

Summary of Changes to

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

*Release 3.5
Based on MedDRA Version 8.1*

ICH-Endorsed Guide for MedDRA Users

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

7 November 2005

The following is a listing of changes made between releases 3.4 and 3.5 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 7.1 to Version 8.1
- 3) Update of examples based on MedDRA version changes

2.4 Choice of term

Added new section 2.4.1 that explains rationale for options in this document:

“In this document, more than one option for term selection is sometimes proposed. This is to allow a solution to accommodate different database configurations and historic working practices.”

In section 2.4.4 (formerly Section 2.4.3), changed example from “*Metastasis*” to “*Metastatic neoplasm*”.

3.2 Death and other patient outcomes

Added the phrase “*consequence of an event or a patient*” to the first paragraph.

3.2.2 Other Patient Outcomes

In the first paragraph, deleted the phrase “*Patient outcomes*” and replaced it with the phrase “*consequence of an event or a patient*”.

3.8.2 The following text and example were deleted:

“Note that a non-specific term is not always linked to the acquired term at a higher level.

Example: “color blindness” is reported, the term “Color blindness” can be selected which links to the HLT “Ocular disorders congenital NEC” through the PT “Colour blindness””

3.10 Investigations

In the first paragraph, deleted the word “*alone*” and replaced it with the phrase “*without qualifiers*”.

3.10.1 Investigation terms without qualifiers

Added the phrase “*such as in the E2b field B.3.1c*” to the end of the paragraph.

3.10.3 Added the following sentence to the example: *“An additional term for elevated potassium (e.g., “Potassium increased”) is not necessary”*.

3.11 Medication/administration errors and accidental exposures.

This section has undergone extensive revision since release 3.4.

The following paragraphs have been added to the beginning of this section.

“As of Version 8.0, there have been a significant number of new and more specific medication error terms added to MedDRA. Information may be reported describing medication errors with or without clinical consequences.

HLGT Medication errors is divided into HLT groupings based on the type of medication errors. The subordinate HLTs are HLT Maladministrations, HLT Medication monitoring errors, HLT Overdoses, HLT Medication errors due to accidental exposures, and HLT Medication errors NEC.”

3.11.1 Added the phrase *“medication error and the”* to the middle of the paragraph and deleted the sentence *“A term can also be selected for the medication error”*. Also, added the following additional example:

“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”

3.11.2 Added the phrases *“or the potential occurrence”* and *“term closest to the type of medication error”* to the paragraph and changed the first example to use the term *“Intramuscular formulation administered by other route”*.

Also, added wording on potential medication error and two additional examples to this section:

“Example: A patient was dispensed the wrong drug strength. The error was detected prior to patient administration. The term “Wrong drug strength selected” can be selected.

Additionally, information may be received describing the potential for a medication error.

Example: A pharmacist notices that the names of two drugs are similar and is concerned that this may result in a medication error. The term “Drug name confusion” can be selected”.

3.11.4 Changed the example to use the term “*Intramuscular formulation administered by other route*”.

3.12.1 Added the phrase “*Overdose terms are grouped under the HLT Overdoses and*” to the paragraph.

3.12.2 Deleted “*signs and/or symptoms*” and replaced it with the phrase “*the clinical consequences*”.

3.12.3 Deleted the phrase “*adverse effect*” and replaced it with “*clinical consequences*”.

3.15 Unexpected therapeutic effect

In the example, deleted the phrase “*on an antihypertensive*” and replaced it with “*using a product*”.

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

Added to “*Japan: Ministry of Health, Labour and Welfare*”: Tetsuya Kusakabe

Deleted from “*Japan: Ministry of Health, Labour and Welfare*”: Kenichi Tamiya, Manabu Yamamoto

Deleted from “*Japan: Japanese Maintenance Organization*”: Akemi Ishikawa

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

Added to “*Japan: Ministry of Health, Labour and Welfare*”: Kenichi Tamiya, Manabu Yamamoto

Added to “*Japan: Japanese Maintenance Organization*”: Akemi Ishikawa