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# Change Request Information

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## **Acknowledgements**

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## **1. CHANGE REQUEST INFORMATION**

### **1.1 PURPOSE**

This document serves to assist subscribers in understanding 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 (CR) reports.

## **2. MedDRA CHANGE REQUESTS**

Change requests allow MedDRA subscribers the opportunity to modify the MedDRA terminology. This section describes the types of changes a subscriber may request, the process for submitting change requests, and an explanation of the MSSO change request process.

### **2.1 WHO MAY SUBMIT A CHANGE REQUEST**

Core Subscribers and Regulators are organizations that can submit MedDRA 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 change requests (CRs) from your organization to the MedDRA MSSO.

In this document both subscriber POC and requesters will be referred to as the "subscriber."

Anyone authorized to submit change requests must use the current valid Subscriber 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 GENERAL GUIDELINES**

This section contains general guidelines to familiarize the user regarding the MedDRA terminology structure and scope. Additional information can be found in the MedDRA Introductory Guide as well as the Introductory Guide for Standardised MedDRA Queries (SMQs) included with your subscription materials or found on the MSSO Web site

([http://www.meddramsso.com/translations/Downloads\\_English.htm](http://www.meddramsso.com/translations/Downloads_English.htm); select Complete Download).

#### **2.2.1 Scope of MedDRA Terminology**

The following medical 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.

### **2.2.2 Terminology Conventions**

The following structural conventions apply to all simple change request types:

- All terms at the PT level and above in the MedDRA terminology are in British English spelling. Lowest Level Terms (LLTs) are in British and American English. An example of a PT is the term *Oedema* while the LLT is *Edema*.
- In general, abbreviations are excluded from levels above the LLT. Abbreviated letters are not punctuated by periods. Abbreviations that are not internationally accepted for a single word or phrase will not be included.
- Capitals are only used in the initial letter of each MedDRA term. Some exceptions are proper names, components of microorganism taxonomic names, and abbreviations.
- Each PT represents a single medical concept, but the concept may be expressed in one or more words.
- Eponymous terms will not be added except when internationally recognized.

### **2.2.3 Processing Conventions**

- Approval or disapproval of change requests will be 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 consistency internationally.

- Changes at the PT and levels are referred to as simple changes. Simple changes are implemented for the fall and spring release.
- Changes that, in the judgment of the MSSO, require changes to the existing hierarchy above the PT level to ensure consistency, medical accuracy, and completeness, are considered complex changes. These changes will be submitted as complex change requests, but only processed for the annual spring release.

Some change request types will be accompanied by additional changes to the terminology at levels below the High Level Term. For example, when promoting an LLT to a PT, existing LLTs may be moved under the newly promoted LLT. The subscriber need not specify these changes in detail. Related changes (called Associate Changes) will be made that are deemed by the MSSO to be required to ensure the consistency, medical accuracy, and quality of MedDRA. In addition, when a PT term is added to MedDRA an LLT term is automatically added due to MedDRA rules. As a result the subscriber does not need to request both the PT and LLT terms be added. Doing so will generate a technical rejection of the LLT request.

## **2.3 HOW TO SUBMIT A CHANGE REQUEST**

There are two methods to submit terminology change requests and one method to submit SMQ change requests. For terminology change requests, submitters may use the web application WebCR or the Subscriber Change Request Form. All SMQ change requests must be submitted using the SMQ Change Request Form.

### **2.3.1 WebCR**

The preferred method of submitting a terminology change request is via WebCR located at: <https://mssotools.com/webcr>. In WebCR, subscribers select from among a list of actions, described later, to request terminology changes. Multiple change requests may be submitted at the same time with a limit of 100 change requests per month. In addition to submitting change requests, WebCR gives subscribers the ability to:

- review the history of a term
- verify a term in MedDRA
- resubmit a term for reconsideration
- track the progress of submissions
- hold change requests or submit it when ready.

To login to WebCR subscribers 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. This 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 staged change requests or use other WebCR features.

For information on using WebCR, please see the WebCR Quick Reference guide at: [http://meddramssso.com/MSSOWeb/mssosubs/coresubs/changereq\\_info.htm](http://meddramssso.com/MSSOWeb/mssosubs/coresubs/changereq_info.htm)

### **2.3.2 Subscriber Change Request Form**

Terminology change requests may be submitted to the MSSO by downloading the Change Request Form, filling it out and submitting it via e-mail. See section 2.3.4 for details. The form must contain data in all required data fields in order to be considered by the MSSO. Required subscriber information includes all of the following - Name, Subscriber ID, CR ID, Date of request, Phone number, and Email contacts.

The columns on the MedDRA change request form are:

- Number (please ensure it remains in sequential order)
- Action (which has a drop down list for the subscriber to choose which category the term requested should fit into)
- Proposed Term
- Justification

In addition, each cell with a red triangle has an explanation as to 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."

### **2.3.3 SMQ Change Request Form**

For SMQ change requests, subscribers must download the SMQ Change Request Form, fill it out and submit it via e-mail. See section 2.3.4 for details. Currently WebCR does not support SMQ change requests. The form must contain data in all required data fields in order to be considered by the MSSO. Required subscriber information includes all of the following - Name, Subscriber ID, CR ID, Date of request, Phone number, and Email contacts.

