

Summary of Changes to

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

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

***Release 3.8
Based on MedDRA Version 17.1***

1 September 2014

The following is a listing of changes made between releases 3.7 and 3.8 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 17.0 to Version 17.1
- 3) Update of examples based on MedDRA version changes

SECTION 1 – INTRODUCTION

The last sentence of the fourth paragraph was modified to include representatives from the Korean regulatory authority in the list of working group members as follows:

This *Data Retrieval and Presentation: Points to Consider* (DRP:PTC) document is an ICH-endorsed guide for MedDRA users. It is updated in step with new MedDRA versions and is a companion document to MedDRA. It was developed and is maintained by a working group charged by the ICH Steering Committee. The working group consists of regulatory and industry representatives of the European Union, Japan, and the United States, as well as representatives from the Canadian and Korean regulatory authorities, the MedDRA Maintenance and Support Services Organization (MSSO) and the Japanese Maintenance Organization (JMO) (see Appendix, Section 6.2 for list of members).

2.1.1 Data conversion considerations

The Examples tables in this section:

Example

Reported	Legacy Term	MedDRA Term
Bowel ischaemia	Gastrointestinal Disorder	Gastrointestinal disorder

Example

Reported	Legacy Term	MedDRA Term
Bowel ischaemia	Gastrointestinal Disorder	Bowel ischaemia

Were changed as follows:

Example

Reported	Legacy Term	MedDRA Term
Gastrointestinal ischaemia	Gastrointestinal Disorder	Gastrointestinal disorder

Example

Reported	Legacy Term	MedDRA Term
Gastrointestinal ischaemia	Gastrointestinal Disorder	Gastrointestinal ischaemia

2.1.2 Impact of data conversion method

The Example table in this section:

Example

Impact of Method 1 Conversion on Search Strategy
If searching with MedDRA PT <i>Bowel ischaemia</i> , cases of bowel ischaemia coded with the legacy term <i>Gastrointestinal disorder</i> would be missed. In this case, it would be important to know the date of the legacy data conversion.

Was changed as follows:

Example

Impact of Method 1 Conversion on Search Strategy
If searching with MedDRA PT <i>Gastrointestinal ischaemia</i> , cases of gastrointestinal ischaemia coded with the legacy term <i>Gastrointestinal disorder</i> would be missed. In this case, it would be important to know the date of the legacy data conversion.

2.6 – MedDRA Versioning

The Example tables in this section:

Example

Impact of Version Changes – Demoted PT
<p>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.</p>

Example

Impact of Version Changes – Change of Primary SOC Assignment
<p>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>.</p>

Were changed as follows:

Example

Impact of Version Changes – Demoted PT
<p>PT <i>Chest tube insertion</i> was included in a query developed using terms in MedDRA Version 17.0. If the query had been re-run on data using MedDRA Version 17.1, these events would not have been found at the PT level because PT <i>Chest tube insertion</i> had been demoted to an LLT and linked to PT <i>Thoracostomy</i>. See Figure 3.</p>

Example

Impact of Version Changes – Change of Primary SOC Assignment
<p>PT <i>Urinary bladder rupture</i> had a primary link to SOC <i>Injury, poisoning and procedural complications</i> and a secondary link to SOC <i>Renal and urinary disorders</i> in MedDRA Version 17.0. In Version 17.1, the primary SOC assignment was changed to SOC <i>Renal and urinary disorders</i> and the secondary assignment to SOC <i>Injury, poisoning and procedural complications</i>. In a primary SOC output of data, PT <i>Urinary bladder rupture</i> will seem to have “disappeared” from SOC <i>Injury, poisoning and procedural complications</i>.</p>

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>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.

Was changed as follows:

Example

Consequence of Version Mismatch of Coded Data and SMQ
PT <i>Thyrotoxic cardiomyopathy</i> was added to SMQ <i>Cardiomyopathy</i> in MedDRA Version 17.1. Using Version 17.0 of this SMQ – which does not contain this PT – would fail to identify cases coded to this term in a database using MedDRA Version 17.1.

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	Maria Luisa Casini
	Sarah Vaughan
European Federation of Pharmaceutical Industries and Associations	Hilary Vass*
	Christina Winter [†]
Health Canada	Polina Ostrovsky
	Lynn Macdonald
Japanese Maintenance Organization	Yutaka Nagao
	Kazuyuki Sekiguchi
	Mitsuru Takano
	Reiji Tezuka
Japan Pharmaceutical Manufacturers Association	Yo Tanaka
	Hitomi Takeshita
MedDRA MSSO	Judy Harrison
Ministry of Health, Labour and Welfare/Pharmaceuticals and Medical Devices Agency	Yuhei Fukuta
	Miki Ohta
	Daisuke Sato
	Makiko Isozaki
Pharmaceutical Research and Manufacturers of America	Milbhor D'Silva
	JoAnn Medbery
US Food and Drug Administration	Sonja Brajovic [#]
	Christopher Breder
Ministry of Food and Drug Safety, Korea	YuBin Lee
	Kyung-Eun Yoon

* 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; Sonoko Ishihara; 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; Anna-Lisa Kleckner; 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 16.1	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

Were changed as follows:

Preferred Terms	Events/Cases		Comment
	Version 17.0	Version 17.1	
Chest tube insertion	15	0 (no longer a PT)	In MedDRA Version 17.0, <i>Chest tube insertion</i> was a PT and in Version 17.1 it was demoted to an LLT under PT <i>Thoracostomy</i>
Thoracostomy	5	20	