

***Summary of Changes to***

**MedDRA<sup>®</sup> DATA RETRIEVAL  
AND PRESENTATION:  
POINTS TO CONSIDER**

*Release 1.6  
Based on MedDRA Version 11.1*

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

**1 October 2008**

The following is a listing of changes made between releases 1.5 and 1.6 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 11.0 to Version 11.1
- 3) Update of examples based on MedDRA version changes
- 4) Update of current and past members of the Points to Consider Working Group (Section 4, Appendices)

## 2.6 MedDRA Versioning

The following paragraphs:

Keep in mind the above changes may impact previous data retrieval approaches and results, including event frequencies. For example, in MedDRA Version 10.1, *Neuropathy* was a PT and in Version 11.0 it was “demoted” to an LLT.

### Example:

MedDRA Version 10.1	Number of Events at PT Level
Neuropathy (PT)	15
Neuropathy peripheral	5
<b>MedDRA Version 11.0</b>	
Neuropathy (no longer a PT)	0
Neuropathy peripheral	20

As noted in the table above, the original query was done in MedDRA Version 10.1 in which there was a PT *Neuropathy*. If the query had been re-run in MedDRA Version 11.0, these events would not have been found at the PT level because in MedDRA Version 11.0, PT *Neuropathy* was demoted to an LLT under PT *Neuropathy peripheral*.

In MedDRA Version 10.1, the primary SOC assignment for PT *Liver injury* was SOC *Injury, poisoning and procedural complications* and the secondary SOC assignment was SOC *Hepatobiliary disorders*. In Version 11.0, the primary SOC assignment was changed to SOC *Hepatobiliary disorders* and the secondary SOC

assignment to SOC *Injury, poisoning and procedural complications*. If one were able to retrieve PTs only under their primary SOC assignment, this term will seem to have “disappeared” from SOC *Injury, poisoning and procedural complications*.

Were changed as follows:

Keep in mind the above changes may impact previous data retrieval approaches and results, including event frequencies. For example, in MedDRA Version 11.0, *Injection site bruising* was a PT and in Version 11.1 it was “demoted” to an LLT.

**Example:**

MedDRA Version 11.0	Number of Events at PT Level
Injection site bruising (PT)	15
Injection site haematoma	5
MedDRA Version 11.1	Number of Events at PT Level
Injection site bruising (no longer a PT)	0
Injection site haematoma	20

As noted in the table above, the original query was done in MedDRA Version 11.0 in which there was a PT *Injection site bruising* . If the query had been re-run in MedDRA Version 11.1, these events would not have been found at the PT level because in MedDRA Version 11.1, PT *Injection site bruising* was demoted to an LLT under PT *Injection site haematoma*.

In MedDRA Version 11.0, the primary SOC assignment for PT *Arterial restenosis* was SOC *Vascular disorders* and the secondary SOC assignment was SOC *Injury, poisoning and procedural complications*. In Version 11.1, 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*.

The terms used for queries should be in the same MedDRA version as the data being queried. For example, new terms might have been included in a query built on MedDRA Version 11.1 that might not be represented in stored data coded in MedDRA Version

10.1; this could lead to search results that are incomplete. On the other hand, a search built on an earlier MedDRA version (e.g., from a closed study), might not detect all of the relevant data in an integrated safety summary (ISS) coded in a later version of MedDRA. Any queries stored in an organization's system should be updated to the appropriate version of MedDRA prior to use on new data.