The columns on the SMQ change request form are:

- Number (please ensure it remains in sequential order)
- Action (which has a drop down list for the subscriber to choose which action item the term requested relates to)
- Proposed Term

- SMQ (choose from a drop down list)
- Justification / explanation.

In addition, each cell with a red triangle has an explanation as to 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."

### 2.3.4 MSSO Change Request Information

Change requests may be submitted via:

Change Request Method	Location	How to submit
Web*	<a href="https://mssotools.com/webcr">https://mssotools.com/webcr</a>	Submit within the application.
Change Request Form	Download at: <a href="http://meddramssso.com/MSSOWeb/mssosubs/coresubs/changereq_info.htm">http://meddramssso.com/MSSOWeb/mssosubs/coresubs/changereq_info.htm</a>	E-mail to: <a href="mailto:mssorequest@ngc.com">mssorequest@ngc.com</a>
SMQ Change Request From*	Download at: <a href="http://meddramssso.com/MSSOWeb/mssosubs/coresubs/changereq_info.htm">http://meddramssso.com/MSSOWeb/mssosubs/coresubs/changereq_info.htm</a>	E-mail to: <a href="mailto:mssorequest@ngc.com">mssorequest@ngc.com</a>

**Table 2-1. MSSO Change Request Information Summary**

\* Note: All SMQ change requests must use the SMQ Change Request form.

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

### 2.3.5 Change Request Form Sheet Elements

This section provides guidelines for filling out the MedDRA change request form (simple / complex) [Reference section 5. of this document for SMQ change request form guidelines], and describes the data to be submitted on the form. All data for the required elements on the change request form must be completed for the change to be accepted for review. The change request form is in Microsoft® (MS) Excel® format and must remain in that format. Change Request forms can be downloaded from the MSSO Web site. Should a subscriber not have web access, please call the MSSO Help Desk at 1-877-258-8280 (USA).

The following data fields appear at the top of each change request form. They are required to be filled out prior to submitting requests to the MSSO.

The Subscriber ID and Change Request ID must be valid for the change request to be processed. If a subscription is expired, the change requests will not be processed and the submitter will be notified immediately. Subscribers that opt to submit terminology change requests via WebCR will not need to provide the information listed below except for the Subscriber ID and CR ID which are used to login to the application.

<b>Data Field</b>	<b>Description</b>	<b>Required/Optional</b>
<b>Subscriber ID</b>	The Subscriber ID is equivalent to your company's User Name and/or your company's MedDRA license number.	Required
<b>Password</b>	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 renewal and/or with every change to your company's primary subscription point of contact.	Required
<b>Change Request ID</b>	This is a unique eight-character subscriber CRID. This identifier, when paired with the Password, will uniquely identify 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
<b>Requester Name</b>	The name of the person who is submitting the request. The MSSO will contact this person as primary if clarifications on the requests need to be made.	Required
<b>Requester Phone</b>	The telephone number is used to contact the requester in the event that the MSSO has a question or clarification is required about a submitted request. If it is not provided, the subscription point of contact will be called.	Optional
<b>Fax</b>	The facsimile number of the requester.	Optional
<b>Email Address</b>	List email address(es) of all parties you wish copied on all correspondences related to these request(s). Additionally, please separate each address within a “;” followed by a space before entering the next address.	Required
<b>Date of Request</b>	The date this form is submitted via email to the MSSO.	Required

**Table 2-2. Change Request Form Sheet Elements**

### 2.3.6 Simple Change Request Actions

This section contains information on the types of simple changes subscribers can request using WebCR or the Change Request Form.

Action	Description	Notes
<b>Add a New PT</b>	Add a new medical concept at the Preferred Term (PT) level of the terminology. If you want the term to be added to a specific High Level Term (HLT), please list it in the Proposed Placement (Optional) field for consideration. You may specify a PT be linked to 1 or more HLTs (within different System Organ Classes (SOC)) or you may leave placement up to the MSSO. The submitter does not need to request to add the same LLT and PT term. If the corresponding PT is accepted the LLT term will automatically be added).	See Intro Guide for criteria
<b>Add a New LLT</b>	Add a synonym or variant to an existing or requested Preferred Term (PT) at the Lowest Level Term (LLT) level of the terminology.	See Intro Guide for criteria
<b>Add a New Term</b>	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.	
<b>Move a PT</b>	Move a currently existing Preferred Term (PT) from one existing High Level Term (HLT) to another existing 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 primary SOC change, please reference the link/unlink PT action below.	WebCR will alert you if the term is no longer a PT prior to submitting. If submitting the form, check the supplemental files (see section 2.3.9) to see if the term is still a PT.
<b>Move an LLT</b>	Move a currently existing Lowest Level Term (LLT) from its current Preferred Term (PT) to another existing or newly requested PT. Submitter does not need to request LLT	Most likely there are associate changes in

