MedDRA

Medical Dictionary
for Regulatory Activities

MedDRA
User Portfolio

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ICH
harmonisation for better health

ACKNOWLEDGEMENTS

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1. INTRODUCTION

The MedDRA User Portfolio document provides user information regarding the products and services associated with a MedDRA subscription.

1.1 WHAT IS MedDRA?

A large, international user base (with varied linguistic and cultural differences) led to the creation of MedDRA – the Medical Dictionary for Regulatory Activities (MedDRA) terminology. MedDRA, developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), is continuously enhanced to meet the evolving needs of its users, who include regulators and industry worldwide. ICH has created a governance structure to nurture and protect the integrity of MedDRA. The ICH MedDRA Steering Committee, appointed by the ICH Assembly, has overall responsibility for the direction of MedDRA, and oversees all the activities of the MedDRA Maintenance and Support Services Organization.

MedDRA is a pragmatic, medically valid terminology with an emphasis on ease of use for data entry, retrieval, analysis, and display, as well as a suitable balance between sensitivity and specificity within the regulatory environment. By providing one source of medical terminology, MedDRA improves the effectiveness and transparency of medical product regulation worldwide.

1.2 WHAT IS THE MedDRA MAINTENANCE AND SUPPORT SERVICES ORGANIZATION (MSSO)?

The MedDRA MSSO serves as the repository, maintainer, distributor, and promoter of the MedDRA terminology. In this capacity, the MSSO ensures the integrity of the terminology. This activity is supported by a structured user change request review process that includes international medical review and translation of approved changes, Help Desk support, training, and international User Groups to facilitate information exchange.

In addition to this role, the MSSO is also the source for the most up-to-date information regarding the terminology and its application within the medical product development lifecycle. Through an international network of experienced healthcare and information technology professionals, the MSSO offers a wide variety of services to support the implementation and maximum utilization of the MedDRA terminology.

1.3 COMMUNICATING WITH THE MSSO

Users can contact the MSSO via:

Subscription E-mail:	mssohelp@meddra.org
Help Desk E-mail:	mssohelp@meddra.org
Change Request E-mail:	mssorequest@meddra.org
Website:	www.meddra.org
Mail:	MedDRA MSSO 12975 Worldgate Drive Herndon, Virginia 20170-6008 USA

Figure 1-1. MedDRA MSSO Contact Information

1.4 MSSO SERVICES

At the direction of the ICH MedDRA Steering Committee, the MedDRA MSSO provides a number of different training opportunities offered to all MedDRA users at no charge.

This includes the following:

Face-to- face training

- Coding with MedDRA
- MedDRA: Safety Data Analysis and SMQs

Webinars

- What is MedDRA and How is it Used?
- 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

Videocasts

The MSSO also provides free training videocasts on a variety of MedDRA-related topics in different languages, including a videocast designed especially for new users entitled "Getting Started with MedDRA." The videocasts can be downloaded or viewed directly from the MedDRA website.

2. THE MedDRA MSSO SUBSCRIPTION

Upon renewal and/or a new subscription to MedDRA, the designated subscription point of contact will receive a welcome letter email containing the company's MedDRA ID and specific information to their account. The email also includes a link to the Self-Service Application (https://ssa.meddra.org) along with a brief message on how to obtain the company's credentials, including MedDRA password and unzip passwords.

After retrieving their credentials, users may access and download all MedDRA files via internet file download which are located on MedDRA website under Downloads.

2.1 MedDRA ID, PASSWORD, CHANGE REQUEST ID (CR ID), AND UNZIP PASSWORD

The MedDRA ID number and Password provide an interface with the MSSO, identifying the user as a valid user, and ensuring the privacy of user interactions with the MSSO. The password **is** case sensitive, so be sure to enter it exactly as provided. The five-digit MedDRA ID, when combined with the subscriber's Password, will uniquely identify each subscription.

An unzip password is unique to a MedDRA release. The unzip password enables users to extract the MedDRA Release files from the MedDRA website onto their computer. The unzip password is also case sensitive. All supported languages are issued the same unzip password for a specific MedDRA version. Unzip passwords are retrieved via the Self-Service Application. Prior to each release, the MSSO sends a message about retrieving the unzip passwords via the Self-Service Application to POCs of each organization.

