

Summary of Changes to

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

*Release 3.14
Based on MedDRA Version 13.0*

ICH-Endorsed Guide for MedDRA Users

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

1 April 2010

The following is a listing of changes made between releases 3.13 and 3.14 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 12.1 to Version 13.0
- 3) Update of examples based on MedDRA version changes
- 4) Links to the MSSO Web site (e.g., in footnotes) have been updated

3.8 Location vs. Infectious agent

Wording in Section 3.8.2:

3.8.2 Not all infection terms in MedDRA describe location. If the suitable MedDRA term with the organism description is not available, the preferred option would be to select the infective agent. It is also considered acceptable to select the infection site term alone or to select terms for both concepts.

Was changed as follows:

3.8.2 Not all infection terms in MedDRA describe location. If the suitable MedDRA term with the organism description is not available, the preferred option would be to select the infective agent. However, each organization should consider the priorities of the specific product and select the site of infection if that is the most appropriate option. It is also considered acceptable to select the infection site term alone or to select terms for both concepts.

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

Michelle Séguin's name was replaced by Lynn Macdonald's for the Health Canada membership.

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

Lynn Macdonald's name was removed and Michelle Séguin's name was added for the Health Canada membership.