



Informal MedDRA User Group Meeting Webinar

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Pharmaceutical Manufacturers and Associations (IFPMA)



Agenda

- WebCR Demonstration
- MSSO change request process
- Things to consider before submitting changes
- Justification and References



WEBCR Demonstration



MSSO

Change Request Process



Change Request Process

1. Changes submitted via WebCR
 - Reviewers blinded to the source of requests to reduce potential bias
2. Initial Review & Recommendation
 - Medical review / research
 - Conforms to MedDRA rules and conventions
 - Provide Initial recommendation
3. Review & comment by International Medical Officers
 - Representatives from the U.S., E.U., and Japan



Change Request Process (cont)

4. Meet to gain consensus on each request
 - Final decision made and recorded
 - Approve
 - Approve not as requested
 - Rejected
 - Suspended
 - Associate changes added as needed
5. Submitter informed via Final notification e-mail.



Things to Consider Before Submitting Change Requests



Identifying Potential Changes

- Change requests should be data driven
 - Analysis
 - Reports
- Examples:
 - No suitable term available for coding
 - Appropriate test result not available
 - LLT distinct medical concept– suggest promotion
 - Two similar terms at PT level – suggest demotion



Identifying Potential Changes (cont)

- Avoid submitting changes to seek guidance
 - May get undesired results
 - Send questions to the MSSO Helpdesk
 - MSSOHelp@NGC.COM



Evaluating potential changes

- Things to consider
 - Valid Medical condition
 - Can it be referenced?
 - Can existing terms suffice?
 - Conforms to MedDRA Rules and Conventions
 - New term represents a single concept
 - Unambiguous
 - International use
 - Placement rules – e.g., “mass” terms
 - Impact on existing terms



Change Request vs. Proactivity Request

- Change Request
 - Needed to meet a specific coding or analysis need
 - Solve a particular issue
 - Example: Add PT *Trisomy 14*
- Proactivity request
 - Broader changes to improve MedDRA for all users
 - Correct inconsistencies
 - Example: Harmonize use of hyphen in "Non-" terms



Change Request Justification

- All change request require an 'adequate' justification statement
 - MSSO goal is to maintain the high quality of MedDRA
 - Difficult to evaluate requests without meaningful input
 - Helpful to understand the context of your request



Change Request Justification

- Adequate justification – statement of need
 - Term needed to code an indication
 - Concept is being reported as an adverse event
 - Changes to existing terms should reflect the potential to improve analysis of coded data.
 - Definitions and references helpful, but not sufficient
 - Context helpful to understand issue



Poor Justification Example 1

Request: Add term *Atopic cataract*

Justification: Atopic cataract is a serious complication of atopic dermatitis. In Dorland's, it is defined as "a type seen in persons with longstanding atopic dermatitis, often in the second to third decade of life".

- Only definition provided; no explanation of need or context of issue



Poor Justification Example 2

Request: Add term *Radiation proctopathy*

Justification: No LLT/PT exists to represent this condition in the MedDRA dictionary.

- Only says term not in MedDRA
- No explanation of need or context of issue
- Existing terms may cover the concept:
 - LLT *Radiation proctitis*, LLT *Diarrhea post irradiation*, or LLT *Rectal mucositis*



Poor Justification Example 3

Request: Move LLT *Lip rough* from PT *Chapped lips* to PT *Buccal mucosal roughening*

Justification: The lip is considered an oral structure in MedDRA and the described medical condition "roughening" is better represented under PT *Buccal mucosal roughening*

- No explanation of coding or analysis issue



Good Justification Example 1

Request: Add LLT Fibroxanthoma

Justification: Our company has received an adverse event report in which the patient experienced this specific disorder. This term is being coded to xanthoma. Although we have PT/LLT *Fibrous histiocyoma* which is described in medical dictionaries as a synonym, we are requesting it be added as an LLT for consistency and accuracy.



Good Justification Example 2

Request: Promote LLT *Incision site pruritus*

Justification: The PT "incision site complication" is too vague. Creating a PT of "incision site pruritus" will provide for the coding of the actual event being reported, as MedDRA has done with the other incision site terms.



