

***Summary of Changes to***

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

*Release 3.10  
Based on MedDRA Version 11.0*

**ICH-Endorsed Guide for MedDRA Users**

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

**1 April 2008**

The following is a listing of changes made between releases 3.9 and 3.10 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 10.1 to Version 11.0
- 3) Update of examples based on MedDRA version changes
- 4) Previously missing footnotes have been re-added to the document

### **Special note**

This release of the *MedDRA Term Selection: Points to Consider* document contain changes such as:

1. Additional section related to age vs. event specificity
2. Additional section related to exposure during pregnancy and breast feeding
3. Expansion of section related to social circumstances
4. Additional section related to off label use

Please note that, due to the newly added sections to the document, the numbering of sections has changed from the last release.

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

The wording in Section 3.1.3:

Alternatively, it is considered sufficient to select terms for only the signs and symptoms.

Was changed as follows:

Alternatively, it is considered sufficient to select terms for only the signs and symptoms, since the signs and symptoms are factual and the provisional diagnosis may change.

The wording in Section 3.1.5:

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.

Was changed as follows:

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

An additional Section 3.1.6 was added as follows:

- 3.1.6 If multiple provisional diagnoses and their characteristic signs and symptoms are provided by the reporter, one can select terms for both, but it is preferable to select terms for only the provisional diagnoses and not for the signs and symptoms. However, terms should also be selected for signs or symptoms that are not generally recognized as part of those provisional diagnoses.

Alternatively, it is considered sufficient to select terms for only the signs and symptoms, since the signs and symptoms are factual and the provisional diagnoses may change.

The wording in 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.

Was changed as follows:

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.

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

The following wording was **removed** from this section:

- 3.3.4 If circumstances of the death are provided, it is acceptable to capture the circumstances with the appropriate term.

*Example: If “assisted suicide” or “mercy killing” is reported, “Euthanasia” can be selected. It is not appropriate to select “Suicide” or “Homicide.”*

### **3.5 Combination terms**

The following example in section 3.5.5 was **removed**:

*Example: If “pain due to cancer” is reported in a patient with cancer, “Cancer pain” can be selected.*

### **3.6 Age vs. Event Specificity**

This is a newly added section as follows:

- 3.6.1 Some MedDRA terms describe the age group and the event. If available, the term with the specific age group and event should be selected.

*Example: If “jaundice in a newborn” is reported, “Neonatal jaundice” can be selected.*

- 3.6.2 If a term is not available to capture both concepts, the preferred option is to select the term for the event and capture the age group in a demographic field.

*Example: If “oral candidiasis in a neonate” is reported, then “Oral candidiasis” can be selected and the neonatal status should be captured in a demographic field.*

Alternatively, it is acceptable to select terms for both age and event.

*Example: If “oral candidiasis in a neonate” is reported, “Oral candidiasis” and “Neonatal candida infection” can be selected.*

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

The following wording has been **removed**:

- 3.8.2.3 A new term can be requested from the MSSO. In general, the MSSO will add such terms if medical significance has been demonstrated (*Introductory Guide*, MedDRA Version 10.1).

### **3.10 Exposures During Pregnancy and Breast Feeding**

This is a newly added section as follows:

MedDRA contains various terms that address exposures to medical products (drug and nondrug) during pregnancy and breast feeding. To select the most

appropriate term(s) to capture the information, first determine if the subject/patient who experienced the event(s) was the mother or the child/fetus.

### 3.10.1 Events in the Mother

#### 3.10.1.1 Patient became pregnant while receiving medication

Pregnancy is not normally considered an adverse event, but organizations may wish to capture this information in their databases.

If the occurrence of pregnancy is reported but there is no pregnancy outcome and no adverse event has occurred, it is appropriate to select both “*Pregnancy*” and “*No adverse effect*” (see Section 3.20).

If the occurrence of pregnancy is reported but there is no pregnancy outcome and it is not known yet whether any adverse event occurred, select “*Pregnancy*” only.

#### 3.10.1.2 Pregnant patient experienced adverse event(s) while receiving medication.

Appropriate term(s) for the adverse event and “*Drug exposure during pregnancy*” can be selected. “*Pregnancy*” can also be selected for the medical history and/or concomitant medical condition.

### 3.10.2 Events in the child or fetus

It is helpful to first determine if the child or fetus was exposed or potentially exposed to the medical product from the mother or the father.

#### 3.10.2.1 Child or fetus experienced adverse event(s) and was exposed to the drug in utero; mother received the product.

Appropriate term(s) should be selected for the adverse event(s). (Note that the patient is the child or fetus). In addition, “*Maternal drugs affecting fetus*” can also be selected (preferred). Alternatively, “*Drug exposure during pregnancy*” can also be selected.