All Commercial, Non-profit / Non-commercial, Regulatory, and Developer subscribers receive a MedDRA ID/Password combination at subscription activation. In addition, Commercial, Non-profit / Non-commercial and Regulatory subscribers receive a Change Request Identification Number (CR ID). These MedDRA ID/Password combinations are used for services and tools including:

- User reserved sections of the MedDRA website
- The Help Desk
- User Group Meeting registration
- MedDRA Training registration
- The MedDRA Version Analysis Tool (MVAT) – an online tool that allows users to compare any two MedDRA release to identify differences between those releases.
- The MedDRA Web-Based Browser
- The Mobile MedDRA Browser

- MapCR – an online tool to propose updates or additions to the MedDRA to SNOMED CT or SNOMED CT to MedDRA mappings
- MedDRA APIs - application program interfaces that provide cloud based MedDRA information in all versions and supported languages
- WebCR – an online tool to submit change requests to modify MedDRA
- The Self-Service Application

See the table below for the required information to access each tool or service.

When accessing:	Required Element(s):
Non-restricted portion of the MedDRA website	None
User reserved areas of MedDRA website (prompts for log in)	MedDRA ID and Password
WebCR (for sending MSSO term, SMQ or translation update change requests)	MedDRA ID and Change Request ID or MedDRA ID and Password for Translation update requests only
MapCR	MedDRA ID, Password, or Change Request ID
MedDRA Version Analysis Tool (MVAT)	MedDRA ID, Password, or Change Request ID
MedDRA APIs	MedDRA ID, Password or API key (see the API webpage for details)
Download MedDRA release files (including English MedDRA files, SMQ files, and corresponding language versions)	MedDRA ID, Password, and Unzip password specified for the file type and the version
MedDRA Web-Based Browser	MedDRA ID, Password, or Change Request ID
Mobile MedDRA Browser	MedDRA ID, Password, or Change Request ID
Self-Service Application	Retrieving MedDRA ID, password, or unzip password – email address of subscription point of contact Check Subscription Status of Business Partners - MedDRA ID and Password Retrieve Subscription Primary Point of Contact - valid email address with organization domain recognized by MedDRA MSSO

	Certificate for Training Attended – email address used to register for face-to-face training and webinar
Training and User Group Registration Submission	Attendee name, country, email address, organization name, MedDRA ID

Table 2-1. Website and Tool Access

The Change Request (CR) ID is used solely for submitting term, SMQ and translation update change requests to the MSSO. Separate MedDRA and CR ID passwords are helpful in situations where subscribing organizations want to allow wide access to MSSO resources, via the MedDRA ID/Password combination, but want to restrict the ability to submit change requests. Users may submit translation update requests only via WebCR using the MedDRA ID and Password.

Anyone who desires to submit change requests should obtain the MedDRA ID and CR ID from the subscription point of contact(s). This login credentials are used to validate authorized users so they can propose change requests. See the Maintenance Rights section of this document for more information on how to submit change requests to the MSSO.

The Password and CR ID change with each subscription renewal or a change in the subscription point of contact.

If you are unable to retrieve the MedDRA ID, Password, Unzip passwords, and CR ID via the Self-Service Application, please contact the MSSO Help Desk using the contact information provided in the section entitled “Communicating with the MSSO.”

2.2 MedDRA USER BENEFITS

The ***MedDRA Subscription*** benefits depend on the type of subscription and contain the following products.

2.2.1 Commercial, Non-profit / Non-Commercial, and Regulatory Level Subscription

A ***Commercial, Non-profit / Non-Commercial, and Regulatory Subscriber*** receives the following:

- An electronic copy (internet file download access) of the MedDRA terminology and supporting documentation in English and all translations

- MedDRA Desktop Browser (available for download from the MedDRA website at no additional cost)
- **MedDRA Web-Based Browser** (internet accessible MedDRA browser at no additional cost)
- **Mobile MedDRA Browser (**internet accessible MedDRA browser designed for mobile devices)
- **MedDRA Version Analysis Tool** (internet accessible application which allows a user to compare any two MedDRA versions to identify the differences between those versions)
- **MedDRA APIs (**application program interfaces that provide cloud based MedDRA information in all versions and supported languages).
- **MapCR** (tool used to submit updates to the MedDRA to SNOMED CT or SNOMED to MedDRA mapping)
- **WebCR** (tool used to submit change requests to the MSSO)
- Maintenance rights (up to 100 change requests per month)
- **Help Desk**
- **User Group** membership
- Access to the user reserved section of the MedDRA website containing valuable information and offers related to the terminology
- Self-Service Application (provides points of contact their MedDRA ID, password, unzip password information, retrieves subscription primary point of contact, training certificates, and confirms subscription status of business partners)

2.2.2 System Developer Subscription

A ***System Developer Subscriber*** receives the following:

- An electronic copy (internet file download access) of the MedDRA terminology and supporting documentation in English and all translations.

