

## ICH PRESS RELEASE

### MedDRA® Management Committee Meeting

Kobe, Japan, June 2018

#### MedDRA Management Committee Supports Global Expansion of MedDRA Use

**Kobe, Japan 2018** – The MedDRA Management Committee met in Kobe, Japan on 2-3 June 2018.

#### Supporting the Global Uptake of MedDRA

The MedDRA Management Committee noted significant achievements in supporting the global expansion of MedDRA use, in accordance with the five-year strategic plan. In recent months, the MSSO, with the support of ICH, has provided implementation training for CFDA, China and MFDS, Republic of Korea, and has conducted MedDRA coding and analysis training for hundreds of local industry participants in those two countries. In the same timeframe, MedDRA training has been conducted for local industry representatives in the Russian Federation and for regulators in Latin America.

Training and support in the local language are considered key to ensuring a successful implementation of MedDRA and the MedDRA Management Committee intends to make provisions for local support in China, Latin America, and the Republic of Korea beginning in 2018. In addition, the MedDRA Management Committee supported augmenting the MSSO training staff in the ICH regions.

The MedDRA Management Committee noted that translations of MedDRA into Korean and Russian are underway and will be added to the current portfolio of 11 MedDRA languages.

#### Removal of Additional Subscription Fee for Japanese Translation

The MedDRA Management Committee is pleased to announce that, effective 1 January 2019, the additional subscription fee of \$850 for the Japanese translation of MedDRA obtained through the MSSO will be eliminated. MSSO subscribers will receive all 11 MedDRA languages included with their subscription at no additional cost.

#### ICH M1 Points to Consider

The MedDRA Management Committee acknowledged the significant work of the ICH M1 Points to Consider (PtC) Working Group in completing a companion document to the PtC documents and endorsed the first edition which will be made available to MedDRA users. This document will provide more detailed guidance, examples, and “Questions and Answers” on topics of regulatory importance. The first edition will address data quality issues and medication errors and will be posted on the MedDRA and JMO websites in mid-2018.

## **Software Tools**

The MSSO reported that a major upgrade to the Web-Based Browser (WBB) will be launched in July 2018. This upgrade will allow MedDRA users to view upcoming changes in MedDRA (supplemental terms); upload data for analysis with SMQs; view primary and secondary link information; and perform advanced search functions.

## **ISO Certification**

The MSSO reported that they had obtained ISO 9001:2015 recertification following successful completion of an audit.

The next scheduled meeting of the MedDRA Management Committee will be on 10-11 November 2018 in Charlotte, North Carolina, USA.

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