MedDRA was developed under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The activities of the MedDRA Maintenance and Support Services Organization (MSSO) are overseen by an ICH MedDRA Management Committee, which is composed of the ICH parties, the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, and the WHO (as Observer).
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Topics

• What’s New with Version 23.0
  – Summary of Changes (including SMQs)
• Special Initiatives
• Proactive Maintenance
• MedDRA Translations
• Update on Points to Consider (PtC) Documents
• WEB-RADR 2
• MedDRA Website Live Chat Feature
• Update on MedDRA IT Tools
• MedDRA Training
• Upcoming Meetings
What's New with MedDRA Version 23.0

- Release on 1 March 2020
- A complex release
- Change request summary:
  - MSSO considered 2,083 change requests, including SMQ requests (not including translation updates)
    - Approved: 1,850
    - Not approved: 225
    - Suspended: 8
- Changes reflect the differences between v22.1 and v23.0
Net Change of Terms per SOC

Version Report

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

• No changes at SOC level
• HLGT changes
  – 1 new, 1 merged
• HLT changes
  – 3 new, 3 merged, 4 moved
• Changes summarized in What’s New v23.0 document and link on Change Requests page of meddra.org website

Summary of SMQ Changes

• One new SMQ added
• See MedDRA Version 23.0 SMQ Introductory Guide for detailed information on new SMQ *Opportunistic infections*
• 106 level 1 SMQs in production
• 499 changes made in existing SMQs, see the Version Report
Device Problem Terms

- In v23.0, MSSO added 114 terms and changed 10 terms as part of initiative to include more device problems in MedDRA, examples below

<table>
<thead>
<tr>
<th>LLT</th>
<th>PT</th>
<th>HLT</th>
<th>Primary SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device fluid leak</td>
<td>Device leakage</td>
<td>Device issues NEC</td>
<td>Product issues</td>
</tr>
<tr>
<td>Device overinfusion</td>
<td>Device infusion issue</td>
<td>Device malfunction events NEC</td>
<td>Product issues</td>
</tr>
<tr>
<td>Device difficult to program</td>
<td>Device difficult to use</td>
<td>Medication errors, product use errors and issues NEC</td>
<td>Injury, poisoning and procedural complications</td>
</tr>
<tr>
<td>Incorrect measurement by device</td>
<td>Device information output issue</td>
<td>Device information output issues</td>
<td>Product issues</td>
</tr>
</tbody>
</table>
Rare and Orphan Diseases

• In v23.0, MSSO added 86 terms as part of initiative to aid in coding indications for rare and orphan diseases, see examples below

<table>
<thead>
<tr>
<th>LLT</th>
<th>PT</th>
<th>HLT</th>
<th>Primary SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amyloid light-chain amyloidosis</td>
<td>Primary amyloidosis</td>
<td>Amyloidosis</td>
<td>Immune system disorders</td>
</tr>
<tr>
<td>Idiopathic CD4 lymphocytopenia</td>
<td>Idiopathic CD4 lymphocytopenia</td>
<td>Leukopenias NEC</td>
<td>Blood and lymphatic system disorders</td>
</tr>
<tr>
<td>FOXN1 deficient severe combined immunodeficiency</td>
<td>Combined immunodeficiency</td>
<td>Immune system abnormalities congenital</td>
<td>Congenital, familial and genetic disorders</td>
</tr>
</tbody>
</table>

• Details in Version Report

Update to Placement of Gene Concepts

• In v23.0, changes to SOC *Congenital, familial and genetic disorders* to improve gene concept placement
  – Covers both acquired and congenital gene concepts
• New HLGT *Chromosomal alterations, gene alterations and abnormal gene variants* replaced HLGT *Chromosomal alterations and abnormal gene carriers*
• HLT *Gene mutations and other alterations NEC* and new HLT *Genetic polymorphisms* added to the new HLGT
• 168 PT placement modifications
• Details in Version Report and Introductory Guide MedDRA Version, Section 6.3
### Update to Placement of Gene Concepts (cont)