- MedDRA Desktop Browser (available for download from the MedDRA website at no additional cost)
- **MedDRA Web-Based Browser** (internet accessible MedDRA browser at no additional cost)
- **Mobile MedDRA Browser (**internet accessible MedDRA browser designed for mobile devices)
- **MedDRA Version Analysis Tool** (internet accessible application which allows a user to compare any two MedDRA version to identify the differences between those versions)
- **MedDRA APIs (**application program interfaces that provide cloud based MedDRA information in all versions and supported languages).
- **MapCR** (tool used to submit updates to the MedDRA to SNOMED CT or SNOMED to MedDRA mapping)
- **Help Desk**
- **User Group** membership
- Access to a user section of the MedDRA website containing valuable information and offers related to the terminology
- **Self-Service Application** (provides points of contact their MedDRA ID, password, unzip password information, retrieves subscription primary point of contact, training certificates and confirms subscription status of business partners)

2.3 MedDRA TERMINOLOGY AND DOCUMENTATION

For detailed information on the MedDRA terminology, refer to the MedDRA Introductory Guide. For information on the content of the MedDRA data files, refer to the MedDRA Distribution File Format Document. Both documents are found in the MedDRA release package and on the Support Documentation section of the MedDRA website. See section 2.8 for more information on what documentation is publicly available on the MedDRA website. For detailed information on how to submit change requests, refer to the Change Request Information document.

Users receive the terminology via internet file download**.** All version information is included on the MedDRA website in the Downloads section.

The Downloads section of the MedDRA website (English MedDRA files / SMQ files) includes:

2.3.1 Terminology

- **MedDRA files**. English, Brazilian Portuguese, Dutch, French, German, Italian, Portuguese, and Spanish are distributed in extended ASCII delimited files. The Japanese translation of MedDRA, developed by the Japanese

Maintenance Organization, is encoded in Shift-JIS format and as of MedDRA Version 24.0 is offered in both Shift-JIS and UTF-8 format. The rest of the supported languages and any future languages are distributed in UTF-8 format. These files also contain a list of the current SMQs in production and the content of those SMQs. The MedDRA files may be viewed in a browser or database.

- **MedDRA Consecutive (SEQ) files**. The MedDRA SEQ files define what changes have taken place in the files since the previous release.

2.3.2 Documentation

Adobe® Acrobat® Reader® is required to read Portable Document Format (PDF) documents.

- A **readme text file*** that lists the contents of all MedDRA files, sequence files, and supporting MedDRA documentation
- The **MedDRA Introductory Guide*** in PDF format
- The **MedDRA Distribution File Format Document*** in PDF format
- The **What's New*** document in PDF format
- The **Introductory Guide for Standardised MedDRA Queries (SMQs)*** in PDF format
- The **SMQ Production Spreadsheet** in Microsoft Excel® (English only)
- The MedDRA Release **Version Reports** in Microsoft Excel® contains specific lists of terms that changed since the latest release
- The **Detail Report** in PDF format contains a listing of all changes considered for the current version of MedDRA (English only) including rejected requests and contains detailed responses from the MSSO to the user about the justification for each particular change.

*These files are provided in English for the following supported languages: Croation, Estonian, Finnish, Greek, Latvian, Lithuanian, Polish and Swedish.

All other languages have translated versions of these documents.

The table in **Appendix A** of this document is a quick reference guide that summarizes the MedDRA terminology and documentation.

2.4 MedDRA RELEASES

As part of the subscription, all users will receive updates of English MedDRA on 1 March and 1 September each year. The supported non-English languages will be available on 15 March and 15 September. These updates will be made available for download from the MedDRA website.

2.5 MedDRA UPDATES AND CHANGES

With each update of the MedDRA terminology, users receive a What's New supporting document describing changes to the MedDRA terminology implemented over the release period, and other items of interest regarding MedDRA and the MSSO. Changes to the actual MedDRA files (terminology) from one version to another can either be viewed in the Supplemental files on the MedDRA website, the Consecutive files (SEQ) at the time of the new release, or by using MVAT.

2.6 HELP DESK SUPPORT

The MSSO Help Desk is mainly accessible by e-mail and will answer questions regarding MSSO products and services, including but not limited to:

- Subscription related requests
- MedDRA scope and structure
- MedDRA versions and release schedules
- Issues with the distributed media (web downloads, and supporting documentation)
- Provided software tools such as MedDRA Desktop and Web-Based Browsers, MVAT, WebCR, MedDRA APIs, Self-Service application, etc.
- User Group inquiries
- MedDRA Training inquiries
- License confirmation(s)
- Supplemental terms
- Standardised MedDRA Queries (SMQs)
- MedDRA website content / clarification
- MedDRA website access or password issues.

