

***Summary of Changes to***

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

*Release 3.4  
Based on MedDRA version 7.1*

**ICH-Endorsed Guide for MedDRA Users**

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

**18 November 2004**

The following is a listing of changes made between versions 3.3 and 3.4 of *MedDRA Term Selection: Points to Consider*:

### **Throughout document**

- 1) Correction of general spelling, punctuation, spacing and format errors;
- 2) Replacement of references to MedDRA version 7.0 to version 7.1
- 3) Update of examples based on MedDRA version changes:

#### **3.8.1, Congenital terms**

Changed the example of “hemangioma” to “night blindness” to reflect the point presented in this section. As of version 7.1, selection of “Hemangioma” would result in a link to PT *Haemangioma*. “Night blindness” links to PT *Acquired night blindness*

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

Deleted from “*Japan: Ministry of Health, Labour and Welfare*”: Chie Kojima

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

Added to “*Japan: Ministry of Health, Labour and Welfare*”: Chie Kojima, Kaori Nomura