



# Blue Ribbon Panel Recommendations on Revisions to the Neoplasm SOC

MedDRA MSSO User Group Meeting  
Chicago, USA  
23 June 2011

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# Background

- *SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps)* - one of the largest SOC

MedDRA Versions							
	2.1	3.0	4.1	6.0	9.0	12.0	13.1
LLT	6299	6339	6922	7269	7662	7873	7876
PT	1338	1361	1570	1632	1629	1695	1699
HLT	200	200	198	196	196	203	203
HLGT	40	40	40	40	40	40	40
Total	7877	7940	8730	9137	9527	9811	9818



# Background (cont)

- Term placement has remained largely unchanged since MedDRA v2.1
- More “stage” (clinical) than “pathology” focused
- Significant changes in malignant neoplasms therapies not reflected in MedDRA
  - Therapies for a genetic characteristic of a specific histologic tumor sub-type
- Neoplasm SOC developed when changes in therapeutic approaches were just beginning



# Background (cont)

- NCI physician proposed a set of revisions
  - Remove “cyst” terms
  - Increase histologic specificity (at PT level)
  - Improve neoplasm classifications
- Support from users to discuss changes in a BRP



# Revisions to Neoplasm SOC BRP

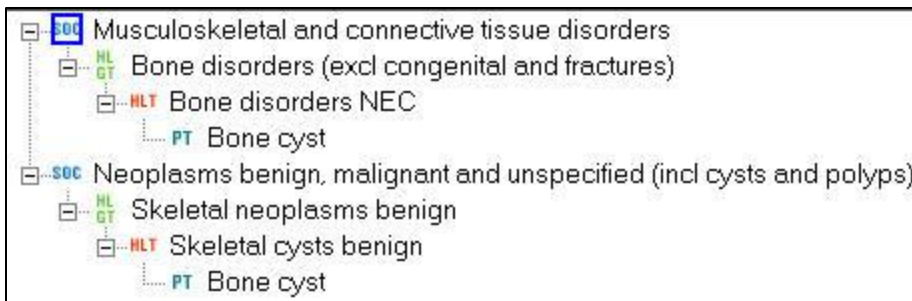
- Blue Ribbon Panel (BRP)
  - Goal: develop recommendations on an issue
  - Panel members represent ICH regions
  - Observers play important role
  - MSSO presents recommendations to Board for approval
- Held 12 April 2011, EMA in London, UK



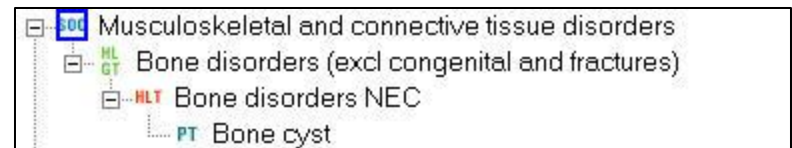
# Proposal 1

- Move "cyst" terms from Neoplasm SOC and keep them only in their "site of manifestation" SOC

## Present



## Future?



- Rationale: "cyst" is an anatomic designation which only very rarely confers the quality of "neoplasia"

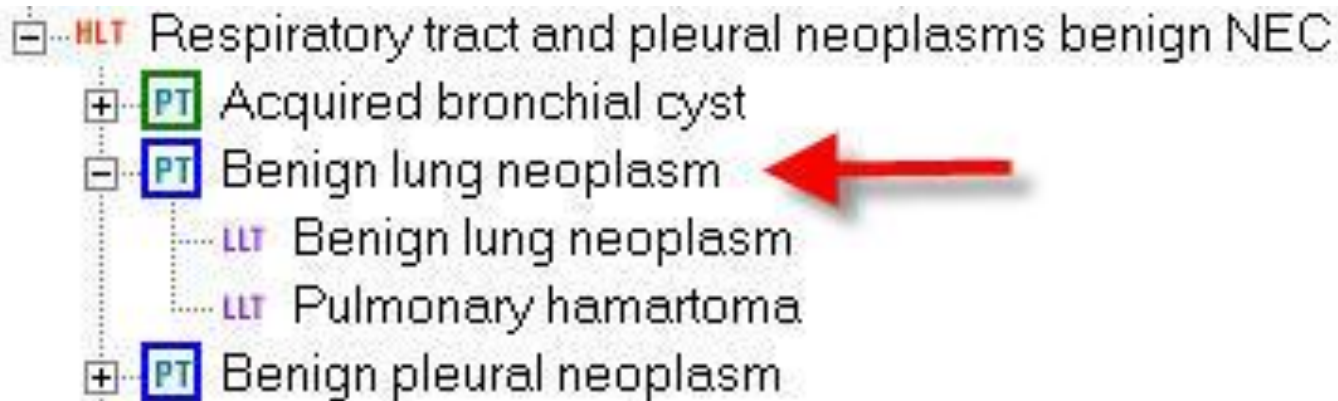


# Proposal 1 – Panel Recommendation

- Do **not** delink “cyst” terms
- There are other methods to analyze “cyst” terms
- Little advantage to be gained by delinking “cyst” terms from Neoplasm SOC

# Proposal 2

- Place more specific histologic tumor types on the PT level
  - Some specific histologic subtypes at the LLT level, but others missing





# “Broad” and “Stage” terms

- MSSO recommends that the relatively “broad” terms for neoplasms (e.g., PT Breast cancer) remain in MedDRA
  - Reported specific tumor type may not be known (e.g., breast cancer vs. medullary carcinoma)
- What should be the fate of the existing “stage” terms in MedDRA (currently at the PT level)?



