

## BRP7

**Title/subject:** Proposed Revisions to the Neoplasm SOC

**Date/location:** 12 April 2011, European Medicines Agency (EMA), London, UK

### **Purpose of BRP 7**

Based on suggestions from a MedDRA user at the US National Cancer Institute (NCI), the MSSO convened BRP7 to discuss possible delinking of “cyst” terms from SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)*, improvement of the specificity of tumour terms at the PT level, and improvement/update of the classification of tumours in MedDRA.

### **Panel members/affiliations**

Stewart Geary (Eisai)  
Jean-Marie Heim (Bristol-Myers Squibb)  
Sebastian Monzon (Roche, EU Industry)  
Gisele Sarosy (National Cancer Institute [ret])  
Multiple FDA experts (FDA)\*  
Atsuo Takashima (National Cancer Center, Japan)  
Kevin Blake (EMA)

[\*Did not attend Panel meeting but FDA's input was presented]

### **Panel recommendations**

The Panel recommended that there be more specific histologic tumour types added to the PT level using standard tumour classification systems; they agreed to advise the MSSO on which classification systems to use. This would allow for aggregation and analysis of specific tumour types in MedDRA and support the development of oncologic therapeutics of specific neoplasms.

The Panel also suggested demoting of all tumour “stage” PTs to LLT level as a way to improve signal detection at the PT level while still allowing “stage” information to be coded.

The Panel did not support the proposal to delink the “cyst” terms from the Neoplasm SOC since there are other methods to analyse “cyst” terms and little advantage would be gained by this action.

### **Outcomes**

The MSSO first studied the impact that the Panel proposals might have on already coded data and new data if their recommendations were to be implemented. The proposed changes were also posted for general user comment. After review of the feedback and analysis, the Management Board endorsed all of the Panel’s recommendations except the proposal to delete all “stage” PTs to LLT level (this may be reconsidered at a future date). The changes were implemented in MedDRA Version 16.0 (March 2013).