

Change Request Justification: A Reminder

Dear MedDRA Subscriber:

The MSSO values input from subscribers for making MedDRA better and more relevant to users' needs through the Change Request process.

To maintain high quality, the MSSO reminds subscribers that all Change Requests – whether submitted by WebCR or by spreadsheet – must be accompanied by a justification statement indicating why the term or change proposed is necessary. Providing a justification helps MSSO Terminology Maintenance staff evaluate the impact of the proposed change to MedDRA. To accept requests without justification may lead to unnecessary changes that only add to the overall maintenance burden for all subscribers.

Justification statements such as “because it is not in MedDRA” or “to be consistent with other terms in MedDRA” are not sufficient; neither is a definition of the concept or a web site reference without additional wording on why such a change is necessary.

Acceptable justification statements – which should be specific – relate to the use of MedDRA for regulatory purposes. Some examples of acceptable justification statements are as follows:

“Our company has received an adverse event report in which the patient experienced this disorder. When searching for a suitable LLT, we found none that was acceptable or close enough in meaning to adequately represent this concept for the purpose of retrieval and evaluation.”

“Our organization would like to promote this LLT because it represents a single medical concept distinct in meaning from its parent PT. Its promotion to PT level will support proper retrieval and analysis of similar MedDRA concepts.”

The MSSO shares with subscribers a desire to make MedDRA as comprehensive as possible for its specific regulatory purpose, while at the same time, balancing the needs of specificity and safety signal assessment.

Please feel free to contact us through our Help Desk (mssohelp@ngc.com) if you have any questions.

Thanks for your continued support of MedDRA.

The MSSO

