



---

# MedDRA Subscriber Portfolio

---

MSSO-DI-6284-1.3.0  
27 August 2009

## **ACKNOWLEDGEMENTS**

### **Trademark**

MedDRA<sup>®</sup> is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

Adobe<sup>®</sup>, Acrobat<sup>®</sup>, and Adobe<sup>®</sup> Acrobat<sup>®</sup> Reader<sup>®</sup> are registered trademarks of Adobe Systems Incorporated.

### **Copyright**

Microsoft<sup>®</sup> Word 2003, Copyright ©1983-2003 Microsoft Corporation. All rights reserved.

Microsoft<sup>®</sup> Excel 2003, Copyright ©1985-2003 Microsoft Corporation. All rights reserved.

Copyright© 2009 Northrop Grumman Corporation. All Rights Reserved.

**TABLE OF CONTENTS**

**1. INTRODUCTION ..... 1**

    1.1 WHAT IS MedDRA? ..... 1

    1.2 WHAT IS THE MedDRA MAINTENANCE AND SUPPORT SERVICES ORGANIZATION (MSSO)? ..... 1

    1.3 THE MSSO ..... 2

    1.4 COMMUNICATING WITH THE MSSO ..... 2

    1.5 MSSO PRODUCTS AND SERVICES ..... 2

**2. THE MedDRA MSSO SUBSCRIPTION ..... 4**

    2.1 USER ID, PASSWORD, CHANGE REQUEST ID (CR ID), AND UNZIP PASSWORD ..... 4

    2.2 MedDRA SUBSCRIBER BENEFITS ..... 6

        2.2.1 Core Level Subscription ..... 6

        2.2.2 Basic or System Developer Subscription ..... 6

    2.3 MedDRA TERMINOLOGY AND DOCUMENTATION ..... 7

        2.3.1 Terminology ..... 7

        2.3.2 Documentation ..... 7

    2.4 MedDRA RELEASES ..... 8

    2.5 MedDRA UPDATES AND CHANGES ..... 8

    2.6 HELP DESK SUPPORT ..... 8

    2.7 USER GROUP MEMBERSHIP ..... 9

    2.8 THE MSSO WEB SITE ..... 9

    2.9 MedDRA TRANSLATIONS DOWNLOAD INSTRUCTION ..... 10

    2.10 MAINTENANCE RIGHTS ..... 11

**Appendix A. MedDRA TERMINOLOGY AND DOCUMENTATION ..... 12**

**LIST OF TABLES**

Table 2-1. Web Site Access ..... 6

**LIST OF FIGURES**

Figure 1-1. MedDRA MSSO Contact Information ..... 2

Figure 2-1. Help Desk Contact Information ..... 9

## **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@ngc.com   |
| Web site:                | www.meddramsso.com  |
| Mail:                    | Northrop Grumman Corporation<br>3975 Virginia Mallory Drive<br>Chantilly, Virginia 20151<br>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

(<http://www.meddramsso.com/MSSOWeb/training/schedule.htm>).

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.

The MSSO offers a variety of coding services, as well as consulting and information technology services such as database conversion for pharmaceutical, biotechnology, academic, and medical device organizations.

Please take a moment to visit our web site

(<http://www.meddramsso.com/MSSOWeb/training/services.htm>) and explore information on MedDRA Services.

## 2. THE MedDRA MSSO SUBSCRIPTION

Upon renewal and/or a new subscription to MedDRA, all subscribers receive a welcome letter email containing subscriber specific information. Once the subscription payment has been received by the MSSO, the Subscriber User ID, Password, Change Request ID (CR ID), and passwords to unzip translation files are emailed to the designated subscription point of contact. Subscribers may access and download all MedDRA files via internet file download which are located on our web site at <http://www.meddramssso.com/mssoweb/index.htm> 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 web site login 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 Password, will uniquely identify each subscription.

A combination of the User ID and Password allows users to access subscriber reserved sections of the MSSO Web site.

Unzip passwords allow and enable you to extract the MedDRA Release files from our web site onto your 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 languages have a different unzip password). The MSSO provides unzip passwords to your company’s designated points of contact prior to every MedDRA Release and after payment is received for your company’s annual renewal to the MedDRA subscription license.

Note: The EMEA MedDRA License number is equivalent to your MedDRA User ID number.

Since the first User Group meeting (July 1999) in Baltimore, Maryland, users have requested a separate User ID and Password to access the change request process from other customer support services (i.e., help desk, web site, and User Group). Customers had personnel who they wanted to access the web site and help desk, but not be able to submit change requests. In an effort to resolve this problem for our customers, the MSSO Customer Operations Group issued new CR ID numbers and notified all core subscribers (see section 2.2) of their new User ID/ Password / CR ID combination. The User ID and CR ID will validate anyone who submits change requests.

Core subscribers receive a Change Request Identification Number (CR ID) in addition to the User ID and Password. The change request identification number is used for submitting change requests to the MedDRA terminology. Passwords and CR IDs change with each renewal and/or change in subscription point of contact. Passwords to unzip

translation files change with each version and are sent to the subscription point of contact prior to its release.

Anyone who desires to make change requests should be given access to the User ID and CR ID so that these numbers can be validated as an authorized user and the user can make change requests that will be counted against the organization's monthly/annual allocation. This CR ID will be used for the change request process only. The original User ID/Password combination received at subscription activation will be used for all other services to include web access, help desk, and User Group attendance.

