



MedDRA Subscriber Portfolio

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ACKNOWLEDGEMENTS

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1. INTRODUCTION

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

As biopharmaceutical companies race to bring new drugs and products to the market and protect public health through improved post-market safety analysis, they can now rely on the worldwide standard in medical terminology – MedDRA.

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. This critical medical resource was developed by the International Conference on Harmonisation (ICH) and is owned by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) acting as trustee for the ICH Steering Committee.

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, and distributor of the MedDRA terminology. In this capacity, the MSSO ensures the integrity of the terminology. This activity is supported by a structured subscriber change request review process that includes international medical review and translation of approved changes, help desk support, 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 products and services to support the implementation and maximum utilization of the MedDRA terminology.

1.3 THE MSSO

Northrop Grumman Corporation, a systems integrator and information technology leader, was selected to establish and operate the MSSO, and established the MSSO operations center in Chantilly, Virginia, USA.

Northrop Grumman Corporation leads an expert team to operate the MedDRA MSSO and has established additional subcontracts with subject matter experts to support MSSO activities in the area of system development, and to support medical review.

1.4 COMMUNICATING WITH THE MSSO

Subscribers can contact the MSSO via:

Subscription E-mail:	mssosubscribe@ngc.com
Help Desk E-mail:	mssohelp@ngc.com
Change Request E-mail:	mssorequest@mssotools.com
Web site:	www.meddramsso.com
Mail:	Northrop Grumman Corporation MedDRA MSSO 3975 Virginia Mallory Drive Chantilly, Virginia 20151 USA
International Toll Free:	877.258.8280 (AT&T Worldwide)
Direct:	703.272.5505 (USA)
Fax:	703.272.5635 (USA)

Figure 1-1. MedDRA MSSO Contact Information

1.5 MSSO PRODUCTS AND SERVICES

The internationally recognized MSSO provides expert assistance with the implementation and use of MedDRA. The MSSO offers a variety of purchasable services to help an organization effectively and efficiently communicate with regulatory agencies worldwide and operate on the forefront of medical information technology.

Coding with MedDRA, MedDRA Safety Data Analysis and SMQs, and other [MedDRA training courses](#) are offered to enable organizations to quickly integrate the terminology into widespread use regardless of their present level of use or understanding. Training videocasts and free downloadable training presentations, such as the Data Quality, Coding and MedDRA Training, are posted on our web site. Webinars are also available, for example MedDRA Coding Basics, and What's New in MedDRA. The MSSO offers both free and paid training courses.

MedDRA needs assessments are offered; the MSSO evaluates and offers suggestions on optimization and implementation of MedDRA on an organization-wide level. The MSSO also has team members with technical expertise and vast MedDRA knowledge to assist with legacy migration services.

Please take a moment to visit our [web site](#) explore information on MedDRA Services.

2. THE MedDRA MSSO SUBSCRIPTION

Upon renewal and/or a new subscription to MedDRA, the designated subscription point of contact receives a welcome letter email containing subscriber specific information. This information includes the Subscriber User ID, Password, passwords to unzip MedDRA files, and with the exception of the Developer subscriber category, the Change Request ID (CR ID). Subscribers may access and download all MedDRA files via internet file download which are located on our web site under [Downloads](#).

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

The User ID number and Password provide an interface with the MSSO, identifying the user as a valid subscriber, and ensuring the privacy of subscriber interactions with the MSSO. The User ID number is the “User Name,” and the Password is the “Password” for authentication purposes. The password **is** case sensitive, so be sure to enter it exactly as provided in your welcome letter email. The five-digit User ID number, when combined with the eight-character subscriber’s Password, will uniquely identify each subscription.

Unzip passwords enable subscribers to extract the MedDRA Release files from the MSSO Web site onto their computer. The Unzip passwords are case sensitive. Please remember that Unzip passwords are also version specific and language specific (i.e., English and EU languages have a single unzip password, and Japanese and other non EU languages have a different unzip password). The MSSO provides unzip passwords to the company’s designated points of contact(s) prior to every MedDRA Release and after the company’s annual renewal to the MedDRA subscription license.

All Core, Basic, Regulatory and Developer subscribers receive a User ID/Password combination and a [Web-Based Browser](#) (WBB) password at subscription activation. In addition, Core, Basic and Regulatory subscribers receive a Change Request Identification Number (CR ID). The User ID/Password combination is used for services such as subscriber reserved sections of the web site, the help desk, and User Group attendance. The User ID/ and WBB password combination is used to access the [MedDRA Web-Based Browser](#). The CR ID is used solely for submitting change requests to MedDRA. Separate subscriber and CR ID passwords is helpful in situations where subscriber organizations want to allow wide access to MSSO resources, via the User ID/Password combination, but restrict the ability to submit change requests.

Anyone who desires to make change requests should obtain the User ID and CR ID from the subscription point of contact(s). This login credential is used to validate authorized user so they can propose change requests.

