

Summary of Changes to

**MedDRA[®] TERM SELECTION:
POINTS TO CONSIDER**

*Release 3.7
Based on MedDRA Version 9.1*

ICH-Endorsed Guide for MedDRA Users

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

10 January 2007

The following is a listing of changes made between releases 3.6 and 3.7 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 9.0 to Version 9.1
- 3) Update of examples based on MedDRA version changes

1.1 Objective of this document

The first sentence of this section was modified by adding “accurate and” before the words “consistent term selection”.

1.3 Background

In the third paragraph of this section, a footnote (number 3) was added which provides a web link to the MedDRA *Introductory Guide*.

2.1 Quality of source data

The second sentence in the first paragraph is new: “If clarification cannot be obtained, refer to Section 3.3., Conflicting/ambiguous/vague information”. (Note: This sentence was the third paragraph of Section 2.1 in release 3.6).

The second paragraph that had been in this section in release 3.6 has been removed.

2.4.3 Changed example from:

Example: If “brittle hair” is reported, “Hair texture abnormal” more accurately reflects the medical concept than the less specific term “Hair disorder”

to:

Example: If “brittle hair” is reported, “Hair breakage” more accurately reflects the medical concept than the less specific term “Hair disorder”

2.4.4 Changed example from:

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

to:

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”

Also, the final paragraph of this section in release 3.6 (begins with “Sometimes more than one choice of term selection...”) has been designated as a new separate section (2.4.5) in release 3.7.

2.5.1 Do not omit reported information

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

If a diagnosis (medical concept) is reported with characteristic signs and symptoms, it is acceptable to select a term only for the diagnosis and not for the signs and symptoms (see Section 3.1.2). As the diagnosis (medical concept) encompasses the signs and symptoms, this is not considered a loss of information.

Original Section 2.5.3 (release 3.6) has been moved to section 3.1.2 in release 3.7 (see below).

2.6 Quality Assurance

In the second paragraph of this section, the words “*Term Selection*” have been added before “*Points to Consider*”.

The third paragraph in this section (begins with “Data clarity can be promoted...”) has been moved here from original Section 2.1 in release 3.6. An additional last sentence has been added as follows:

For example, an organization may wish to make investigators and monitors aware of the issues of reporting “combination” terms (see Section 3.4).

3.1 Diagnoses and provisional diagnoses with signs and symptoms

The title of this section has been changed from the title in release 3.6, which was “**Provisional diagnoses**”.

Section 3.1.2 is newly placed here. This paragraph and two of the examples were in the original Section 2.5.3 in release 3.6. Besides having been moved to this part of the document, the word “provisional” has been deleted from three places in this paragraph.

The numbering of this part of the document has changed; original Section 3.1.2 is now 3.1.3; original Section 3.1.3 is now 3.1.4, etc.

In Section 3.1.3 (originally Section 3.1.2 in release 3.6), the first of two original examples has been deleted.

In Section 3.1.4 (originally Section 3.1.3 in release 3.6), the words “diagnoses or” and “diagnosis or” have been added to this paragraph, before the words “provisional diagnoses” and “provisional diagnosis”, respectively.

In Section 3.1.5 (originally Section 3.1.4 in release 3.6), the original wording:

If multiple provisional diagnoses are reported together with signs and symptoms, it is considered sufficient to select terms for only the signs and symptoms. It is also acceptable to select terms for each provisional diagnosis in addition to the signs and symptoms.

Example: If a differential diagnosis that includes “pulmonary embolism, myocardial infarction, and congestive heart failure” is reported along with “chest pain, cyanosis, shortness of breath, and blood pressure decreased”, then “Chest pain”, “Cyanosis”, “Shortness of breath”, and “Blood pressure decreased” can be selected

has been changed as follows (changes are in **bold**):

If multiple **diagnoses or** provisional diagnoses are reported together with signs and symptoms, **one can select terms for both, but** it is considered sufficient to select **a term for only the diagnosis or provisional diagnosis and not for the signs and symptoms.**

*Example: If a differential diagnosis that includes “pulmonary embolism, myocardial infarction, and congestive heart failure” is reported along with “chest pain, cyanosis, shortness of breath, and blood pressure decreased”, then “**Pulmonary embolism**”, **Myocardial infarction**”, **Congestive heart failure**” along with “Chest pain”, “Cyanosis”, “Shortness of breath”, and “Blood pressure decreased” can be selected*

3.4 Combination terms

The following paragraph and example have been added to Section 3.4.4:

However, be aware that splitting may occasionally result in loss of information unless one is attentive to the particular terms selected and especially where they lie in the MedDRA hierarchy.

Example: If “Hematoma due to an animal bite” is reported, “Animal bite” and “Traumatic hematoma” can be selected. Note that “Traumatic hematoma” is more appropriate than “Hematoma” based on the linkage in the MedDRA hierarchy (HLT Non-site specific injuries NEC and HLT Haemorrhages NEC for “Traumatic hematoma”; HLT Haemorrhages NEC for “Hematoma”)

3.7 Pre-existing medical conditions

Section 3.7.3 had been added; this is the original Section 3.4.5 from release 3.6 minus the “pain due to cancer” example.

3.11 Medication/administration errors and accidental exposures

In Section 3.11.1, the wording of the examples:

Example: If “hives due to medication error” is reported, “Hives” can be selected. “Medication error” can also be selected

Example: A patient was administered the wrong drug and experienced hypotension. The term “Hypotension” can be selected. In addition, “Wrong drug administered” can be selected.

has been changed as follows (changes are in **bold**):

*Example: If “hives due to medication error” is reported, “Hives” **and** “**Medication error**” can be selected*

*Example: A patient was administered the wrong drug and experienced hypotension. The term “Hypotension” **and** “Wrong drug administered” can be selected.*

In Section 3.11.2, the following new example has been added:

Example: A patient reports that tablets of a different strength are the same color and shape and this may result in a medication error. The term “Circumstance or information capable of leading to medication error” can be selected.

In Section 3.11.3, the wording of the examples:

Example: If “nurse splashed an injectable drug in her eye” is reported, “Inadvertent exposure to drug” can be selected

Example: If “child exposed to drug during breast feeding” is reported, “Drug exposure via breast milk” can be selected

has been changed as follows (changes are in **bold**):

*Example: If “nurse splashed an injectable drug in her **own** eye” is reported, “Inadvertent exposure to drug” can be selected*

*Example: If “child exposed to **maternal** drug during breast feeding” is reported, “Drug exposure via breast milk” can be selected*

Two new sections on medication errors, with examples, have been added to the document. These are Section 3.11.5 and 3.11.6.

3.19 Indication for product use

The following sentence has been added to the end of the third paragraph:

Because of the nature of such data, terms from almost any SOC, including SOC *Investigations*, may be selected for an indication.

4.1 Current members of the ICH *Points to Consider* working group:

The individual listed for “Canada: Health Canada” was changed from Bill Wilson to Heather Sutcliffe.

4.1 Past members/affiliations of the ICH *Points to Consider* working group:

Bill Wilson was added under “Canada: Health Canada”.