



PRESS RELEASE

Osaka, Japan, ICH MedDRA[®] Management Board Meeting

ICH MedDRA Management Board Supports
MedDRA's Continued Evolution and High Quality Maintenance

Osaka, 10 November 2013 – The ICH MedDRA Management Board met in Osaka, Japan on 9-10 November 2013.

ISO Certification

The Japanese Management Board reported on the Japanese Maintenance Organization's (JMO) activities, and noted an increase in pharmaceutical company subscribers compared to the same period last year. The ICH MedDRA Management Board congratulated the JMO on receiving its first ISO 9001 certification in 2013. It was also noted that the MedDRA Maintenance and Support Services Organization (MSSO) had retained its ISO certification following successful completion of an annual audit.

2014 MSSO Subscription Rates

Starting in 2014, the MSSO will introduce a new subscription level, Commercial 6, for organisations with annual revenue (or turnover) of \$20 billion USD or more. In the past few years, several large organisations have merged and this has caused the MSSO and the ICH MedDRA Management Board to implement a change in the subscription structure, designed to rebalance the cost to the upper end of the range of subscription levels. Prices for the existing levels (Non-Commercial/Non-Profit, Commercial 0-5, and Developer) levels have not increased over the last nine years.

Organisation of a Blue Ribbon Panel

A MedDRA Blue Ribbon Panel will meet in the USA in the first half of 2014 to address the scope of MedDRA as a medical and regulatory terminology and how it may evolve to meet the needs of its users. Topics to be discussed in relation to a potential expansion of the scope of MedDRA include the addition of manufacturing product quality terms and the further support of device related terms.

MedDRA Special Session

The ICH MedDRA Management Board welcomed to a special session in Osaka representatives of Regional Harmonisation Initiatives and of Drug Regulatory Authorities/Department of Health interested in MedDRA. During this session, presentations included transitioning to and accessing MedDRA, the

development and maintenance of translations, and an overview of the evolution and scope of the terminology.

ICH Decision to Undertake a New Call for Tender

In 1999, ICH released MedDRA as its standardised medical terminology. The maintenance and support of MedDRA is contracted to a MSSO. ICH has decided that a new Call for Tender should be undertaken. This decision represents the interest of the ICH to conform with good business practices and does not reflect on the performance of the current contractor. ICH will publish a Request for Information/Call for Expression of Interest in early 2014, in order to identify interest from potential service providers.

The next scheduled meeting of the Board will be on 31 May - 1 June 2014 in Minneapolis, MN, USA.

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