

***Summary of Changes to***

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

*Release 1.5  
Based on MedDRA Version 11.0*

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

**1 April 2008**

The following is a listing of changes made between releases 1.4 and 1.5 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 10.1 to Version 11.0
- 3) Update of examples based on MedDRA version changes

### 2.6 MedDRA Versioning

The wording and tables related to examples of version changes:

Keep in mind the above changes may impact previous data retrieval approaches and results, including event frequencies. For example, in MedDRA Version 10.0, *Electrocardiogram QT corrected interval prolonged* was a PT and in Version 10.1 it was “demoted” to an LLT.

#### Example:

MedDRA Version 10.0	Number of Events at PT Level
Electrocardiogram QT corrected interval prolonged (PT)	15
Electrocardiogram QT prolonged	5
MedDRA Version 10.1	Number of Events at PT Level
Electrocardiogram QT corrected interval prolonged (no longer a PT)	0
Electrocardiogram QT prolonged	20

As noted in the table above, the original query was done in MedDRA Version 10.0 in which there was a PT *Electrocardiogram QT corrected interval prolonged*. If the query had been re-run in MedDRA Version 10.1, these events would not have been found at the PT level because in MedDRA Version 10.1, PT *Electrocardiogram QT corrected interval prolonged* was demoted to an LLT under PT *Electrocardiogram QT prolonged*.

In MedDRA Version 10.0, the primary SOC assignment for PT *Retinal scar* was SOC *Eye disorders*; in Version 10.1, the primary SOC assignment was changed to SOC *Injury, poisoning and procedural complications* and the secondary SOC assignment to SOC *Eye disorders*. If one were able to retrieve PTs only under their primary SOC assignment, this term will seem to have “disappeared” from SOC *Eye disorders*.

has been 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 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
MedDRA Version 11.0	Number of Events at PT Level
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 *Neuropath* 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*.

**3.2.3.2 Search by Standardised MedDRA Queries (SMQs)**

Wording of the first and second bullets were slightly reordered, but the generally meanings are unchanged.

Wording of the third bullet:

- It is essential for the MedDRA user to carefully read the SMQ Introductory Guide before applying an SMQ in order to fully understand the scope of the SMQ and to properly apply algorithms (an optional feature).

Has been changed as follows:

- It is essential for the MedDRA user to carefully read the *Introductory Guide for Standardised MedDRA Queries (SMQs)* before applying an SMQ in order to fully understand the scope of the SMQ and to properly apply algorithms or weightings (optional features).

The last bullet of this section:

- For SMQs which contain HLGTs and or HLTs it is also important to verify whether the database structure will allow for retrieval of only primary PTs under the included HLTs or whether also secondary PTs will be retrieved (see also Section 2.3)Has been deleted.

Has been deleted.