<table>
<thead>
<tr>
<th>PT Moved</th>
<th>From HLT</th>
<th>In SOC</th>
<th>To HLT</th>
<th>In SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acquired gene mutation</td>
<td>Acquired gene mutations and other alterations</td>
<td>General disorders and administration site conditions</td>
<td>Gene mutations and other alterations NEC</td>
<td>Congenital, familial and genetic disorders</td>
</tr>
<tr>
<td>Acquired mitochondrial DNA deletion</td>
<td>Acquired gene mutations and other alterations</td>
<td>General disorders and administration site conditions</td>
<td>Genetic mitochondrial abnormalities NEC</td>
<td>Congenital, familial and genetic disorders</td>
</tr>
<tr>
<td>NAT1 polymorphism</td>
<td>Acquired gene mutations and other alterations</td>
<td>General disorders and administration site conditions</td>
<td>Genetic polymorphisms</td>
<td>Congenital, familial and genetic disorders</td>
</tr>
<tr>
<td>Vascular endothelial growth factor overexpression</td>
<td>Acquired gene mutations and other alterations</td>
<td>General disorders and administration site conditions</td>
<td>Gene mutations and other alterations NEC</td>
<td>Congenital, familial and genetic disorders</td>
</tr>
</tbody>
</table>

### Proactive Maintenance
Proactivity Request Review

• Proactive maintenance process allows users to address inconsistencies, make corrections or suggest improvements
• 2 proactivity proposals implemented in MedDRA v23.0
  – Review of “disseminated” or “systemic” concepts terms
  – Placement of “abrasion” terms
• Details of implemented changes in What’s New Version 23.0 document

MedDRA Translations
MedDRA Translations

- Brazilian Portuguese MedDRA released in v23.0
- MedDRA is available in 14 languages
  - Brazilian Portuguese, Chinese, Czech, Dutch, English, French, German, Hungarian, Italian, Japanese, Korean, Portuguese, Russian, and Spanish
  - Translation includes all terms and documentation

Update on Points to Consider (PtC) Documents
Annual Update of PtC Documents

• Approved by MedDRA Management Committee and ICH
• Starting with v23.0 in March 2020, PtC documents will be updated annually with the March release of MedDRA
  – MedDRA Term Selection
  – MedDRA Data Retrieval and Presentation
• Stable documents with minor changes each release
• More user-friendly schedule
  – Easier for users to update conventions just once a year
  – Accommodates initial translation and subsequent updates in new languages

Translations of PtC Documents

• Full PtC documents will be translated into selected languages to support uptake of MedDRA in new regions
  – Chinese, Korean, and Spanish
• Based on v23.0 release of PtC documents
• Available by September 2020
• Updated annually in March
PtC Companion Document

- Updated medication errors section will be available in May 2020
- New section on product quality is being drafted – To be discussed at PtC Working Group meeting in May 2020

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>Term Selection</td>
<td>MedDRA Term Selection: Points to Consider</td>
<td>Promote accurate and consistent coding with MedDRA</td>
<td>English, Japanese, and other selected languages</td>
<td>Updated annually with the March release of MedDRA (starting with MedDRA Version 23.0)</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, Japanese, and other languages with an available translation of the full MTS:PTC document)</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, Japanese, and other selected languages</td>
<td>Updated annually with the March release of MedDRA (starting with MedDRA Version 23.0)</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, Japanese, and other languages with an available translation of the full DRP:PTC document)</td>
<td>Update as needed</td>
</tr>
</tbody>
</table>
### PtC Documents (cont)

<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>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 updates based on users' needs. First edition covers data quality and medication errors. New section on product quality is being drafted.</td>
<td>English and Japanese</td>
<td>Updated as needed</td>
</tr>
</tbody>
</table>

### WEB-RADR 2

(***WEB Recognising Adverse Drug Reactions***):

SNOMED CT – MedDRA Mapping
WEB-RADR 2

• WEB-RADR 2 project funded by Innovative Medicines Initiative (IMI)
• ICH is a partner (along with SNOMED International)
  – MSSO participating as ICH’s subcontractor

