



Change Request Information

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1. CHANGE REQUEST INFORMATION

1.1 PURPOSE

This document serves to assist MedDRA users to understand how to submit change requests to the MSSO.

1.2 SCOPE

This document contains requirements and guidelines on how to submit change requests, tips on submitting changes, and explains how to interpret disposition change request reports.

2. CHANGE REQUESTS

Change requests allow MedDRA users the opportunity to modify MedDRA. This section describes the types of changes a user may request, how to submit change requests, and an explanation of the MSSO change request process.

2.1 WHO MAY SUBMIT A CHANGE REQUEST

Core, Basic, and Regulator subscriber categories may submit change requests (CRs). CRs are sent to the MSSO via the organization's subscription point of contact (POC). The POC is the person in your organization who is responsible for your MedDRA subscription. This person may authorize one or more "requesters." A requester is a person in your organization authorized to submit change requests to the MSSO. Subscribing organizations may authorize as many requesters as they see fit. The subscriber POC and all "requesters" in your organization are the only people that can submit CRs from your organization to the MedDRA MSSO.

In this document both subscriber POC and requesters are referred to as the "submitter."

Anyone authorized to submit change requests must use the current valid User ID and Change Request ID (CR ID) that are assigned to your organization when submitting change requests. CR IDs are reassigned every year.

2.2 SCOPE AND CONVENTIONS OF MedDRA

The following guidelines apply to all change request types:

- MedDRA is applicable to all phases of drug development (excluding animal toxicology) and to the health effects of devices. All change requests must fall within the scope of the terminology to be accepted.
- The categories of terms that fall within the scope of MedDRA are:
 - Symptoms
 - Signs
 - Diseases
 - Diagnoses
 - Therapeutic indications – including symptoms, signs, diseases, diagnoses, or prophylaxis of disease and modification of physiological function
 - Names and qualitative results of investigations (including pharmacokinetics) (e.g., increased, decreased, normal, abnormal, present, absent, positive, negative)

- Surgical and medical procedures
- Medical, social, and family history.

For more information on MedDRA's structure, scope and specific conventions, please see the latest versions of the MedDRA Introductory Guide and the Introductory Guide for Standardised MedDRA Queries (SMQs), found on the [download section](#) of the MSSO Web site.

Approval or disapproval of change requests are determined by the MSSO based on both compliance with the rules and conventions of MedDRA (see the MedDRA Introductory Guide) and medical judgment concerning accuracy, completeness, and internationally accepted medical conventions.

2.3 MedDRA VERSIONS AND CHANGE REQUEST CATEGORIES

The MSSO implements two releases per year – one with simple changes and the other with complex and simple changes. See below for explanations of simple and complex changes.

The complex release version is designated by a trailing 0 (e.g., 14.0) and is available on 1 March of each year. The simple release version is designated by a trailing 1 (e.g., 14.1) and is available on the 1 September each year.

The MSSO groups change requests into three general categories: MedDRA changes, SMQ changes, and translation corrections. The following explains each category.

- **MedDRA changes**

MedDRA changes are requests to make modifications to the English language MedDRA. These changes include adding new terms (e.g., add a LLT, PT, HLT) or moving terms within the terminology (e.g., demote a PT, move an HLT, etc.). For details on specific MedDRA change request actions, please see Appendix A.

The MSSO divides MedDRA changes into two groupings: simple changes and complex changes.

- Simple changes are those made to the PT and LLT level only
- Complex changes are any changes made above the PT level (i.e., HLT, HLTG, or SOC level).

Complex changes are reviewed and approved changes implemented for inclusion in MedDRA only during the beginning of the Complex release change request processing phase (May – August). MedDRA users may

request a complex change at any time, but should be aware that any submitted complex change request are held until this timeframe. Simple changes are reviewed and approved changes implemented in both releases (x.0 and x.1).

- **SMQ change requests**

Standardised MedDRA Query (SMQ) change requests are requests to make modifications to the English language SMQs. The most common changes are to add a new PT to an existing SMQ or to change the scope of a PT in an SMQ (e.g. from broad search to narrow search). For details on specific SMQ change request actions, please see Appendix B. For specific information on SMQs, please see the latest version of the Introductory Guide for Standardised MedDRA Queries (SMQs).

- **Translation corrections**

The MSSO supports a number of languages in addition to English. When new terms are added in English, they are subsequently translated into the supported languages. Users may submit a translation correction for one of the supported languages to correct a misspelled term or suggest an improved translation to an existing term. Please see Appendix C for the required translation correction information.

2.4 HOW TO SUBMIT A CHANGE REQUEST

There are two methods to submit change requests: WebCR – a web based application that accepts **all change request categories** – and the Change Request Forms. The table below summarizes these two methods.

