issues</td>
<td>Product issues</td>
</tr>
<tr>
<td>Manufacturing materials issues</td>
<td>Product issues</td>
</tr>
<tr>
<td>Manufacturing production issues</td>
<td>Product issues</td>
</tr>
<tr>
<td>Marginal zone lymphomas NEC</td>
<td>Blood and lymphatic system disorders</td>
</tr>
<tr>
<td></td>
<td>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</td>
</tr>
<tr>
<td>Paraphilias and paraphilic disorders</td>
<td>Psychiatric disorders</td>
</tr>
<tr>
<td>Product distribution and storage issues</td>
<td>Product issues</td>
</tr>
<tr>
<td>Product supply and availability issues</td>
<td>Product issues</td>
</tr>
<tr>
<td>Somatic symptom disorders</td>
<td>Psychiatric disorders</td>
</tr>
<tr>
<td>Varicose veins NEC</td>
<td>Vascular disorders</td>
</tr>
</tbody>
</table>
### Complex Changes (cont)

**Five merged HLTs**

<table>
<thead>
<tr>
<th>Merged HLT</th>
<th>To HLT</th>
<th>SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaphylactic responses</td>
<td>Anaphylactic and anaphylactoid responses</td>
<td>Immune system disorders</td>
</tr>
<tr>
<td>Mental retardations</td>
<td>Intellectual disabilities</td>
<td>Psychiatric disorders</td>
</tr>
<tr>
<td>Paraphilias</td>
<td>Paraphilias and paraphilic disorders</td>
<td>Psychiatric disorders</td>
</tr>
<tr>
<td>Somatoform disorders</td>
<td>Somatic symptom disorders</td>
<td>Psychiatric disorders</td>
</tr>
<tr>
<td>Varicose veins non-site specific</td>
<td>Varicose veins NEC</td>
<td>Vascular disorders</td>
</tr>
</tbody>
</table>

**Five moved HLTs**

<table>
<thead>
<tr>
<th>HLT</th>
<th>From SOC</th>
<th>To HLGT</th>
<th>In SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product contamination and sterility issues</td>
<td>General disorders and administration site conditions</td>
<td>Product quality, supply, distribution, manufacturing and quality system issues</td>
<td>Product issues</td>
</tr>
<tr>
<td>Product label issues</td>
<td>General disorders and administration site conditions</td>
<td>Product quality, supply, distribution, manufacturing and quality system issues</td>
<td>Product issues</td>
</tr>
<tr>
<td>Product packaging issues</td>
<td>General disorders and administration site conditions</td>
<td>Product quality, supply, distribution, manufacturing and quality system issues</td>
<td>Product issues</td>
</tr>
</tbody>
</table>
Complex Changes (cont)

- Five moved HLTs (cont)

<table>
<thead>
<tr>
<th>HLT</th>
<th>From SOC</th>
<th>To HLGT</th>
<th>In SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product physical issues</td>
<td>General disorders and administration site conditions</td>
<td>Product quality, supply, distribution, manufacturing and quality system issues</td>
<td>Product issues</td>
</tr>
<tr>
<td>Product quality issues NEC</td>
<td>General disorders and administration site conditions</td>
<td>Product quality, supply, distribution, manufacturing and quality system issues</td>
<td>Product issues</td>
</tr>
</tbody>
</table>

Summary of SMQ Changes

- Three new SMQs added
  - SMQ *Drug reaction with eosinophilia and systemic symptoms syndrome*
  - SMQ *Hypoglycaemia*
  - SMQ *Medication errors*
- Existing SMQ *Pulmonary hypertension* was revised (see v19.0 SMQ Introductory Guide for details)
- 101 level 1 SMQs in production
- 935 PT changes made in SMQs, including PTs added to three new SMQs
SOC Product issues

• New (27th) SOC implemented in MedDRA Version 19.0
• Accommodates non-clinical/non-patient related concepts pertaining to products
• Important concepts as they may affect patient safety
• Includes terms relevant for issues with
  – Product quality
  – Devices
  – Manufacturing and quality systems
  – Supply and distribution
  – Counterfeit products
SOC Product issues (cont)

• Goal of product quality terms in MedDRA is to support recording of product quality issues and any associated adverse events using a single terminology

• Potential uses of product quality terms, including manufacturing and distribution issues
  – Reporting product defects to regulatory authorities
  – Track and trend quality issues or deviations in organizations’ internal databases

Contents

In MedDRA v19.0
• 5 new PTs in HLGT
  Device issues
• 8 new PTs in HLGT
  Product quality, supply, distribution, manufacturing and quality system issues
Impact on Existing Data

MedDRA Version 18.1

- General disorders and administration site conditions
- Body temperature conditions
- Complications associated with device
- Device issues
- Fatal outcomes
- General system disorders NEC
- Product quality issues
  - Product contamination and integrity issues
    - Exposure via contaminated device
    - Product cleaning inadequate
    - Product contamination
    - Product contamination chemical
    - Product contamination microbial
    - Product contamination physical
    - Product contamination with body fluid
    - Product sterilization
    - Suspected transmission of an infectious agent via product
    - Transmission of an infectious agent via product
  - Product labeling issues
  - Product packaging issues
  - Product physical issues
  - Product quality issues NEC
- Therapeutic and nontherapeutic effects (excl toxicity)
- Trivial disorder NEC

