



# MedDRA Update

Gaithersburg, MD  
29 September 2017

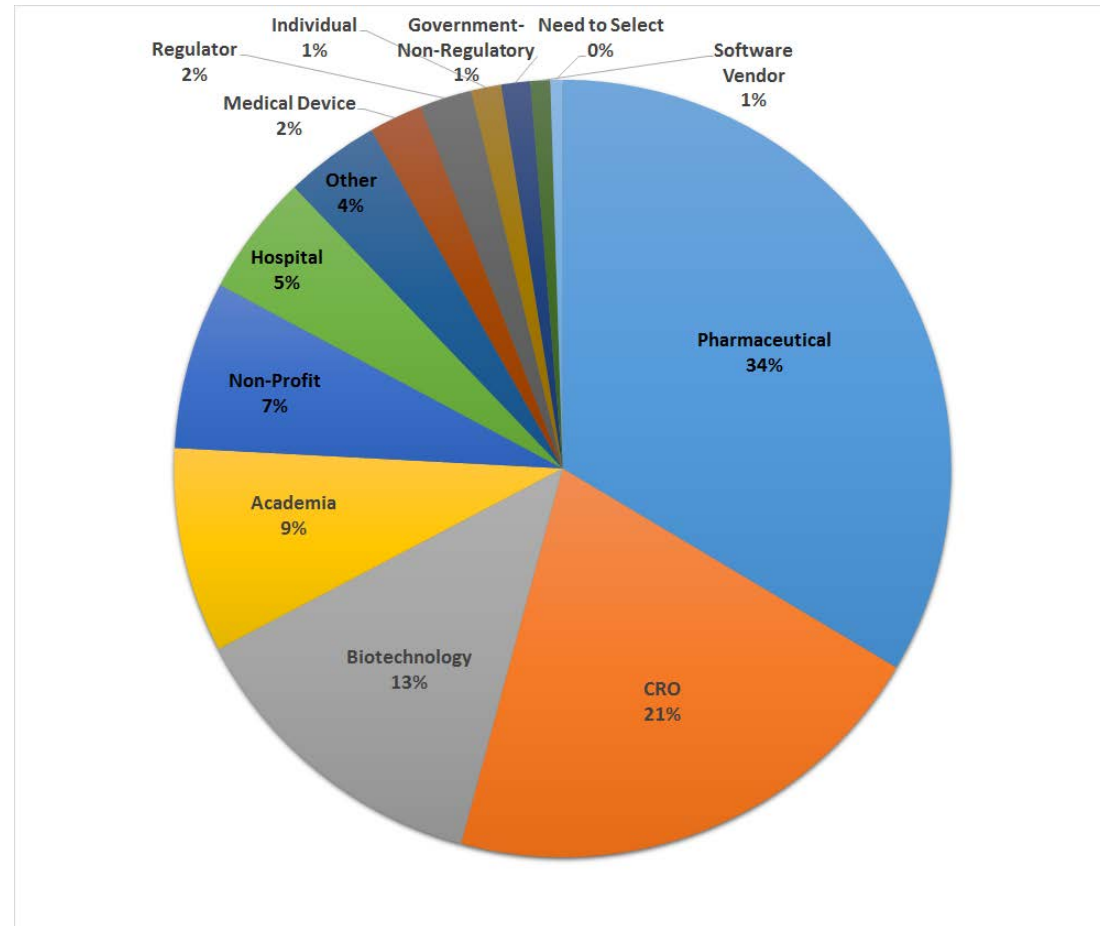




MedDRA

# MedDRA Users Profile

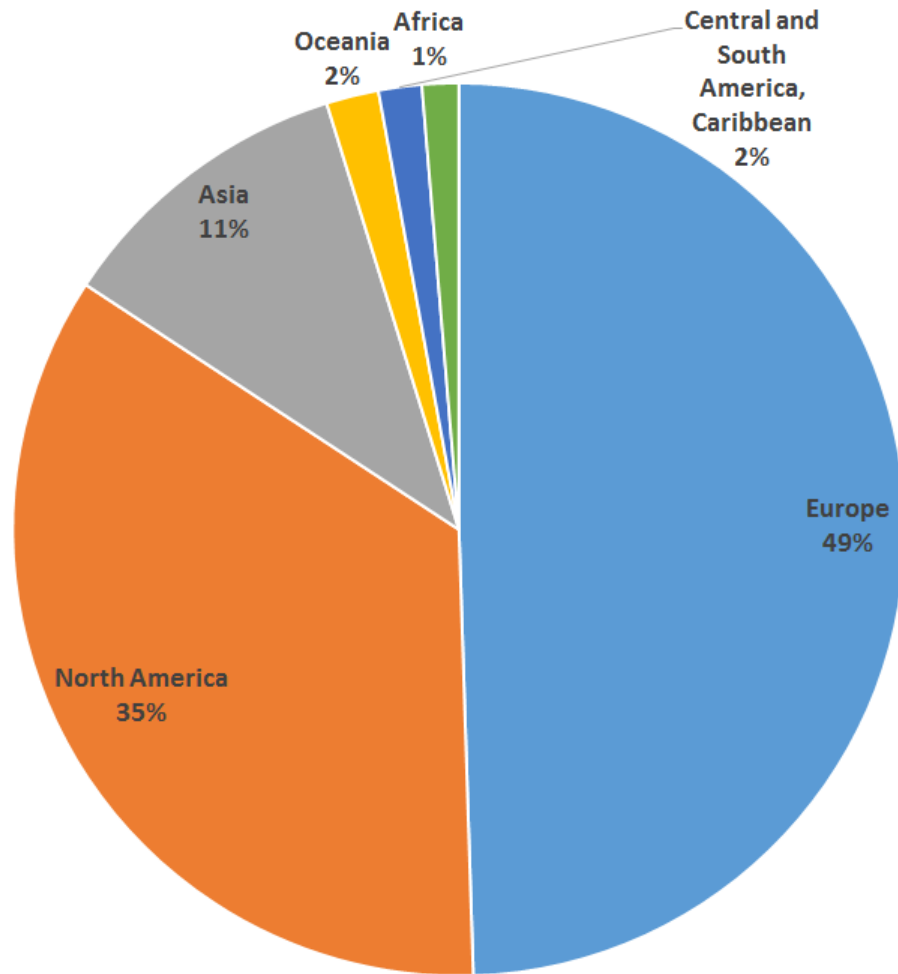
- As of August 2017
  - ~5,000 Subscribing organizations (MSSO+JMO)
  - 109 Countries
- Graph shows type of organizations (self identified)





MedDRA

# MedDRA Users by Region and Top 20 Countries



Country	Count
United States	1386
Germany	324
United Kingdom	310
France	242
Italy	218
Spain	139
China	129
Canada	115
Poland	78
Australia	77
South Korea	76
Netherlands	75
India	74
Switzerland	72
Sweden	70
Belgium	68
Greece	51
Denmark	47
Austria	46
Israel	46



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# 2017 MedDRA Subscription Rates

- 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



