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 23.1
  - Summary of Changes (including SMQs)
- Proactive Maintenance
- Update on Points to Consider (PtC) Documents
- MSSO Staff Addition
- Update on WEB-RADR 2
- Update on MedDRA IT Tools
- MedDRA Training
- Audience Polling
- Upcoming Meetings
What's New with MedDRA Version 23.1

- Release on 1 September 2020
- A simple release
- Change request summary:
  - MSSO considered 1,541 change requests, including SMQ requests (not including translation updates)
    - Approved: 1,182
    - Not approved: 351
    - Suspended: 8
- Changes reflect the differences between v23.0 Update and v23.1
### Net Change of Terms per SOC

- **Blood and lymphatic system disorders**: 20 terms
- **Cardiac disorders**: 28 terms
- **Congenital, familial and genetic disorders**: 151 terms
- **Ear and labyrinth disorders**: 17 terms
- **Endocrine disorders**: 13 terms
- **Eye disorders**: 22 terms
- **Gastrointestinal disorders**: 70 terms
- **General disorders and administration site conditions**: 70 terms
- **Hepatobiliary disorders**: 18 terms
- **Immune system disorders**: 28 terms
- **Infections and infestations**: 94 terms
- **Injury, poisoning and procedural complications**: 137 terms
- **Investigations**: 123 terms
- **Metabolism and nutrition disorders**: 25 terms
- **Musculoskeletal and connective tissue disorders**: 77 terms
- **Neoplasms benign, malignant and unspecified (incl cysts and polyps)**: 31 terms
- **Nervous system disorders**: 64 terms
- **Pregnancy, puerperium and perinatal conditions**: 62 terms
- **Product issues**: 62 terms
- **Psychiatric disorders**: 37 terms
- **Reproductive system and breast disorders**: 15 terms
- **Respiratory, thoracic and mediastinal disorders**: 24 terms
- **Reproductive system and breast disorders**: 84 terms
- **Skin and subcutaneous tissue disorders**: 57 terms
- **Social circumstances**: 40 terms
- **Surgical and medical procedures**: 141 terms
- **Vascular disorders**: 97 terms

### Version Report

<table>
<thead>
<tr>
<th>Report Title</th>
<th>Total Unique Terms between selected versions</th>
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<td>1 New LLTs including New PTs</td>
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<td>274</td>
</tr>
<tr>
<td>3 Promotions</td>
<td>15</td>
</tr>
<tr>
<td>4 Demotions</td>
<td>31</td>
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<td>5 LLTs under different PTs</td>
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<td>7 PT Primary SOC Changes</td>
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<td>8 MedDRA Term Name Changes</td>
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</tr>
<tr>
<td>9 MedDRA Code Switches</td>
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<tr>
<td>10 Currency Changes</td>
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<tr>
<td>11 Complex Changes</td>
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<tr>
<td>12 BMI Changes</td>
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<td>13 PT Changes in SMQs</td>
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<td>14 LLT Changes in SMQs</td>
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Summary of SMQ Changes

• Two new SMQs added
  - COVID-19
  - Immune-mediated/autoimmune disorders
• See MedDRA Version 23.1 SMQ Introductory Guide for detailed information
• 108 level 1 SMQs in production
• 296 changes made in existing SMQs, see the Version Report

COVID-19 Terms

• Over 60 more COVID-related terms added to MedDRA Version 23.1
• Link to COVID-19 resources is on Home page of MedDRA website
  - Includes spreadsheet of COVID-19 related terms
### Examples of COVID-19 Terms Added in Version 23.1

<table>
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<tr>
<th>LLT</th>
<th>PT</th>
<th>HLT</th>
<th>Primary SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 aggravated</td>
<td>COVID-19</td>
<td>Coronavirus infections</td>
<td>Infections and infestations</td>
</tr>
<tr>
<td>Multisystem inflammatory syndrome in children</td>
<td>Multisystem inflammatory syndrome in children</td>
<td>Immune and associated conditions NEC</td>
<td>Immune system disorders</td>
</tr>
<tr>
<td>SARS-CoV-2 sepsis</td>
<td>SARS-CoV-2 sepsis</td>
<td>Coronavirus infections</td>
<td>Infections and infestations</td>
</tr>
<tr>
<td>SARS-CoV-2 molecular test positive</td>
<td>SARS-CoV-2 test positive</td>
<td>Virus identification and serology</td>
<td>Investigations</td>
</tr>
<tr>
<td>SARS-CoV-2 IgG antibody test</td>
<td>SARS-CoV-2 antibody test</td>
<td>Virus identification and serology</td>
<td>Investigations</td>
</tr>
<tr>
<td>Drug shortage due to pandemic</td>
<td>Product availability issue</td>
<td>Product supply and availability issues</td>
<td>Product issues</td>
</tr>
</tbody>
</table>

### Proactive Maintenance
Proactivity Request Review

- Proactive maintenance process allows users to address inconsistencies, make corrections or suggest improvements
- No proactivity proposals implemented in MedDRA v23.1
- Proactivity proposals should be sent to mssohelp@meddra.org
- Providing a detailed justification is helpful in evaluation of your request

