

Recommendations of the First MedDRA “Blue Ribbon Panel” (May 2003) Endorsed by the MedDRA Management Board

The MedDRA Management Board wishes to recognize the contributions of the members of the first MedDRA “Blue Ribbon Panel” (BRP) which convened in Reston, Virginia, USA on 15 May 2003. Representation consisted of individuals from both regulatory bodies and the biopharmaceutical industry within the ICH regions, all with expertise in MedDRA.

The purpose of this BRP was to provide the Management Board with information to support the Board’s oversight and policy formation regarding MedDRA. At this particular meeting, the BRP was asked to review, discuss and make recommendations on the general scope and level of specificity. During the course of their discussions, members of the BRP provided the MedDRA Maintenance and Support Services Organization (MSSO) with a series of recommendations on how MedDRA should be maintained currently and in the future.

The following is a summary of the recommendations that are endorsed by the Management Board:

SOC Investigations

- 1) At the Preferred Term (PT) level, general “serology” terms can be requested. More specific terms related to immunoglobulin class can be linked as Lowest Level Terms (LLTs) to these “serology” PTs. E.g., LLT *Borrelia burgdorferi immunoglobulin G* is linked to PT *Borrelia burgdorferi serology*. The same general approach can be used to request investigations involving DNA analysis. Medical judgment needs to be applied for certain specific diseases where such specificity should instead be represented at the PT level.
- 2) The MSSO will not process so-called “internal” Change Requests (i.e., generated by MSSO maintenance activities) simply to create a full complement of qualitative results for any given test or investigation. In other words, if a subscriber’s request to add a PT Test *increased* is processed and accepted, the MSSO will not automatically add PT Test *negative*, PT Test *normal*, PT Test *abnormal*, etc. Subscriber requests to add such additional “complementary” terms will be assessed through the usual Change Request process.
- 3) For investigations that are rare, esoteric, or “experimental”, subscribers may be asked by the MSSO term maintenance personnel to provide compelling evidence of a regulatory need for such a term in MedDRA and that no other existing term in MedDRA will adequately represent the concept.

- 4) For subscriber requests to add terms for a measured metabolite or substance in various types of specimens (e.g., blood, urine, plasma, cerebrospinal fluid, etc.), the following applies: if there is a clinically different interpretation for results in different specimen sources (e.g., “blood glucose increased” vs. “blood CSF increased”), then the terms are distinct concepts and will be represented by separate PTs. If the clinical interpretation of results for different specimen types is the same, then one broad PT can be added with specimen types represented at the LLT level as needed.

Other SOCs

- 1) The MSSO will not add “normal” conditions to the terminology unless the subscriber can provide compelling evidence that a regulatory need for such a term in MedDRA exists.
- 2) There will be no change in the current policy governing the acceptance of “prophylaxis” terms. Presently, they are evaluated on an individual basis for medical significance.
- 3) In general, the MSSO will allow MedDRA to expand into new areas of medicine based on user input alone. In other words, the MSSO will respond to, but will not initiate on its own, requests to expand MedDRA into areas such as gene therapies, devices, vaccines, etc.
- 4) The rules governing the acceptance of terms such as lexical variants, anatomical variations, etc. are unchanged. In most cases, these change requests will be rejected.