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# 2017 MedDRA Subscription Rate Table

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

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

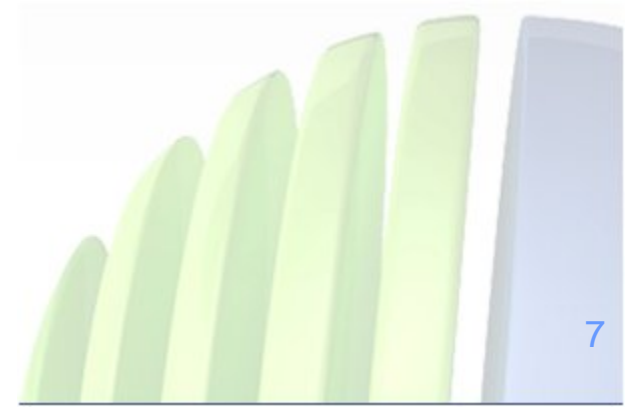


- MSSO certified as ISO 9001:2015 compliant
  - ISO 9001:2015 standard is an internationally recognized quality management system standard developed by the International Standards Organization (ISO)
- MSSO has held ISO certifications continuously since 2003
- Involves:
  - Inspection of SoPs
  - Inspection 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
- 1<sup>st</sup> User Group Meetings in India
  - Mumbai and Bangalore (February 2017)
- China
  - Beijing (September 2017)
- US Industry Meeting
  - Gaithersburg (September 2017)