MedDRA Version 19.0

- Product issues
  - Device issues
  - Product quality, supply, distribution, manufacturing and quality system issues
    - Counterfeit, falsified and substandard products
    - Manufacturing facilities and equipment issues
    - Manufacturing issues NEC
    - Manufacturing laboratory controls issues
    - Manufacturing materials issues
    - Manufacturing production issues
    - Product contamination and integrity issues
      - Exposure via contaminated device
      - Product cleaning inadequate
      - Product contamination
      - Product contamination chemical
      - Product contamination microbial
      - Product contamination physical
      - Product contamination with body fluid
      - Product sterilization
      - Suspected transmission of an infectious agent via product
      - Transmission of an infectious agent via product
    - Product label issues
    - Product packaging issues
    - Product physical issues
    - Product quality issues NEC
    - Product supply and availability issues

Proactive Maintenance
**Proactivity Request - Changes in SOC Psychiatric disorders**

- Align SOC with DSM-V and prevailing mental disorder concepts
- 98 total changes – 35 new terms added, 63 changes to existing terms

<table>
<thead>
<tr>
<th>New Term Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New PT</strong></td>
</tr>
<tr>
<td>Speech sound disorder</td>
</tr>
<tr>
<td>Illness anxiety disorder</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Term Move Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demoted PT</strong></td>
</tr>
<tr>
<td>Phonological disorder</td>
</tr>
<tr>
<td>Hypochondriasis</td>
</tr>
</tbody>
</table>

**Proactivity Request – Maternal, Fetal, and Neonatal Terms**

- Term additions requested to align MedDRA with adverse event grading system being developed by EU-funded EVERREST project
- To conduct clinical trial of maternal growth factor therapy to improve fetal growth
- 18 new terms added

<table>
<thead>
<tr>
<th>New PT</th>
<th>Primary HLT</th>
<th>Primary SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foetal compartment fluid collection</td>
<td>Foetal complications NEC</td>
<td>Pregnancy, puerperium and perinatal conditions</td>
</tr>
<tr>
<td>Foetal movement disorder</td>
<td>Dyskinesias and movement disorders NEC</td>
<td>Nervous system disorders</td>
</tr>
<tr>
<td>Foetal renal imaging abnormal</td>
<td>Foetal and neonatal imaging procedures</td>
<td>Investigations</td>
</tr>
</tbody>
</table>
Proactivity Request - Surgical Shunts Versus Spontaneous Shunts

• Inconsistent placement in MedDRA of surgical and spontaneous shunt terms
• Terms for surgical procedures placed in SOC *Surgical and medical procedures*, terms for conditions/disorders placed in appropriate “disorder” SOC
• For other shunt concepts that could represent either a procedure or condition/disorder, unqualified shunt term considered a condition/disorder and counterpart term qualified with the word “procedure” considered a surgical concept
• 2 new terms added, changes made to 11 existing terms

<table>
<thead>
<tr>
<th>LLT Move</th>
<th>From PT</th>
<th>To PT</th>
<th>Primary SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesocaval shunt</td>
<td>Portal shunt</td>
<td>Portal shunt procedure (new PT)</td>
<td>Surgical and medical procedures</td>
</tr>
<tr>
<td>Portacaval shunt</td>
<td>Portal shunt</td>
<td>Portal shunt procedure (new PT)</td>
<td>Surgical and medical procedures</td>
</tr>
<tr>
<td>Femoral-popliteal shunt</td>
<td>Vascular shunt</td>
<td>Peripheral artery bypass (existing PT)</td>
<td>Surgical and medical procedures</td>
</tr>
</tbody>
</table>
Proactivity Request – Non-traumatic LLTs under HLTs Implying Trauma

- Several LLTs specify non-traumatic nature but are placed under PTs which lose non-traumatic concept (while including a primary link to SOC *Injury, poisoning and procedural complications*) or that are under HLTs implying trauma

<table>
<thead>
<tr>
<th>LLT</th>
<th>PT</th>
<th>HLT</th>
<th>SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-traumatic extradural haemorrhage</td>
<td>Epidural haemorrhage</td>
<td>Primary - Cerebral injuries NEC; Secondary - Traumatic central nervous system haemorrhages, Nervous system haemorrhagic disorders</td>
<td>Primary - Injury, poisoning and procedural complications; Secondary – Nervous system disorders, Vascular disorders</td>
</tr>
<tr>
<td>Non-traumatic rupture of patellar tendon</td>
<td>Tendon rupture</td>
<td>Primary - Muscle, tendon and ligament injuries; Secondary - Tendon disorders</td>
<td>Primary - Injury, poisoning and procedural complications; Secondary – Musculoskeletal and connective tissue disorders</td>
</tr>
</tbody>
</table>