## MedDRA Change Requests

Action	Description	Notes
	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 have a specific preference (The MSSO examines all LLTs under the PT in this situation).	relation to this action
<b>Promote an LLT</b>	Promote an existing Lowest Level Term (LLT) to the Preferred Term (PT) level of the hierarchy. You may specify the promoted term be linked to 1 or more HLTs (within different SOCs) or you may leave placement up to the MSSO.	
<b>Demote a PT</b>	Demote a Preferred Term (PT) to the Lowest Level Term (LLT) level of the hierarchy under an existing or requested PT. This action can be considered the same as “merging” a PT. The MedDRA code is retained and the term will appear only as an LLT under the designed PT.	WebCR will alert you if the term is no longer a PT prior to submitting. If submitting the form, check the supplemental files (see section 2.3.9) to see if the term is still a PT.
<b>Swap a PT with LLT</b>	Swap the placement of a Preferred Term (PT) and a Lowest Level Term (LLT). The PT is in effect demoted, and the LLT simultaneously promoted. This action prevents the subscriber from submitting two requests of 1) demote PT then 2) promote LLT and instead does it in one step. Please indicate the Term as the PT term and in the justification field indicate which LLT it is to be swapped with.	Check WebCR or the supplemental files (see section 2.3.9) to see if LLT is still under the PT prior to submitting.
<b>Change Status of LLT</b>	Change status of Lowest Level Term (LLT) from current to non-current, or from non-current to current. Remember: If a term is made non-current, its placement is still maintained in the terminology.	Terms frequently misspelled on the web or in practice are sometimes not made non-current

Action	Description	Notes
		due to frequent use.
<b>Link/Unlink a PT</b>	Link/Unlink a Preferred Term from an HLT outside of the PT's Primary SOC. Justification line should indicate which HLT to unlink it from / link it to as the PT may be linked to more than one HLT. Note: If trying to move a PT within one single SOC or between different secondary SOCs, please reference the "Move a PT" action in the above table.	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.
<b>Reassign SOC</b>	Reassign Primary System Organ Class. Only PTs can have this action associated with them. Please use the Term field to specify the PT and the Justification field to indicate which SOC to reassign as primary for the PT.	This cannot be done at the LLT level.
<b>Rename PT / LLT</b>	Rename Preferred Term (PT) / Lowest Level Term (LLT) and in the justification line indicate the exact term you would like it to be renamed to. Note: This action is reserved for correcting spelling and grammatical errors. ICD-9 and other adopted terms cannot be renamed. If renaming changes the concept the request will not be approved.	You may choose to rename either a PT or an LLT.

**Table 2-3. Simple Change Request Actions**

### 2.3.7 Change Request Requirements, Tips, and Suggestions

**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, it 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. Nor are statements that say a term is not in MedDRA without explaining the need.

In instances where the MSSO receives a change request without adequate justification, the request will be put on hold. The MSSO will contact the subscriber and request justification for the submitted change requests. If the MSSO does not receive feedback from the subscriber within 30 days of the request for justification, the change will be rejected.

**Submitting Terminology and SMQ requests** - If a subscriber wants to submit both SMQ and terminology change request simultaneously, subscribers may submit the terminology change request via WebCR and the SMQ request using the SMQ change request form. Alternatively, subscribers may submit both types of requests using the respective SMQ and terminology change request forms which may be submitted as attachments to a single email.

**Form must be received as an attachment in ONLY Excel Format** – 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.

**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. Terms received in all capitals are not compatible with the MSSO system and have to be manually entered when received.

**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@ngc.com](mailto:MSSORequest@ngc.com) and arrangements will be made with the Terminology Maintenance Manager. Requests that involve reviewing multiple related terms with a common action will not be held to the timelines and/or guidelines of change requests.

**MedDRA term history on the web** - Prior to submitting your requests you may use the Term/History search feature in WebCR to determine if other terms can serve your organization's needs, to determine if the same term or change has recently been considered by the MSSO or has been rejected. Alternatively, subscribers 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 under supplemental changes.

**Review your notifications** – The Receipt Notification should be reviewed upon receipt by the submitter to make sure the MSSO has captured all of the requests

correctly. The Final Notification should be reviewed for outcomes and an email verifying receipt sent back to the MSSO. See section 2.3.9 and 2.3.10.

**CC members of your organization** – The MSSO includes all email addresses entered by the subscriber in the WebCR requester profile or that are 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 e-mail addresses.

**Change requests via telephone** - No change requests will be accepted verbally by phone.

**Ask us a question!** – For terminology specific questions related to submitting change requests, please email [MSSORequest@ngc.com](mailto:MSSORequest@ngc.com); for all other questions related to MedDRA, please email [MSSOHelp@ngc.com](mailto:MSSOHelp@ngc.com).

### 2.3.8 Change Request Tracking

Each change request will have an assigned batch number and a unique ten-digit change request number that can be used to track the status of the change request. Receipt and final notifications will include the batch and change request numbers (see section 2.3.9 and 2.3.10 for Receipt and Final Notification information). Using the batch number or change request number, the WebCR CR history feature will show the status of submitted change requests.

Alternatively, subscribers may contact the MSSO Help Desk (<http://www.MSSOHelp@ngc.com> or 1-877-258-8280).

Receipt Notification will be sent to the requester within 24-48 hours of the MSSO receipt of the request. This notification states the date and time the change request was received, the action requested, and the request tracking numbers.

Final Notification will be sent upon completion of the review (within 10 working days), and will indicate the disposition of each change request. All requests will include the MSSO rationale for all actions. For tracking purposes, we request that you acknowledge receipt of each Final Notification received by replying to the e-mail.

### 2.3.9 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 an appropriate change. The request must be unambiguous, within scope and guidelines for making changes to the terminology, and must be medically valid and internationally acceptable. Change requests that fail to meet any of these criteria will be rejected by the MSSO and notification will be sent to the requester. Requests may be disapproved during any phase of the process where this criterion is not met.

