

Summary of Changes to

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

*Release 3.6
Based on MedDRA Version 9.0*

ICH-Endorsed Guide for MedDRA Users

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

28 March 2006

The following is a listing of changes made between releases 3.5 and 3.6 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 8.1 to Version 9.0
- 3) Update of examples based on MedDRA version changes

2.4 Choice of term

2.4.2 Changed example from:

Example: The term “HIV viral load increased” was added to MedDRA following a user’s request

to:

Example: The term “HCV coinfection” was added to MedDRA following a user’s request

3.11 Medication/administration errors and accidental exposures

3.11.2 Changed example from:

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.

to:

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