Submission method	Location	How to submit
WebCR	https://mssotools.com/webcr	Submit within the application
MedDRA Change Request Form	Download at: http://www.meddramsso.com/subscriber_download_change_request.asp	Email to: mssorequest@mssotools.com
SMQ Change Request Form		
Translation Correction Request Form		

Table 2-1. MSSO Change Request Information Summary

For questions about or issues with submitting change requests, please contact the MSSO Help Desk at mssohelp@ngc.com, or 1-877-258-8280 (USA).

2.4.1 WebCR

The preferred method of submitting a change request is via [WebCR](#). In WebCR, submitters select from among a list of actions, described in the Appendix, to request MedDRA changes, SMQ changes, or translation corrections. Multiple change requests may be submitted at the same time up to a limit of 100 change requests per month with the exception of translation corrections which are unlimited. In addition to submitting change requests, WebCR gives users the ability to:

- Verify if an English term exists in MedDRA
- Review when an English term was added to MedDRA
- Search the history of all change requests considered by the MSSO since MedDRA v5.1
- Resubmit a rejected request for reconsideration
- Track the progress of submitted requests
- Hold proposed change requests and submit them when ready

To log in to WebCR, submitters must supply their Subscriber ID, Change request identification (CR ID), or optionally, their subscription password. The Subscriber ID serves as the user name and the CR ID is the password. The subscription password may also be used in lieu of the CR ID for **read only** access (i.e., no ability to submit changes) to WebCR. Read only access is useful in situations where an organization wants to limit the number of people who can submit change requests, but allow others within the organization to review queued (unsubmitted) change requests or use other WebCR features.

For information on using WebCR, please see the WebCR Quick Reference guide on the [change request section](#) of the MSSO Web site and refer to the Appendix of this document for an explanation of change request actions.

2.4.2 Change Request Forms

In addition to WebCR, change requests may be submitted to the MSSO by downloading the appropriate [Change Request Form](#), filling it out and submitting it via email to mssorequest@mssotools.com. There is a separate form for each change request category: MedDRA changes, SMQ changes and translation corrections. The change request forms are in Microsoft® (MS) Excel® format and must remain in that format. Each cell in the form with a red triangle has an explanation of what is required in that field. An example of a completed form can be found under the second tab at the bottom of the form labeled "For Example." The forms must contain data in all required data fields in order to be considered by the MSSO. Required subscriber identification information includes the following in the table shown below.

Change Request Information

Data Field	Description	Required/ Optional
User ID	The User ID is equivalent to your company's User Name and your company's MedDRA license number.	Required
Password	The Password is a unique eight-character password that is used for access to the MSSO Web site and is case sensitive. It is subject to change with every subscription renewal and with every change to your company's primary subscription point of contact.	Required
Change Request ID	This is a unique eight-character subscriber CR ID. This identifier, when paired with the Password, uniquely identifies each subscription. The MSSO suggests that this information (i.e., CR ID and Password) be given only to users who are authorized to make change requests for a subscription.	Required
Requester Name	The name of the person who is submitting the request. The MSSO contacts this person if clarification on change requests needs to be made.	Required
Requester Phone	The telephone number is used to contact the requester if the MSSO has a question or if clarification is required about a submitted request. If the requestor's telephone number is not provided, the subscription point of contact is called.	Optional
Fax	The fax number of the requester.	Optional
Email Address	List email addresses of all parties you wish copied on all correspondences related to these requests. Additionally, please separate each address within a ";" followed by a space before entering the next address.	Required
Date of Request	The date this form is submitted via email to the MSSO.	Required

Table 2-2. Change Request Form Sheet Elements

The User ID and Change Request ID must be valid for the change request to be processed. If a subscription is expired, the change requests are not processed, and the submitter is notified immediately. MedDRA users that opt to submit change requests via WebCR do not need to provide the information listed above except for the User ID (Subscriber ID) and CR ID, which are used to login to the application.

3. THE MSSO CHANGE REQUEST PROCESS

The MSSO change request process is described briefly below. This process consists of steps to ensure the change request originates from a valid MedDRA subscriber, is complete, and is medically evaluated. Following this process ensures that approved changes are incorporated quickly, efficiently, and accurately and that MedDRA users have access to the most up-to-date, consistent terminology.



Figure 3-1. Change Request Process

CR Received. The MSSO verifies the subscription status for non-WebCR submissions. WebCR performs this function for web-based submissions automatically. The MSSO send submitters an initial Receipt Notification via email within 48 hours after a change request has been received.

The following figure displays the receipt notification attachment submitters receive.