- Change requests undergo an initial series of checks to ensure the validity and completeness of the request. Subscriber name, Subscriber ID number, and subscriber CR ID will be validated by the MSSO.
- Requests are checked against existing terminology for duplicates, related change requests, and previously rejected change requests.
- Requests are dated and time stamped as they arrive at the MSSO. Receipt Notifications are sent to the subscriber.
- When submitting change requests using the form, they will be checked to ensure all required fields are complete. Incomplete/invalid requests will be disapproved and notification will be sent describing the rationale for the rejection.
- Change requests are then processed as follows:
  - An initial medical assessment is made to ensure the request is unambiguous and within the scope of MedDRA.
  - The request is checked to ensure it complies with MedDRA change request guidelines.
  - The MSSO will define the terms involved with the request and review and recommend term placement. Requests are then prepared for international medical review.
  - MSSO reviewers then conduct an international medical review to ensure the request is medically valid. The international reviewers are in Germany, Spain, Japan (representatives of the Japanese Maintenance Organization), and the United States.
  - After the international review, a series of quality control measures are executed and, when successfully completed, the change request result is loaded into the supplemental database.

The MSSO updates WebCR and posts a list of the supplemental terms on the MSSO Web site on a weekly basis. Subscribers are encouraged to use WebCR or review these changes on the MSSO Web site before submitting new requests.

The MSSO is required with each change request submission to send subscribers an initial Receipt Notification via e-mail within 48 hours after their changes have been received and logged into our system. The following figure displays the receipt notification subscribers will receive.

**Notification of Receipt or Administrative Action**

**A** User ID #: 10466

<b>B</b> CR Number	<b>C</b> CR Action	<b>D</b> Term	<b>E</b> 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 2-1. Notification of Receipt or Administrative Action**

**Notification of Receipt or Administrative Action:**

- a. User ID #: User ID (same as Subscriber ID)
- b. Assigned Change Request Numbers: Identified for tracking purposes the CR number is identified with each change request.
- c. Requested Action: Requested action by the requester
- d. Term Requested: Term that is requested by the requester
- 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 printed, Batch Number, Version number and number of pages.

**2.3.10 Understanding Your Disposition Reports**

The Final Notification serves to inform the subscriber of the outcomes of each change request submitted. Below is a list of outcomes for change requests; all categories appear in one -.pdf report as the Final Notification to the subscriber. See figure 2-3.

**Approved as Requested** – A Change request is approved as a valid request by the international medical review team which is composed of physicians from the USA, EU, and Japan. For newly added terms, this category also indicates that the change request is approved at the level the subscriber requested.

**Approved not as Requested** – A Change request is approved as a valid request by the international medical review team which is composed of physicians from the USA, EU, and Japan, but the wording of the requested term may have been changed, while the concept remains the same, but may be represented by a broader term; Requested level of term placement may have changed from LLT to PT, or PT to LLT; Requested American spelling terms will be taken with British spelling as the PT with the American spelling at the LLT level; requested LLT mapped to a different PT than the one proposed. The same outcome is also applied to SMQ change requests that are approved but either with attributes different from the one requested, such as scope, category, and weight, or requested terms that are approved for an SMQ that are different from the requested SMQ but within the same SMQ tree.

**Rejected** – A Change request is not approved by the international medical review of USA, EU, and Japan. All changes must be valid in all three ICH regions. Change requests that are not accepted can be contested by resubmitting the requested term(s) with additional justification on the Subscriber Change Request Form.

**NOTE:** Alternate actions in the form of associate changes may be made by the MSSO. These may produce an end result similar or the same as a request that has been rejected, therefore, even if a term appears as rejected in a report it still can appear in MedDRA. For example a request to add a term at both the PT and LLT level. Due to MedDRA rules the LLT is automatically entered when the PT is entered, but the request to add the LLT will be given a technical rejection. The end result is the same. In some cases multiple requests can be implemented more simply than requested. This will be implemented by an associate change or changes while the original requests will be rejected.

**Associate** – Change requests that are a direct result from a subscriber's change request, additional actions, are called associate changes. Associate changes are not charged against a subscriber's monthly change request allotment. They are produced and recorded in the original batch file (starting with the number "3") and are sent to the subscriber as part of the Final Notification. For example, in the original batch file, an LLT Back pain is moved, however, the MSSO determines that based on the expected move, the lexical variant LLT *Pain back* should also be moved. The second move is recorded and processed, not being charged to the subscriber, and included in the subscriber's Final Notification.

**Suspended** – A suspended change request requires additional research or consultation with specific subject matter experts. Any complex change requests, and/or other requests contingent on a particular complex change, will await resolution until the complex change release. A Final Notification of Suspended

terms is also sent upon resolution with indication in the body of the notice about whether the terms in question have ultimately been approved or rejected.

