

Summary of Changes to

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

ICH-Endorsed Guide for MedDRA Users

***Release 4.2
Based on MedDRA Version 14.1***

1 October 2011

The following is a listing of changes made between releases 4.1 and 4.2 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 14.0 to Version 14.1
- 3) Update of examples based on MedDRA version changes
- 4) Links to the MSSO Web site (e.g., in footnotes) have been updated

3.10.2 Events in the child or fetus

One of the examples in this section:

Example

Setting/Patient	Reported	LLT Selected
Child/fetus with AE; <i>exposed in utero</i> ; mother took product	Pregnant woman taking drug X had fetal tachycardia noted on routine examination	Fetal tachycardia Drug exposure in utero OR Maternal drug exposure

Was changed as follows:

Example

Setting/Patient	Reported	LLT Selected
Child/fetus with AE; <i>exposed in utero</i> ; mother took product	Pregnant woman taking drug X had fetal tachycardia noted on routine examination	Fetal tachycardia Drug exposure in utero OR Drug exposure during pregnancy

3.14.5 Investigation terms without qualifiers

The text and examples in this section:

Terms in SOC *Investigations* **without qualifiers** may be used to record test names (such as in E2B field B.3.1c).

Example

Information/Reported	LLT Selected for Test Name	Comment
Cardiac output measured	Cardiac output	
Blood glucose increased	Blood glucose	Do not select <i>Blood glucose increased</i> as a test name; enter "increased" in the result data field

Were changed as follows:

Terms in SOC *Investigations* **without qualifiers** may be used to record test names when entering diagnostic test data (such as in E2B field B.3.1c).

Example

Information/Reported (Verbatim)	LLT Selected for Test Name	Comment
Cardiac output measured	Cardiac output	
Increased blood sugar	Blood glucose	LLT <i>Blood glucose increased</i> should not be selected as it is both a test name and a result*

* Enter a qualifier (e.g., "increased") or a numeric result (if available) into the "Result" data field of the E2B format.

3.16 – Transmission of Infectious Agent via Medicinal Product

The examples in this section:

Example

Reported	LLT Selected
Suspected transmission of Hepatitis C via blood product	Suspected transmission of an infectious agent via a medicinal product Hepatitis C
Confirmed transmission of Hepatitis C	Transmission of an infectious agent via a

Reported	LLT Selected
via blood product	medicinal product Hepatitis C

Were changed as follows:

Example

Reported	LLT Selected
Patient received a nasal spray product and later developed a severe nasal infection with <i>Burkholderia cepacia</i> . Cultures of unopened containers of the nasal spray grew <i>B. cepacia</i>	Transmission of an infectious agent via a medicinal product Burkholderia cepacia infection
Patient received a blood transfusion and developed Hepatitis C	Transfusion-transmitted infectious disease Hepatitis C

3.22.1 Lack of effect

The text in this section:

The **preferred option** is to select only the “lack of effect” term even if consequences are also reported. However, terms may also be selected for events resulting from the lack of effect; these can be recorded in database fields for adverse event, medical history or product indication.

Was changed as follows:

The **preferred option** is to select only the “lack of effect” term even if consequences are also reported. However, terms may also be selected for events associated with the lack of effect.

4.2 – Links and References

The link for the MedDRA Introductory Guide:

Document	Link
MedDRA Introductory Guide*	https://meddramsso.com/secure/subscriber_download_translations.asp

Was changed as follows:

Document	Link
MedDRA Introductory Guide	<a href="http://meddramsso.com/files_acrobat/intguide_14_1_English_u
pdate.pdf">http://meddramsso.com/files_acrobat/intguide_14_1_English_u pdate.pdf

And the link for the MSSO's Recommendations for Single Case Reporting:

Document	Link
MSSO's Recommendations for Single Case Reporting	http://meddramsso.com/files_acrobat/VCGuidesemiannual.pdf

Was changed as follows:

Document	Link
MSSO's Recommendations for Single Case Reporting	http://meddramsso.com/files_acrobat/VCGuide_semiannual.pdf