

WebCR Quick Reference

System Requirements:

WebCR will support Microsoft Internet Explorer and Firefox. WebCR functions may not work as designed with other web browsers (e.g., Chrome, Safari). No additional software is needed to use WebCR.

Login Screen

Web site: <https://mssotools.com/webcr>

- **Subscriber ID:** Enter your five digit MedDRA Subscription ID
- **Password:** Enter your CR ID or Subscription password

CR ID password: Allows you to add, edit and submit change requests

Subscription password:
Allows read only access

Batch: A set of one or more change requests. A user can have un-submitted and submitted batch files. All batch files remain available for users to view after submission to the MSSO. Queuing (staging) an un-submitted batch can allow an organization to have multiple people review sets of changes via read only access prior to submission to the MSSO. To edit and submit batches, the user must login using the CR ID as the password.

Home Page:

Change request actions are shown in the middle of the screen, menu options are on the right and any un-submitted requests are displayed on the bottom of the screen.

Actions: Presented in four groupings:

1. **Add/Change MedDRA term:** Contains all the actions for LLTs, PTs, HLTs, HLGTs and SOCs
2. **SMQ Changes:** Are specifically for SMQ requests
3. **Translation Changes:** Are for translations corrections only
4. **Reconsider:** Ask the MSSO to reconsider a rejected change request submitted through WebCR

Required Data: Required fields are marked "required" and cannot be left blank when saving a change request. There are optional fields that may be used to provide more information for a request.

Submit Change Request: A batch is submitted to the MSSO by clicking on the Submit button on the main Change Request screen.

All un-submitted batches can be viewed under their own categories (e.g., MedDRA, SMQ, and Translation) below the change request actions.

Menu Options:

Menu options are located on the right side of the screen.

1. **Home:** Brings you to the main Change Request screen
2. **View Submitted Batches:** Allows you to view all your submitted batches
3. **Search MedDRA Term:** Query MedDRA terms in the current release and weekly supplemental changes; this information can be helpful to review before entering change request information
4. **Search CR History:** Query all change requests considered by the MSSO since MedDRA v5.1
5. **Submitter Profile:** Modify your profile: e.g., name, contact information, and email addresses to receive receipt and final notifications
6. **Logout:** Exit from WebCR. A warning message will remind the user if there are any un-submitted change requests. (Note that if the user exits the program by closing the browser, no message will be provided.)

Editing Saved Change Requests: Un-submitted change requests are located at the bottom of the Home Page. Change requests can be edited by clicking on the un-submitted batch, clicking on the "Select" link next to the change request. Make any edits and click on "Save" at the bottom of the request.

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 request these actions via WebCR.

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.
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. 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. WebCR automatically identifies the term status (current or non-current) and selects the opposite state.
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 eight-digit code is retained and the term appears only as an LLT under the designated PT. All LLTs that resided under the demoted PT will now reside under the designated PT.

Appendix A – MedDRA Terminology Request Actions

Simple Changes	
Action	Description
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. 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 is it necessary 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.
Rename PT/LLT	Rename either a Preferred Term (PT) or a Lowest Level Term (LLT). Note: Renaming a term is reserved for correcting spelling and grammatical errors only. ICD-9 and other adopted terms 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

Appendix A – MedDRA Terminology Request Actions

Simple Changes	
Action	Description
	substituted for two separate requests to: 1) demote a PT then 2) promote LLT.
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.

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 MedDRA website 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.
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.
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 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.
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.

Complex Changes	
Action	Description
Merge HLT	Subsume a current High Level Term (HLT) under another existing or proposed HLT. All PTs are moved under the surviving HLT. Note: The MedDRA eight-digit code and the merged HLT are lost in this action. The MSSO retains the MedDRA eight-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 HLGT. Note: The MedDRA eight-digit code and the merged HLGT are lost in this action. The MSSO retains the MedDRA eight-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). 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). 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). 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). WebCR provides specific fields to specify the HLGT you would like to unlink the HLT from.
Unlink an HLGT from SOC	Remove a link to a High Level Grouping Term (HLGT) from a System Organ Class (SOC WebCR provides a specific field to specify which SOC to unlink the HLGT from.

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. Users 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. What is the regulatory need for this SMQ? (Provide evidence of regulations, guidance, or recommendations to report/monitor this medical condition or aspect of medicinal product use) 3. Would this SMQ be applicable to more than one product/therapeutic area? 4. Why is the current MedDRA hierarchy or any existing SMQ not suitable to address the question? 5. What is your current practice for addressing the question? Provide examples of your strategy and terms included in the search.

SMQ Changes	
Action	Description
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."
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 eight-digit code and the merged SMQ are lost in this action. The MSSO retains the MedDRA eight-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

SMQ Changes	
Action	Description
	<p>see the latest version of the SMQ Introductory Guide for 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 in WebCR.</p> <ol style="list-style-type: none">1. English term name of the term you wish to modify2. The MedDRA eight-digit code of the term (WebCR will auto populate)3. The language4. The current translation of the term5. 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>