#### 3.10.2.2 Child or fetus experienced adverse event(s) and was exposed to the drug in utero; father received the product.

Appropriate term(s) should be selected for the adverse event(s). (Note that the patient is the child or fetus). In addition, “*Transmission of drug via semen*” can also be selected.

3.10.2.3 Child experienced an adverse event and was exposed to the drug from breast milk.

Appropriate term(s) should be selected for the adverse event(s). (Note that the patient is the child). In addition, “*Drug exposure via breast milk*” can also be selected..

### 3.14.1 Investigation terms without qualifiers

Additional wording was added to this section as follows:

*Example: If “blood glucose increased” is reported, and the user wishes to capture laboratory results, the term “blood glucose” can be selected for the test name and the free text “increased” can be entered in the result field. It is not appropriate to put “blood glucose increased” as a test name.*

### 3.15 Medication/administration errors and accidental exposures

The following example was added to Section 3.15.5:

*Example: If a patient is administered a sulfonamide-based drug when it was clearly noted in his medical file that he had a sulfa allergy, “Documented hypersensitivity to administered drug” may be selected.*

### 3.17 Overdose/Toxicity/Poisonings

The following example was **removed** from Section 3.15.1:

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

### 3.18 Device terms

The following example in Section 3.18.2 (previously Section 3.16.2):

*Example: If “medical device related infection” is reported, “Device related infection” can be selected.*

Was changed as follows:

*Example: If a patient with a vascular implant developed an implant site*

*vascular infection" is reported, "Vascular implant infection" can be selected.*

**3.22 Modification of effect** (previously Section 3.20)

The following wording was **removed**:

3.20.3 It is considered appropriate to use lack of effect terms when the information reported clearly communicates that the expected effect was not obtained.

**3.23 Social circumstances**

The following table:

<b>SOC Social circumstances</b>	<b>“Disorder” SOC</b>
Alcoholic	Alcoholism

Was modified as follows:

<b>SOC Social circumstances</b>	<b>“Disorder” SOC</b>
Alcoholic	Alcoholism
Drug abuser	Drug abuse
Tobacco user	Nicotine dependence
Glue sniffer	Glue sniffing

Additional wording was added to this section as follows:

Note that abuse terms not associated with drugs/substances appear in SOC *Social circumstances* regardless of whether they refer to the person or the condition. The following example is illustrative.

<b>SOC Social circumstances</b>	
<b>LLT</b>	<b>PT</b>
Child abuse	Child abuse
Child abuser	Child abuse
Elder abuse	Elder abuse
Elder abuser	Elder abuse

**3.23.1 Illegal acts and concepts of crime or abuse (excluding drug/substance related abuse terms)**

All illegal acts of crime or abuse (excluding drug and/or other substance related abuse terms) link to the SOC *Social circumstances*.

*Example: If “Physical assault” is reported the selected term “Physical assault” links to the SOC Social circumstances*

#### 3.23.1.1 Perpetrator

LLT terms representing the perpetrator are directly related to the corresponding PT term describing the unlawful act/crime committed

*Example: If the reported patient history indicates that the patient is a known sexual offender, “Sexual offender” can be selected which would links to the PT “Sexual abuse”.*

(Note: The LLT “Sexual offender” links to the SOC *Social circumstances*.)

#### 3.23.1.2 Victim

PT terms representing the victims of unlawful acts are preceded by “*Victim of*”. Associated unqualified terms representing the victim are represented at the LLT level.

*Example: If it was reported that the patient was a childhood sexual assault victim, “Childhood sexual assault victim” can be selected, which links to the PT “Victim of sexual abuse”.*

(Note: The LLT “Childhood sexual assault victim” links to the SOC *Social circumstances*.)

### 3.26 Off label use

This is a newly added section as follows:

Use of a product for an indication for which it is not labeled is referred to as “off label use.”

#### 3.26.1 Indications for use

If a medical condition is reported as an indication and “off label use“ is also reported, the condition can be selected for the indication field. “Off label use” should only be selected if that is the only information available. Alternatively, both the indication and “Off label use,” can be selected.

*Example: If the reported indication is “hypertension and this is an off label use”, “Hypertension” can be selected, or “Hypertension” and “Off label use” can be selected.*

*Example; If the reported indication is “Off label use”, “Off label use” can be selected.*

### **3.26.2 ADR/AEs**

If ADR/AEs are a consequence of use of a product for an indication for which it is not labeled, terms for the ADR/AEs should be selected. Alternatively, terms for both the ADR/AEs and “Off label use” can be selected.

*Example: If “a patient was administered a drug off label for pulmonary hypertension and the patient suffered a stroke,” stroke” can be selected. Alternatively both “Stroke” and “Off label use” can be selected.*