# Unqualified Test Name Term List

- 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





MedDRA

# 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

The screenshot shows the MedDRA website interface. At the top left is the MedDRA logo and the text 'Medical Dictionary for Regulatory Activities'. Below this is a navigation bar with buttons for 'Home', 'About MedDRA', 'How to Use', 'Training', 'Subscription', 'News & Events', a RSS icon, and a plus sign. The main content area is titled 'Unqualified Test Name Term List' with a breadcrumb trail: 'Support Documentation / How to Use / Home'. Under the title, there is a 'Description' section with text explaining that unqualified test name terms are used in data transmission standards. Below the description are two sections: 'Supporting Documentation' with a link to 'Unqualified Test Name Term List (pdf)' and 'Term List' with a link to 'Unqualified Test Name Term List (MedDRA Version 19.1) (xlsx)'.



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# 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



MedDRA

# Patient Friendly Terms

- 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



# Mapping Initiatives

- 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

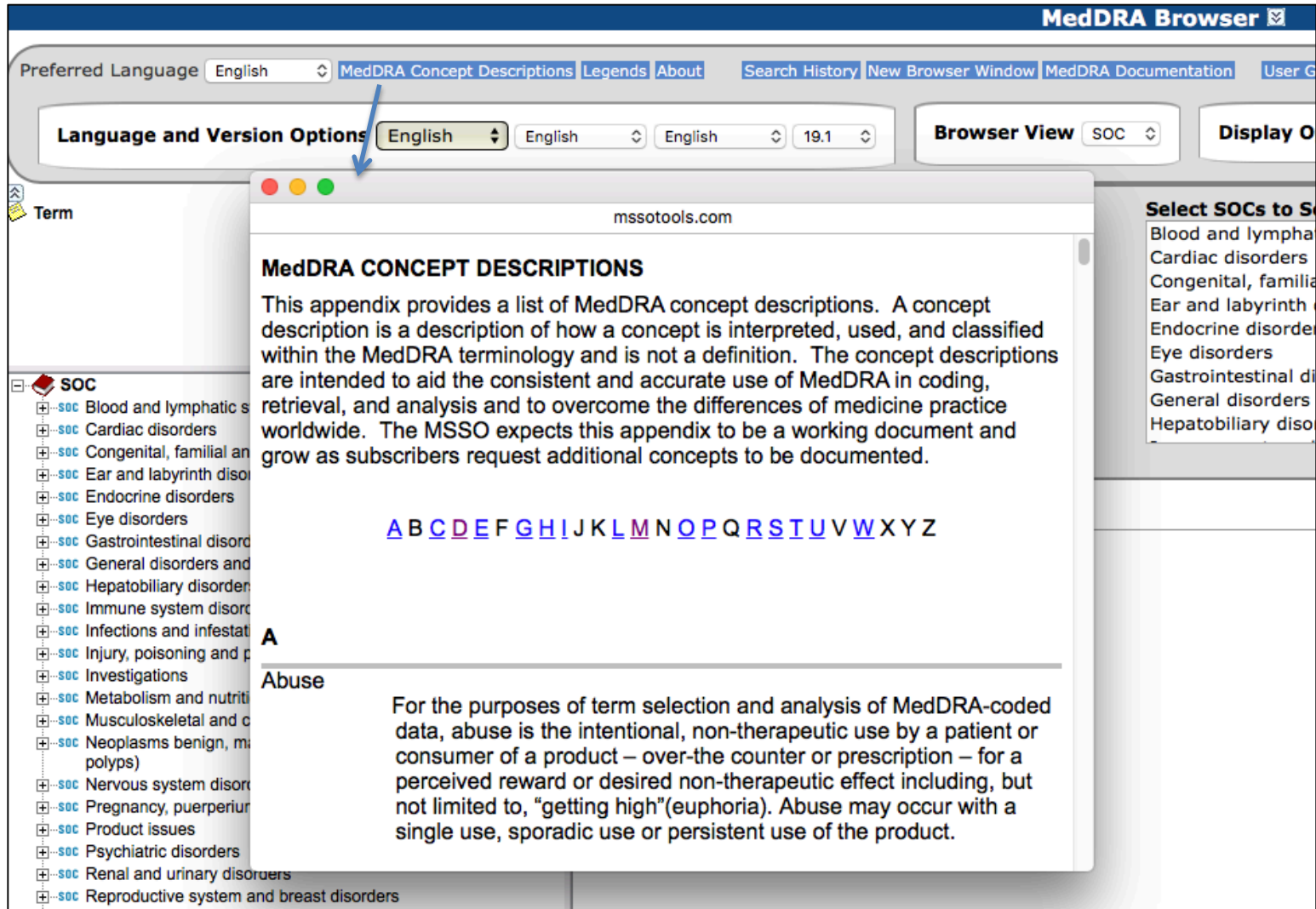


MedDRA

# 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

# Concept Descriptions (cont)



The screenshot shows the MedDRA Browser interface. At the top, there is a navigation bar with the title "MedDRA Browser" and several menu items: "Preferred Language" (set to English), "MedDRA Concept Descriptions" (highlighted), "Legends", "About", "Search History", "New Browser Window", "MedDRA Documentation", and "User G". Below the navigation bar is a "Language and Version Options" section with dropdown menus for "English", "English", "English", and "19.1". To the right, there is a "Browser View" dropdown set to "SOC" and a "Display O" button.

The main content area is titled "MedDRA CONCEPT DESCRIPTIONS" and contains the following text:

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.

Below the text is a navigation bar with letters A through Z. The letter "A" is selected, and the following concept description is displayed:

**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.

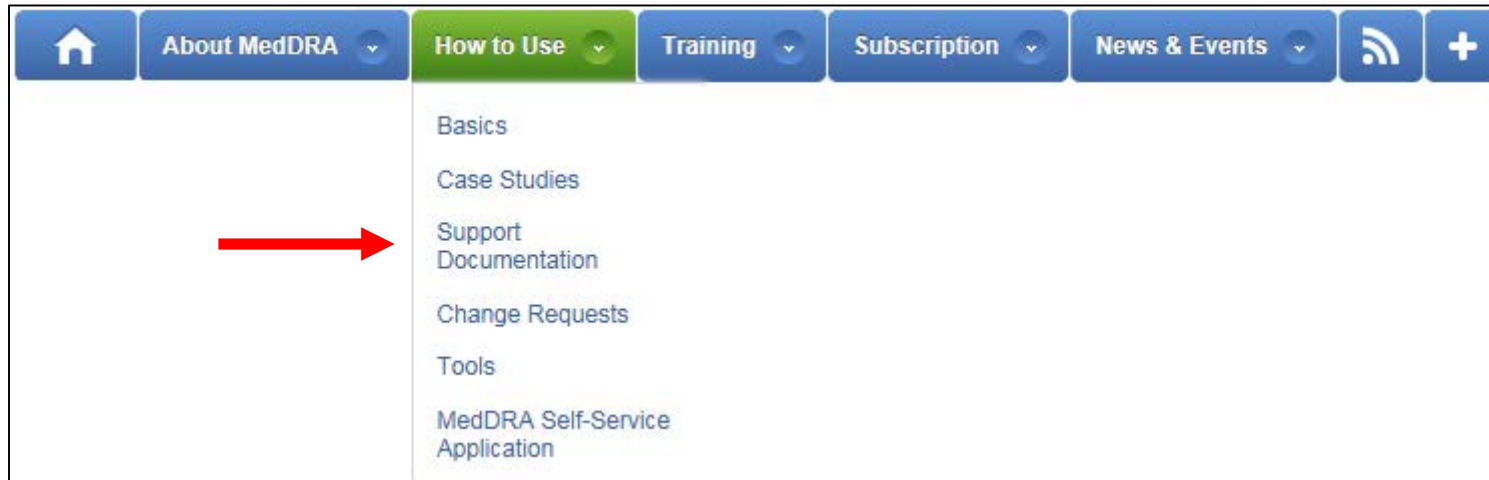
On the left side of the browser, there is a "Term" section with a "SOC" dropdown menu. Below it is a list of SOC categories, each with a plus sign icon:

- soc Blood and lymphatic s
- soc Cardiac disorders
- soc Congenital, familial an
- soc Ear and labyrinth diso
- soc Endocrine disorders
- soc Eye disorders
- soc Gastrointestinal disor
- soc General disorders and
- soc Hepatobiliary disorder
- soc Immune system disorc
- soc Infections and infestat
- soc Injury, poisoning and p
- soc Investigations
- soc Metabolism and nutriti
- soc Musculoskeletal and c
- soc Neoplasms benign, ma
- soc polyps)
- soc Nervous system disorc
- soc Pregnancy, puerperiu
- soc Product issues
- soc Psychiatric disorders
- soc Renal and urinary disorders
- soc Reproductive system and breast disorders

On the right side, there is a "Select SOCs to S" section with a list of SOC categories:

- Blood and lymphatic
- Cardiac disorders
- Congenital, familia
- Ear and labyrinth
- Endocrine disorder
- Eye disorders
- Gastrointestinal di
- General disorders
- Hepatobiliary diso

# MedDRA User Documentation



- 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”



# Training Tab Screenshot

The screenshot shows a web browser window with the URL <https://www.meddra.org/training/schedule>. The page title is "MedDRA Training". Below the title are two buttons: "Click Here for Face to Face Training" and "Click Here for Webinars". The main content is a grid of training events. Each event card displays the month and year (SEP), the event title, the date, the number of spots left, and the location.

Month/Year	Event Title	Date	Spots Left	Location
SEP 04/2017	Face-to-Face Training - Coding with MedDRA	04/2017	0 left	Beijing, China
SEP 05/2017	Face-to-Face Training - MedDRA: Safety Data Analysis and SMQs	05/2017	0 left	Beijing, China
SEP 13/2017	Face-to-Face Training - Coding with MedDRA	13/2017	0 left	Boston, Massachusetts, USA
SEP 14/2017	Face-to-Face Training - MedDRA: Safety Data Analysis and SMQs	14/2017	0 left	Boston, Massachusetts, USA
SEP 20/2017	Face-to-Face Training - Coding with MedDRA	20/2017	0 left	Bonn, Germany
SEP 21/2017	Face-to-Face Training - Coding with MedDRA	21/2017	0 left	Copenhagen, Denmark
SEP 21/2017	Face-to-Face Training - MedDRA: Safety Data Analysis and SMQs	21/2017	0 left	Bonn, Germany
SEP 22/2017	Face-to-Face Training - MedDRA: Safety Data Analysis and SMQs	22/2017	8 left	Copenhagen, Denmark



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# 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)



MedDRA

# 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

# MedDRA Website Training Materials Page

Medical Dictionary for Regulatory Activities

Home About MedDRA How to Use **Training** Subscription News & Events RSS +

## Training Materials / Training / Home

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

General / Basics		
> Topic	Presentation	Training Type
Coding		
> Topic	Presentation	Training Type
Retrieval / Analysis (SMQs)		
> Topic	Presentation	Training Type
MedDRA Versioning		
> Topic	Presentation	Training Type
Tools		
> Topic	Presentation	Training Type



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# MedDRA Website Training Materials Page (cont)

