

Summary of Changes to

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

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

***Release 3.6
Based on MedDRA Version 16.1***

1 October 2013

The following is a listing of changes made between releases 3.5 and 3.6 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 16.0 to Version 16.1
- 3) Update of examples based on MedDRA version changes
- 4) Deletion of specific links in body of document; all links and references are now in Appendix, Section 6.1

1.3 – How to Use this Document

The wording in the last paragraph in this section:

The document is not a substitute for MedDRA training. It is essential for users to have knowledge of MedDRA’s structure and content. For optimal use of MedDRA, one should refer to the MedDRA *Introductory Guide*, the *Introductory Guide for Standardised MedDRA Queries (SMQs)* (See Appendix, Section 6.1) and the *MedDRA Term Selection: Points to Consider* document; these documents are available with each MedDRA subscription.

Was changed as follows (note the deletion of “these documents are available with each MedDRA subscription”):

The document is not a substitute for MedDRA training. It is essential for users to have knowledge of MedDRA’s structure and content. For optimal use of MedDRA, one should refer to the MedDRA *Introductory Guide*, the *Introductory Guide for Standardised MedDRA Queries (SMQs)* (See Appendix, Section 6.1) and the *MedDRA Term Selection: Points to Consider* document.

2.6 – MedDRA Versioning

The Example tables in this section:

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 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 *Anaesthetic complication foetal* had a primary link to *SOC Pregnancy, puerperium and perinatal conditions* and a secondary link to *SOC Injury, poisoning and procedural complications* in MedDRA Version 15.1. In Version 16.0, the primary SOC assignment was changed to *SOC Injury, poisoning and procedural complications* and the secondary assignment to *SOC Pregnancy, puerperium and perinatal conditions*. In a primary SOC output of data, PT *Anaesthetic complication foetal* will seem to have "disappeared" from *SOC Pregnancy, puerperium and perinatal conditions*.

Were changed as follows:

Example

Impact of Version Changes - Demoted PT

PT *Colonic obstruction* was included in a query developed using terms in MedDRA Version 16.0. If the query had been re-run on data using MedDRA Version 16.1, these events would not have been found at the PT level because PT *Colonic obstruction* had been demoted to an LLT and linked to PT *Large intestinal obstruction*. See Figure 3.

Example

Impact of Version Changes - Change of Primary SOC Assignment

PT *Ectopic pregnancy with intrauterine device* had a primary link to *SOC General disorders and administration site conditions* and a secondary link to *SOC Pregnancy, puerperium and perinatal conditions* in MedDRA Version 16.0. In Version 16.1, the primary SOC assignment was changed to *SOC Pregnancy, puerperium and perinatal conditions* and the secondary assignment to *SOC General disorders and administration site conditions*. In a primary SOC output of data, PT *Ectopic pregnancy with intrauterine device* will seem to have "disappeared" from *SOC General disorders and administration site conditions*.

3.2.1 Overview by primary System Organ Class

The wording in the fourth paragraph in this section:

The Internationally Agreed Order of SOCs was developed for consistency irrespective of language or alphabet (see Figure 5). The SOC order was based upon the relative importance of each SOC in AR/AE reports. Use of the Internationally Agreed Order may be applicable to certain regulatory functions, e.g., the SPC guideline and PSURs (see the MedDRA *Introductory Guide* and MedDRA ASCII files). Organizations that share data should agree on the order of SOCs when preparing data for presentation.

Was changed as follows (“and PSURs” was deleted):

The Internationally Agreed Order of SOCs was developed for consistency irrespective of language or alphabet (see Figure 5). The SOC order was based upon the relative importance of each SOC in AR/AE reports. Use of the Internationally Agreed Order may be applicable to certain regulatory functions, e.g., the SPC guideline (see the MedDRA *Introductory Guide* and MedDRA ASCII files). Organizations that share data should agree on the order of SOCs when preparing data for presentation.

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>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.

Was changed as follows:

Consequence of Version Mismatch of Coded Data and SMQ

PT *Tachycardia induced cardiomyopathy* was added to SMQ *Cardiomyopathy* in MedDRA Version 16.1. Using Version 16.0 of this SMQ - which does not contain this PT - would fail to identify cases coded to this term in a database using MedDRA Version 16.1.

5.1 – Modified MedDRA Query Based on an SMQ

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 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.

