November 13, 2017

Release Notes

Detailing the updates of the EU eCTD Module 1 Specification

The published version 3.0.2 has been subsequently updated as a new pharmacovigilance procedure requires additional clarifications and a modified file name convention for eAF documents and their annexes was required to be included. An updated version 3.0.3 is now available.

Note: The version change does not result in a change of the DTD. No further technical action is needed.

The following aspects are addressed:

1. The previous recommendation on **file name convention for the electronic application form and their annexes** was changed to become mandatory. Applicants are encouraged to use the new file name for eAF documents and their annexes with immediate effect as the newly required file names will also pass the current validation criteria.

2. Due to the implementation of a new procedural guidance (pilot) on how post-authorisation measures following PSUR observations, so called **PSUFU procedure** for nationally authorised products only, should be submitted, the description of the respective **submission type** 'pam-mea' is modified.