

Summary of Changes to

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

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

***Release 3.7
Based on MedDRA Version 17.0***

1 March 2014

The following is a listing of changes made between releases 3.6 and 3.7 of the *MedDRA Data Retrieval and Presentation: Points to Consider* document.

Throughout document

- 1) Correction of general spelling, punctuation, spacing, figure numbering, and format errors
- 2) Replacement of references to MedDRA Version 16.1 to Version 17.0
- 3) Update of examples based on MedDRA version changes
- 4) Changes made to conform to ICH document style, i.e., hyphenation, use of UK English spellings, and Arial font throughout

2.6 – MedDRA Versioning

The Example tables in this section:

Example

Impact of Version Changes – Demoted PT
<p>PT <i>Colonic obstruction</i> 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 <i>Colonic obstruction</i> had been demoted to an LLT and linked to PT <i>Large intestinal obstruction</i>. See Figure 3.</p>

Example

Impact of Version Changes – Change of Primary SOC Assignment
<p>PT <i>Ectopic pregnancy with intrauterine device</i> had a primary link to SOC <i>General disorders and administration site conditions</i> and a secondary link to SOC <i>Pregnancy, puerperium and perinatal conditions</i> in MedDRA Version 16.0. In Version 16.1, the primary SOC assignment was changed to SOC <i>Pregnancy, puerperium and perinatal conditions</i> and the secondary assignment to SOC <i>General disorders and administration site conditions</i>. In a primary SOC output of data, PT <i>Ectopic pregnancy with intrauterine device</i> will seem to have “disappeared” from SOC <i>General disorders and administration site conditions</i>.</p>

Were changed as follows:

Example

Impact of Version Changes – Demoted PT
PT <i>Pleural haemorrhage</i> was included in a query developed using terms in MedDRA Version 16.1. If the query had been re-run on data using MedDRA Version 17.0, these events would not have been found at the PT level because PT <i>Pleural haemorrhage</i> had been demoted to an LLT and linked to PT <i>Haemothorax</i> . See Figure 3.

Example

Impact of Version Changes – Change of Primary SOC Assignment
PT <i>Decreased activity</i> had a primary link to SOC <i>Psychiatric disorders</i> and a secondary link to SOC <i>General disorders and administration site conditions</i> in MedDRA Version 16.1. In Version 17.0, the primary SOC assignment was changed to SOC <i>General disorders and administration site conditions</i> and the secondary assignment to SOC <i>Psychiatric disorders</i> . In a primary SOC output of data, PT <i>Decreased activity</i> will seem to have “disappeared” from SOC <i>Psychiatric disorders</i> .

3.2.3.1 Focused searches by secondary SOC assignments

The Example table in this section:

Example

Programming a List of PTs in Primary and Secondary SOC Locations
SOC Eye disorders HLGT Vision disorders HLT Visual field disorders PT Hemianopia PT Hemianopia heteronymous PT Hemianopia homonymous PT Scotoma (primary SOC location) PT Tunnel vision PT Uhthoff's phenomenon PT Visual field defect
6 of 7 PTs are primary to SOC Nervous system disorders

Was changed as follows:

Example

Programming a List of PTs in Primary and Secondary SOC Locations
SOC Eye disorders HLGT Vision disorders HLT Visual pathway disorders PT Chiasma syndrome PT Optic nerve disorder (primary SOC location) PT Optic neuropathy (primary SOC location) PT Toxic optic neuropathy (primary SOC location) PT Visual cortex atrophy PT Visual pathway disorder
3 of 6 PTs are primary to SOC Nervous system disorders

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>Tachycardia induced cardiomyopathy</i> was added to SMQ <i>Cardiomyopathy</i> 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.

Was changed as follows:

Example

Consequence of Version Mismatch of Coded Data and SMQ
PT <i>Splenic artery thrombosis</i> was added to SMQ <i>Embolic and thrombotic events, arterial</i> in MedDRA Version 17.0. Using Version 16.1 of this SMQ – which does not contain this PT – would fail to identify cases coded to this term in a database using MedDRA Version 17.0.

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 and Associations	Hilary Vass*
	Christina Winter†
Health Canada	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

Regulatory Chair

† 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 and Associations	Barry Hammond [†] ; Reinhard Fescharek [†]
Health Canada	Alison Bennett, 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 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

Were changed as follows:

Preferred Terms	Events/Cases		Comment
	Version 16.1	Version 17.0	
Pleural haemorrhage	15	0 (no longer a PT)	In MedDRA Version 16.1, <i>Pleural haemorrhage</i> was a PT and in Version 17.0 it was demoted to an LLT under PT <i>Haemothorax</i>
Haemothorax	5	20	

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