

MedDRA®



“Hot Topics” for MedDRA



“Hot Topics”

- *SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps)*
- MedDRA Definitions
- MedDRA and Signal Generation
- Primary Paths and Data Storage



SOC *Neoplasms, etc.*

- What are the facts?
 - Very large SOC
 - Second only to SOC *Investigations* in number of PTs (1795 in Version 9.0)
 - Organized in a fairly uniform way:
 - Most systems have groupings for “benign” and “malignant and unspecified”
 - Leukemias and lymphomas are different
 - PTs have stages as well as “recurrent”, “non-resectable”, etc.



SOC *Neoplasms, etc.* (cont)

- What are the facts? (cont)
 - This SOC was developed by US's National Cancer Institute (NCI)
 - Lymphomas follow the REAL classification



SOC *Neoplasms, etc.* (cont)

- What are the questions?
 - For what purpose is this SOC used?
 - Primarily history and indication?
 - What other terminologies are used for neoplasm cases?
 - Does the current structure of MedDRA address users needs sufficiently?
 - If not, how could it be improved?
 - The MSSO needs to know – is it worth the effort to improve this SOC?

SOC *Neoplasms, etc.* (cont)

- SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps)
 - + HL
GT Breast neoplasms benign (incl nipple)
 - + HL
GT Breast neoplasms malignant and unspecified (incl nipple)
 - + HL
GT Cancer-related morbidities
 - + HL
GT Cutaneous neoplasms benign
 - + HL
GT Endocrine neoplasms benign
 - + HL
GT Endocrine neoplasms malignant and unspecified
 - + HL
GT Gastrointestinal neoplasms benign
 - + HL
GT Gastrointestinal neoplasms malignant and unspecified
 - + HL
GT Haematopoietic neoplasms (excl leukaemias and lymphomas)
 - + HL
GT Hepatic and biliary neoplasms benign
 - + HL
GT Hepatobiliary neoplasms malignant and unspecified

SOC *Neoplasms, etc.* (cont)

- [-] HL
GT Leukaemias
 - [+] HLT Leukaemias acute lymphocytic
 - [+] HLT Leukaemias acute myeloid
 - [+] HLT Leukaemias acute NEC
 - [+] HLT Leukaemias chronic lymphocytic
 - [+] HLT Leukaemias chronic myeloid
 - [+] HLT Leukaemias chronic NEC
 - [+] HLT Leukaemias chronic T-cell
 - [+] HLT Leukaemias lymphocytic NEC
 - [+] HLT Leukaemias myeloid NEC
 - [+] HLT Leukaemias NEC
 - [+] HLT Myelodysplastic syndromes
- [+] HL
GT Lymphomas Hodgkin's disease
- [+] HL
GT Lymphomas NEC
- [+] HL
GT Lymphomas non-Hodgkin's B-cell
- [+] HL
GT Lymphomas non-Hodgkin's T-cell
- [+] HL
GT Lymphomas non-Hodgkin's unspecified histology

SOC *Neoplasms, etc.* (cont)

- [-] HL
CT Leukaemias
 - [-] HLT Leukaemias acute lymphocytic
 - + [PT] Acute lymphocytic leukaemia
 - + [PT] Acute lymphocytic leukaemia (in remission)
 - + [PT] Acute lymphocytic leukaemia recurrent
 - + [PT] B precursor type acute leukaemia
 - + [PT] B-cell type acute leukaemia
 - + [PT] Mature B-cell type acute leukaemia
 - + [PT] T-cell type acute leukaemia
 - + HLT Leukaemias acute myeloid
 - + HLT Leukaemias acute NEC
 - [-] HLT Leukaemias chronic lymphocytic
 - + [PT] Chronic lymphocytic leukaemia
 - + [PT] Chronic lymphocytic leukaemia (in remission)
 - + [PT] Chronic lymphocytic leukaemia recurrent
 - + [PT] Chronic lymphocytic leukaemia refractory
 - + [PT] Chronic lymphocytic leukaemia stage 0
 - + [PT] Chronic lymphocytic leukaemia stage 1
 - + [PT] Chronic lymphocytic leukaemia stage 2



SOC *Neoplasms, etc.*

- More facts:
 - Approximately 480 subscriber change requests involving a neoplasm term since Version 5.1 (4.42% of all subscriber change requests)
 - Most occurred during “metastasi(e)s” review (Version 6.1)
 - A few changes with the Version 6.1 “NOS” review
 - A few in Version 9.0 due to NCI requests



SOC Neoplasms, etc.

- More facts:
 - Otherwise, fairly steady at approximately 60 requests per MedDRA version
 - Most common request is to add a PT
 - Many of those were accepted at LLT level
 - 22PTs, 598 LLTs added since Version 5.1



MedDRA Definitions

- What are the facts?
 - Individual MedDRA terms do not have definitions
 - Introductory Guide provides some general usages (e.g., “dilation” vs. “dilatation”)
 - Some subscribers and terminology experts have suggested definitions
 - Might assist with finding related terms in MedDRA (e.g., pancreatitis and its associated signs and symptoms; or “hepatic” and “liver” terms)
 - Might help with term assignment (coding)



MedDRA Definitions (cont)

- What are the questions?
 - Are definitions useful for the intended use of MedDRA?
 - How would MedDRA users utilize terms with definitions?
 - Are reference links useful for the use of MedDRA?
 - Maintenance issues?



MedDRA and Signal Generation

- What are the questions?
 - Does MedDRA “work” for various signal detection/generation approaches (e.g., PRR)?
 - What is the user community’s experience?
 - What about SMQs?



MedDRA and Signal Generation (cont)

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EDITORIAL

Signal detection in pharmacovigilance: empirical evaluation of data mining tools

How to quickly identify safety signals from post-marketing data is a constant challenge for regulators and manufacturers of drugs, vaccines, and devices. As regulatory agencies and manufacturers are bur-

bound of EBGm's 95% confidence interval (EB05). Another major variation of the Bayesian approach that has been proposed for signal detection, the Bayesian Confidence Propagation Neural Network⁵ (BCPNN)

Moreover, investigators need to consider whether clinically overlapping events are coded in a hierarchical manner and whether related adverse event terms should be grouped together to detect safety signals. For example, there are multiple, highly overlapping adverse event codes related to specific forms of drug-induced liver injury, particularly in highly granular adverse event dictionaries such as MedDRA[®].



Primary Paths and Data Storage

- What are the questions?
 - What is typically “stored” at the time of coding/data entry (e.g., LLT, PT, HLT, etc.)
 - Does the system allow for more than one PT → SOC path?
 - If not, which one is stored?
 - How are secondary SOC analyses performed?



Primary Paths and Data Storage (cont)

- “*MedDRA Term Selection: Points to Consider*” (release 3.5)

“MedDRA is a standardized terminology. **It is considered essential that *ad hoc* structural changes in MedDRA not occur.** The assignment of terms across SOCs is pre-determined within the terminology and should not be altered by users. If MedDRA users believe that term(s) are inappropriately placed in the hierarchy, they should inform the MSSO by the change request process.”



Discussion