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

• Full PtC documents are being translated into selected languages to support uptake of MedDRA in new regions
  – Chinese, Korean, Spanish
• Based on v23.0 release of PtC documents
• Available by October 2020
• Updated annually in March

PtC Companion Document

• Release 1.1 made available in July 2020
  – Revisions and new examples in medication errors section
PtC Companion Document (cont)

• New section on product quality in final draft stage
  – Expected to be available in last quarter of 2020

MSSO Staff Addition
Meet Dr. Julia Gao

- Hired as Medical Officer
- Joined MSSO in July 2020
- Has a medical degree with internal medicine background
- Has extensive experience in MedDRA coding
- Provides local support and training for subscribers
- Lives in Beijing, China

Update on WEB-RADR 2
WEB-RADR 2

• Stands for **WEB** Recognizing **Adverse Drug Reactions**

• 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
**Mapping Steps**

- **Nov 2019**
  - Bi-directional Term Mapping Complete

- **March 2020**
  - Alpha Test Period Begins
  - Scope includes format and content
  - Test Protocol Developed
  - Regulatory, Industry, Vendor, Clinical Users, and Member country Testers Identified

- **Sept 2020**
  - Alpha Test Period Ends

- **April 2021**
  - Production Version of the Maps made available to licensed SNOMED/MedDRA Users

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

**Next Steps**

- **Analyze Alpha Test/Review Feedback – October 2020**
- **Extend the scope of the maps to include relevant COVID-19 terms**
- **Production release of the maps - April 2021**
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/
  – Stakeholder-focused webinars on Events Page

Update on MedDRA IT Tools
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

Application Program Interfaces - Examples

**Input**

**Data:** List of MedDRA Terms

**Request:** SMQ Analysis

**Output:**

List of SMQ matches per the inputted term list

**Input**

**Data:** List of MedDRA Terms

**Request:** MedDRA hierarchy

**Output:**

MedDRA primary & Secondary SOC hierarchy information

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

- February and May 2020 webinars on APIs posted on MedDRA website
- User evaluation period through August 2020
- APIs expected to be deployed in October of 2020

API Information

- Where can I go to get documentation and updates?
  
  https://www.meddra.org

Direct link:

https://www.meddra.org/meddra-apis
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”
**Webinar Titles**

- What is MedDRA and How is it Used? (formerly “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

**Changes to the MedDRA Training Offerings**

- F2F courses currently suspended in most locations
- Number of webinar offerings significantly expanded
- Webinars offered in English, Spanish, Chinese and Korean
- Webinar duration extended to up to 120 minutes*
- Webinars being made more interactive

*Can vary based on the webinar topic and level of interaction needed
Changes to Make Webinars More “Interactive”

- Expanded timeframe allows slower pace and greater depth, more time for questions
- More demonstration time for MedDRA tools (browsers, MVAT, SMQ/Hierarchy Analysis tools)
- “Overlapping” webinar slides will be eliminated at instructor discretion
- More coding examples can be added to courses
- Polling tool (Poll Everywhere) being used to permit attendee feedback in real time

Webinar Training Tab

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</table>
Audience Polling

Polling Topics

- MedDRA website Live Chat
- MedDRA Social Media platforms
- MSSO Open Sessions
MedDRA Website Live Chat
MedDRA Website Live Chat Feature

• 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

Were You Aware of Website Live Chat?

Yes

No
Have You Used Website Live Chat?

Yes

No

MedDRA Social Media Platforms
Were You Aware MedDRA is on Several Social Media Platforms?

Yes

No

Please Select All of the MedDRA Social Media Platforms That You Have Visited

Facebook A
WhatsApp B
WeChat C
Twitter D
Linkedin E
YouTube F
What is Your Favorite Social Media Platform?

Facebook
WhatsApp
WeChat
Twitter
LinkedIn
YouTube

MSSO Open Sessions
MSSO Open Sessions

- New informational forum offered by MSSO staff
- MedDRA users submit questions, in advance, to mssotraining@meddra.org for discussion
- Topics can include use of MedDRA documentation and MSSO tools for coding and data analysis
- Instructions for submitting questions are found on Open Session page on MedDRA website "Training" tab
Were You Aware of the MSSO Open Sessions?

Yes

No

Have You Attended One of the Open Sessions?

Yes

No
### If Yes, How Valuable Was the Session?

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<td>Not Very Valuable for Me</td>
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### Upcoming Meetings

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Blue Ribbon Panel (BRP) - MedDRA and Information Technology (IT)

- Format: Virtual meeting
- Date: Thursday, 10 September 2020
- Time: 10:00 – 11:30 U.S. EST, 16:00 – 17:30 CET
- BRPs are forums for MedDRA experts to discuss challenging topics
- Results of MedDRA IT survey will be used as input and recommendations will be presented to MedDRA Management Committee
- Open to all MedDRA users in an interactive format
- Registration form on the Blue Ribbon Panel page of MedDRA website, deadline is 8 September 2020

Other MedDRA User Group Meetings

- Chinese MedDRA User Group Meeting, date and place to be determined
- European MedDRA User Group webinar, 5 November 2020, 9:00-10:30 U.S. EST/15:00-16:30 CET
- More details to be posted to User Group page on MedDRA website when available
Thank You

Questions?

Email: mssohelp@meddra.org