**MSSO Final Disposition Report**

**G** User ID #: 10466

CR Number	CR Action	Term	Disposition	Final Placement	MedDRA #
<b>H</b> 2006338126	<b>I</b> Add a New PT	<b>J</b> Proposed PT Vasogenic oedema	<b>K</b> Approved Not as Requested	<b>L</b> Proposed LLT Vasogenic cerebral oedema To PT Brain oedema	<b>M</b> 10067275 Current 10048962 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	10067278 Current 10048962 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 10048962 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	10067277 Current 10048962 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 microhaemorrhages 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.					
<b>N</b> Monday, October 1, 2007 Batch Number : 10001503 Version 10.0 Page 1 of 2					

Figure 2-2. MSSO Final Disposition Report

**MSSO Final Disposition Report:**

- g. User ID #: User ID (same as Subscriber ID)
- h. CR Number: Assigned change request numbers: Identified for tracking purposes the CR number is identified with each change request. If there is a related change request, as in an associate batch, this number is identified below the CR number.
- i. CR Action: Requested action by the requester
- j. Term: Term that is requested by the requester

- k. Disposition: The disposition of the terms after Consensus. The categories are: Approved as Requested, Approved Not as Requested, Rejected and Suspended.
- l. Final Placement: Action implemented: The action that was actually implemented is identified including the assigned MedDRA Codes; Levels affected by the change and hierarchy links. (For this report, the requested change must always equal the implemented change.)
- m. MedDRA #: the MedDRA code assigned to each term as it is placed in MedDRA.
- 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, and page number.

### 3. SIMPLE CHANGE REQUEST ACTIONS IN DETAIL

All required data elements of the change request form must be provided in order for the simple change request(s) to be accepted for processing. The following sections identify the different types of simple change requests described in the table below, and the data elements associated with each request. The data elements include required elements (those that are needed for processing) and optional elements that may or may not be provided by the subscriber.

#### 3.1 ADD A NEW PT REQUIREMENTS AND GUIDELINES

- The PT must represent a single, internationally accepted medical concept not already found in the terminology.
- Each PT is assigned a Primary System Organ Class (SOC) that determines which SOC the term appears under in cumulative data outputs.

Data Field	Data to Enter	Required/ Optional
Action	In WebCR, select Add Term from the action menu and choose the PT radio button. In the form, choose Add a new PT from the dropdown list.	Required
Proposed Term	The PT proposed for addition to the terminology. Term must not already exist in database.	Required
Placement Consideration	Please also indicate primary/secondary SOCs proposed. If primary/secondary SOCs are not proposed, they will be determined by the MSSO. The requester can propose association of the PT to as many SOCs as are appropriate, but the PT can only be associated with a single HLT in any one SOC.	Optional
Justification	The requester must explain why this term is needed and why an existing MedDRA term does not suffice. Please include references here if applicable.	Required

**Table 3-1. New PT Change Request Elements**

### 3.2 ADD A NEW LLT REQUIREMENTS AND GUIDELINES

The subscriber is requesting addition of a synonym to an existing PT at the LLT level of the terminology:

- An LLT can only be linked to an existing PT or one suggested by the subscriber in a separate change request.
- The LLT may be a synonym of an existing term, as distinct from a new linguistic/lexical variant. Thus, for example, “injection of conjunctiva” might be accepted as a synonym for “bloodshot eye” or “eye looks bloodshot” and “eyes bloodshot appearance” would not be accepted.
- The LLT must differ from existing LLTs in a significant way. LLTs that differ in the following details only will not be accepted: spelling, word order, hyphenation, and plurality. The exception to this rule is the addition of American English spellings.
- An LLT that differs from existing LLTs only in respect of body site or laterality will usually not be added. If there is a particular feature of that condition occurring in a site that renders it unique, it should be added as a PT, not an LLT.
- An LLT that is non-specific or ambiguous will not be added.

Data Field	Data to Enter	Required/ Optional
Action	In WebCR, select Add Term from the action menu and choose the LLT radio button. In the form, choose Add a new LLT from the dropdown list.	Required
Proposed Term	The LLT proposed for addition to the terminology. Term must not already exist in database.	Required
Placement Consideration	The requester may provide information as to which PT they would like to see the new LLT placed under. If the PT is not specified, the MSSO will make this determination.	Optional
Justification	The requester must explain why this term is needed and why an existing MedDRA term does not suffice. Please include references here if applicable.	Required

**Table 3-2. New LLT Change Request Elements**

### 3.3 ADD A NEW TERM REQUIREMENTS AND GUIDELINES

The subscriber is requesting the addition of a new term to MedDRA:

- The new term is suggested by the requester.
- The term must not be vague in concept otherwise it will not be accepted.
- The term must differ from existing MedDRA PTs or LLTs in a significant way.
- Use this command/action when it is not clear at which level the term should be placed (either PT or LLT) or the requester would rather leave placement level up to the MSSO's determination.

Data Field	Data to Enter	Required/Optional
Action	In WebCR, select Add Term from the action menu and choose the Either radio button. In the form, choose Add a new term from the dropdown list.	Required
Proposed Term	The term proposed for addition to the terminology as either an LLT or PT. Term must not already exist in database.	Required
Placement Consideration	The MSSO will make placement determination. The requestor may suggest a number of different placements applicable or desired.	Optional
Justification	The requester must explain why this term is needed and why an existing MedDRA term does not suffice. Please include references here if applicable.	Required

**Table 3-3. New Term Change Request Elements**

### 3.4 MOVE A PT REQUIREMENTS AND GUIDELINES

This will result in the movement of a currently existing PT from one High Level Term (HLT) to another HLT:

- The PT must exist in the current terminology or in the MedDRA supplemental database.
- This command / action can be used under two circumstances: (1) the subscriber wants to move a PT from one HLT to another HLT within the same SOC, or (2) the subscriber wants to move a PT from an HLT in a secondary SOC to another HLT in another secondary SOC. If the move is from an HLT in the primary SOC, the link / unlink PT action is a better option.

