

## Impact of Potential Changes to Neoplasm SOC (BRP7)

### Request for User Review

The MSSO encourages all MedDRA users, and especially those involved with oncology products in development or on the market, to review a set of spreadsheets that describe *potential changes* to terms in SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* (“Neoplasm SOC”).

The aim of this review is to provide the MSSO with feedback on the impact these changes could have on your MedDRA coded data (including medical history and indication data, as well as coded adverse event data). Your feedback will help the MedDRA Management Board and the MSSO determine how to implement these changes into MedDRA. We encourage high level comments (e.g., impact of demotion of “stage” terms) rather than feedback on specific terms.

Please provide your feedback to the [MSSO Help Desk](#) by **Friday 13 April 2012**.

### Background

In April 2011, the MSSO held its seventh Blue Ribbon Panel (BRP7) to discuss proposed changes to the Neoplasm SOC. The key recommendations from the Panel were:

1. Demote “stage” Preferred Terms (PTs) in the Neoplasm SOC to Lowest Level Terms (LLTs)

Example: There are currently four “stage” PTs for colorectal cancer: *Colorectal cancer stage I*, *Colorectal cancer stage II*, *Colorectal cancer stage III* and *Colorectal cancer stage IV*. The proposal would demote all four of these terms to LLTs linked to existing PT *Colorectal cancer*.

2. Place additional specific histologic tumor type terms at PT level. In some cases, this would involve promoting an existing LLT to PT level (e.g., LLT *Medullary carcinoma of breast*) and in other cases, a new PT would be added (e.g., PT *Serous cystadenocarcinoma of pancreas*)

Note that the Panel’s proposal for adding new histologic types at PT level included a recommendation to only fill obvious “gaps” in MedDRA without adding rare, esoteric concepts unless to fulfill a user’s request.

Also, the Panel recommended that “broad” PT concepts for tumors, (e.g., PT *Laryngeal cancer*) be *retained* in MedDRA to allow for coding and analysis when the reported information does not indicate histologic specificity.

3. Reference standard tumor classification systems for adding new PTs.

Note that, for this preliminary review of changes, the World Health Organization’s (WHO) standard histologic classifications were used *when available*. If a WHO

classification for a particular organ does not exist, then standard pathology texts and Web resources were referenced instead.

The table below summarizes the number of proposed changes to the Neoplasm SOC (based on MedDRA v14.1)

### Number of changes to MedDRA by organ system/HLGT and change type

Organ System/HLGT (MedDRA v14.1)	NO CHANGE	ADD NEW TERM (PT)	PROMOTE LLT	DEMOTE PT	MOVE LLT	RENAME	MAKE NON-CURRENT	TOTAL CHANGES
Breast	73	14	6	8	96	3	0	127
Endocrine	129	15	7	17	43	1	1	84
Gastrointestinal	395	36	22	96	935	0	11	1100
Haematopoietic*	855	30	3	227	1192	0	1	1453
Hepatobiliary	64	14	7	30	185	0	0	236
Mesothelioma	21	5	0	0	6	0	0	11
Miscellaneous	173	6	2	31	66	0	0	105
Nervous system	116	6	5	19	47	3	0	80
Ocular	66	2	0	3	3	0	0	8
Plasma cell	31	2	3	4	26	0	0	35
Renal and urinary tract	130	10	2	53	315	0	0	380
Reproductive female	157	21	20	77	386	0	2	506
Reproductive gender unspecified	13	0	0	0	0	0	0	0
Reproductive male	70	14	10	40	90	0	0	154
Respiratory	191	25	21	97	541	0	0	684
Skeletal	45	3	4	10	57	0	1	75
Skin	119	6	8	24	31	0	0	69
Soft tissue	83	15	7	43	71	0	1	137
<b>Totals</b>	<b>2731</b>	<b>224</b>	<b>127</b>	<b>779</b>	<b>4090</b>	<b>7</b>	<b>17</b>	<b>5244</b>

(\* Includes lymphoma and leukaemia HLGTs)

### Orientation to Spreadsheets

The spreadsheets are organized around High Level Group Terms (HLGTs) and High Level Terms (HLTs) in the Neoplasm SOC that contain malignant and “unspecified” tumor concepts. Benign tumors were not included in the review of terms.

Please note the columns in each spreadsheet:

A	B	C	D	E	F	G	H	I	J	K	L	M	N
HLGT	HLT	PT	LLT	NO CHANGE	ADD NEW TERM (PT)	PROMOTE LLT	DEMOTE PT	RELINK DEMOTED TERM TO THIS PT	MOVE LLT	MOVE TO THIS PT	RENAME (see COMMENT)	MAKE NC	COMMENT

Columns A through D represent the terms as they are in MedDRA v14.1. The focus for this exercise/review is on changes to the **PTs** (Column C) and **LLTs** (Column D).

- An “X” under “NO CHANGE” (Column E) means no changes are proposed for this PT/LLT
- An “X” under “ADD NEW TERM (PT)” (Column F) means a proposed added PT/LLT
- An “X” under “PROMOTE LLT” (Column G) means the LLT in Column D will become a (new) PT
- An “X” under “DEMOTE PT” (Column H) means the PT in Column C will become an LLT. *Note that this is usually accompanied by an “X” under RELINK DEMOTED TERM TO THIS PT in Column I*
- An “X” under “MOVE LLT” (Column J) means that the LLT in Column D will be moved to another PT *listed under “MOVE TO THIS PT” in Column K*
- An “X” under “RENAME (see COMMENT)” (Column L) is a proposal for a minor wording change of the existing PT or LLT
- An “X” under “MAKE NC” (Column M) is a proposal to make non-current the LLT in Column D
- MSSO comments are displayed under “COMMENT” (Column N)

The final row of data in each spreadsheet provides the summary of total number of changes.

### **Providing Feedback**

Please provide your feedback on these potential changes to the MSSO via our Help Desk. Again, your assessment of the *impact of these changes on your coded data – including analysis of those data* – are of the highest interest to the MSSO and the Management Board, but other types of input will also be considered.

Please contact the [MSSO Help Desk](#) if you have any questions.

Thank you in advance for your help with this effort to improve MedDRA.

The MSSO