• As of August 2017
  – ~5,000 Subscribing organizations (MSSO+JMO)
  – 109 Countries
• Graph shows type of organizations (self identified)
MedDRA Users by Region and Top 20 Countries

- Europe: 49%
- North America: 35%
- Asia: 11%
- Oceania: 2%
- Africa: 1%
- Central and South America, Caribbean: 2%

### Top 20 Countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>1386</td>
</tr>
<tr>
<td>Germany</td>
<td>324</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>310</td>
</tr>
<tr>
<td>France</td>
<td>242</td>
</tr>
<tr>
<td>Italy</td>
<td>218</td>
</tr>
<tr>
<td>Spain</td>
<td>139</td>
</tr>
<tr>
<td>China</td>
<td>129</td>
</tr>
<tr>
<td>Canada</td>
<td>115</td>
</tr>
<tr>
<td>Poland</td>
<td>78</td>
</tr>
<tr>
<td>Australia</td>
<td>77</td>
</tr>
<tr>
<td>South Korea</td>
<td>76</td>
</tr>
<tr>
<td>Netherlands</td>
<td>75</td>
</tr>
<tr>
<td>India</td>
<td>74</td>
</tr>
<tr>
<td>Switzerland</td>
<td>72</td>
</tr>
<tr>
<td>Sweden</td>
<td>70</td>
</tr>
<tr>
<td>Belgium</td>
<td>68</td>
</tr>
<tr>
<td>Greece</td>
<td>51</td>
</tr>
<tr>
<td>Denmark</td>
<td>47</td>
</tr>
<tr>
<td>Austria</td>
<td>46</td>
</tr>
<tr>
<td>Israel</td>
<td>46</td>
</tr>
</tbody>
</table>
• All subscription rates reduced at least 9-10%
• 2016 Commercial 2 subscription rate now divided into two levels:
  – New 2017 Commercial 2 rate
    • Revenue of $10-$20 Million USD reduced 50% to $2,765
  – New 2017 Commercial 3 rate
    • Revenue of $20-$500 Million USD reduced to $4,976
• As of January 2017, no longer a fee for Chinese MedDRA translation
# 2017 MedDRA Subscription Rate Table

<table>
<thead>
<tr>
<th>MedDRA Subscription Types</th>
<th>2017 Annual Subscription Rates</th>
<th>Additional Rates for Japanese Translation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Authority</td>
<td>$0 USD</td>
<td>$0 USD</td>
</tr>
<tr>
<td>Non-Commercial / Non-Profit</td>
<td>$0 USD</td>
<td>$850 USD</td>
</tr>
<tr>
<td>Commercial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Parent Company Annual Revenue or Turnover)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 0 (Annual Revenue &lt; $1 Million)</td>
<td>$171 USD</td>
<td>$850 USD</td>
</tr>
<tr>
<td>Level 1 (Annual Revenue $1-$10 Million)</td>
<td>$724 USD</td>
<td>$850 USD</td>
</tr>
<tr>
<td>Level 2 (Annual Revenue $10-$20 Million)</td>
<td>$2,765 USD</td>
<td>$850 USD</td>
</tr>
<tr>
<td>Level 3 (Annual Revenue $20-$500 Million)</td>
<td>$4,976 USD</td>
<td>$850 USD</td>
</tr>
<tr>
<td>Level 4 (Annual Revenue $500 Million-$1 Billion)</td>
<td>$10,440 USD</td>
<td>$850 USD</td>
</tr>
<tr>
<td>Level 5 (Annual Revenue $1-$5 Billion)</td>
<td>$43,316 USD</td>
<td>$850 USD</td>
</tr>
<tr>
<td>Level 6 (Annual Revenue $5-$20 Billion)</td>
<td>$57,194 USD</td>
<td>$850 USD</td>
</tr>
<tr>
<td>Level 7 (Annual Revenue &gt; $20 Billion)</td>
<td>$74,620 USD</td>
<td>$850 USD</td>
</tr>
<tr>
<td>System Developer</td>
<td>$2,691 USD</td>
<td>$850 USD</td>
</tr>
</tbody>
</table>

Note: 76% of all MedDRA users pay no fee or $724 (or less)
ISO Certification

• MSSO certified as ISO 9001:2015 compliant
  – ISO 9001:2015 standard is an internationally recognized quality management system standard developed by the International Standards Organization (ISO)
• MSSO has held ISO certifications continuously since 2003
• Involves:
  – Inspection of SoPs
  – Inspection of records to support the use of SoPs
  – Interviews with MSSO staff to ensure understanding of processes
Combined User Group Meetings with UMC

- Since we have many common users, it helps attendees when meetings are back-to-back
- **1st User Group Meetings in India**
  - Mumbai and Bangalore (February 2017)
- **China**
  - Beijing (September 2017)
- **US Industry Meeting**
  - Gaithersburg (September 2017)
MSSO developed an unqualified test name term list
- PT *Blood glucose*
- These terms should never be reported as AEs
- Intended for use in E2B test name field only

Standardised, complete list of test name terms is a useful tool for checking data quality
- Intended as recommendation only
- Maintained by MSSO with each MedDRA release
- Available now
List Available for Download

- Support Documentation page on MedDRA.org
- Spreadsheet of LLT/PT names and codes from *Investigations* SOC
  - >3,700 terms
- Explanatory document
  - Purpose, uses, development of list
- Also available in Japanese on JMO website
PtC Updates

• MedDRA Term Selection
  – Revised examples in Exposures during Pregnancy and Breast Feeding (Section 3.10)

