

Summary of Changes to

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

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

***Release 3.2
Based on MedDRA Version 14.1***

1 October 2011

The following is a listing of changes made between releases 3.1 and 3.2 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 14.0 to Version 14.1
- 3) Update of examples based on MedDRA version changes
- 4) Links to the MSSO Web site have been updated

2.6 – MedDRA Versioning

The two example tables:

Example

Impact of Version Changes – Demoted PT
<p><i>PT Malignant neoplasm progression</i> was included in a query developed using terms in MedDRA Version 13.1. If the query had been re-run on data using MedDRA Version 14.0, these events would not have been found at the PT level because <i>PT Malignant neoplasm progression</i> had been demoted to an LLT and linked to <i>PT Neoplasm malignant</i>. See Figure 3.</p>

Example

Impact of Version Changes – Change of Primary SOC Assignment
<p><i>PT Retinal scar</i> had a primary link to <i>SOC Injury, poisoning and procedural complications</i> and a secondary link to <i>SOC Eye disorders</i> in MedDRA Version 13.1. In Version 14.0, the primary SOC assignment was changed to <i>SOC Eye disorders</i> and the secondary assignment to <i>SOC Injury, poisoning and procedural complications</i>. In a primary SOC output of data, <i>PT Retinal scar</i> will seem to have "disappeared" from <i>SOC Injury, poisoning and procedural complications</i>.</p>

Was changed as follows:

Example

Impact of Version Changes – Demoted PT

Impact of Version Changes - Demoted PT

PT *Reflux oesophagitis* was included in a query developed using terms in MedDRA Version 14.0. If the query had been re-run on data using MedDRA Version 14.1, these events would not have been found at the PT level because PT *Reflux oesophagitis* had been demoted to an LLT and linked to PT *Gastrooesophageal reflux disease*. See Figure 3.

Example

Impact of Version Changes - Change of Primary SOC Assignment

PT *Corneal scar* had a primary link to SOC *Injury, poisoning and procedural complications* and a secondary link to SOC *Eye disorders* in MedDRA Version 14.0. In Version 14.1, the primary SOC assignment was changed to SOC *Eye disorders* and the secondary assignment to SOC *Injury, poisoning and procedural complications*. In a primary SOC output of data, PT *Corneal scar* will seem to have "disappeared" from SOC *Injury, poisoning and procedural complications*.

4.5 – SMQs and MedDRA Version Changes

The example table in this Section:

Example

Consequence of Version Mismatch of Coded Data and SMQ

PT *Metabolic cardiomyopathy* was added to SMQ *Cardiomyopathy* in MedDRA Version 14.0. Using Version 13.1 of this SMQ - which does not contain this PT - would fail to identify cases coded to this term in a database using MedDRA Version 14.0.

Was changed as follows:

Example

Consequence of Version Mismatch of Coded Data and SMQ

PT *Diastolic dysfunction* was added to SMQ *Cardiac failure* in MedDRA Version 14.1. Using Version 14.0 of this SMQ - which does not contain this PT - would fail to identify cases coded to this term in a database using

Consequence of Version Mismatch of Coded Data and SMQ

MedDRA Version 14.1.

6.1 – Links and References

The links for the MedDRA Introductory Guide and for the Introductory Guide for Standardised MedDRA Queries:

Document	Link
MedDRA Introductory Guide*	https://meddramsso.com/secure/subscriber_download_translations.asp
Introductory Guide for Standardised MedDRA Queries (SMQs)*	https://meddramsso.com/secure/subscriber_download_translations.asp

Were changed as follows:

Document	Link
MedDRA Introductory Guide	http://meddramsso.com/files_acrobat/intguide_14_1_English_update.pdf
Introductory Guide for Standardised MedDRA Queries (SMQs)	http://meddramsso.com/files_acrobat/SMQ_intguide_14_1_English_update.pdf

And the link to the ICH E2E: Pharmacovigilance Planning document:

Document	Link
ICH E2E: Pharmacovigilance Planning	http://www.ich.org/MediaServer.jserv?@_ID=1195&@_MODE=GLB

Was changed as follows:

Document	Link
ICH E2E: Pharmacovigilance Planning	http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2E/Step4/E2E_Guideline.pdf

6.2.1 Current members of the ICH Points to Consider Working Group

Sonja Brajovic's name was added as a US Food and Drug Administration member.

6.3 Figures

Figure 1: "Joint sprain" was replaced with "Ligament sprain" because PT *Joint sprain* was demoted in MedDRA v14.1.

Figure 3:

MedDRA Version 13.1	Number of Events at PT Level
Malignant neoplasm progression (PT)	15
Neoplasm malignant	5
MedDRA Version 14.0	
MedDRA Version 14.0	Number of Events at PT Level
Malignant neoplasm progression (no longer a PT)	0
Neoplasm malignant	20

Figure 3 – In MedDRA Version 13.1, Malignant neoplasm progression was a PT and in Version 14.0 it was demoted to an LLT

Was changed as follows:

MedDRA Version 14.0	Number of Events at PT Level
Reflux oesophagitis (PT)	15
Gastrooesophageal reflux disease	5
MedDRA Version 14.1	
Number of Events at PT Level	
Reflux oesophagitis (no longer a PT)	0
Gastrooesophageal reflux disease	20

Figure 3 – In MedDRA Version 14.0, Reflux oesophagitis was a PT and in Version 14.1 it was demoted to an LLT