

Summary of Changes to

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

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

***Release 3.5
Based on MedDRA Version 16.0***

1 April 2013

The following is a listing of changes made between releases 3.4 and 3.5 of *Data Retrieval and Presentation: Points to Consider*.

Throughout document

- 1) Correction of general spelling, punctuation, spacing, figure numbering, and format errors
- 2) Replacement of references to MedDRA Version 15.1 to Version 16.0
- 3) Update of examples based on MedDRA version changes

2.6 – MedDRA Versioning

The Example tables in this section:

Example

Impact of Version Changes - Demoted PT
PT <i>Cytolytic hepatitis</i> was included in a query developed using terms in MedDRA Version 15.0. If the query had been re-run on data using MedDRA Version 15.0, these events would not have been found at the PT level because PT <i>Cytolytic hepatitis</i> had been demoted to an LLT and linked to PT <i>Hepatitis</i> . See Figure 3.

Example

Impact of Version Changes - Change of Primary SOC Assignment
PT <i>Oropharyngeal scar</i> had a primary link to SOC <i>Gastrointestinal disorders</i> and a secondary link to SOC <i>Respiratory, thoracic and mediastinal disorders</i> in MedDRA Version 15.0. In Version 15.1, the primary SOC assignment was changed to SOC <i>Respiratory, thoracic and mediastinal disorders</i> and the secondary assignment to SOC <i>Gastrointestinal disorders</i> . In a primary SOC output of data, PT <i>Oropharyngeal scar</i> will seem to have "disappeared" from SOC <i>Gastrointestinal disorders</i> .

Were changed as follows:

Example

Impact of Version Changes - Demoted PT
PT <i>AIDS encephalopathy</i> was included in a query developed using terms in MedDRA Version 15.1. If the query had been re-run on data using MedDRA

Impact of Version Changes - Demoted PT
Version 16.0, these events would not have been found at the PT level because PT <i>AIDS encephalopathy</i> had been demoted to an LLT and linked to PT <i>AIDS dementia complex</i> . See Figure 3.

Example

Impact of Version Changes - Change of Primary SOC Assignment
PT <i>Anaesthetic complication foetal</i> had a primary link to <i>SOC Pregnancy, puerperium and perinatal conditions</i> and a secondary link to <i>SOC Injury, poisoning and procedural complications</i> in MedDRA Version 15.1. In Version 16.0, the primary SOC assignment was changed to <i>SOC Injury, poisoning and procedural complications</i> and the secondary assignment to <i>SOC Pregnancy, puerperium and perinatal conditions</i> . In a primary SOC output of data, PT <i>Anaesthetic complication foetal</i> will seem to have "disappeared" from <i>SOC Pregnancy, puerperium and perinatal conditions</i> .

4.5 – SMQs and MedDRA Version Changes

The Example table in this section:

Example

Consequence of Version Mismatch of Coded Data and SMQ
PT <i>Uveitic glaucoma</i> was added to SMQ <i>Glaucoma</i> in MedDRA Version 15.1. Using Version 15.0 of this SMQ - which does not contain this PT - would fail to identify cases coded to this term in a database using MedDRA Version 15.1.

Was changed as follows:

Example

Consequence of Version Mismatch of Coded Data and SMQ
PT <i>Dystonic tremor</i> was added to SMQ <i>Dystonia</i> in MedDRA Version 16.0. Using Version 15.1 of this SMQ - which does not contain this PT - would fail to identify cases coded to this term in a database using MedDRA Version 16.0.

5.1 – Modified MedDRA Query Based on an SMQ

One of the rows of the Example table in this section:

Example

Modified MedDRA Queries based on SMQs	
Changing the scope (narrow or broad) of an SMQ term	A product is being investigated for severe cutaneous adverse reactions (SCARs) including a potential for drug rash with eosinophilia and systemic symptoms (also called DRESS syndrome). SMQ <i>Severe cutaneous adverse reactions</i> has PT <i>Drug rash with eosinophilia and systemic symptoms</i> as a broad search term. For this query, it may be useful to include PT <i>Drug rash with eosinophilia and systemic symptoms</i> in the narrow search.

Was changed as follows (note minor wording change for the PT *Drug reaction with eosinophilia and systemic symptoms*):

Example

Modified MedDRA Queries based on SMQs	
Changing the scope (narrow or broad) of an SMQ term	A product is being investigated for severe cutaneous adverse reactions (SCARs) including a potential for drug rash with eosinophilia and systemic symptoms (also called DRESS syndrome). SMQ <i>Severe cutaneous adverse reactions</i> has PT <i>Drug reaction with eosinophilia and systemic symptoms</i> as a broad search term. For this query, it may be useful to include PT <i>Drug reaction with eosinophilia and systemic symptoms</i> in the narrow search.

6.2.1 Current members of the ICH Points to Consider Working Group

Designation of the current and former Rapporteurs:

Affiliation	Member
European Federation of	Hilary Vass**

Affiliation	Member
Pharmaceutical Industries Associations	Christina Winter*
US Food and Drug Administration	John (Jake) Kelsey*

* Current co-Rapporteurs

** Acting Rapporteur for June 2010 meeting of Working Group

Was changed as follows:

Affiliation	Member
European Federation of Pharmaceutical Industries Associations	Hilary Vass*
	Christina Winter†
US Food and Drug Administration	John (Jake) Kelsey*

* Current co-Rapporteurs

† Former Rapporteur

Also, the name of Alison Langevin (Health Canada) was changed to Alison Bennett.

6.3 Figures

To make the document easier to read, the figures have been placed on one page each.

Figure 3: The examples (related to MedDRA version changes) for this figure:

Preferred Terms	Events/Cases		Comment
	Version 15.0	Version 15.1	
Cytolytic hepatitis	15	0 (no longer a PT)	In MedDRA Version 15.0, <i>Cytolytic hepatitis</i> was a PT and in Version 15.1 it was demoted to an LLT under PT <i>Hepatitis</i> .
Hepatitis	5	20	

Figure 3 – Impact of MedDRA version changes – demotion of a PT

Were changed as follows:

Preferred Terms	Events/Cases		Comment
	Version 15.1	Version 16.0	
AIDS encephalopathy	15	0 (no longer a PT)	In MedDRA Version 15.1, <i>AIDS encephalopathy</i> was a PT and in Version 16.0 it was demoted to an LLT under PT <i>AIDS dementia complex</i> .
AIDS dementia complex	5	20	

Figure 3 – Impact of MedDRA version changes – demotion of a PT