

***Summary of Changes to***

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

*Release 1.4  
Based on MedDRA Version 10.1*

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

**12 September 2007**

The following is a listing of changes made between releases 1.3 and 1.4 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 10.0 to Version 10.1
- 3) Update of examples based on MedDRA version changes

Please note that, due to removal of Section 2.5 from the document (see below), the numbering of sections, has changed from the last release.

### 2.5 Special Search Categories

This entire section has been removed from the document.

### 2.6 MedDRA Versioning

The following bullet has been **removed** from this section (formerly Section 2.7):

- Adding or deleting a PT in an SSC

In addition, 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 9.1, *Bronchitis acute* was a PT and in Version 10.0 it was “demoted” to an LLT.

#### Example:

MedDRA Version 9.1	Number of Events at PT Level
Bronchitis acute (PT)	15
MedDRA Version 10.0	Number of Events at PT Level
Bronchitis acute (no longer a PT)	0
Bronchitis	15

As noted in the table above, the original query for bronchitis acute was done in MedDRA Version 9.1 in which there was a PT Bronchitis acute. If the query had been re-run in MedDRA Version 10.0, these events would not have been found at the PT level because in MedDRA Version 10.0, PT Bronchitis acute was demoted to an LLT under PT *Bronchitis*.

In MedDRA Version 9.1, the primary SOC assignment for PT *Post procedural sepsis* was SOC *Injury, poisoning and procedural complications*; in Version 10.0, the primary SOC assignment was changed to SOC *Infections and*

*infestations* 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*.

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 10.0, *Electrocardiogram QT corrected interval prolonged* was a PT and in Version 10.1 it was “demoted” to an LLT.

**Example:**

<b>MedDRA Version 10.0</b>	<b>Number of Events at PT Level</b>
Electrocardiogram QT corrected interval prolonged (PT)	15
Electrocardiogram QT prolonged	5
<b>MedDRA Version 10.1</b>	
<b>Number of Events at PT Level</b>	
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*.

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

Wording of the second bullet:

- More than thirty SMQs are currently in production.

has been changed as follows:

- More than fifty SMQs are currently in production.

#### **4.1 Current members of the ICH *Points to Consider* working group**

John (Jake) Kelsey and Christina Winter were added as new co-Rapporteurs.

Osamu Handa was added as a new member from the Japanese Maintenance Organization.

Morell David was added as a new member from the Commission of the European Communities.

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

Dolores Montero was added under Commission of the European Communities.

Reinhard Fescharek (past-Rapporteur) was added under European Federation of Pharmaceutical Industries Associations.