Notification of Receipt or Administrative Action

A User ID #: 10466

B CR Number	C CR Action	D Term	E Data Entry Date
2006338126	Add a New PT	Proposed PT Vasogenic oedema	04-Dec-2006
2006338127	Add a New PT	Proposed PT Cytotoxic oedema	04-Dec-2006
2006338128	Add a New PT	Proposed PT Cerebral microhaemorrhage	04-Dec-2006

F Monday, December 04, 2006 Batch Number: 10001503 Version: 10.0 Page 1 of 1

Figure 3-2. Notification of Receipt or Administrative Action

- The following describes the Notification of Receipt or Administrative Action.
- a. User ID #: This is the subscription ID, which also serves as the user login to WebCR.
 - b. Assigned Change Request Numbers: This number uniquely identifies each request for tracking purposes. Use this number to communicate with the MSSO about a specific request. See the section on change request tracking for more information.
 - c. Requested Action: Requested change submitted by the requester (e.g., add a term to an SMQ)

- d. Term Requested: Term associated with the request
- e. Data Entry Date/Time Received
- f. Date, Batch Number, Version number and Page Number: The footer of every page on the report identifies the date the report was generated, Batch Number (see the section on change request tracking), Version number and number of pages.

CR Verified. The MSSO reviews submission justification information and checks for redundant requests currently being processed or previously processed.

CR Tracked. The MSSO submits the request into the MSSO change request Workflow Management System. See the section on change request tracking for more information.

CR Evaluated. An MSSO Medical Officer evaluates requests against MedDRA rules and conventions, makes an initial recommendation to accept or reject a request and provides a justification for the recommendation.

IMO Review. A panel of International Medical Officers (IMOs) from the three ICH regions (US, EU, Japan) review change requests and either agree with the initial Medical Officer evaluation or propose alternate changes.

Consensus. The MSSO coordinates consensus of IMOs on acceptance or rejection of requests, term placement, and final notification statements (comments substantiating a decision).

Final Notification. The MSSO implements final disposition and placement in MedDRA (if approved) for each request. Changes are verified by an MSSO Medical Officer for compliance with MedDRA rules and conventions. The audit trail is verified for quality control, and a final disposition notice, called the MSSO Final Disposition Report, is distributed to the submitter via email. The Final Disposition Report serves to inform the submitter of the outcome of each change request submitted. For tracking purposes, we request that you acknowledge receipt of each Final Disposition Report received by replying to the email. All Final Disposition Reports include the rationale for MSSO actions. See figure 3-3.

Change Request Information

MSSO Final Disposition Report

G User ID #: 10466

CR Number	CR Action	Term	Disposition	Final Placement	MedDRA #
H 2006338126	I Add a New PT	J Proposed PT Vasogenic oedema	K Approved Not as Requested	L Proposed LLT Vasogenic cerebral oedema To PT Brain oedema	M 10067276 Current 10046962 Current
MSSO comment: The proposal to add new PT Vasogenic cerebral oedema is approved but not as requested and will be added as an LLT under PT Brain oedema. Vasogenic cerebral oedema: most common form due to a breakdown of tight endothelial junctions which make up the BBB. This allows normally excluded intravascular proteins and fluid to penetrate into cerebral parenchymal extracellular space. Please note associate changes.					
Associate-2006352015 Related CR-2006338126	Add a New LLT	Proposed LLT Vasogenic cerebral edema	Approved as Requested	Proposed LLT Vasogenic cerebral edema To PT Brain oedema	10067276 Current 10046962 Current
MSSO comment:					
2006338127	Add a New PT	Proposed PT Cytotoxic oedema	Approved Not as Requested	Proposed LLT Cytotoxic oedema To PT Brain oedema	10067276 Current 10046962 Current
MSSO comment: The proposal to add new PT Cytotoxic oedema is approved but not as requested and will be added as an LLT under PT Brain oedema. Cytotoxic cerebral oedema: here BBB is intact, due to encephalopathy, early stroke or hypoxia, cardiac arrest, pseudotumour cerebri, cerebral toxins. Cytotoxic oedema occurs when brain osmolality exceeds serum osmolality and water passes into brain eg after water intoxication or rapid reduction of blood glucose. Please note associate changes.					
Associate-2006352016 Related CR-2006338127	Add a New LLT	Proposed LLT Cytotoxic edema	Approved as Requested	Proposed LLT Cytotoxic edema To PT Brain oedema	10067276 Current 10046962 Current
MSSO comment:					
2006338128	Add a New PT	Proposed PT Cerebral microhaemorrhage	Approved Not as Requested	Proposed LLT Cerebral microhaemorrhage To PT Cerebral haemorrhage	10067277 Current 10008111 Current
MSSO comment: The proposal to add new PT Cerebral microhaemorrhage is approved but not as requested and will be added as an LLT under PT Cerebral haemorrhage. With the advent of modern MRI imaging techniques, cerebral microhemorrhages have been increasingly recognized on gradient-echo (GE) or T2*-weighted MRI sequences in different populations. However, in clinical practice, their diagnostic value, associated risk, and prognostic significance are often unclear. Please note associate changes.					

