

***Summary of Changes to***

**MedDRA<sup>®</sup> TERM SELECTION:  
POINTS TO CONSIDER**

*Release 3.8  
Based on MedDRA Version 10.0*

**ICH-Endorsed Guide for MedDRA Users**

**Application to Adverse Drug Reactions /Adverse Events  
&  
Medical and Social History & Indications**

**2 April 2007**

The following is a listing of changes made between releases 3.7 and 3.8 of *MedDRA Term Selection: Points to Consider*:

### **Throughout document**

- 1) Correction of general spelling, punctuation, spacing, and format errors
- 2) Replacement of references to MedDRA Version 9.1 to Version 10.0
- 3) Update of examples based on MedDRA version changes

### **Special note**

This release of the *MedDRA Term Selection: Points to Consider* document contains a number of important changes such as:

1. Identification of “preferred options”
2. Additional section related to suicide/self-harm
3. Additional section related to neoplasms
4. Additional medication error term examples
5. Additional examples in some existing sections (e.g., Section 2.1, **Quality of source data**)

Please note that, due to some newly added sections to the document, the numbering of sections in the document, especially from Section 3.3 onward, has changed from the last release.

#### **1.1 Objective of this document**

A new third paragraph has been added to this section as follows:

At the request of users, in some cases where there is more than one option for selecting terms, a “preferred option” is identified. **The fact that a “preferred option” is identified does not limit MedDRA users to using that option.**

#### **2.1 Quality of source data**

A new set of examples have been added to this section as follows:

*Example: The presence or absence of a single letter in the reported verbatim text can make a difference in the final term selected. If “lip sore” is reported, select “Lip sore” (PT “Lip pain”). If “lip sores” are reported, select “Sores lip” (PT “Cheilitis”). Similarly, if “sore gums” are reported, select “Sore gums” (PT “Gingival pain”) and if “sores gum” is reported, select “Sores gum” (PT “Gingivitis”).*

## 2.2 Level of term selection

New text and examples have been added to this section as follows:

MedDRA users should be aware of the degree of specificity that MedDRA terms may have and the challenges this specificity may pose for appropriate term selection.

Below are examples that illustrate the specificity of MedDRA:

- Gender terms

MedDRA generally excludes demographic descriptors, such as gender and age, but some terms with gender qualifiers are included when the gender renders the concept unique.

*Example: There are terms “Infertility”, “Infertility female” and “Infertility male” in MedDRA.*

It is recommended that organization-specific coding guidelines address instances in which it is important to capture gender-specific concepts. MedDRA users should also consider the impact of gender-specific terms when comparing MedDRA coded data to data coded with older terminologies which may not have had corresponding gender-specific terms. For example, if the organization’s prior terminology had only a single term for “breast cancer”, consider the impact of selecting gender-specific terms for breast cancer for current data.

- Post-operative terms

MedDRA contains some post-operative terms. The most specific terms should be selected.

*Example: If “Post-operative bleeding” is reported, “Postoperative bleeding” (not “Bleeding”) can be selected.*

- Newly added terms

A new version of MedDRA is released every six months. When using a new version of MedDRA, additional, more specific LLTs may be available for term selection.

## 2.4 Choice of term

The example in Section 2.4.4:

*Example: If “metastatic gallbladder cancer” were not represented in MedDRA by a single term, it would be appropriate to select “Gallbladder cancer” or “Metastatic carcinoma” or both “Gallbladder cancer” and “Metastatic carcinoma.”*

Has been changed as follows:

*Example: If “metastatic uterine cancer” were not represented in MedDRA by a single term, it would be appropriate to select “Uterine cancer” or “Metastatic carcinoma” or both “Uterine cancer” and “Metastatic carcinoma.”*

### **3.1 Diagnoses and provisional diagnoses with signs and symptoms**

The following wording in Section 3.1.2:

If both a diagnosis and its characteristic signs and symptoms are provided by the reporter, one can select terms for both, but it is considered sufficient to select a term for only the diagnosis and not for the signs and symptoms.

Has been changed as follows:

If both a diagnosis and its characteristic signs and symptoms are provided by the reporter, one can select terms for both, but it is preferable to select a term for only the diagnosis and not for the signs and symptoms.

