Summary of Changes to

**MedDRA® 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

| **Impact of Version Changes – Demoted PT** |
| --- |
| PT *Chest tube insertion* 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 *Chest tube insertion* had been demoted to an LLT and linked to PT *Thoracostomy*. See Figure 3. |

Example

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

Were changed as follows:

Example

| **Impact of Version Changes – Demoted PT** |
| --- |
| PT *Mycotic aneurysm* 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 *Mycotic aneurysm* had been demoted to an LLT and linked to PT *Infective aneurysm*. See Figure 3. |

Example

| **Impact of Version Changes – Change of Primary SOC Assignment** |
| --- |
| PT *Dry gangrene* had a primary link to SOC *Skin and subcutaneous tissue disorders* and a secondary link to SOC *Vascular disorders* in MedDRA Version 17.1. In Version 18.0, the primary SOC assignment was changed to SOC *Vascular disorders* and the secondary assignment to SOC *Skin and subcutaneous tissue disorders*. In a primary SOC output of data, PT *Dry gangrene* will seem to have “disappeared” from SOC *Skin and subcutaneous tissue 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 *Thyrotoxic cardiomyopathy* was added to SMQ *Cardiomyopathy* 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. |

Was changed as follows:

Example

| **Consequence of Version Mismatch of Coded Data and SMQ** |
| --- |
| PT *Radiation associated cardiac failure* was added to SMQ *Cardiac failure* 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. |

## 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†; 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; 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 1: The examples (related to MedDRA version changes) for this figure:

| **OTHER TERMINOLOGY** **PREFERRED TERMS** | **No. of EVENTS** | **MedDRA Version 17.1****PREFERRED TERMS** | **No. of EVENTS** |
| --- | --- | --- | --- |
| Infection | 15 | Upper respiratory tract infectionNasopharyngitisInfectionLower respiratory tract infectionSkin infection | 72141 |
| Abdominal pain | 9 | Abdominal pain Abdominal pain upperAbdominal tenderness | 432 |
| Accidental injury | 4 | InjurySkin lacerationLigament sprainBack injury | 1111 |

*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):

| **OTHER TERMINOLOGY** **PREFERRED TERMS** | **No. of EVENTS** | **MedDRA Version 18.0****PREFERRED TERMS** | **No. of EVENTS** |
| --- | --- | --- | --- |
| Infection | 15 | Upper respiratory tract infectionNasopharyngitisInfectionLower respiratory tract infectionSkin infection | 72141 |
| Abdominal pain | 9 | Abdominal pain Abdominal pain upperAbdominal tenderness | 432 |
| Accidental injury | 4 | InjuryLacerationLigament sprainBack injury | 1111 |

*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*, Chest tube insertion* was a PT and in Version 17.1 it was demoted to an LLT under PT *Thoracostomy* |
| 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*, Mycotic aneurysm* was a PT and in Version 18.0 it was demoted to an LLT under PT *Infective aneurysm* |
| 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:



*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*