N Monday, October 1, 2007 Batch Number: 10001503 Version 10.0 Page 1 of 2

Figure 3-3. MSSO Final Disposition Report

The following describes the Final Disposition Report:

- g. User ID #: This is the subscription ID, which also serves as the user login to WebCR.
- h. CR Number: Each change request is assigned a unique number for tracking purposes. If there is a related change request, called an associate change, (see below) this number is identified below the CR number.
- i. CR Action: Requested action by the submitter (e.g., add a PT)
- j. Term: Term name associated with the request
- k. Disposition: The outcome of a requested change. The categories are: Approved as Requested, Approved Not as Requested, Rejected and Suspended. See below for an explanation.
- l. Final Placement: For approved requests, the final placement information shows where the request is placed in the terminology. For example, if a PT is added to MedDRA, the final placement information

shows the primary and secondary (if applicable) HLTs under which the PT resides.

- m. MedDRA #: The MedDRA 8-digit code associated with the final placement information, including new terms.
- n. Date, Batch Number, Version Number and Page number: The footer of each page of the report identifies the release this change is planned for, Date the report is printed, Batch number (see the section on change request tracking), and page number.

Below is an explanation of outcomes for change requests.

- **Approved as Requested** – A change request is approved exactly as requested by the submitter. For example, the term name and the level (e.g., LLT) are implemented without any modification of the request.
- **Approved not as Requested** – A change request is approved but not exactly as request by the submitter. Examples include but are not limited to:
 - Modifying the wording of the requested term
 - Adding a term at a level different from the request (e.g., adding a term requested as a PT to the LLT level)
 - Performing a different action that results in the same or similar outcome.

This principle also applies to SMQ change requests and translation corrections. For example with SMQ changes, modifications to proposed scope, category, and weight, are considered approved not as requested.

- **Rejected** – A change request is not approved (i.e., not implemented). There are a variety of reasons for rejecting a request which include, but are not limited to:
 - Requests for new terms that fall outside the scope of MedDRA
 - Terms that are represented by existing concepts in MedDRA
 - Terms that are not internationally recognized.

Change requests that are not accepted can be contested by using the reconsideration feature in WebCR or by resubmitting the request using the appropriate change request form.

- **Suspended** – The MSSO may suspend a request for the following reasons:
 - The request requires additional research or consultation with specific subject matter experts
 - The request may have a significant impact on MedDRA user’s legacy coded data
 - The request is part of – or related to – a special initiative currently under review.
 - To seek further information from the submitter if the justification of the request is not sufficient or if the MSSO has a specific question about the request.

Any complex change requests, or other requests contingent on a particular complex change, await resolution until the complex change timeframe described above.

Once suspended requests are resolved, a Final Notification of Suspended terms is sent out which indicates whether the changes in question have been approved or rejected. The final disposition of these requests has one of three decisions. “Approved after suspension,” “Approved Not as Requested after Suspension,” or “Rejected after Suspension.”

NOTE: Alternate actions, called associate changes, may be made by the MSSO to appropriately adjust the terminology in response to submitted requests. For example, if a request to move LLT *Back pain* is approved and the MSSO determines the lexical variant LLT *Pain back* should also be moved, it creates an associate change to do so. The associate change is recorded and processed, but is not charged against the monthly cap of 100 requests; the associate change is included in the Final Disposition Report received by the submitter.

The MSSO may reject a submitter’s request and perform associate changes in lieu of the request. For example, a submitter requests a new PT, but the MSSO determines that there is an existing LLT that can represent the concept and should be on the PT level. In this situation, the MSSO rejects the original request to add the new PT, but performs an associate change to promote the LLT to the PT level.

Web Posting. The MSSO posts implemented requests weekly on the MSSO Web site as supplemental or interim changes that are later incorporated into the official MedDRA versioned release. The WebCR database is updated with all considered requests and their outcomes. MedDRA users are encouraged to use WebCR or the MSSO Web site to review these changes before submitting new requests.

3.1 CHANGE REQUEST TRACKING

The MSSO uses two numbers to track change requests.

- **Batch number:** used to identify a group of changes requests submitted at one time by a single submitter, and it also identifies the request category (e.g., MedDRA change, translation correction). **Change Request (CR) number:** a ten-digit number that uniquely identifies each request.

Receipt and final notifications include the batch and CR numbers (see section 3 for Receipt Notification and Final Disposition Report information). Submitters can use the batch number or CR number to search WebCR via the change request history feature to view the status of submitted change requests. Alternatively, one may contact the MSSO Help Desk (MSSOHelp@ngc.com or 1-877-258-8280).