Change requests may be submitted using the web-based software tool for change request entry (WebCR) at <https://mssotools.com/webcr/>. WebCR allows users to submit change requests online, search for the history of processed change requests dated back to 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 subscriber id as the username and the CR ID as the password. Using the password instead of the CR ID allows 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 change requests.

Change requests may also be submitted to [mssorequest@ngc.com](mailto:mssorequest@ngc.com) using the Subscriber Change Request Form, which can be downloaded from the MSSO Web site at [http://meddramsso.com/MSSOWeb/mssosubs/coresubs/changereq\\_info.htm](http://meddramsso.com/MSSOWeb/mssosubs/coresubs/changereq_info.htm).

For detailed information on how to submit change requests, please visit the MSSO Web site at [http://www.meddramsso.com/MSSOWeb/mssosubs/coresubs/changereq\\_info.htm](http://www.meddramsso.com/MSSOWeb/mssosubs/coresubs/changereq_info.htm). Your User ID and Password are required for login.

| <b>When accessing:</b>   | <b>Required Element(s):</b>   |
|--|---|
| 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 Area of MedDRA MSSO Web site (including English MedDRA files, SMQ files, and Translation files) | User ID, Password, and Unzip password specified for the file type and the version |

|              |   |
|--------------|---|
| MedDRA Forum | The first prompt is for the MSSO assigned User ID / Password associated with the subscription. The second allows the subscriber to originate their own registration data utilizing a DIFFERENT User ID and Password for this application. It is not the same as the subscription specific User ID and Password given by the MSSO. |
|--------------|---|

**Table 2-1. Web Site Access**

If the User ID, Password, Unzip passwords, and CR ID are not received, please contact MSSO Customer Operations using the contact information provided in Section “Communicating with the MSSO” of this document.

## 2.2 MedDRA SUBSCRIBER BENEFITS

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

### 2.2.1 Core Level Subscription

A **Core 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 Browser** version available for download from the web site at no additional cost
- **Help desk** support M – F, 9:00 am – 5:00 pm EST
- Maintenance rights (e.g., **change requests**)
- **User Group** membership
- Access to the subscriber reserved section of the MSSO **Web site** containing valuable information and offers related to the terminology

Note: US Government agencies default to a Core Level subscription in most cases.

### 2.2.2 Basic or System Developer Subscription

A **Basic or 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 Browser** version available for download from the web site 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 (available on the web site).

Subscribers receive the terminology via internet file download. All version information is included on the MSSO Web site ([www.meddramssso.com](http://www.meddramssso.com)) in the Downloads, or New Subscriber Information sections.

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

### 2.3.1 Terminology

- The **MedDRA ASCII files**. MedDRA is delivered in 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<sup>®</sup> Acrobat<sup>®</sup> Reader<sup>®</sup> 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<sup>®</sup> (English only)
- The MedDRA Release **Version Reports** in Microsoft Excel<sup>®</sup> contains specific lists of terms that changed since the latest release (English only)
- **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 a single, annual fee, core subscribers will receive updates of the MedDRA terminology, 1 March and 1 September each year. The complete version of the MedDRA terminology update is available for download from the web site.

## **2.5 MedDRA UPDATES AND CHANGES**

With each update of the MedDRA terminology, subscribers receive a What's New supporting document listing 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)
- 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:                  | <a href="mailto:mssohelp@ngc.com">mssohelp@ngc.com</a> |
| Fax:                     | 703.272.5635 (USA)                                     |

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

|                                 |  |
|---------------------------------|--|
| E-mail for JMO Subscribers:     | <a href="mailto:helpdesk.jmo@sjp.or.jp">helpdesk.jmo@sjp.or.jp</a> |
| E-mail for non-JMO Subscribers: | <a href="mailto:info.jmo@sjp.or.jp">info.jmo@sjp.or.jp</a>         |

**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@sjp.or.jp](mailto:info.jmo@sjp.or.jp).

## **2.8 THE MSSO WEB SITE**

The MSSO Web site can be found at [www.meddramsso.com](http://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
- Change request information, including instructional document and change request forms
- Subscriber specific announcements
- Archived documentation

## 2.9 MedDRA TRANSLATIONS DOWNLOAD INSTRUCTION

Downloading the English MedDRA terminology files, SMQ files, Japanese and European MedDRA translation 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](http://www.meddramsso.com).
2. Click on the Downloads link at the top.
3. When prompted, enter your User ID and (subscription specific) Password.
4. Double-click on the file type you would like to download.
5. When prompted, enter your unzip password associated with the type of files.
6. 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).

## 2.10 MAINTENANCE RIGHTS

As part of a Core subscription, the subscriber receives maintenance rights in the form of routine 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.

Simple Change Requests include the following:

- Adding, moving, renaming, and demoting New terms, Preferred Terms (PT), and Lowest Level Terms (LLT)
- Promoting a Lowest Level Term (LLT)
- Swapping a PT with an LLT
- Changing the status of an LLT (current / non-current)
- Adding / deleting PTs to/ from 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 and will be maintained by the MSSO with input from subscribers via User Group meetings, web feedback, and surveys. Complex changes may be submitted at any time, but will only be considered for implementation once yearly for the March release.

The Change Request Information document, located on the Downloads page, describes in detail the type of change requests to which the subscriber is entitled. 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, as well as 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 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 that for use with the MedDRA Desktop Browser Release 3.0 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 ###.xls       | 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 ###.xls     | Details of Production SMQs  |