The Help Desk will forward questions requiring medical expertise to the MSSO Medical Officers for resolution.

The MSSO Help Desk can be contacted via:

E-mail: mssohelp@meddra.org

The MedDRA/J (Japanese MedDRA) Help Desk can be contacted via:

https://www.jmo.pmrj.jp/

Figure 2-1. Help Desk Contact Information

2.7 USER GROUP MEMBERSHIP

The MSSO established an international MedDRA User Group to provide a forum for users and the MSSO to share lessons learned in the use and implementation of MedDRA. The User Group also serves as a discussion point for enhancements to the terminology, updates to current initiatives being undertaken by the MSSO, and proposed changes to the services offered by the MSSO.

The MSSO sponsors MedDRA User Group meetings multiple times per year in different regions of the world. Information on User Group meetings is posted on the MedDRA website under the user group section.

A User Group for Japanese users is held separately in Japan, by the Japanese Maintenance Organization. If you are a MedDRA/J user interested in attending the Japanese MedDRA User Group meeting, please contact the Japanese Maintenance Organization at

https://www.jmo.pmrj.jp/.

2.8 THE MedDRA WEBSITE

The MedDRA website can be found at www.meddra.org. The Downloads section of the MedDRA website is reserved for users. The MedDRA ID and Password are required.

Information on the MedDRA website that is restricted to users includes:

- MedDRA downloadable files including: MedDRA terminology and SMQs in English and translated versions (password protected; unzip required)
- SMQ Original documentation
- MedDRA version documentation including: Supplemental changes (updated weekly) and Term outcomes
- MedDRA Desktop Browser
- Archived documentation

Information on the MedDRA website that is not restricted includes:

- MedDRA Best Practices document
- MedDRA Points to Consider (PtC) documents
  - MedDRA Term Selection Points to Consider
  - MedDRA Data Retrieval and Presentation Points to Consider
  - Points to Consider Companion Document
  - Condensed versions of the Points to Consider documents
- MedDRA release documents
  Introductory Guide
  Introductory Guide for Standardised MedDRA Queries (SMQs)
  What's New in MedDRA
  MedDRA Distribution File Format Document
- Patient-Friendly Term list
- Unqualified Test Name Term List
- Pediatric and Gender Adverse Event Term Lists (no longer maintained as of MedDRA Version 19.0)

This information can be found on the Support Documentation page of the website.

2.9 MedDRA BROWSERS and MVAT

The MSSO offers three free software applications to view the MedDRA terminology. The MedDRA Desktop Browser (MDB) has been developed using the Microsoft Windows® .Net™ 2.0 platform and is compatible with Windows 7 and above. The MDB is intended for download on individual workstations only and is posted in the Download section of the MedDRA website under MedDRA Software Tools section. A login is required to download this tool.

The MedDRA Web-Based Browser is an Internet accessible application. To access the MedDRA Web-Based Browser, open your internet browser and enter URL: https://tools.meddra.org/WBB and log in using your MedDRA ID and Password.

The MedDRA Mobile Browser is an Internet accessible application which is designed for mobile devices. To access the MedDRA Moble Browser, open your internet browser on your device and enter URL: https://mmb.meddra.org and log in using your MedDRA ID and Password.

The MedDRA Version Analysis Tool (MVAT) is an Internet accessible application provides term change information which may assist users with up versioning their data to newer MedDRA releases. To access the MVAT, open your internet browser and enter URL: https://tools.meddra.org/mvat and log in using your MedDRA ID and Password.

2.10 MedDRA TERMINOLOGY DOWNLOAD INSTRUCTION

Downloading the English and non-English MedDRA terminology files from the MedDRA website requires user login. The MedDRA ID and Password are required to validate your access to the files on initial login.

Prior to each MedDRA update, the MSSO sends a message to MedDRA POCs advising them to retrieve the unzip passwords via the Self-Service Application.

Please be aware that as the unzip passwords change with every release, the information will need to be disseminated to appropriate members of the organization by the subscription point of contact.

To download files:

1. Go to www.meddra.org and select Downloads.
2. Select the release and language version you are interested in downloading from the menu
3. Save the zipped file (which contains the MedDRA Release files) to your hard drive
4. Extract the files to a directory on your computer
5. When prompted for **Password** – enter the applicable Unzip Password
6. Extract the files to your location of choice (terminology files may then be loaded into the MedDRA Desktop Browser – see MedDRA Browser User Manual on the MedDRA website or the Browsers section on the MedDRA website for instructions on uploading files to the browser).

