Dear MedDRA users,

We are currently in a very exceptional time with the COVID-19 pandemic demanding flexible approaches to ensure that any scientific and medical information from the COVID-19 outbreak can be captured, shared and analysed appropriately. This concerns both post-marketing and pre-marketing data. The ICH MedDRA Management Committee has decided to provide the new COVID-19 terms within the MedDRA dictionary in a very expedited fashion.

You have been informed about a change in the release process of MedDRA version 23.0 on April 10, 2020 already. With this communication we want to share some further details:

- On April 19, the MSSO and the JMO will re-release the previously distributed version 23.0 of the terminology including the usual files and translations in English and Japanese. This re-release will also contain new COVID-19 related terms and revisions.

- We urge you to implement this re-released version 23.0 by May 4 in your systems in line with the currently established procedure for the global transition date for a new version of MedDRA. The MedDRA Management Committee also urges all Regulators to do the same.

- We recognize that your internal process for up-versioning, such as user training or definition of search strategies, may be already in progress based on the previously distributed version 23.0. Regulators on the MedDRA Management Committee have agreed that during this unprecedented time and during this up-versioning to version 23.0, process-related activities such as training on the use of the additional COVID-19 terms can be done at a reasonable time after the implementation on May 4. In this regard, the MedDRA Management Committee encourages other regulators to show flexibility as well.

- Please note that SMQs included in the version 23.0 re-release will remain unchanged at this moment from version 23.0 released March 1. More information will follow shortly regarding existing SMQs in view of the new COVID-19 terms. In the interim a spreadsheet will be provided with the version 23.0 re-release to provide a search list and strategy for COVID-19 related terms before the development of a COVID-19 SMQ.

- The English and Japanese re-released versions will be available on April 19 and the other translations will follow as soon as possible after this date.

This is an unprecedented situation that requires fast action and we thank you for your support of this effort for the benefit of public health.

The ICH MedDRA Management Committee