3.2 CHANGE REQUEST TURNAROUND TIMES

The turnaround time to receive a decision (Final Disposition Report) for submitted changes depends on the change request category.

Submitters receive a Final Disposition Report within 10 working days for MedDRA changes. The exception is for requests received immediately after the cutoff dates to consider requests for the next release (1 June and 1 December). In these cases, such requests are reviewed by the MSSO the month after the cutoff date.

For SMQ and Translation corrections, there is no specific turnaround time due to the nature of these requests. The MSSO tries to provide a resolution to these requests as soon as possible.

4. SUBMISSION REQUIREMENTS, TIPS AND SUGGESTIONS

The following is a set of requirements, tips and suggestions for submitting change requests to the MSSO.

- **Adequate justifications for EACH request must be present** – The MSSO requires that an adequate justification accompany each change request in order to be evaluated by the MSSO medical staff. Adequate justification means including a statement indicating why the change request is necessary. Examples of adequate justification may include statements which explain that a concept is needed because it is included in a spontaneous report, the concept is listed on a label, is being reported in a clinical trial, or another reason that explains why a change is needed.

Justification statements may be accompanied by relevant definitions and other illustrative medical or scientific information, but such information by itself is not adequate justification, or are statements that say a term is not in MedDRA without explaining the need.

When the MSSO receives a change request without adequate justification, the request is suspended. The MSSO contacts the submitter and requests justification for the submitted change request. If the MSSO does not receive feedback from the submitter within 30 days of the request for justification, the change is rejected.

- **DO NOT SUBMIT entries in capital letters** – Terms should only have the first letter of the first word capitalized unless the word is an acronym.
- **Review your notifications** – The Receipt Notification should be reviewed immediately by the submitter to make sure all requests have been captured correctly. The Final Disposition Report should be reviewed for outcomes and an email verifying receipt sent back to the MSSO.
- **Carbon Copy (CC) members of your organization** – The MSSO includes all email addresses entered by the submitter in the WebCR requester profile or included in the email request when submitting the form. Please make sure to cc those members whom you would like to be included when using the form or update the WebCR requester profile with additional email addresses.
- **Change requests via telephone** – No change requests are accepted verbally by phone.
- **MedDRA term history on the web** – Prior to submitting your requests, you may use the Term/Change Request History search feature in WebCR to determine if other terms can serve your organization's needs, or determine if the same term or change has recently been considered and acted upon by the MSSO. Alternatively, submitters may review supplement files on the MSSO Web site and check the cumulative Detail Report to identify if your term has been previously requested. These reports are located under the [Download section](#) of the MSSO Web site under "Supplemental Changes".
- **Forms must be received as an attachment in Excel Format ONLY** – If submitting requests using the form, do not save as a -.pdf, -.pcf; or -.tif. **Files must be editable** in order to copy them and reduce data entry errors.
- **One line item is one action/request** – When using the change request form, requests should take up one line item for their action. In other words, be specific in your requests. If you are interested in the MSSO reviewing multiple related terms with a common action, please email this detail separately to MSSORequest@mssotools.com, and arrangements will be made with the Terminology Maintenance Manager.
- **Ask us a question!** – For questions related to submitting change requests, please email MSSORequest@mssotools.com; for all other questions related to MedDRA, please email MSSOHelp@ngc.com.

APPENDIX A. MEDDRA REQUEST ACTIONS

This section contains information on the types of MedDRA Request Actions. The actions are divided into two groups: simple changes and complex changes. Users can request these actions using WebCR or the Change Request Form.

Please see the latest version of the MedDRA Introductory Guide for information on MedDRA's structural elements, hierarchy, rules and conventions, and specific information on each System Organ Class (SOC).

Simple Changes	
Action	Description
Add a New LLT	Add a synonym or variant to an existing or requested Preferred Term (PT) at the Lowest Level Term (LLT) level of the terminology. You may optionally request the proposed LLT to be added to a specific PT in the field provided in WebCR or the Proposed Placement field in the form.
Add a New PT	Add a new medical concept at the Preferred Term (PT) level of the terminology. You may optionally specify a PT be linked to a primary and (if applicable) a secondary HLT within different System Organ Classes (SOC) or you may leave placement up to the MSSO. To indicate specific placement information, please enter in the fields provided in WebCR or the Proposed Placement field in the form. If you wish to add another secondary link, add a separate change request and use the action "Link PT to HLT." The submitter does not need to request to add the same LLT and PT term. If the corresponding PT is accepted the LLT term is automatically added.
Add a New Term	Add a new term to any level of the terminology. Use this action when you are unsure as to what level to request a new term. If approved, the MSSO determines the placement.
Change Status of LLT	Change status of Lowest Level Term (LLT) from current to non-current, or from non-current to current. When using this command in WebCR, the application automatically identifies the term status (current or non-current) and selects the opposite state. When using the form, please indicate the status change (current or non-current).
Demote a PT	Demote a Preferred Term (PT) to the Lowest Level Term (LLT) level of the hierarchy under an existing or requested PT. The MedDRA 8-digit code is retained and the term appears only as an LLT under the designated PT. All LLTs that

