

## **MSSO Comment on the Primary System Organ Class (SOC) Allocation in MedDRA**

### **Purpose**

This document explains the concept of the primary SOC allocation in MedDRA and why the primary SOC should not be individually selected by MedDRA users. To do so undermines one of the main goals in using MedDRA as a regulatory standard.

### **MedDRA as an ICH Standard**

MedDRA was developed by an ICH Expert Working Group to address many of the limitations of older adverse event terminologies (e.g., COSTART). In the past, organizations that used these terminologies freely “edited” them (e.g., added custom terms) to suit specific needs and to overcome their limitations. The result was a lack of any real standard terminology in the adverse event reporting regulatory environment at that time. The intent of ICH, in developing MedDRA, was to have a standard, medically rigorous, and well-maintained terminology to facilitate communication.

Specifically, some of the applications for MedDRA are:

- To aggregate reported terms in medically meaningful groupings for review, analysis and/or summary of safety data
- To facilitate identification of common data sets for evaluation of clinical and safety information
- To facilitate consistent retrieval of specific cases or medical conditions from a database
- To improve consistency in comparing and understanding safety signals and aggregated clinical data
- To facilitate electronic data interchange of clinical safety information.

The ICH also authorized a group of drug safety experts (from regulatory authorities and industry) to draft the “*MedDRA Term Selection: Points to Consider*” document as guideline for MedDRA usage in coding adverse events, medical and social history, and indications. This ICH-endorsed document states (**bold** added for emphasis):

*“MedDRA is a standardized terminology. It is considered essential that ad hoc structural changes in MedDRA not occur. **The assignment of terms across SOC is pre-determined within the terminology and should not be altered by users.**”*

(NOTE: This document can be found at [http://meddramssso.com/subscriber\\_library\\_ptc.asp](http://meddramssso.com/subscriber_library_ptc.asp)).

## The Reason for a Primary SOC

MedDRA is a multi-axial terminology meaning that a Preferred Term (PT) may be linked to more than one SOC. For example, PT *Dyspnoea* has a link to both SOC *Respiratory, thoracic and mediastinal disorders* (its organ system of manifestation) and to SOC *Cardiac disorders* (because of its connection to heart disease). Each PT is assigned a primary SOC to avoid “double counting” while retrieving information from all SOCs (i.e., a cumulative SOC-by-SOC data output). The other SOCs to which a multi-axial PT is linked are called “secondary” SOCs.

In most instances, PTs relating to diseases or signs and symptoms are assigned to the prime manifestation site SOC. So, for PT *Dyspnoea*, the primary SOC is SOC *Respiratory, thoracic and mediastinal disorders*. However, there are exceptions for three types of terms:

- Terms for congenital and hereditary anomalies are assigned to SOC *Congenital, familial and genetic disorders* as the primary SOC.
- Terms for benign and malignant neoplasms are assigned to SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* as primary SOC. This does not apply to cyst and polyp terms. These terms have as their primary SOC assignment their site of manifestation SOC
- Terms for infections are assigned to SOC *Infections and infestations* as the primary SOC.

These primary SOC assignment rules were instituted as MedDRA was being developed in order to aggregate certain critical issues (congenital anomalies, neoplasms, and infections) into specific places in MedDRA to facilitate safety signal detection. Note that the primary SOC allocations are “hard-wired” into the MedDRA ASCII files.

### Can a Primary SOC Allocation be Changed?

Yes, any MedDRA basic or core subscriber may submit a proposal to change the primary SOC assignment for any given term through the usual Change Request process. In considering a subscriber’s request, the MSSO will carefully review the justification provided along with the already established allocation rules.

The MSSO is aware that coders and dictionary managers are sometimes asked to re-assign the default primary SOC allocation for specific PTs to one of the organization’s choosing. As noted above, the MSSO strongly discourages this practice as we believe it undermines the intent of MedDRA as a standard terminology. For example, a reviewer at regulatory authority would find it difficult to compare the safety data of similar products from two different companies if one freely assigned the PTs to SOCs of their choosing and the other used the standard primary SOC allocations.