

Summary of Changes to

**MedDRA[®] DATA RETRIEVAL
AND PRESENTATION:
POINTS TO CONSIDER**

Release 2.2

Based on MedDRA Version 13.0

**ICH-Endorsed Guide for MedDRA Users on
Data Output**

1 April 2010

The following is a listing of changes made between releases 2.1 and 2.2 of *Data Retrieval and Presentation: 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

2.5 MedDRA Versioning

The following wording:

Keep in mind the above changes may impact previous data retrieval approaches and results, including event frequencies. For example, in MedDRA Version 12.0, *Hip swelling* was a PT and in Version 12.1 it was “demoted” to an LLT.

As noted in the table in Figure 3, the original query was done in MedDRA Version 12.0 in which there was a PT *Hip swelling*. If the query had been re-run in MedDRA Version 12.1, these events would not have been found at the PT level because in MedDRA Version 12.1, PT *Hip swelling* was demoted to an LLT under PT *Joint swelling*.

In MedDRA Version 12.0, the primary SOC assignment for PT *Wound haemorrhage* was SOC *Vascular disorders* and the secondary SOC assignment was SOC *Injury, poisoning and procedural complications*. In Version 12.1, the primary SOC assignment was changed to SOC *Injury, poisoning and procedural complications* and the secondary SOC assignment to SOC *Vascular disorders*. If one were able to retrieve PTs only under their primary SOC assignment, this term will seem to have “disappeared” from SOC *Vascular disorders*.

Was changed as follows (see also 6.3 Figures below):

Keep in mind the above changes may impact previous data retrieval approaches and results, including event frequencies. For example, in MedDRA Version 12.1, *Pacemaker complication* was a PT and in Version 13.0 it was “demoted” to an LLT.

As noted in the table in Figure 3, the original query was done in MedDRA Version 12.1 in which there was a PT *Pacemaker complication*. If the query had been re-run in MedDRA Version 13.0, these events would not have been found at the PT level because in MedDRA Version 13.0, PT *Pacemaker complication* was demoted to an LLT under PT *Medical device complication*.

In MedDRA Version 12.1, the primary SOC assignment for PT *Ectopic hormone secretion* was SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* and the secondary SOC assignment was SOC *Endocrine disorders*. In Version 13.0, the primary SOC assignment was changed to SOC *Endocrine disorders* and the secondary SOC assignment to SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)*. If one were able to retrieve PTs only under their primary SOC assignment, this

term will seem to have “disappeared” from SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)*.

4.5 SMQs and MedDRA Version Changes

Wording in this example:

Example:

PT *Traumatic lung injury* was added to SMQ *Accidents and injuries* in MedDRA Version 12.1. Using the Version 12.0 of this SMQ – which does not contain this PT – would fail to identify cases coded to this term in a database using MedDRA Version 12.1.

Was changed as follows:

Example:

PT *Spinal column injury* was added to SMQ *Accidents and injuries* in MedDRA Version 13.0. Using the Version 12.1 of this SMQ – which does not contain this PT – would fail to identify cases coded to this term in a database using MedDRA Version 13.0.

6.1 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.

6.2 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.

6.3 Figures

Figure 3:

MedDRA Version 12.0	Number of Events at PT Level
Hip swelling (PT)	15
Joint swelling	5

MedDRA Version 12.1	Number of Events at PT Level
Hip swelling (no longer a PT)	0
Joint swelling	20

Figure 3 – In MedDRA Version 12.0, Hip swelling was a PT and in Version 12.1 it was demoted to an LLT

Was changed as follows:

MedDRA Version 12.1	Number of Events at PT Level
Pacemaker complication (PT)	15
Medical device complication	5
MedDRA Version 13.0	Number of Events at PT Level
Pacemaker complication (no longer a PT)	0
Medical device complication	20

Figure 3 – In MedDRA Version 12.1, Pacemaker complication was a PT and in Version 13.0 it was demoted to an LLT