ICH PRESS RELEASE

MedDRA Management Committee Meeting
Charlotte, USA, November 2018

MedDRA Management Committee Recognises 20 Years of MedDRA

Geneva, 23 November 2018


MedDRA Celebrates its 20th Anniversary in 2019

The MedDRA Management Committee noted that 1 March 2019 will mark the 20 year anniversary of the first release of MedDRA. Since its inception in 1999, MedDRA has experienced remarkable growth as a true international standard with currently over 5,500 subscribing organisations in more than 120 countries using 11 language translations. The MedDRA Management Committee acknowledged the importance of maintaining and developing MedDRA for the benefit of users and it remains committed to supporting the continued global uptake of the terminology in the years to come.

Subscription Fees

As a further initiative to assist the global uptake of MedDRA, the MedDRA Management Committee is pleased to announce that there will be a 5% reduction in MedDRA subscription fees for all subscription levels, effective in 2019. Details will be available on the MedDRA website.

This reduction is a reflection of the continued success of MedDRA as a global standard in public health. With an expanding user base, the costs of maintaining and developing the terminology can be distributed more widely, whilst still providing the same high standard of tools and services to MedDRA users.

The MedDRA Management Committee previously announced that, effective 1 January 2019, the additional subscription fee of $850 for the Japanese translation of MedDRA will be removed. Subscribers will receive all MedDRA languages included with their MSSO (Maintenance and Support Services Organization) subscription at no additional cost.

Supporting the Global Use of MedDRA

The MedDRA Management Committee noted significant achievements in supporting the global implementation and use of MedDRA, in accordance with the five-year strategic plan. By the end of 2018, the MSSO will have provided MedDRA training to around 5,500 industry and regulatory users worldwide. The MSSO is appointing local support personnel who will provide training, Help Desk support, and promotion of MedDRA in China, India, Latin America, and the Republic of Korea. The MedDRA Management Committee noted that the Russian translation of MedDRA is well underway.

The MedDRA Management Committee welcomes the continuing collaboration with the WHO Collaborating Centre for International Drug Monitoring (Uppsala Monitoring Centre) in supporting countries transitioning...
from WHO-ART to MedDRA for pharmacovigilance activities. A MedDRA training session was held in Geneva, Switzerland on 8 November, as part of the 2018 WHO Annual Meeting of Representatives of the National Pharmacovigilance Centers (NPCs). There were close to 190 participants from 82 countries in this session.

The MedDRA Management Committee is pleased to announce that it has granted approval for a MedDRA Special Licence for MFDS, Republic of Korea. These Special Licences are intended to help government agencies worldwide to give access to MedDRA coding for non-commercial users and small commercial organisations with low revenue and limited IT resources; the provision of the Special Licence will help support the uptake of MedDRA in the Republic of Korea.

**MedDRA↔SNOMED Mapping**

The MedDRA Management Committee welcomed the involvement of ICH/MSSO and SNOMED International in the IMI WEB-RADR 2 project which aims to deliver a bi-directional mapping between the two terminologies. This mapping is intended to serve as a sustainable resource in support of global public health activities.

**ICH M1 Points to Consider**

The MedDRA Management Committee acknowledged the significant work of the ICH M1 Points to Consider (PtC) Working Group and noted that condensed versions of the PtC documents were posted on the MedDRA website in early November 2018. The condensed versions focus on the fundamental principles of term selection and data retrieval, and are intended to support the implementation and use of MedDRA in the ICH regions and beyond. They are available in all MedDRA languages except for English and Japanese; the English and Japanese PtC documents will continue to be maintained and updated as the full reference documents.

**Software Tools**

The MSSO reported that a major upgrade to the Web-Based Browser (WBB) was launched in October 2018. This upgrade allows 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.

The next scheduled meeting of the MedDRA Management Committee will be on 1-2 June 2019 in Amsterdam, the Netherlands.

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