When a PT is moved, the MSSO will migrate subordinate LLTs as appropriate and separate requests to move them are not needed.

Data Field	Data to Enter	Required/ Optional
Action	In WebCR, select Move PT from the Action menu. In the form, choose Move PT from the dropdown list.	Required
Proposed Term	Indicate the PT proposed by the requester for movement from one HLT to another HLT within a single SOC. PT term must already exist in database. Request is not meant for moves between two different SOCs. In this case, see action for Link / Unlink PT.	Required
Placement Consideration	WebCR automatically fills in the primary HLT of PT being requested, but the requestor must indicate which HLT the PT should be moved to. In the form, the requester must provide information as to which HLT the PT is being requested to be moved from and to. The HLT terms must already exist in the terminology.	Required
Justification	The requester must explain why this change is needed. Please include references here if applicable.	Required

**Table 3-4. Move a PT Change Request Elements**

### 3.5 MOVE AN LLT REQUIREMENTS AND GUIDELINES

Requests the movement of a currently existing LLT from one existing PT to another:

- The LLT must exist in the current terminology or in the MedDRA supplemental terms.
- An LLT can only be linked to one PT.
- The “From” and “To” PTs must exist in the current terminology or the MedDRA supplemental database, or may be proposed by the requester.
- If subscriber is requesting to move a PT, they do not need to also request to move the identical LLT (MSSO will automatically process that if the PT is approved to be moved).

Data Field	Data to Enter	Required/ Optional
Action	In WebCR, select Move LLT from the Action Menu. In the form, choose Move an LLT from the dropdown list.	Required
Proposed Term	Indicate the LLT proposed by the requester for movement from one PT to another PT. Both “from” and “to” PT terms must already exist in database or be a related request by subscriber.	Required
Placement Consideration	WebCR automatically fills in the PT of LLT being requested, but the requestor must indicate which PT the LLT should be moved to. In the form, the requester must provide information as to which PT the LLT is being requested to be moved from and to.	Required
Justification	The requester must explain why this change is needed. Please include references here if applicable.	Required

**Table 3-5. Move an LLT Change Request Elements**

### 3.6 PROMOTE AN LLT - TO PT STATUS REQUIREMENTS AND GUIDELINES

The subscriber is requesting that an LLT be promoted to the PT level of the terminology:

- When an LLT is promoted to PT, it must adhere to all the guidelines for adding a PT.
- The LLT must exist in the current terminology or the MedDRA supplemental database.
- The MSSO will migrate LLTs as appropriate.

The requester may specify one or more HLTs for the newly promoted LLT (now a PT if approved) to link to in multiple SOCs or leave placement up to the MSSO's discretion.

Data Field	Data to Enter	Required/Optional
Action	In WebCR choose Promote an LLT from the Action Menu. In the form, choose Promote an LLT from the dropdown list.	Required
Proposed Term	Indicate the currently existing LLT to be promoted to the PT level.	Required
Placement Consideration	WebCR automatically fills in the PT of LLT being requested for promotion. The requester may or may not provide HLT linking information for the newly promoted LLT (now a PT if accepted). However, the requestor should provide information on a specific placement if the requestor wishes to place the newly promoted PT in a different HLT than the PT from which it was promoted.	Optional
Justification	The requester must explain why this change is needed. Please include references here if applicable.	Required

**Table 3-6. Promote an LLT – To PT Status Change Request Elements**

### 3.7 DEMOTE A PT REQUIREMENTS AND GUIDELINES

Results in a PT being demoted to the LLT level of the terminology:

- The PT to demote must be present in the current terminology or in the MedDRA supplemental database.

- The demoted PT must be placed under an existing PT, or a new PT suggested by the requester in a separate change request.
- The MSSO will migrate LLTs as appropriate.
- This action is considered the same as “Merging” a PT.
- The MedDRA code is retained and the term will appear as an LLT subsequent to processing.

Data Field	Data to Enter	Required/ Optional
Action	In WebCR, select Demote PT from the Action Menu. In the form, choose Demote a PT from the dropdown list.	Required
Proposed Term	The PT to be demoted to the LLT level of the terminology. Term must already exist in the database as a current PT.	Required
Placement Consideration	WebCR requires the subscriber to list which PT the proposed PT should be demoted under. The subscriber may wish to add additional information in the placement consideration field in WebCR. In the form, the requestor must indicate which PT the proposed PT should be demoted under.	Optional
Justification	The requester must explain why this change is needed. Please include references here if applicable.	Required

**Table 3-7. Demote a PT Change Request Elements**

### 3.8 CHANGE STATUS OF LLT REQUIREMENTS AND GUIDELINES

The subscriber is requesting that a current LLT becomes non-current or a non-current LLT becomes current in the terminology:

- For the status of an LLT to be changed it must be present in the terminology.
- LLT terms either carry a flag of Current or Non-current.
- LLT terms carrying a non-current flag are still maintained in the terminology (in other words, their most correct placement is maintained).
- LLT terms carrying a non-current flag still carry their original MedDRA code.