WEB-RADR 2 (cont)

• Work Package 4 “Terminology Mapping and Maintenance”
  – Develop an initial bi-directional mapping between SNOMED CT and MedDRA
    • SNOMED-encoded EHR data converted to MedDRA for adverse event reporting
    • MedDRA-coded regulatory data feeding into clinical decision support systems
  – Develop ownership, maintenance, licensing, and distribution agreements between ICH and SNOMED International
Map Examples

- **MedDRA to SNOMED CT map**

<table>
<thead>
<tr>
<th>LST Code</th>
<th>LST Name</th>
<th>SNOMED CT ID</th>
<th>Fully Specified Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>10003083</td>
<td>ARDS</td>
<td>67782005</td>
<td>Acute respiratory distress syndrome (disorder)</td>
</tr>
<tr>
<td>10003846</td>
<td>AV block</td>
<td>233917008</td>
<td>Atrioventricular block (disorder)</td>
</tr>
<tr>
<td>10000059</td>
<td>Abdominal discomfort</td>
<td>43364001</td>
<td>Abdominal discomfort (finding)</td>
</tr>
<tr>
<td>10007075</td>
<td>Abdominal hysterectomy</td>
<td>116341005</td>
<td>Abdominal hysterectomy (procedure)</td>
</tr>
<tr>
<td>10000373</td>
<td>Accident automobile</td>
<td>426772002</td>
<td>Automobile accident (event)</td>
</tr>
<tr>
<td>10007881</td>
<td>Antenatal supportive care</td>
<td>386495004</td>
<td>Vomiting management (regime/therapy)</td>
</tr>
<tr>
<td>10003193</td>
<td>Arteriovenous malformation</td>
<td>24551003</td>
<td>Arteriovenous malformation (morphologic abnormality)</td>
</tr>
</tbody>
</table>

- **SNOMED CT to MedDRA map**

<table>
<thead>
<tr>
<th>SNOMED CT ID</th>
<th>Fully Specified Name</th>
<th>LST Code</th>
<th>LST Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>233965008</td>
<td>Abdominal aortic aneurysm (disorder)</td>
<td>10000054</td>
<td>Abdominal aortic aneurysm</td>
</tr>
<tr>
<td>116341005</td>
<td>Abdominal hysterectomy (procedure)</td>
<td>10000075</td>
<td>Abdominal hysterectomy</td>
</tr>
<tr>
<td>433640000</td>
<td>Abnormal cerebellar Papezianic (finding)</td>
<td>10065164</td>
<td>Papezianic smear abnormal</td>
</tr>
<tr>
<td>48549004</td>
<td>Acquired hemolytic anemia (disorder)</td>
<td>10055191</td>
<td>Acquired hemolytic anemia</td>
</tr>
<tr>
<td>32700003</td>
<td>Attrition (finding)</td>
<td>10001125</td>
<td>Attrition</td>
</tr>
<tr>
<td>91934008</td>
<td>Allergy to nut (finding)</td>
<td>10054959</td>
<td>Allergy to nuts</td>
</tr>
<tr>
<td>216434001</td>
<td>Baby normal at birth (finding)</td>
<td>10021757</td>
<td>Normal baby</td>
</tr>
<tr>
<td>42684007</td>
<td>Bacillus Calmette-Guerin vaccination (procedure)</td>
<td>10072099</td>
<td>Tuberculosis immunization</td>
</tr>
</tbody>
</table>

Next Steps

- SNOMED International and ICH/MSSO will maintain the production maps

- **SNOMED CT to MedDRA map**

<table>
<thead>
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<td>Tuberculosis immunization</td>
</tr>
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</table>

- **SNOMED International and ICH/MSSO will maintain the production maps**

- **SNOMED International and ICH/MSSO will maintain the production maps**
More SNOMED-MedDRA Mapping Information

