

Summary of Changes to

**MedDRA[®] TERM SELECTION:
POINTS TO CONSIDER**

ICH-Endorsed Guide for MedDRA Users

***Release 4.7
Based on MedDRA Version 17.0***

1 March 2014

The following is a listing of changes made between releases 4.6 and 4.7 of the *MedDRA Term Selection: Points to Consider* document

Throughout document

- 1) Correction of general spelling, punctuation, spacing, 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

3.6.2 No available MedDRA term includes both age and event information

The Example table in this section:

Example

| Reported | LLT Selected | Preferred Option | Comment |
|---------------------------|-----------------------------------|------------------|---|
| Pancreatitis in a newborn | Pancreatitis | ✓ | Record patient age in a demographic field |
| | Pancreatitis Neonatal disorder | | Record patient age in a demographic field. In addition, select LLT <i>Neonatal disorder</i> . |

Was changed as follows (note the deletion of the Comment column):

Example

| Reported | LLT Selected | Preferred Option |
|---------------------------|-----------------------------------|------------------|
| Pancreatitis in a newborn | Pancreatitis | ✓ |
| | Pancreatitis Neonatal disorder | |

3.7.3 Event occurring at multiple body sites

The Example table in this section:

Example

| Reported | LLT Selected | Comment |
|-------------------------------|-----------------------|---|
| Skin rash on face and neck | Skin rash | <i>LLT Rash on face and LLT Neck rash both link to PT Rash</i> |
| Oedema of hands and feet | Oedema of extremities | <i>LLT Oedema hands and LLT Oedematous feet both link to PT Oedema peripheral. However, LLT Oedema of extremities most accurately reflects the event in a single term</i> |

Was changed as follows (note modification of comment in first row to add LLT *Skin rash*):

Example

| Reported | LLT Selected | Comment |
|----------------------------|-----------------------|---|
| Skin rash on face and neck | Skin rash | LLT <i>Rash on face</i> , LLT <i>Neck rash</i> , and LLT <i>Skin rash</i> all link to PT <i>Rash</i> |
| Oedema of hands and feet | Oedema of extremities | LLT <i>Oedema hands</i> and LLT <i>Oedematous feet</i> both link to PT <i>Oedema peripheral</i> . However, LLT <i>Oedema of extremities</i> most accurately reflects the event in a single term |

3.14.5 Investigation terms without qualifiers

The wording and Example table in this section:

Terms in SOC *Investigations* **without qualifiers** may be used to record test names when entering diagnostic test data.

Example

| Information/Reported (Verbatim) | LLT Selected for Test Name | Comment |
|---------------------------------|----------------------------|--|
| Cardiac output measured | Cardiac output | |
| Increased blood sugar | Blood glucose | LLT <i>Blood glucose increased</i> should not be selected as it is both a test name and a result* |

* Enter a qualifier (e.g., “increased”) or a numeric result (if available) into the “Result” data field.

Were changed as follows (note the references to the E2B data elements and the change in the second example to show a test result reported with a numeric value):

Terms in SOC *Investigations* **without qualifiers** may be used to record test names when entering diagnostic test data in the ICH E2B electronic transmission standard.

Example

| Information/Reported (Verbatim) | LLT Selected for Test Name | Comment |
|---------------------------------|----------------------------|--|
| Cardiac output measured | Cardiac output | |
| Haemoglobin 7.5 g/dL | Haemoglobin | LLT <i>Haemoglobin decreased</i> should not be selected as it is both a test name and a result* |

* MedDRA is used only for test names, not test results, in the E2B data elements for Results of Tests and Procedures

3.16.4 Drug diversion

This is a **new** sub-section that did not exist in the previous version of the document. It includes a concept description for drug diversion and an Example table:

For the purposes of term selection and analysis of MedDRA-coded data, drug diversion means that a drug is diverted from legal and medically necessary uses toward uses that are illegal and typically not medically authorised or necessary.

Example

| Reported | LLT Selected |
|---|---|
| Pharmacist stole medications from the pharmacy and sold them to others for recreational use | Drug diversion |
| A person put a sedative into the patient's drink | Drug diversion Accidental exposure to drug |

4.3.1 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

4.3.2 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