Simple Changes	
Action	Description
	resided under the demoted PT will now reside under the designated PT.
Link a PT to HLT	Link a PT to an HLT outside of the PT's current Primary SOC. WebCR requires you to specify the HLT to link. When using the change request form please indicate which HLT to link the PT to in the Proposed Placement field. Note: If trying to move a PT within one single SOC or between different secondary SOCs, please reference the "Move a PT" action. If the move results in primary SOC change, the MSSO must first link the PT to the new HLT, reassign the primary SOC from the old SOC to the new SOC, and then unlink from the old HLT.
Move an LLT	Move a currently existing Lowest Level Term (LLT) from its current Preferred Term (PT) to another existing or newly requested PT. You must specify the PT you wish the LLT to be moved to. The submitter does not need to request LLT moves if its identical PT is requesting to be moved, nor do you need to request LLTs be moved that are subordinate to a PT when the PT is being moved, unless you wish to place the LLT under a different PT.
Move a PT	Move a currently existing Preferred Term (PT) from one existing High Level Term (HLT) to another existing or proposed High Level Term (HLT). This action is best used when moving a PT between HLTs in the same SOC or secondary HLTs of different SOCs. For PT moves from one SOC to another that result in a primary SOC change, please reference the link/unlink PT actions.
Promote an LLT	Promote an existing Lowest Level Term (LLT) to the Preferred Term (PT) level of the hierarchy. You may optionally specify the promoted term be linked to a primary and (if applicable) a secondary HLT (in different SOCs) or you may leave placement up to the MSSO.
Reassign Primary SOC	Reassign Primary System Organ Class of a PT. Only PTs can have this action associated with them. In WebCR add the PT you wish to reassign and the SOC you wish to reassign it to. For the form, please use the Term field to specify the PT and the Justification field to indicate which SOC to reassign as primary for the PT.
Rename PT/LLT	Rename either a Preferred Term (PT) or a Lowest Level Term (LLT). When using the form, please indicate in the justification line the exact term you would like it to be renamed to. Note: Renaming a term is reserved for correcting spelling and grammatical errors only. ICD-9 and other adopted terms

Simple Changes	
Action	Description
	cannot be renamed. If a proposed renaming changes the concept, the request is not approved, and the MSSO will consider whether the proposed term should be added as a new term.
Swap a PT with LLT	Switch the placement of a Preferred Term (PT) and a Lowest Level Term (LLT). The PT is in effect demoted, and the LLT simultaneously promoted to a PT. The LLT specified to be swapped must be linked to the specified PT. This action can be substituted for two separate requests to: 1) demote a PT then 2) promote LLT. If using the form, please enter the PT name in Term field and in the justification field indicate which LLT it is to be swapped with.
Unlink a PT	Unlink a PT from an HLT outside of the PT's Primary SOC. WebCR allows you to select from currently linked HLTs. If using the form, please indicate in the justification field which HLT to unlink the PT from as the PT may be linked to more than one HLT.

Requests requiring changes or additions to the High Level Term (HLT), High Level Group Term (HLGT), and System Organ Class (SOC) levels of the terminology are called complex change requests. All complex change requests received are placed on suspension until the review of complex changes timeframe (usually May – August) in preparation for the complex release on 1 March. Proposed changes are reviewed and posted on the MSSO Web site where MedDRA users can review the proposed changes. Users also have the opportunity to comment on proposed complex changes prior to implementation. The MSSO reviews all comments received before implementing complex changes.