Data Field	Data to Enter	Required/ Optional
Action	In WebCR select Change Status from the Action Menu. In the form, choose Change status of LLT from the dropdown list.	Required
Proposed Term	The LLT to be assigned a change of status. Term must already exist in the database as a current or non-current LLT.	Required
Placement Consideration	WebCR automatically identifies the currency status of an LLT. The placement consideration field is optional. For the form, the requester must provide information as to whether they would like to make an LLT current (if non-current) or non-current (if current).	Optional (WebCR) Required (Form)
Justification	The requester must explain why this change is needed. Please include references here if applicable.	Required

**Table 3-8. Change Status of LLT Change Request Elements**

### 3.9 LINK/UNLINK A PT REQUIREMENTS AND GUIDELINES

The subscriber is requesting the deletion of an existing link from a PT to an existing HLT OR is requesting the addition of a non-existent link from a PT to an existing HLT:

- This command / action is used for three purposes: (1) Link a PT to another HLT, (2) Unlink a PT from a currently linked HLT, or (3) move a PT from a primary SOC to another SOC by requesting first to link the PT to another HLT in one SOC, reassigning the primary SOC, and then requesting the same PT be unlinked from the existing HLT in the existing SOC.
- For PT moves within the same SOC or between secondary SOCs, the Move PT action may be used. Please review the action description Move a PT.
- The PT must exist in the current terminology or the MedDRA supplemental database.
- The HLT must exist in the current terminology or the MedDRA supplemental database.
- For a link to be deleted, the PT / HLT relationship must exist in the current terminology or the MedDRA supplemental database.

The link being added or deleted is not restricted to secondary SOCs, however, when unlinking from a primary SOC, the requester must specify the new primary SOC to link the term to in the Placement Consideration or Justification field.

Example: PT A is linked primary to SOC *Infections and infestations* and secondary to SOC *Skin and subcutaneous tissue disorders*. The requestor may request to unlink from SOC *Skin and subcutaneous tissue disorders*, and may request to link to SOC *Blood and lymphatic system disorders*, but if the request is to unlink from primary SOC *Infections and infestations*, they are required to specify the new primary link. In this example, the new primary link could default to SOC *Skin and subcutaneous tissue disorders* or another SOC could be chosen if appropriate.

Data Field	Data to Enter	Required/ Optional
Action	In WebCR Link a PT to an HLT and Unlink a PT from an HLT are separate actions. Select Other Change Request from the action menu and select either Link a PT to an HLT or Unlink a PT from an HLT. In the form, choose Link/unlink a PT from the dropdown list.	Required
Proposed Term	Indicate the PT the requester desires to have linked/unlinked.	Required
Placement Consideration	In WebCR, the requestor may provide additional information on the linking / unlinking of the PT. For the form, the requester must provide information as to whether they are unlinking from an HLT (specify which), linking to an additional HLT (specify which), or moving the PT from one HLT / SOC to another HLT / SOC by linking to one (specify which) and unlinking from the other.	Optional (WebCR) Required (Form)
Justification	The requester must explain why this change is needed. Please include references here if applicable.	Required

**Table 3-9. Link/Unlink a PT Change Request Elements**

#### 4. COMPLEX CHANGE REQUESTS

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 considered complex change requests.

Because of the nature of the Complex Change Requests, they are handled slightly differently. All complex change requests received are placed on suspension until review for the next complex release because their placement requires a modification to the MedDRA hierarchy (above the PT level). Complex changes are addressed once a year during the March release of MedDRA. Items are reviewed, approved and posted on the web site where subscribers are made aware of the proposed changes and have the opportunity to comment prior to any type of complex implementation. In WebCR, the majority of actions to request complex changes are found under the All Other option in the Action menu. If using the Change Request Form, select the appropriate action from the drop down menu.

##### 4.1 VALID COMPLEX CHANGE REQUEST ACTIONS

Action	Description	Notes
<b>Add a new SOC</b>	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 subscriber community support is needed to approve. Include the proposed name of the SOC as well as the reason for adding it to the terminology.	Contact <a href="mailto:MSSO.Request@ngc.com">MSSO Request @ngc.com</a> with intention to submit.
<b>Add a new HLGT</b>	Add a new High Level Group Term (HLGT) to the terminology. Include the proposed name of the HLGT as well as the reason for adding it to the terminology and which SOC it should map to.	Be as specific as possible.
<b>Add a new HLT</b>	Add a new High Level Term (HLT) to the terminology. Include the proposed name of the HLT as well as the reason for adding it to the terminology and which HLGT/SOC it should map to.	Be as specific as possible.
<b>Rename HLT/ HLGT/ SOC</b>	In WebCR, use the Rename term command on the Action menu. Choose this command to alter the name of a current MedDRA hierarchy term. Indicate in the Term field the current term affected, and in the justification field, what the reason for the rename is, as well as the newly proposed name. Note: This action is reserved for spelling and grammatical errors.	Please do not ask for reviews of complete HLTs here.
<b>Merge HLT</b>	Merge one current MedDRA High Level Term (HLT) up under another. In the Term field indicate which HLT	Note: MedDRA code and the

