

MedDRA Version 15.0 Proposed Complex Changes and MedDRA v14.1 Pregnancy Exposure and Pharmacogenetic Term Additions

Dear MedDRA User:

The MSSO has posted [proposed complex changes](#) for MedDRA Version 15.0 on our web site. Complex changes are any changes to the MedDRA hierarchy, i.e., the High Level Terms (HLT), High Level Group Terms (HLGT), or System Organ Classes (SOC), which may impact your use of MedDRA. We encourage your comments both for and against these proposed changes so we may understand their potential impact.

The deadline for your response to the proposed complex changes is 29 July 2011. Please send your comments to MSSORequest@mssotools.com.

For MedDRA v14.1, the MSSO has added a group of pharmacogenetic concepts which focus on genetic concepts and factors that have a potential impact on drug therapy.

In a separate initiative, new sets of pregnancy exposure terms have been added to MedDRA, and existing terms have been reorganized to make them easier to use for pharmacovigilance purposes.

Please go to the [announcements section](#) in the subscriber area of the MSSO Web site for specific details on both of these initiatives. There are proposed complex changes to further reorganize the pregnancy exposure terms at the HLT level and to add more pharmacogenetic concepts under new HLTs. For details, please review the [proposed complex changes](#) for MedDRA v15.0 on our web site.

Thank you,

MedDRA MSSO