

***Summary of Changes to***

**MedDRA<sup>®</sup> TERM SELECTION:  
POINTS TO CONSIDER**

*Release 3.3  
Based on MedDRA version 7.0*

**ICH-Endorsed Guide for MedDRA Users**

**Application to Adverse Drug Reactions / Adverse Events  
&  
Medical and Social History & Indications**

**9 June 2004**

The following is a listing of changes made between versions 3.2 and 3.3 of *MedDRA Term Selection: Points to Consider*:

### **Throughout document**

- 1) Correction of general spelling, punctuation, spacing and format errors to create more consistency throughout the document;
- 2) Replacement of references to MedDRA version 6.1 to version 7.0
- 3) Update of examples based on MedDRA version changes:
  - a. Section 3.3.3, changed "Unevaluable reaction" to "Unevaluable event" as this more closely represents the reported information;
  - b. Section 3.10.5. "Liver function tests raised" is a non-current LLT; this example has been changed to "Liver function tests abnormal"
  - c. Section 3.13.2. "Drug level increased" has been changed to "Anticonvulsant drug level increased" as this better reflects the reported term
  - d. Section 3.15. "Benefit unexpected" is a non-current LLT; this example has been changed to "Unexpected therapeutic effect"

### **2.6 Quality Assurance**

Fourth paragraph, fourth sentence. Change "...by the usual change request process" to "...by the change request process". (Delete "usual")

#### **3.3.1 Conflicting information:**

Example. Change "*Potassium abnormal*", *can be selected*" to "*Serum potassium abnormal*" *can be selected*". (Insert "serum" as this LLT is more close to the reported term in the example).

#### **3.6.2 Location vs. Infectious agent**

For all three examples, "*Respiratory fungal infection*" changed to "*Respiratory chlamydial infection*" and "*Fungal infection*" changed to "*Chlamydial infection*". The example has changed because LLT "*Respiratory tract infection fungal*" has been added to MedDRA since version 6.1.

#### **3.8.1 Congenital terms**

The following text was added to the end of this section:

Note that a non-specific term is not always linked to the acquired term at a higher level.

*Example: “Color blindness” is reported, the term “Color blindness” can be selected which links to the HLT “Ocular disorders congenital NEC” through the PT “Colour blindness”*

#### **4.1 Current members of the ICH *Points to Consider* working group:**

Added to “*Japan: Ministry of Health, Labour and Welfare*”: Manabu Yamamoto  
Added to “*Japan: Japan Pharmaceutical Manufacturers Association*”: Takayoshi Ichikawa and Yo Tanaka  
Added to “*Japan: Japan Maintenance Organization*”: Akemi Ishikawa  
Added to “*United States: Pharmaceutical Research and Manufacturers of America*”: JoAnn Medbery  
Added to “*United States: MedDRA MSSO*”: Patricia Mozzicato

#### **4.2 Past members of the ICH *Points to Consider* working group:**

Title of appendix changed to “**Past members/affiliations of the ICH *Points to Consider* working group**”.  
Added to “*Japan: Japan Pharmaceutical Manufacturers Association*”: Kunikazu Yokoi