Proactivity Request – Non-traumatic LLTs under HLTs Implying Trauma (cont)

- Primary link to SOC *Injury, poisoning and procedural complications* retained for non-traumatic terms; “injury” concept includes non-traumatic factors like aging, fibrosis, inflammation and drug effects
- Four non-traumatic LLTs under PT *Epidural haemorrhage* in HLT *Traumatic central nervous system haemorrhages* were addressed
  - Two of the four terms made non-current (the other two were already non-current)
  - Avoids precedent of creating qualified/non-qualified terms for multiple haemorrhage concepts at different anatomic sites within MedDRA
Update on Points to Consider Documents

• Updated documents based on MedDRA Version 19.0 available on 1 March 2016
  – MedDRA and JMO websites
  – Word (“clean” and “redlined”), PDF, HTML

• Minimal impact of new SOC *Product issues*
  – Term Selection – edits to Section 3.28 Product quality issues to reference new SOC and HLGT
  – Data Retrieval and Presentation – edits to add new SOC in Appendix 6.3 International Order of SOCs
Update on MedDRA IT Tools

MedDRA Desktop Browser 4.0 Now Available

• Updated to match new features added to Web-Based Browser (WBB)
  – New search algorithm
    • Change to a single line entry for searches
  – Search result categories
    • Exact match, Lexical variant, Synonym search, Contains search
  – Research bin import function
MedDRA Desktop Browser (cont)

- New Features*
  - Language specific interface
  - Display term hierarchy when exporting search results and Research Bin
  - Export search results and Research Bin contents in multiple languages
  - Export SMQs in multiple languages

*These features will be added to next version of WBB expected in Spring 2016
MedDRA User Interface Language Selection

MedDRA Desktop Browser – Research bin with hierarchy information

• Primary SOC hierarchy of terms exported from the research bin
**MedDRA Version Analysis Tool Report Update**

- MVAT 2.0 launched May 2015
- The “LLTs under different PTs” report in the Data Impact module was changed to provide expanded information
- Change made based on user feedback
- Expanded report on LLT changes was confusing for some users
- MVAT updated in November 2015 to accommodate two LLT Data Impact reports

**MVAT Data Impact Report**

- Two reports on LLT changes available:
  - Changes focused only on uploaded data
  - Comprehensive changes
MedDRA Training

MSSO Free Training Program

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

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

• Locations
  – US, Europe, Asia, South America, and “virtual”
Summary of 2015 Training

- 56 face-to-face sessions were conducted in Europe, North America, South America, and Asia
- 24 webinars
  - 1322 connections
  - Africa, Asia, Australia, Europe, Middle East, North America, Russia/Eurasia, and Central/South America

Developer Webinar

- Goals
  - MSSO to provide information about a new MedDRA System Organ Class (SOC)
  - Provide information about what is available to developers
  - MSSO to share feedback from users on systems that incorporate MedDRA
  - Obtain your feedback on MedDRA from an IT perspective
- Intended audience
  - Software developers (commercial and internal tools), IT staff, data managers
- Scheduled for 29 March 2016
  - Will be recorded and available on MedDRA.org
Topics

• Implementation of new Product issues SOC
• What’s Available with each Release
• Feedback from MedDRA users related to IT
  – Secondary SOC views
  – Supporting “split coding”
  – International Order of SOCs
  – SMQ support
• Future Plans
  – Cloud distribution of MedDRA

Revision of Free Webinars

• Revision driven by user feedback
• Goals
  – Shorten webinars to target duration of 60 minutes
  – Organize webinars into content “modules”
  – Offer levels of courses within modules (as appropriate)
  – Make webinars more interactive
  – Provide more demonstrations of browsers and tools
• Updated webinars go live in April 2016
New 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)

Upcoming Meetings
European MedDRA User Group Meeting

• When: Tuesday, 05 April 2016
  – 08:30–16:00 CET
• Where:
  Grand Elysée Hotel AG,
  Rothenbaumchaussee 10
  Hamburg, Germany
• Open to all MedDRA users
• Features speakers from MHRA and MSSO
• See User Group page on MedDRA website for registration and agenda

Other User Group Meetings

• US User Group Meeting
  - When: Thursday, 30 June 2016
  - Where: Philadelphia, PA (US DIA Annual Meeting)
  - Open to all MedDRA users
  - More details to be posted to User Group page on MedDRA website
• Chinese User Group Meeting
  - When and Where: To be determined
  - Open to all MedDRA users
  - More details to be posted to User Group page on MedDRA website
US Industry MedDRA User Group Meeting

- When: Thursday, 15 September 2016
- Hosted by Abbvie
  - Mettawa, Illinois (suburban Chicago)
- Open to all MedDRA users
- MSSO will attend
- More details to be posted to User Group page on MedDRA website

Thank You

Questions?

David W. Richardson, M.D.

Email: mssohelp@meddra.org