↳ *The Top 12 Things to Know about the MedDRA Website*

*Videocast  
Streaming - English  
Download - English*





MedDRA

# Supplemental files

- 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












# Supplemental files (cont)

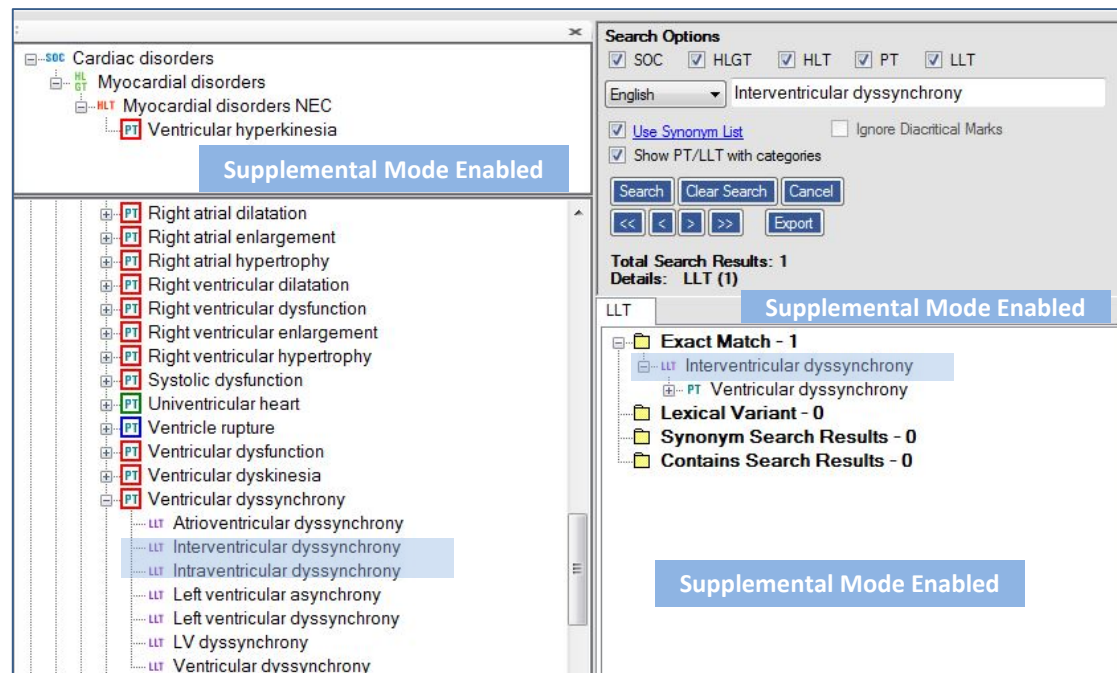
## MedDRA Version 20.0 Supplemental Changes

[Downloads](#) / [Home](#)

Comprehensive	PDF format	SEQ ASCII format	Date
Comprehensive changes for MedDRA 20.0			12 Aug 2016
Segmented	PDF format	SEQ ASCII format	Date
Supplemental changes for MedDRA 20.0			12 Aug 2016
Supplemental changes for MedDRA 20.0			5 Aug 2016
Supplemental changes for MedDRA 20.0			29 July 2016

# 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:



The screenshot displays the MedDRA search interface. On the left, a tree view shows the hierarchy: Cardiac disorders > Myocardial disorders > Myocardial disorders NEC > Ventricular hyperkinesia. A blue callout box 'Supplemental Mode Enabled' is positioned over the tree. The main list shows various PT (Preferred Term) and LLT (Lower Level Term) entries, with 'Interventricular dyssynchrony' selected and highlighted in blue. A second blue callout box 'Supplemental Mode Enabled' is placed over this entry. On the right, the 'Search Options' panel shows search criteria: SOC, HLGT, HLT, PT, and LLT are all checked. The language is set to English, and the search term is 'Interventricular dyssynchrony'. Search options include 'Use Synonym List' (checked), 'Ignore Diacritical Marks' (unchecked), and 'Show PT/LLT with categories' (checked). Search buttons (Search, Clear Search, Cancel) and navigation buttons (left and right arrows) are visible. Below the search options, it shows 'Total Search Results: 1' and 'Details: LLT (1)'. A third blue callout box 'Supplemental Mode Enabled' is placed over the search results panel, which shows an 'Exact Match - 1' category containing the selected LLT 'Interventricular dyssynchrony' and its PT 'Ventricular dyssynchrony'. Other categories like 'Lexical Variant - 0', 'Synonym Search Results - 0', and 'Contains Search Results - 0' are also listed.



# Self Service Application

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

A screenshot of the MedDRA Self-Service Application web page. The page has a white background with a blue header. On the left, there is a MedDRA logo and the text "MedDRA Self-Service Application" in green, with "Medical Dictionary for Regulatory Activities" below it. On the right, there is a link for "MedDRA MSSO Privacy Policy Statement". Below the header, there is a "Message from MedDRA" section with a welcome message and contact information. On the right side, there is a vertical menu of blue buttons with white text: "Self-Service Application Home", "Retrieve MedDRA ID", "Retrieve MedDRA Password", "Retrieve MedDRA Unzip Password", "Check Organization Status", "Retrieve Primary Point of Contact (POC)", and "Generate Certificate for Training Attended". At the bottom, there is a footer with contact information and copyright details.



**MedDRA**

Medical Dictionary  
for Regulatory Activities

Thank You

Questions?