Also, the following example in Section 3.1.2 has been **deleted**:

*Example: If “chest pain, dyspnea, diaphoresis, and jaundice (possible myocardial infarction)” is reported, “Myocardial infarction” and “Jaundice” can be selected*

The following wording in Section 3.1.3:

If both a provisional diagnosis and its characteristic signs and symptoms are provided by the reporter, one can select terms for both, but it is considered sufficient to select a term for only the provisional diagnosis and not for the signs and symptoms.

Has been changed as follows:

If both a provisional diagnosis and its characteristic signs and symptoms are provided by the reporter, one can select terms for both, but it is preferable to select a term for only the provisional diagnosis and not for the signs and symptoms.

### **3.2 Death and Other Patient Outcomes**

Additional wording and an example have been added to Section 3.2.1.3:

The manner of death (e.g., natural, accidental, suicide, homicide) should not be inferred, but captured only if stated specifically by the reporter.

*Example: If the autopsy report states, “The cause of death was natural,” “Death from natural causes” can be selected.*

### **3.3 Suicide and Self-harm**

This is a newly added section with text and examples. Please refer to release 3.8 of the document for the details.

### **3.4 Conflicting/ambiguous/vague information**

Additional wording and an example have been added to Section 3.4.2

#### **Ambiguous information:**

It may be advisable to seek clarification for some terms as the final result of term selection may be very different.

*Example: COLD may refer to the common cold (PT “Nasopharyngitis”) or Chronic Obstructive Lung Disease (PT “Chronic obstructive pulmonary disease”).*

### **3.6 Body site vs. Event specificity** (formerly Section 3.5)

There is a minor addition to the Section 3.6.2 (formerly Section 3.5.2) as follows:

Not all MedDRA terms describe body sites. If the suitable MedDRA term with the specific site description is not available the relevant medical event should have priority.

This has changed to:

Not all MedDRA terms describe body sites. If the suitable MedDRA term with the specific site description is not available, in general, the relevant medical event should have priority.

Additional wording and an example have also been added to Section 3.6.2:

There will however be occasions when medical judgment is required and the body site description should have priority.

*Example: If “cyanosis at injection site” is reported, “Injection site reaction” can be selected instead of “Cyanosis” as cyanosis implies a generalized disorder.*

### **3.7 Location vs. Infectious agent**

A preferred option has been designated for Section 3.7.2 (formerly Section 3.6.2).

### **3.8 Pre-existing medical conditions**

The example in Section 3.8.2.2 (formerly Section 3.7.2.2):

*Example: If “progression of Alzheimer’s disease” is reported, “Alzheimer’s disease” and “Disease progression” can be selected*

Has been changed as follows:

*Example: If “progression of Addison’s disease” is reported, “Addison’s disease” and “Disease progression” can be selected.*

### **3.10 Neoplasms**

This is a newly added section with text and examples. Please refer to release 3.8 of the document for the details.

### **3.11 Medical/Surgical Procedures**

A preferred option has been designated for Section 3.11.2 (formerly Section 3.9.2).

### **3.13 Medication/administration errors and accidental exposures** (formerly Section 3.11)

There is a newly added section – Section 3.13.5 – with text and examples. Please refer to release 3.8 of the document for the details.

### **3.14 Overdose/Toxicity/Poisonings** (formerly Section 3.12)

Additional examples have been added to Section 3.14.1 (formerly Section 3.12.1): as follows:

*Example: If “A child was accidentally poisoned when she ingested an ammonia cleaning product is reported, “Accidental poisoning” can be selected.*

*Example: If “Patient was bitten by a copperhead snake and experienced thrombocytopenia” is reported, “Thrombocytopenia” can be selected, or “Venom poisoning” can be selected.*

**3.15 Drug interactions** (formerly Section 3.13)

An additional example has been added to Section 3.15.1 (formerly Section 3.13.1).

Also, a new sentence was added to Section 3.15.2 (formerly Section 3.13.2) as follows:

Labeled drug interactions may constitute medication errors. (See Section 3.13.5).

**3.21 Indication for product use** (formerly Section 3.19)

A preferred option has been designated for Section 3.21.2.2 (formerly Section 3.19.2.2).