Was changed as follows (PT *Drug reaction with eosinophilia and systemic symptoms* had its scope changed from broad to narrow in SMQ *Severe cutaneous adverse reactions* in MedDRA Version 16.1 and therefore this example is no longer applicable):

Modified MedDRA Queries based on SMQs	
Changing the scope (narrow or broad) of an SMQ term	A product is being investigated for the potential for hyperglycemia and diabetes mellitus. SMQ <i>Hyperglycaemia/new onset diabetes mellitus</i> has PT <i>Increased insulin requirement</i> as a broad search term. For this query, it may be useful to include PT <i>Increased insulin requirement</i> in the narrow search.

6.1 – Links and References

The table of links and references in this section was replaced as follows:

The following documents and tools can be found on the MedDRA website: (www.meddra.org):

- MedDRA Term Selection: Points to Consider document (also available on the JMO website: www.pmrj.jp/jmo/php/indexe.php)
- MedDRA Introductory Guide
- Introductory Guide for Standardised MedDRA Queries (SMQs)
- Pediatric and Gender Adverse Event Term Lists
- MedDRA Change Request Information document
- MedDRA Web-based Browser
- MedDRA Desktop Browser
- MedDRA Version Report (lists all changes in new version) *
- MedDRA Version Analysis Tool (compares any two versions) *
- Production SMQ spreadsheet*
- List of system tools that support SMQs

* Requires user ID and password to access

The following document can be found on the ICH website (www.ich.org):

- ICH E2E: Pharmacovigilance Planning

6.2.1 Current members of the ICH Points to Consider Working Group

The table of current members was replaced and updated as follows:

Affiliation	Member
Commission of the European Communities	Sarah Vaughan
	Maria Luisa Casini
European Federation of Pharmaceutical Industries Associations	Hilary Vass*
	Christina Winter [†]
Health Canada	Alison Bennett
	Lynn Macdonald
Japanese Maintenance Organization	Yutaka Nagao
	Kazuyuki Sekiguchi
	Reiji Tezuka
Japan Pharmaceutical Manufacturers Association	Yo Tanaka
MedDRA MSSO	Judy Harrison
Ministry of Health, Labour and Welfare/Pharmaceuticals and Medical Devices Agency	Sonoko Ishihara
	Makiko Isozaki
	Yuuhei Fukuta
Pharmaceutical Research and Manufacturers of America	Anna-Lisa Kleckner
	JoAnn Medbery
US Food and Drug Administration	Sonja Brajovic
	Christopher Breder

* Current Rapporteur

[†] Former Rapporteur

6.2.2 Former members of the ICH Points to Consider Working Group

The table of former members was replaced and updated as follows:

Affiliation	Member
Commission of the European Communities	Dolores Montero
	Carmen Kreft-Jais
	Morell David
European Federation of Pharmaceutical Industries Associations	Barry Hammond [†] ; Reinhard Fescharek [†]
Health Canada	Heather Morrison; Michelle Séguin; Heather Sutcliffe; Bill Wilson
Japanese Maintenance Organization	Osamu Handa; Akemi Ishikawa; Yasuo Sakurai; Yuki Tada
Japan Pharmaceutical Manufacturers Association	Takayoshi Ichikawa; Akemi Ishikawa; Satoru Mori; Yasuo Sakurai; Kunikazu Yokoi
MedDRA MSSO	JoAnn Medbery; Patricia Mozzicato
Ministry of Health, Labour and Welfare/Pharmaceuticals and Medical Devices Agency	Tamaki Fushimi; Wakako Horiki; Kazuhiro Kemmotsu; Tatsuo Kishi; Chie Kojima; Emiko Kondo; Hideyuki Kondou; Kemji Kuramochi; Tetsuya Kusakabe; Kaori Nomura; Izumi Oba; Shinichi Okamura; Yoshihiko Sano; Nogusa Takahara; Kenichi Tamiya; Daisuke Tanaka; Shinichi Watanabe; Takashi Yasukawa; Go Yamamoto; Manabu Yamamoto; Nobuhiro Yamamoto
Pharmaceutical Research and Manufacturers of America	David Goldsmith; Sidney Kahn; Susan M. Lorenski; Margaret M. Westland [†]
US Food and Drug Administration	Miles Braun; Andrea Feight; John (Jake) Kelsey [†] ; Brad Leissa; Toni Piazza-Hepp

[†] Former Rapporteur

6.3 Figures

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

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

Were changed as follows:

Preferred Terms	Events/Cases		Comment
	Version 16.0	Version 16.1	
Colonic obstruction	15	0 (no longer a PT)	In MedDRA Version 16.0, <i>Colonic obstruction</i> was a PT and in Version 16.1 it was demoted to an LLT under PT <i>Large intestinal obstruction</i>
Large intestinal obstruction	5	20	

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