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 change requests via WebCR, subscribers must use the User ID as the username and the CR ID as the password. Using the subscription’s password instead of the CR ID permits read-only access to

WebCR. Read-only access to WebCR is useful for team reviews of un-submitted change requests and gives an organization the ability to limit who can submit changes.

Change requests may also be submitted to mssorequest@mssotools.com using the [Subscriber Change Request Form](#).

For detailed information on how to submit change requests, please visit [the change request section of the](#) MSSO Web site.

When accessing:	Required Element(s):
Non-restricted portion of the MedDRA MSSO Web site	None
Subscriber reserved areas of MedDRA MSSO Web site (prompts for log in)	User ID and Password
Change Request Information form to send to the MSSO	User ID, Password, and CR ID
WebCR (for sending MSSO change requests electronically)	User ID and CR ID
Download MedDRA release files (including English MedDRA files, SMQ files, and Translation files)	User ID, Password, and Unzip password specified for the file type and the version
MedDRA Web-Based Browser	User ID and MedDRA Web-Based Browser password

Table 2-1. Web Site Access

Passwords and CR IDs change with each subscription renewal or a change in the subscription point of contact. Passwords to unzip translation files change with each version and are sent to the subscription point of contact prior to their release.

If the User ID, Password, Unzip passwords, and CR ID are not received, please contact MSSO Help desk using the contact information provided in the section entitled “Communicating with the MSSO.”

2.2 MedDRA SUBSCRIBER BENEFITS

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

2.2.1 Core, Basic, and Regulatory Level Subscription

A **Core, Basic, and Regulatory Subscriber** receives the following:

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

- **MedDRA Desktop Browser** (available for download from the web site at no additional cost)
- [MedDRA Web-Based Browser](#) (internet accessible MedDRA browser at no additional cost)
- **Help desk** support M – F, 9:00 am – 5:00 pm EST
- Maintenance rights (up to 100 **change requests** per month)
- **User Group** membership
- Access to the subscriber reserved section of the MSSO **Web site** containing valuable information and offers related to the terminology

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 available EU languages
- **MedDRA Desktop Browser** (available for download from the web site at no additional cost)
- [MedDRA Web-Based Browser](#) (internet accessible MedDRA browser at no additional cost)
- **Help desk** support M – F, 9:00 am – 5:00 pm EST
- **User Group** membership
- Access to a subscriber section of the MSSO **Web site** containing valuable information and offers related to the terminology

2.3 MedDRA TERMINOLOGY AND DOCUMENTATION

For detailed information on the MedDRA terminology, refer to the MedDRA Introductory Guide provided with your MedDRA subscription. For information on the content of the MedDRA files, refer to the MedDRA ASCII and Consecutive Files Documentation. For detailed information on how to submit change requests, refer to the [Change Request Information document](#).

Subscribers receive the terminology via internet file download. All version information is included on the MSSO [Web site](#) in the [Downloads](#) section.

The [Downloads section](#) of the web site (English MedDRA files / SMQ files) includes:

2.3.1 Terminology

- **MedDRA ASCII files.** MedDRA is delivered in extended ASCII file format and may be viewed in a browser or database. These files also contain a list of the current SMQs in production and the content of those SMQs in ASCII file format.
- **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 ASCII files, sequence files, and supporting MedDRA documentation
- The **MedDRA Introductory Guide** in Portable Document Format (PDF)
- The **MedDRA ASCII and Consecutive Files Documentation** 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 (English only)
- 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 subscriber about the justification for each particular change.

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 subscribers 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 of September. These updates will be made available for download from the MSSO Web site.

2.5 MedDRA UPDATES AND CHANGES

With each update of the MedDRA terminology, subscribers 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 ASCII files (terminology) from one version to another can either be viewed in the Supplemental files on the web site, or in the Consecutive files (SEQ) at the time of the new release.

2.6 HELP DESK SUPPORT

The MSSO help desk provides coverage in English and is accessible by phone, e-mail, or fax. The help desk will answer questions regarding MSSO products and services, including:

- Subscription related requests
- MedDRA scope and structure
- MedDRA versions and release schedules
- Issues with the distributed media (web downloads, and supporting documentation)
- MedDRA Desktop and Web-Based Browsers
- User Group inquiries
- License confirmation(s)
- Supplemental terms
- Standardised MedDRA Queries (SMQs)
- Web site content / clarification
- Web site access or password issues.

The help desk will forward questions requiring medical expertise to the MSSO International Medical Officers for resolution.

The MSSO help desk can be contacted via:

International Toll Free:	877.258.8280 (AT&T)
Direct:	703.272.5505 (USA)
E-mail:	mssohelp@ngc.com
Fax:	703.272.5635 (USA)

The MedDRA/J (Japanese MedDRA) help desk can be contacted via:

E-mail for JMO Subscribers:	helpdesk.jmo@pmrj.jp
E-mail for non-JMO Subscribers:	info.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 subscribers 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 MedDRA User Group meets two times per year—once in each of the ICH regions, USA and Europe respectively. Upcoming User Group meetings, minutes, and briefings are posted on the MSSO Web site.