# Genetics Play a Key Role

- Oncologic therapies are being targeted at specific histologic types of tumors
- Authorized products have indications like:
  - "EGFR expressing metastatic colorectal carcinoma with non-mutated (wild-type) KRAS"

- HLT Breast and nipple neoplasms malignant
  - PT Breast cancer
    - LLT Adenoid cystic breast carcinoma
    - LLT Apocrine breast carcinoma
    - LLT Breast adenocarcinoma
    - LLT Breast cancer
    - LLT Breast cancer aggravated
    - LLT Breast cancer invasive NOS
    - LLT Breast cancer NOS
    - LLT Breast cancer stage unspecified
    - LLT Breast carcinoma
    - LLT Breast carcinoma NOS
    - LLT Breast ductal cancer infiltrating
    - LLT Breast ductal cancer invasive
    - LLT Breast ductal carcinoma
    - LLT Breast lump (malignant)
    - LLT Breast tumor malignant
    - LLT Breast tumour malignant
    - LLT Ca breast
    - LLT Carcinoma breast
    - LLT Colloidal breast carcinoma
    - LLT Estrogen receptor positive breast cancer ←
    - LLT HER-2 positive breast cancer ←
    - LLT Infiltrating ductal breast cancer
    - LLT Invasive ductal breast cancer
    - LLT Lobular breast carcinoma invasive
    - LLT Lobular carcinoma of breast
    - LLT Malignant breast neoplasm
    - LLT Medullary carcinoma of breast
    - LLT Mucinous breast cancer
    - LLT Oestrogen receptor positive breast cancer ←
    - LLT Papillary breast carcinoma
    - LLT Tubular breast cancer



# Proposal 2 – Panel Recommendation

- Demote “stage” PTs to LLT
  - Allows users to code to such terms while improving/preserving signal detection
- Keep non-specific “broad” neoplasm terms (e.g., LLT/PT *Breast cancer*)
- Add combination terms – histologic type + genetic marker – that are common, distinct entities
  - When users identify a specific need
  - Should be **limited in scope** and not a single large-scale revision to MedDRA



# Proposal 3

- Update the Neoplasm SOC according to standard tumor classification systems
  - E.g., WHO classification systems
- Changes to classification systems over time needs to be considered
- Terms out of date with current classifications need to be addressed
  - Probably made into non-current LLTs



# Potential Malignant Lung Neoplasms Changes

SOC	HLGT	HLT	PT	LLT
				Neoplasms benign, malignant and unspecified (incl cysts and polyps)
				Respiratory and mediastinal neoplasms malignant and unspecified
				Lung neoplasms malignant
				Adenocarcinoma of lung
				Adenocarcinoma acinar of lung
				Adenocarcinoma of lung with mixed subtypes
				Adenocarcinoma papillary of lung
				Bronchioloalveolar carcinoma mucinous
				Bronchioloalveolar carcinoma nonmucinous
				Bronchioloalveolar mixed mucinous and non-mucinous or intermediate cell type
				Clear cell adenocarcinoma of lung
				Mucinous ("colloid") adenocarcinoma of lung
				Mucinous cystadenocarcinoma of lung
				Signet-ring adenocarcinoma of lung
				Solid adenocarcinoma of lung with mucin
				Well-differentiated fetal adenocarcinoma of lung
				Lung neoplasm malignant
				Lung cancer
				Lung neoplasm malignant NOS
				Small cell carcinoma of lung
				Combined small cell carcinoma of lung
				Squamous cell carcinoma of lung
				Squamous cell carcinoma basaloid of lung
				Squamous cell carcinoma clear cell of lung
				Squamous cell carcinoma papillary of lung
				Squamous cell carcinoma small cell of lung



# Impact of Proposals 2 and 3

- Impact to MedDRA is difficult to gauge
  - Increased degree of specificity would allow for aggregation and analysis
  - Impact could be thousands of terms
    - New terms (could be thousands)
    - Promoted LLTs
- MedDRA v14.0 Neoplasm SOC
  - 1938 PTs
  - 8441 LLTs



# Proposal 3 – Panel Recommendation

- Reference existing standard tumor classification systems when processing subscriber change requests
- Seek an ICH decision on which classification system(s) to reference
- Panelists agreed to advise MSSO on which tumor classification systems to reference if needed



# Management Board – June 2011

- Board OK with Proposal 1
- **Deferred** decision for Proposals 2 & 3
  - Will re-address at next meeting (November 2011)



# In the Meantime...

- MSSO Medical Team will work to explore potential impacts more fully
  - E.g., how data may look if “stage” PTs are demoted
- Goal is to provide Board with additional data to help in their decision
- Please send any additional comments on the BRP recommendations:  
[mssohelp@ngc.com](mailto:mssohelp@ngc.com)



# Discussion