

***Summary of Changes to***

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

*Release 3.13  
Based on MedDRA Version 12.1*

**ICH-Endorsed Guide for MedDRA Users**

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

**1 October 2009**

The following is a listing of changes made between releases 3.12 and 3.13 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 12.0 to Version 12.1
- 3) Update of examples based on MedDRA version changes

### **3.1 Diagnoses and provisional diagnoses with or without signs and symptoms**

A new paragraph was added to this section:

Note that the preferred option for a single or multiple provisional diagnosis(es) is to select a term(s) for the diagnosis(es) as well as terms for signs and symptoms. The alternate approach is to select terms for only the signs and symptoms; this is because the diagnosis(es) – being provisional – is subject to change while the signs and symptoms are not.

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

The following wording:

When an ADR/AE is reported in association with a consequence of an event or a patient outcome, a term for the ADR/AE should be selected and the outcome should be captured in the appropriate field.

#### **3.2.1 Death**

3.2.1.1 Death is an outcome and is not usually considered to be an ADR/AE.

*Example: If “death due to myocardial infarction” is reported, “Myocardial infarction” can be selected and death should be captured as the outcome.*

3.2.1.2 If multiple ADR/AEs are reported in association with a fatal outcome, MedDRA terms for each reported event should be selected.

*Example: If “constipation, ruptured bowel, peritonitis, sepsis, and patient died” are reported, “Constipation”, “Perforated bowel”, “Peritonitis”, and “Sepsis” can be selected, and death should be captured as the outcome.*

3.2.1.3 If the only information reported is death, then the most specific death term available should be selected.

*Example: If a reporter states only that “a patient was found dead”, “Found dead” can be selected.*

If circumstances of the death are provided (e.g., natural, accidental, suicide, homicide), and the term exists, it should be selected. However, circumstances of death 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.*

Was changed and re-ordered as follows:

Death is an outcome and is not usually considered to be an ADR/AE. In general, when an ADR/AE is reported along with a patient outcome, a term for the ADR/AE should be selected and the outcome should be captured in the appropriate field. However, some death terms in MedDRA provide additional clinical information and should be considered for term selection as described in the following examples:

### **3.2 1 Death**

3.2.1.1 If there are ADRs/AEs reported along with death, select terms for the ADRs/AEs. The fatal outcome can be otherwise captured in the appropriate data field.

*Example: If “death due to myocardial infarction” is reported, “Myocardial infarction” can be selected and death should be captured as the outcome.*

*Example: If “constipation, ruptured bowel, peritonitis, sepsis, and patient died” are reported, “Constipation”, “Perforated bowel”, “Peritonitis”, and “Sepsis” can be selected, and death should be captured as the outcome.*

3.2.1.2 If the only information reported is death, then the most specific death term available should be selected. Circumstances of death should not be inferred, but captured only if stated by the reporter.

*Example: If a reporter states only that “a patient was found dead”, “Found dead” can be selected.*

*Example: If a reporter states that “a patient dies during childbirth”, “Maternal death during childbirth” can be selected.*

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

3.2.1.3 If the particular death term adds important clinical information to the case, it can be selected.

*Example: If “patient experienced a rash and had sudden cardiac death” is reported, “Rash” and “Sudden cardiac death” can be selected.*

### **3.9 Pre-existing medical conditions**

One of the examples in this section:

*Example: If “halitosis worsened” is reported, “Halitosis” only can be selected.*

Was changed as follows (note that the word “only” has been removed):

*Example: If “halitosis worsened” is reported, “Halitosis” can be selected.*

### **3.22 Modification of effect**

Some examples in this section:

*Example: If “antibiotic didn’t work” is reported, “Lack of drug effect” can be selected.*

*Example: If “patient took drug and her headache didn’t go away, drug ineffective” is reported, “Drug ineffective” can be selected.*

Were changed and re-ordered as follows:

*Example: If “patient took drug and her headache didn’t go away, drug ineffective” is reported, selecting only “Drug ineffective” is preferred.*

*Example: If “antibiotic didn’t work” is reported, “Lack of drug effect” can be selected.*