

Summary of Changes to

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

*Release 1.3
Based on MedDRA Version 10.0*

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

2 April 2007

The following is a listing of changes made between releases 1.2 and 1.3 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 9.1 to Version 10.0
- 3) Update of examples based on MedDRA version changes

2.3 Organization-Specific Data Characteristics

New wording has been added to the bullet called “Coding practices over time” as follows:

- **Coding practices over time. For example, MedDRA users should consider the impact of gender-specific terms when comparing MedDRA coded data to data coded with older terminologies which may not have had corresponding gender-specific terms. If the organization’s prior terminology had only a single term for “breast cancer”, consider the impact of selecting gender-specific terms for breast cancer for current data.**

2.5 Special Search Categories

The following wording:

SSCs have been a part of MedDRA since its initial introduction to users. However, Standardised MedDRA Queries (SMQs) are more recent and more robust queries and the utility of SSCs has been diminished. As a result, the MSSO will discontinue the maintenance and distribution of SSCs in March 2007 (MedDRA Version 10.0) and will archive the existing SSC files on the subscriber section of the MSSO Web site. For MedDRA Version 9.1, SSCs will receive minimal maintenance (e.g., new Preferred Terms (PTs) will be considered for inclusion in existing SSCs), and no new SSCs will be developed.

Has been changed as follows:

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2.6 Standardised MedDRA Queries

The following wording:

SMQs differ from SSCs in several ways:

- SMQs are developed from a case definition of a medical condition.
- SMQs can contain grouping terms (HLTs and HLGTs) as well as PTs, whereas SSCs only contain PTs.

Has been changed as follows:

Characteristics of SMQs include:

- SMQs are developed from a case definition of a medical condition.
- SMQs can contain grouping terms (HLTs and HLGTs) as well as PTs.

2.6 MedDRA Versioning

The example and text below:

Example:

MedDRA Version 9.0	Number of Events at PT Level
Coronary artery surgery (PT)	15
MedDRA Version 9.1	Number of Events at PT Level
Coronary artery surgery (no longer a PT)	0
Coronary artery bypass	15

As noted in the table above, the original query for circulatory depression was done in MedDRA Version 9.0 in which there was a PT *Coronary artery surgery*. If the query had been re-run in MedDRA Version 9.1, these events would not have been found at the PT level because in MedDRA Version 9.1, PT *Coronary artery surgery* was demoted to an LLT under PT *Coronary artery bypass*.

In MedDRA Version 9.0, the primary SOC assignment for PT *Vomiting in pregnancy* was SOC *Pregnancy, puerperium and perinatal conditions*; in Version 9.1, the primary SOC assignment was changed to SOC *Gastrointestinal disorders* and the secondary SOC

assignment to SOC *Pregnancy, puerperium and perinatal conditions*. If one were able to retrieve PTs only under their primary SOC assignment, this term will seem to have “disappeared” from SOC *Pregnancy, puerperium and perinatal conditions*.

Has changed as follows:

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*.

3.2.1 Overview by Primary System Organ Class

The example for **Primary SOC Output Listing** has been changed so that the SOCs are in English alphabetical order and in International Agreed Order.

3.2.3.2 Search by Standardised MedDRA Queries (SMQs)

Wording of the second bullet as follows:

- A certain number of SMQs have been developed. If an available SMQ is relevant to the search, it may be used. Do not modify the term content or structure of the SMQ unless there is a compelling reason to do so since altering it makes it non-standard. If altering an SMQ is absolutely necessary, document the changes made.

Has been changed as follows:

- More than thirty SMQs are currently in production. If an available SMQ is relevant to the search, it may be used. Do not modify the term content or structure of the SMQ unless there is a compelling reason to do so since altering it makes it non-standard. If altering an SMQ is absolutely necessary, document the changes made.