

PRESS RELEASE

Seville, Spain, MedDRA® Management Board Meeting

The Management Board Further Enhances the Use of MedDRA

Seville, 6 November 2011 – The MedDRA Management Board met in Seville, Spain on 5 - 6 November 2011.

The MedDRA Management Board is pleased to announce that the 2012 MSSO MedDRA subscription fees will remain the same as 2011. This is the 7th consecutive year that the subscription rates have not increased.

This was the fourth time the MedDRA Management Board hosted an open session to welcome the Regional Harmonisation Initiative and Drug Regulatory Authorities/Departments of Health members of the ICH Global Cooperation Group (GCG). Regulatory representatives of ICH and non-ICH regions shared their perspectives on the use of MedDRA in regulatory reporting and pharmacovigilance processes. Australian TGA, EMA, UK MHRA, and US FDA were among the presenters.

Further to training conducted in China, Panama and Singapore in 2011, the Board continues to work closely with ICH GCG members to support requests for training beyond ICH regions.

The Board recognizes and supports the ongoing valuable work of Council for International Organizations of Medical Sciences (CIOMS) SMQ Working Group. In addition to developing new SMQs, there will be an update to the CIOMS “Development and Rational Use of Standardised MedDRA Queries (SMQs)” publication that will provide guidance on the use and implementation of SMQs.

The MedDRA Version Analysis Tool (MVAT) is scheduled to be released to users in the first quarter of 2012. This new tool is part of an evolving suite of software applications, such as the Desktop Browser and Web-Based Browser, that facilitates the use of MedDRA. MVAT will enhance the user’s ability to easily compare any two versions of MedDRA.

The Japanese Management Board (JMB) reported on the activities of the Japanese Maintenance Organization (JMO). They noted that there is growth in the number of JMO subscribers due to increased use by academics.

The Board acknowledged that the Seville meeting would be the final meeting of long-standing Board member Mr. Morell David who will leave shortly his position at the UK MHRA. The Board expressed its sincere appreciation for Mr. David’s significant contribution to the MedDRA project over the years.

The next scheduled meeting of the Board will be on 2 - 3 June 2012 in Fukuoka, Japan.

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