Justification Statement Tips

Help us make the right decision:

- Provide statement of need
- Provide context if possible
- Definitions and references helpful, but not sufficient by themselves
- Make sure MSSO can access references
- Do not include company name or product name
 - Reduce potential bias by reviewers



Change Request Resources

- Change Request Home Page
 - WebCR Quick Start guide
 - Change Request Information Document
 - How to submit changes
 - Explains change request process
 - How to interpret disposition reports
 - Tips and guidelines
 - Change request action explanations

http://www.meddramsso.com/subscriber_download_change_request.asp



Questions?





Change request process at Bayer Healthcare

Dr. Carol-Ann Wilson

Head Global Medical Coding



Agenda

- Who identifies a potential CR?
- How candidates are documented and researched?
- Who manages WebCR tool – central vs. distributed use of tool?
- Who receives notification? How are notifications distributed?
- What happens to supplemental terms? Why are they helpful?



Who identifies a potential CR?

- A potential CR may be identified by
 - Colleagues in operational coding (Medical Coders)
 - Physicians involved in coding QC (Medical Dictionary Experts)
 - Colleagues in Drug Safety Case Processing or Risk Management or Medical Experts in Clinical Development
 - New indications for drug use
 - Specific therapeutic areas that are not yet appropriately represented in MedDRA

How candidates are documented and researched?



- CRs are submitted with supportive literature via email to the primary point of contact (PPC) of the company for CR submission (Head Global Medical Coding)
 - To avoid redundancies/ duplicate requests
 - To facilitate consistent communication with the MSSO
- PPC reviews CR, checks against history of CRs in WebCR tool and MedDRA/ CR rules
 - Some experience is needed to make this evaluation
- PPC processes CR or sends rejection to the requester with appropriate justification

How candidates are documented and researched (2)?



- Triggers for the submission of CRs
 - Requests for new terms to better capture safety data e.g. in new therapeutic indications
 - Inconsistencies in MedDRA, redundancies on PT level, missing SOC linkages, ambiguous terms
 - Issue has to be relevant for safety data analysis (no pure “academic” background)
- The feedback from the MSSO is useful, even when the CR is rejected
 - Example: Reported term “*Restrictive airways disorder*” was submitted as CR
 - MSSO rejected with reference to PT / LLT *Restrictive pulmonary disease* as adequate to represent the concept

Who manages WebCR tool – central vs. distributed use of tool?



- WebCR tool is managed centrally, all entries and submissions are done by the PPC
 - Experience increases probability of CR approval by MSSO
 - CRs are submitted when
 - Urgent clarification of coding is needed
 - A new synonym is entered in the synonym list which is coded to the most appropriate LLT
 - When CR for a new LLT is accepted, the synonym will be mapped to the LLT that is equal to the corresponding PT
 - With the new version, the synonym will be mapped to the newly released LLT
 - Appropriate number of CRs is reached (20-30)
 - Only urgent single CRs should be submitted shortly before the Freeze date for the next MedDRA version

Who manages WebCR tool – central vs. distributed use of tool (2)?



- All Medical Dictionary Experts and selected Medical Coders have read access
 - To check entry of “their” CRs and justification (transparency and training)
 - To search CR history
 - To review submitted batches and the MSSO response

Who receives notification? How are notifications distributed?



- Notification is received by PPC
 - Distributes to all colleagues with read access to WebCR tool and who have submitted individual CRs
 - Requires some administration effort (tracking)
 - Within the Coding function, MSSO response is analyzed and relevant synonyms are reviewed and remapped, if appropriate
 - All CR notifications are stored on the shared drive of the Coding function under “MedDRA versioning documentation”
- In the case of rejection, the original requester is asked to confirm the necessity for re-submission
 - Additional justification and literature is then needed

What happens to supplemental terms? Why are they helpful?



- Supplemental terms are helpful to understand the “MedDRA philosophy” and the MSSO view
 - They can be used as a guidance for coding and synonym list mapping until the MedDRA changes are released
- Supplemental terms can also be analyzed shortly before the freeze date for the next MedDRA version to
 - Check whether any changes are questionable or could have critical impact on the safety profile of company drugs (medical accuracy, frequencies)
 - Submit single CRs to try to correct decisions related to the supplemental terms



Thank you!
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