A User Group for Japanese subscribers is held separately, hosted by the Japanese Maintenance Organization. If you are a MedDRA/J subscriber interested in attending the Japanese MedDRA User Group meeting, please email the Japanese Maintenance Organization at info.jmo@pmri.jp.

2.8 THE MSSO WEB SITE

The MSSO Web site can be found at www.meddramsso.com. Certain areas of the web site are reserved for subscribers. The User ID and Password, provided in the MedDRA MSSO subscription welcome letter, are required to access these areas of the web site. The User ID is the “User Name” and the Password is the “Password” for web site access. The password is case sensitive.

Information on the MSSO Web site that is restricted to subscribers includes:

- SMQ updates (password protected; unzip required)
- MedDRA downloadable files including: MedDRA terminology in English and translated versions (password protected; unzip required)
- User Group presentations
- MedDRA version documentation including: What’s New document, Supplemental changes (updated weekly), Term outcomes, and more
- Subscriber specific announcements
- Archived documentation

2.9 MedDRA DESKTOP AND WEB-BASED BROWSER

The MSSO offers two complementary software applications to view the MedDRA terminology. The [MedDRA Desktop Browser 3.0.2 \(MDB3\) beta](#) has been developed using the Microsoft Windows® .Net™ 2.0 platform and is compatible with Windows XP® Professional SP2. The MDB3 is intended for download on individual work stations only and is posted in the [Download section](#) of the MSSO Web site under MedDRA Software Tools section.

The MedDRA Web-Based Browser an Internet accessible application. To access the [MedDRA Web-Based Browser](#), please open your internet browser and enter URL: <https://www.meddrabrowser.org/dsnavigator/>. Please login using your User ID and the MedDRA Web-Based Browser Password issued at subscription activation.

2.10 MedDRA TERMINOLOGY DOWNLOAD INSTRUCTION

Downloading the English and non-English MedDRA terminology files from the MSSO Web site requires subscriber login. The User ID is the “User Name” and Password is the “Password” to validate your access to the files on initial login.

Prior to each MedDRA update, the MSSO sends the subscription point of contact (listed on the Subscription Agreement) a letter providing the unzip passwords necessary to unzip the MedDRA files. Please refer to this letter for the passwords to the respective languages for each release. If you are not in possession of this information, please contact the subscription point of contact listed for your organization’s MedDRA subscription.

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.meddramsso.com and select Current Subscriber.
2. Click on Downloads or select Current Release from the menu.(Under Current Release Version of MedDRA, please select **MedDRA ### Data and Documentation**.)
3. When prompted, enter your User ID and Password.
4. Click on the desired MedDRA terminology translation
5. Save the zipped file (which contains the MedDRA Release files) to your hard drive
6. Extract the files to a directory on your computer
7. When prompted for **Password** – enter the applicable Unzip Password
8. Extract the files to your location of choice (terminology files may then be loaded into the MedDRA Browser – see MedDRA Browser User Manual on the web site or the New Subscriber Information section on the web site for instructions on uploading files to the browser).

2.11 MAINTENANCE RIGHTS

As part of a Core, Basic, and Regulatory subscription, the subscriber 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 subscribers via broadcast e-mail messages, User Group meetings, or surveys.

In addition, subscribers 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 [Downloads page](#), describes in detail the type of change requests to which the subscriber 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.

Appendix A. MedDRA TERMINOLOGY AND DOCUMENTATION

File or Document	Type	File Name and Suffix (type)	Description Summary
MedDRA ASCII files	Terminology	*.asc	The MedDRA database / terminology files / List and content of the current Production SMQ data structure
MedDRA Consecutive files	Terminology	*.seq	Delta between current and previous release by individual record
MedDRA history file	Optional File	meddra_history.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
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 ASCII files.
MedDRA Introductory Guide	Supporting documentation	Intguide_##.pdf	Guidelines and conventions for use of MedDRA broken down by System Organ Class
Introductory Guide for SMQs	Supporting documentation	SMQ_intguide_##.pdf	Summary document listing guidelines and conventions for use of SMQs
MedDRA ASCII and Consecutive Files Documentation	Supporting documentation	ASCII_seq_datafiles_##.doc	Explanation of the MedDRA terminology ASCII (flat file) and MedDRA SEQ file data structure
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
ReadMe	Supporting documentation	!!readme_##.txt	Summary of release content
MedDRA Detail Report	Supporting documentation	Detail Report_###.pdf	Contains a listing of implemented change requests for the current version of MedDRA.
Version Reports	Supporting documentation	VersionReport_###.xlsx	Detailed reports with specific lists of terms with changes since the latest release in a pliable .xls format
SMQ Production Spreadsheets	Supporting documentation	SMQ-Spreadsheet_###.xlsx	Details of Production SMQs