



PRESS RELEASE

Minneapolis, MN, USA, ICH MedDRA[®] Management Board Meeting

ICH MedDRA Management Board Supports MedDRA's Continuing Evolution

Minneapolis, 1 June 2014 – The MedDRA Management Board met in Minneapolis, MN, USA on 31 May - 1 June 2014.

Blue Ribbon Panel

On 29 April 2014, a MedDRA Blue Ribbon Panel met in Gaithersburg, MD, USA, to discuss whether the scope of MedDRA should be re-defined in its role as an international medical and regulatory terminology. In order to accommodate the evolving needs of the user community, possibility of expansion of the terminology into new requested topic areas was discussed. Questions including how to establish general criteria when considering potential areas for expansion (e.g., manufacturing product quality concepts) and where these can be placed in MedDRA were explored. The MedDRA Management Board considered the Panel's recommendations and requested the MSSO to develop impact analyses, following which the Board will communicate its decisions to the MedDRA user community.

ICH Points to Consider

The ICH M1 Points to Consider Working Group will be discussing refinements to the coding of medication errors in MedDRA and providing support to the EMA medication errors project. It was also noted that the Points to Consider documents in English and Japanese were released simultaneously with MedDRA Version 17.0 on 1 March 2014.

Support for MedDRA Users

The MSSO reported on the development of software tools, including a new Web-based browser (WBB) which will replace the current Web-based browser by the end of 2014. The WBB will have a similar look and feel as the current MedDRA Desktop Browser and will add to the existing suite of tools which the Board has directed the MSSO to develop in support of MedDRA users. The MSSO will provide training to MedDRA users for the WBB in the form of webinars and videocasts.

MSSO & JMO Continued Evolution

The Japanese Management Board reported on the Japanese Maintenance Organization's (JMO) activities, and noted an increase in subscribers compared to the same period last year.

The MSSO also reported on the growth of its subscriber base. Future areas of focus for the MSSO include supporting the global use of MedDRA and exploring interoperability between MedDRA and other medical terminologies used in the arena of patient safety.

Special Session

The MedDRA Management Board welcomed representatives of Regional Harmonisation Initiatives and of Drug Regulatory Authorities/Department of Health to a special session on MedDRA. Presentations included regulators' experiences with transitioning to MedDRA.

MSSO Call for Tender

In Minneapolis, ICH agreed the timeframe for the launch of a Call for Tender in mid-August for the contract for the MedDRA MSSO. ICH's primary goal is to ensure that there is minimal impact for MedDRA users. Further tender details will be made available on the ICH website in July.

The next scheduled meeting of the Board will be on 8 - 9 November 2014 in Lisbon, Portugal.

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