## Complex Change Requests

Action	Description	Notes
	should be subordinated. Give the reason for the request in the justification field as well as which other HLT you would like the term merged up under.	merged HLT will be lost in this instance.
<b>Merge HLGT</b>	Merge one current MedDRA High Level Group Term (HLGT) up under another. In the Term field indicate which HLGT should be subordinated. Give the reason for the request in the Justification field as well as which other HLGT you would like the term merged up under.	Note: MedDRA code and the merged HLGT will be lost in this instance.
<b>Link/Unlink an HLT</b>	Link or unlink a High Level Term (HLT) from a High Level Group Term (HLGT). In the Term field indicate which HLT you would like linked or unlinked. In the Placement Consideration field indicate where you would like it linked (which HLGT). If unlinking, and the HLT term is currently multi-axial, please specify which HLGT you would like it unlinked from. In the Justification field, explain the reason for the request. In WebCR Link / Unlink are separate actions. In the form, specify if the action is to link or unlink an HLT.	
<b>Link/Unlink an HLGT</b>	Link or unlink a High Level Group Term (HLGT) from a System Organ Class (SOC). In the Term field indicate which HLGT you would like linked or unlinked. In the Placement Consideration field indicate where you would like it linked (which SOC). If unlinking, and the HLGT term is currently multi-axial, please specify which SOC you would like it unlinked from. In the Justification field, explain the reason for the request. In WebCR Link / Unlink are separate actions. In the form, specify if the action is to link or unlink an HLGT.	

**Table 4-1. Valid Complex Change Request Actions**

## 5. STANDARDISED MedDRA QUERIES (SMQ) CHANGE REQUESTS

### 5.1 PROCESSING SMQ CHANGE REQUESTS

SMQ Change Requests are handled differently than the Change Requests related to the MedDRA terminology. SMQ Change Requests are not bound to the 10 working day turnaround time due to the amount of review and research necessary to consider SMQ change requests. Subscribers will continue to receive Receipt Notifications within 24-48 hours, but the Final Notifications do not have a restricted timeframe.

There is a separate Excel form posted on the web site for submitting SMQ requests. This form should **only** be used for SMQ Change Requests.

Note: To add a term to an SMQ that is not currently in MedDRA, a subscriber will first have to submit a Change Request via WebCR or the Subscriber Change Request Form to add that term to the MedDRA terminology. The request to add a PT to an SMQ must be entered on the SMQ Change Request Form.

### 5.2 MAINTENANCE GUIDELINES FOR SMQ CHANGE REQUESTS

The following are the proposed MSSO guidelines for SMQ maintenance:

- SMQ Change Requests will undergo the same medical and technical reviews applied to other MedDRA Change Requests.
- The SMQs will be maintained with each release of MedDRA. This means that each release of MedDRA will have the SMQ files updated based on changes in MedDRA. The MSSO will implement procedures to review the applicability of new MedDRA PTs or promoted LLTs to existing SMQs.
- Generally, the MSSO does not plan on re-testing SMQs based on changes in MedDRA. If the MSSO believes there is a significant change that may impact the results of an SMQ, the MSSO may consult with the CIOMS SMQ Working Group concerning re-testing.
- SMQ Change Requests will be accepted for both releases of MedDRA each year. Currently, the March release is a Complex Change release (LLT, PT and all levels of hierarchy can be changed); the September release is limited to LLT and PT changes.
- SMQ Change Requests received by the MSSO will be acknowledged in the same timeframe as current Change Requests (95% of Change Requests will be acknowledged within 24 hours of receipt, 100% within 48 hours).
- Final disposition of SMQ Change Requests will not be time limited. Given the type of change and the time it may take to decide the impact of a

Change Request, the SMQ Change Requests will not have the same response time criteria associated with them.

- Subscribers will receive a Final Notification of approval, disapproval or suspension of all SMQ Change Requests and rationale.
- Approved SMQ Change Requests will be included in the supplemental postings of the MSSO.
- Not Approved SMQ Change Requests (without organizational affiliation) will be posted with the other disapproved Change Requests from routine MedDRA maintenance.
- The MSSO will include SMQ changes in the “What’s New” document published with each release of MedDRA.

### 5.3 SMQ CHANGE REQUEST ACTION SUMMARY

Type of Change (Choose this action in the dropdown list)	Description
Add a New SMQ	Subscribers can propose a new SMQ with or without the detail of the terms included in the SMQ.
Rename an SMQ	Subscribers can propose to rename an existing SMQ.
Change Status of an SMQ	Subscribers can propose to make an existing active SMQ inactive or an existing inactive SMQ active.
Merge SMQ	Subscribers can propose a merger of two (or more) SMQs into a single SMQ.
Move an SMQ	Subscribers can propose to change the hierarchy associated with an SMQ.
Update SMQ Description	Subscribers can change the description of an SMQ. The description addressed here is the description included in the distributed ASCII text not the description included in the SMQ Introductory Guide.
Update SMQ Source	Subscribers can change the source of an SMQ.
Update SMQ Note	Subscribers can change the note associated with an SMQ.
Update SMQ Algorithm Flag	Subscribers can change the algorithm flag associated with the SMQ.
Add Term to SMQ	Subscribers can propose to add a term to an existing SMQ. <b>**Term must currently exist in MedDRA**</b>
Change Term Status in an SMQ	Subscribers can propose to change the status of a MedDRA term in an existing SMQ (e.g., active to inactive or inactive to active).

<b>Type of Change (Choose this action in the dropdown list)</b>	<b>Description</b>
Update MedDRA Term Scope Field	Subscribers can propose to change the scope associated with a term included in an SMQ (e.g., broad to narrow or narrow to broad).
Update MedDRA Term Category Field	Subscribers can propose to change the category field associated with a term included in an SMQ.

**Table 5-1. SMQ Change Request Action Summary**