• European MedDRA User Group Webinar December 2019
  – User Group page on MedDRA website: https://www.meddra.org/user-groups
  – Presentation slides and recording
• WEB-RADR 2
  – https://web-radr.eu/web-radr2/

MedDRA Website Live Chat Feature
MedDRA Website Live Chat Feature

- New feature of MedDRA website
- Allows users to ask questions and interact with Help Desk staff
- Not 24/7, but available when the MSSO global support team is online
- Chat tool will inform users if staff are not available
  – Help Desk will follow up with any submitted questions
MedDRA Website Live Chat Feature (cont)

www.meddra.org

Update on MedDRA IT Tools
Mobile WBB

- Mobile MedDRA Browser
  - Search MedDRA terms and codes via a mobile platform
    - Smart Phone
    - Tablet
- Now has multi-lingual interface
  - Deployed in January 2020
- Similar features as the Web-Based Browser
- Simple browsing and searching functions provided

https://mmb.meddra.org

MedDRA APIs

- MedDRA Application Program Interface (API)
  - Response to requests from users
  - Open software model which allows for more flexibility
  - Allows users to develop their own MedDRA tools
  - Provides a proven tool that accurately depicts MedDRA
MedDRA APIs

- Webinars held on 11 and 12 February 2020 to provide overview
  - Webinars were recorded for future viewing; posted on MedDRA website
  - Evaluation period February to August 2020
  - Deployment in 4th quarter 2020
  - If interested in evaluation, please contact mssohelp@meddra.org

Application Program Interfaces - Examples

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

- **Input**: SMQ Analysis
  **API**
  **Outputs**: List of SMQ matches per the inputted term list

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

- **Input**: MedDRA hierarchy
  **API**
  **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

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAR 10/2020</td>
<td>Face to Face Training - Coding with MedDRA</td>
<td>Paris, France</td>
</tr>
<tr>
<td>MAR 25/2020</td>
<td>Face to Face Training - MedDRA: Safety Data Analyze and SMRs</td>
<td>Hyderabad, India</td>
</tr>
<tr>
<td>APR 08/2020</td>
<td>Face to Face Training - MedDRA: Safety Data Analyze and SMRs</td>
<td>Istanbul, Turkey</td>
</tr>
</tbody>
</table>

### Webinar Training Tab

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEB 27/2020</td>
<td>What's New with MedDRA Version 3.2 and the MSDB</td>
<td>Webinar</td>
</tr>
<tr>
<td>MAR 10/2020</td>
<td>What's New with MedDRA Version 3.0 and the MSDB</td>
<td>Webinar</td>
</tr>
<tr>
<td>MAR 15/2020</td>
<td>Data Analysis and Query Building with MedDRA</td>
<td>Webinar</td>
</tr>
<tr>
<td>MAR 16/2020</td>
<td>MedDRA Overview</td>
<td>Webinar</td>
</tr>
</tbody>
</table>
# Summary of 2019 Training

<table>
<thead>
<tr>
<th></th>
<th>Attendees</th>
<th>Sessions</th>
<th>Locations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face-to-Face Training</td>
<td>3,664</td>
<td>126</td>
<td>North and South America, Asia/Eurasia, Australia, Europe, Middle East, North Africa, Russia, Scandinavia</td>
</tr>
<tr>
<td>Webinars</td>
<td>3,221 connections</td>
<td>31</td>
<td>Worldwide</td>
</tr>
</tbody>
</table>

## Upcoming Meetings
European MedDRA / WHO Drug Meeting

- Dates: Wednesday & Thursday, 1 & 2 April 2020
- Time: 9:00 – 16:30 (April 1), 9:00 – 17:00 (April 2)
- Where:
  DoubleTree by Hilton Amsterdam Centraal Station
- MedDRA User Group Meeting on 1 April
- WHO Drug User Group Meeting on 2 April
- Open to all MedDRA users
- Registration form posted to User Group page on MedDRA website

Other MedDRA User Group Meetings – Additional Details to Follow

- Chinese MedDRA User Group Meeting, Shanghai, China, date to be determined
- 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