Complex Changes	
Action	Description
Add a new HLT	Add a new High Level Term (HLT) to the terminology. If you want the term to be added to a specific High Level Grouping Term (HLGT), please list it in the field provided in WebCR or the Proposed Placement field in the form.
Add a new HLGT	Add a new High Level Group Term (HLGT) to the terminology. If you want the term to be added to a specific System Organ Class (SOC), please list it in the field provided in WebCR or the Proposed Placement field in the form.
Add a new SOC	Add a new System Organ Class (SOC) to the terminology. Due to the implication and impact of this action, much consideration, Management Board approval, and overwhelming MedDRA user community support is needed to approve. Include the proposed name of the SOC as well as the robust justification for adding it to the terminology.
Link an HLT to HLGT	Link a High Level Term (HLT) to an existing or proposed High Level Group Term (HLGT). WebCR requires you to specify which HLGT to link to. When using the change request form please indicate which HLGT to link the HLT to in the Proposed Placement field.
Link an HLGT to SOC	Link a High Level Grouping Term (HLGT) to an existing or proposed System Organ Class (SOC). WebCR requires you to specify which SOC to link to. When using the change request form please indicate which SOC to link the HLGT to in the Proposed Placement field.
Merge HLT	Subsume a current High Level Term (HLT) under another existing or proposed HLT. All PTs are moved under the surviving HLT. If using the form, indicate in the term field which HLT should be subordinated. Note: The MedDRA 8-digit code and the merged HLT are lost in this action. The MSSO retains the MedDRA 8-digit code and term name to ensure this information is not reused.
Merge HLGT	Subsume one current High Level Group Term (HLGT) under another existing or proposed HLGT. All HLTs are moved under the surviving

Complex Changes	
Action	Description
	HLGT. If using the form, indicate in the term field which HLGT should be subordinated. Note: The MedDRA 8-digit code and the merged HLGT are lost in this action. The MSSO retains the MedDRA 8-digit code and term name to ensure this information is not reused.
Move HLT to HLGT	Move a currently existing High Level Term (HLT) from one existing High Level Grouping Term (HLGT) to another existing or proposed HLGT. This action is best used when moving a HLT between HLGTs in the same SOC. For HLT moves from one SOC to another, please reference the link and unlink HLT action below.
Rename HLT	Change the name of an existing High Level Term (HLT). When using the form, please indicate in the justification line the exact term you would like it to be renamed to. Note: Renaming a term is reserved for correcting spelling and grammatical errors only. If a proposed renaming changes the concept, the request is not approved, and the MSSO will consider whether the proposed term should be added as a new term.
Rename HLGT	Change the name of an existing High Level Grouping Term (HLGT). When using the form, please indicate in the justification line the exact term you would like it to be renamed to. Note: Renaming a term is reserved for correcting spelling and grammatical errors only. If a proposed renaming changes the concept, the request is not approved, and the MSSO will consider whether the proposed term should be added as a new term.
Rename SOC	Change the name of an existing System Organ Class (SOC). When using the form, please indicate in the justification line the exact term you would like it to be renamed to. Note: Renaming a term is reserved for correcting spelling and grammatical errors only. If a proposed renaming changes the concept, the request is not approved, and the MSSO will consider whether the proposed term should be added as a new term.
Unlink an HLT from HLGT	Remove a link of a High Level Term (HLT) from a High Level Group Term (HLGT). If using the form, indicate which HLT you would like unlinked in the Term field. In the Placement Consideration field indicate which HLGT you would like to unlink the HLT from. WebCR provides specific fields to specify this information.
Unlink an HLGT from SOC	Remove a link to a High Level Grouping Term (HLGT) from a System Organ Class (SOC). If using the form, indicate which HLGT you would like unlinked in the Term field. In the Placement Consideration field indicate which SOC you would like to unlink the HLGT from. WebCR provides specific fields to specify this information.

APPENDIX B. SMQ CHANGE REQUESTS

This section discusses the Standardised MedDRA Query (SMQ) change request actions that one may submit to the MSSO for consideration. There are a few points to consider:

- The SMQs are maintained with each release of MedDRA.
- To add a proposed term (i.e., term not in MedDRA) to an existing SMQ, a submitter first must submit a MedDRA change request, then request an SMQ change.
- Generally, the MSSO does not re-test SMQs based on version-related changes in MedDRA. If the MSSO believes there is a significant change that may impact the search results of an SMQ, the MSSO may consult with the CIOMS SMQ Working Group concerning re-testing.
- Approved SMQ Change Requests are included in the supplemental postings.

SMQ Changes	
Action	Description
Add a New SMQ	<p>Add a new SMQ. Subscribers can propose a new SMQ with or without the detail of the terms included in the SMQ. For each request for a new SMQ, a submitter must include answers to the following questions.</p> <ol style="list-style-type: none"> 1. What is the scientific/pharmacovigilance question that led to the request for this SMQ? 2. Is the current MedDRA hierarchy (e.g., HLTs, PTs) or any existing SMQ suitable to address the question? If not, what are the deficiencies in the hierarchy or existing SMQs that should be addressed? 3. Would your organization be able to address this question without this new SMQ, and if so, how? (That is, what would be the strategy and terms used?) 4. Which SMQ structure (i.e., broad/narrow, hierarchical, algorithm) do you think would best