2.11 MAINTENANCE RIGHTS

As part of a Commercial, Non-profit / Non-Commercial, and Regulatory subscription, the user receives maintenance rights in the form of change requests to the MedDRA terminology (in English). The MSSO divides change requests into two major categories: simple changes and complex changes. Simple change

requests are selective changes at the Preferred Term (PT) level and below in the MedDRA terminology structure and comprise the majority of requests submitted.

Examples of simple Change Requests include:

- Adding, moving, renaming, and demoting New terms, Preferred Terms (PT), and Lowest Level Terms (LLT)
- Promoting a Lowest Level Term (LLT)
- Demoting a PT to an LLT
- Changing the status of an LLT (current / non-current)
- Adding PTs to Standardised MedDRA Queries (SMQs)
- Reassigning the Primary System Organ Class (SOC) of a PT term
- Linking a PT to / from an HLT

Major hierarchical changes (High Level Term and above) are complex changes to the MedDRA terminology. Complex changes may be submitted at any time, but will only be considered for implementation once yearly for the March release. Before enacting specific complex changes MSSO will seek feedback from users via broadcast e-mail messages, User Group meetings, or surveys.

In addition, users that use a non-English version of MedDRA may request corrections to terms translated from English to one of the supported languages to correct a misspelling or offer an improved translation for a term.

The Change Request Information document, located on the Change Request Information page, describes in detail the type of change requests to which the user is entitled and how to submit them. If you are not familiar with the MedDRA terminology, please read the MedDRA Introductory Guide as well as the Standardised MedDRA Queries (SMQ) Introductory Guide before proceeding to the Change Request Information document. The Introductory Guides provide an understanding of the MedDRA scope and structure, and will make the change request process and SMQ production files easier to understand.

Change requests may be submitted using the on-line change request application (WebCR). WebCR allows users to submit change requests online, search for the history of change requests considered by the MSSO since MedDRA Version 5.1, check status of change requests that are in process, and conduct team reviews of un-submitted change requests within the subscriber organization. To submit term and SMQ change requests via WebCR, users must use the MedDRA ID as the username and the CR ID as the password. See table 2-1. Using the MedDRA password instead of the CR ID permits translation update requests submission only and may be useful for team reviews of un-submitted change requests.

For detailed information on how to submit change requests, please visit the change request section of the MedDRA website.

Appendix A. MedDRA TERMINOLOGY AND DOCUMENTATION

File or Document	Type	File Name and Suffix (type)	Description Summary
MedDRA data files	Terminology	*.asc	The MedDRA database / terminology files / List and content of the current Production SMQ data structure. Provided in all supported languages.
MedDRA Consecutive files	Terminology	*.seq	Delta between current and previous release by individual record. Provided in all supported languages.
MedDRA history file	Optional File	meddra_history_english.asc	An optional file for use with the MedDRA Desktop Browser Release 3.0.2 Beta. The file contains the information that allows the browser to display the history of terms in MedDRA. The history file is specific to each language. Provided in all supported languages.
MedDRA Release File	Optional file	meddra_release.asc	An optional file for use with the MedDRA Desktop Browser Release 3.0.2 Beta. It contains version and language information that allows the browser to identify a specific version MedDRA and language when loading the files. Provided in all supported languages.
MedDRA Introductory Guide	Supporting documentation	Intguide_##.pdf	Guidelines and conventions for use of MedDRA broken down by System Organ Class. Provided in many supported languages.
Introductory Guide for SMQs	Supporting documentation	SMQ_intguide_##.pdf	Summary document listing guidelines and conventions for use of SMQs. Provided in many supported languages.
MedDRA Distribution File Format Document	Supporting documentation	dist_file_format_##.doc	Explanation of the MedDRA terminology (flat file) and MedDRA SEQ file data structure. Provided in many supported languages.
What's New documentation	Supporting documentation	Whatsnew_##.pdf	Text highlights of current release, established conventions, and updates on hot topics; includes statistical data for the release. Provided in many supported languages.
ReadMe	Supporting documentation	!!readme_##.txt	Summary of release content. Provided in many supported languages.
MedDRA Detail Report	Supporting documentation	Detail Report_###.pdf	Contains a listing of implemented change requests for the current version of MedDRA. Provided in English only.
Version Reports	Supporting documentation	VersionReport_###.xlsx	Detailed reports with specific lists of terms with changes since the latest release in a pliable .xls format. Provided in all supported languages.
SMQ Production Spreadsheets	Supporting documentation	SMQ-Spreadsheet_###.xlsx	Details of Production SMQs. Provided in English only.