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 *Bowel ischaemia*, cases of bowel ischaemia coded with the legacy term *Gastrointestinal disorder* 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 *Gastrointestinal ischaemia*, cases of gastrointestinal ischaemia coded with the legacy term *Gastrointestinal disorder* 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** |
| --- |
| PT *Pleural haemorrhage* 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 *Pleural haemorrhage* had been demoted to an LLT and linked to PT *Haemothorax*. See Figure 3. |

Example

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

Were changed as follows:

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*. |

## 4.5 – SMQs and MedDRA Version Changes

The Example table in this section:

Example

| **Consequence of Version Mismatch of Coded Data and SMQ** |
| --- |
| PT *Splenic artery thrombosis* was added to SMQ *Embolic and thrombotic events, arterial* 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 *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. |

## 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*, Pleural haemorrhage* was a PT and in Version 17.0 it was demoted to an LLT under PT *Haemothorax* |
| 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*, Chest tube insertion* was a PT and in Version 17.1 it was demoted to an LLT under PT *Thoracostomy* |
| Thoracostomy | 5 | 20 |