SMQ Changes	
Action	Description
	<p>address the question?</p> <p>5. How often would your organization need this SMQ (e.g., only once to address a very specific emerging issue or regularly/routinely)?</p>
Add Term to SMQ	Add a PT to an existing SMQ. Please specify the term name and the SMQ it should be added to with justification.
Change Status of an SMQ	This action requests to make an existing active SMQ inactive or an existing inactive SMQ active. Please indicate the SMQ name and which status to change it to: "active" or "inactive."
Change Term Status in an SMQ	This action requests to change the status of a PT in an existing SMQ to either active or to inactive. Please indicate the PT name, the SMQ it is under and, which status to change it to: "active" or "inactive." If using the form please indicate the status in the Justification field.
Merge SMQ	This action is a request to subsume an existing SMQ under an existing or newly requested SMQ. All PTs in the merged SMQ are moved under the remaining SMQ. Please enter the SMQ name you wish to merge (demote) and enter the SMQ you wish to remain. Note: The MedDRA 8-digit code and the merged SMQ are lost in this action. The MSSO retains the MedDRA 8-digit code and SMQ name to ensure this information is not reused.
Move a PT to another SMQ	This action moves an existing Preferred Term (PT) from an existing SMQ to an existing or newly requested SMQ. Please include the existing PT name you wish to move and the SMQ you wish to move it to.
Move an SMQ	This action moves an existing SMQ under an existing or newly requested SMQ. This action assumes that you are moving a sub-search SMQ (i.e., not level 1 SMQ).
Rename an SMQ	This is a request to modify the name of an SMQ. Please include which SMQ you wish to rename and the proposed new name of the SMQ.
Update MedDRA Term Category	This is a request to change the category field associated with a Preferred Term (PT) in an existing SMQ. Please see the latest version of the SMQ Introductory Guide for

SMQ Changes	
Action	Description
	<p>an explanation of term category. Include the existing PT name you wish to change the category of, the SMQ name under which the PT resides, and the proposed term category letter.</p>
Update MedDRA Term Scope	<p>This action is a request to change the scope associated with a Preferred Term (PT) in an existing SMQ from broad scope to narrow scope or from narrow to broad scope.</p> <p>Please see the latest version of the SMQ Introductory Guide for an explanation of scope and specific information on the scope parameters (broad/narrow) of a specific SMQ.</p> <p>Include the existing PT name you wish to change the scope of, the SMQ name under which the PT resides, and which scope setting - either "Narrow" or "Broad."</p>
Update MedDRA Term Weight	<p>This action is a request to change the weight field associated with a Preferred Term (PT) in an existing SMQ.</p> <p>Please see the latest version of the SMQ Introductory Guide for an explanation of term weight.</p> <p>Enter the existing PT name you wish to change the weight of, the SMQ name under which the PT resides, and the term weight number.</p>
Update SMQ Algorithm Flag	<p>This action is a request to change the algorithm field associated with an existing SMQ.</p> <p>For detailed information, see the "Algorithm" section under a particular algorithmic SMQ in the latest version of the SMQ Introductory Guide.</p> <p>Include the existing SMQ name you wish to change the algorithm of and the Boolean expression of the algorithm.</p>

SMQ Changes	
Action	Description
Update SMQ Description	<p>This action is a request to change the description information of an SMQ. The description information addressed here is the description included in the distributed extended ASCII text not the description included in the SMQ Introductory Guide.</p> <p>Please submit the entire text including the changes you wish to make to the SMQ description. Alternatively submit an attachment with the desired text.</p>
Update SMQ Source	<p>This action is a request to change the information in the source field of an SMQ. The source addressed here is the source information included in the distributed extended ASCII text not the source information (references) of an SMQ included in the SMQ Introductory Guide.</p> <p>Please submit the entire text including the changes you wish to make to the SMQ source field. Alternatively submit an attachment with the desired text.</p>
Update SMQ Note	<p>This action is a request to change the note associated with an SMQ. The note information addressed here is the wording of the note field in the distributed ASCII text.</p> <p>Please submit the entire text including the changes you wish to make to the SMQ note field. Alternatively submit an attachment with the desired text.</p>

APPENDIX C. TRANSLATION CORRECTION REQUESTS

Translation corrections allow MedDRA users to request corrections to a term translated from the English language to one of the other languages currently supported by the MSSO. A user may wish to do this to correct a misspelled term or offer an improved translation to an existing translated term. Translation corrections do not count against the monthly 100 change request limit.

Translation Correction	
Action	Description
Rename Translated Term	<p>Rename a term translated from English into a supported language. The following information is required for each request whether using WebCR or the Translation Correction form.</p> <ol style="list-style-type: none"> 1. English term name of the term you wish to modify 2. The MedDRA 8-digit code of the term (WebCR will auto populate) 3. The language 4. The current translation of the term 5. The term name you would like to replace it with. <p>Note: For questions about the Japanese translation, please contact the Japanese Maintenance Organization.</p>