• Condensed PtC
  – To be translated into all MedDRA languages except English and Japanese (2018 timeframe)
  – Version independent; focus on general principles
  – To support adoption and consistent use of MedDRA worldwide

• Companion PtC
  – More detailed guidance, examples, and “Questions and Answers”
    • Data quality, medication errors, product quality issues
  – “Living” document with updates based on users’ needs
  – Available in English and Japanese only
  – Initial version planned for release in 2018
MSSO developing set of MedDRA terms that are “patient friendly” to support patient reporting through mobile apps and web portals
- Part of WEB-RADR project

“Patient friendly” concept difficult to define upfront so chose a data-driven approach
- Terms patients have used in reports in datasets
- Similar terms that patients would be likely to use
- Review of draft list by patient stakeholders
Patient Friendly Terms (cont)

• Plan to distribute on MedDRA website
  – LLT names and codes in spreadsheet
  – Explanatory document

• For use in apps and web portals
  – Regulatory authorities
  – Industry

• Will be maintained with each MedDRA version
  – Currency check of included LLTs
• Regulatory and industry users interested in getting access to more sources of data
• Mappings from SNOMED CT, ICD 10/11 to MedDRA
  – Other terminologies to be determined
• MSSO will participate in a new IMI initiative to develop the mechanism and framework to develop MedDRA mappings
Concept Descriptions

- Descriptions of how a concept is interpreted, used, and classified in MedDRA
  - Not a definition
- Intended to aid accurate and consistent use of MedDRA in coding and retrieval
- Overcome differences in medical practice worldwide
  - Descriptions aim to be broadly consistent with definitions across different regulatory regions
- See Appendix B of MedDRA Introductory Guide
- Accessible in MSSO’s Browsers
MedDRA CONCEPT DESCRIPTIONS

This appendix provides a list of MedDRA concept descriptions. A concept description is a description of how a concept is interpreted, used, and classified within the MedDRA terminology and is not a definition. The concept descriptions are intended to aid the consistent and accurate use of MedDRA in coding, retrieval, and analysis and to overcome the differences of medicine practice worldwide. The MSSO expects this appendix to be a working document and grow as subscribers request additional concepts to be documented.

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

A

Abuse

For the purposes of term selection and analysis of MedDRA-coded data, abuse is the intentional, non-therapeutic use by a patient or consumer of a product – over-the-counter or prescription – for a perceived reward or desired non-therapeutic effect including, but not limited to, “getting high” (euphoria). Abuse may occur with a single use, sporadic use or persistent use of the product.
• MedDRA user documentation is available on the MedDRA website
  – MedDRA Introductory Guide
  – SMQ Introductory Guide
  – What’s New Document
  – Distribution File Format Document
• No Password Needed to Access these files
MedDRA User Documents

MedDRA Version 20.0 English March 2017

MedDRA Points to Consider (Available in English and Japanese)

- MedDRA Term Selection: Points to Consider Release 4.13 Based on MedDRA Version 20.0
- Redline of Changes to MedDRA Term Selection: Points to Consider Release 4.13 Based on MedDRA Version 20.0
- MedDRA Data Retrieval and Presentation: Points to Consider Release 3.13 Based on MedDRA Version 20.0
- Redline of Changes to MedDRA Data Retrieval and Presentation: Points to Consider Release 3.13 Based on MedDRA Version 20.0

Additional MedDRA Guides

- Introductory Guide MedDRA Version 20.0
- Introductory Guide for Standardised MedDRA Queries (SMQs) Version 20.0
- What’s New MedDRA Version 20.0
- MedDRA Distribution File Format Document Version 20.0
- Implemented Complex Changes for Version 20.0
MSSO Free Training Program

- **Formats**
  - Face-to-face sessions, webinars, videocasts

- **Languages**
  - English, French, German, Spanish, Mandarin Chinese

- **Locations**
  - Worldwide and “virtual”
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)
New MedDRA Videocast

- Entitled “The Top 12 Things to Know about the MedDRA Website”
- 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

**Training Materials**

MedDRA training materials are available as presentations and videocasts for streaming to your computer (.wmv) or for downloading (.zip).

<table>
<thead>
<tr>
<th>Topic</th>
<th>Presentation</th>
<th>Training Type</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General / Basics</strong></td>
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<tr>
<td><strong>Coding</strong></td>
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<tr>
<td><strong>Retrieval / Analysis (SMQs)</strong></td>
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<tr>
<td><strong>MedDRA Versioning</strong></td>
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<tr>
<td><strong>Tools</strong></td>
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<td></td>
</tr>
<tr>
<td>The Top 12 Things to Know about the MedDRA Website</td>
<td>Videocast Streaming - English Download - English</td>
<td></td>
</tr>
</tbody>
</table>
MSSO posts weekly interim changes to MedDRA

Purpose:
- Provide information on changes that will appear in the next MedDRA Version

Posting includes:
- Weekly changes
- Comprehensive changes to date
- A PDF file describing all changes considered
- Sequential extended ASCII files that can be applied to non production environments
### MedDRA Version 20.0 Supplemental Changes

<table>
<thead>
<tr>
<th></th>
<th>PDF format</th>
<th>SEQ ASCII format</th>
<th>Date</th>
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</table>
Supplemental files (cont)

• How many use supplemental files or information?

• MSSO plans to include supplemental files as an option in a future WBB and MVAT update

• Example:
Self Service Application

- New Application
- Provides User ID, Passwords, POC, Subscription status, Training certificates
- In future, this is how users will access new passwords
Thank You

Questions?