

***Summary of Changes to***

**MedDRA<sup>®</sup> DATA RETRIEVAL  
AND PRESENTATION:  
POINTS TO CONSIDER**

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

***Release 3.9  
Based on MedDRA Version 18.0***

**1 March 2015**

The following is a listing of changes made between releases 3.8 and 3.9 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 17.1 to Version 18.0
- 3) Update of examples based on MedDRA version changes

### 2.6 – MedDRA Versioning

The Example tables in this section:

Example

<b>Impact of Version Changes – Demoted PT</b>
<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>.</p> <p>See Figure 3.</p>

Example

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

Were changed as follows:

Example

<b>Impact of Version Changes – Demoted PT</b>
<p>PT <i>Mycotic aneurysm</i> was included in a query developed using terms in MedDRA Version 17.1. If the query had been re-run on data using MedDRA Version 18.0, these events would not have been found at the PT level because PT <i>Mycotic aneurysm</i> had been demoted to an LLT and linked to PT <i>Infective aneurysm</i>.</p> <p>See Figure 3.</p>

Example

<b>Impact of Version Changes – Change of Primary SOC Assignment</b>
<p>PT <i>Dry gangrene</i> had a primary link to SOC <i>Skin and subcutaneous tissue disorders</i> and a secondary link to SOC <i>Vascular disorders</i> in MedDRA Version 17.1. In Version 18.0, the primary SOC assignment was changed to SOC <i>Vascular disorders</i> and the secondary assignment to SOC <i>Skin and subcutaneous tissue disorders</i>. In a primary SOC output of data, PT <i>Dry gangrene</i> will seem to have “disappeared” from SOC <i>Skin and subcutaneous tissue disorders</i>.</p>

#### 4.5 – SMQs and MedDRA Version Changes

The Example table in this section:

Example

<b>Consequence of Version Mismatch of Coded Data and SMQ</b>
<p>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.</p>

Was changed as follows:

Example

<b>Consequence of Version Mismatch of Coded Data and SMQ</b>
<p>PT <i>Radiation associated cardiac failure</i> was added to SMQ <i>Cardiac failure</i> in MedDRA Version 18.0. Using Version 17.1 of this SMQ – which does not contain this PT – would fail to identify cases coded to this term in a database using MedDRA Version 18.0.</p>

## 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
	Kavita Chadda
European Federation of Pharmaceutical Industries and Associations	Hilary Vass*
	Christina Winter†
Health Canada	Alison Bennett
	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
	Kiyomi Ueno
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
World Health Organization	Daisuke Tanaka

\* 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; Sarah Vaughan
European Federation of Pharmaceutical Industries and Associations	Barry Hammond <sup>†</sup> ; Reinhard Fescharek <sup>†</sup>
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; 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 <sup>†</sup>
US Food and Drug Administration	Miles Braun; Andrea Feight; John (Jake) Kelsey <sup>†</sup> ; Brad Leissa; Toni Piazza-Hepp

<sup>†</sup> Former Rapporteur

### 6.3 Figures

Figure 1: The examples (related to MedDRA version changes) for this figure:

<b>OTHER TERMINOLOGY PREFERRED TERMS</b>	<b>No. of EVENTS</b>	<b>MedDRA Version 17.1 PREFERRED TERMS</b>	<b>No. of EVENTS</b>
Infection	15	Upper respiratory tract infection Nasopharyngitis Infection Lower respiratory tract infection Skin infection	7 2 1 4 1
Abdominal pain	9	Abdominal pain Abdominal pain upper Abdominal tenderness	4 3 2
Accidental injury	4	Injury Skin laceration Ligament sprain Back injury	1 1 1 1

*Figure 1 – How data coded to a single concept from another terminology may be expressed by several PTs in MedDRA*

Were changed as follows (note the change of Skin laceration to Laceration):

<b>OTHER TERMINOLOGY PREFERRED TERMS</b>	<b>No. of EVENTS</b>	<b>MedDRA Version 18.0 PREFERRED TERMS</b>	<b>No. of EVENTS</b>
Infection	15	Upper respiratory tract infection Nasopharyngitis Infection Lower respiratory tract infection Skin infection	7 2 1 4 1
Abdominal pain	9	Abdominal pain Abdominal pain upper Abdominal tenderness	4 3 2
Accidental injury	4	Injury Laceration	1 1

OTHER TERMINOLOGY PREFERRED TERMS	No. of EVENTS	MedDRA Version 18.0 PREFERRED TERMS	No. of EVENTS
		Ligament sprain	1
		Back injury	1

Figure 1 – How data coded to a single concept from another terminology may be expressed by several PTs in MedDRA

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

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	

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

Were changed as follows:

Preferred Terms	Events/Cases		Comment
	Version 17.1	Version 18.0	
Mycotic aneurysm	15	0 (no longer a PT)	In MedDRA Version 17.1, <i>Mycotic aneurysm</i> was a PT and in Version 18.0 it was demoted to an LLT under PT <i>Infective aneurysm</i>
Infective aneurysm	5	20	

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

Figure 4: The footnote was changed to indicate that the primary SOC output listing shown is based on MedDRA Version 17.1:

SOC (System Organ Class)		Number of all reactions*	Number of reactions* where outcome of report was fatal
HLGT	PT		
<b>Nervous system disorders</b>			
<b>Mental impairment disorders</b>			
Mental impairment (excl dementia and memory loss)	Disturbance in attention	1	0
<b>Movement disorders (incl parkinsonism)</b>			
Dyskinesias and movement disorders NEC	Psychomotor hyperactivity	2	0
Tremor (excl congenital)	Tremor	3	0
<b>Neurological disorders NEC</b>			
Disturbances in consciousness NEC	Somnolence	1	0
Neurological signs and symptoms NEC	Dizziness	1	0
<b>Seizures (incl subtypes)</b>			
Seizures and seizure disorders NEC	Convulsion	2	0
<b><i>Nervous system disorders SOC Total</i></b>		<b>10</b>	<b>0</b>
<b>Psychiatric disorders</b>			
<b>Anxiety disorders and symptoms</b>			
Anxiety symptoms	Activation syndrome	1	0
	Agitation	2	0
	Anxiety	2	0
	Stress	1	0
<b>Depressed mood disorders and disturbances</b>			
Depressive disorders	Depression	1	0
<b>Disturbances in thinking and perception</b>			
Thinking disturbances	Thinking abnormal	1	0
<b>Schizophrenia and other psychotic disorders</b>			
Psychotic disorder NEC	Psychotic disorder	1	0
<b>Sleep disorders and disturbances</b>			
Disturbances in initiating and maintaining sleep	Insomnia	1	0
<b><i>Psychiatric disorders SOC Total</i></b>		<b>10</b>	<b>0</b>

Figure 4 – Primary SOC output listing, MedDRA Version 17.1 – example. Note that some PTs are multiaxial, however, this figure shows only the primary SOC assignments