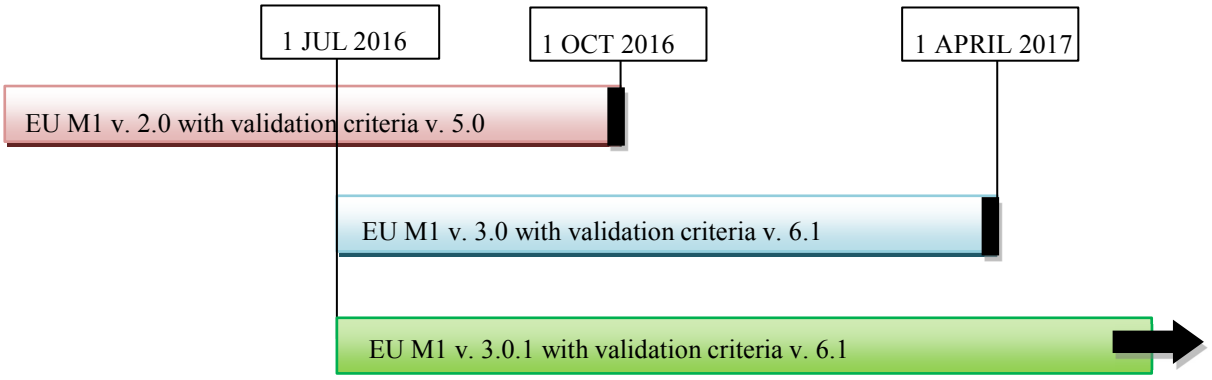
Updated 08 July 2016

Release Notes

Detailing the updates of the EU eCTD Module 1 Specification

The published version 3.0 has been updated to version 3.0.1 to correct pick list values and the updated version was published in May 2016. Both versions entered into force on 1st July 2016. The versions 3.0 and 3.0.1 will replace v2.0 on 1 October 2016 after which submissions in v2.0 will no longer be accepted.
Submissions following versions 3.0 and 3.0.1 will both be accepted from 1st October 2016 for a parallel period of 6 months until 1 April 2017. The use of version 3.0.1 will be mandatory from 1 April 2017.



The following aspects are addressed:

1. Under the EMA policy on publication of clinical data for medicinal products for human use, on conclusion of the regulatory procedure and the relevant decision a subset of clinical data from the regulatory application is published (Modules 2.5, 2.7, 5, appendices 16.1, 16.1.2, 16.1.9). The data published takes into account redaction of individual personal data and commercial confidential information.
   This regulatory activity will enable submission of subset of clinical data for publication. This subset and sequence life cycle is separate to that of the regulatory submission for evaluation. The clinical data for publication is submitted at a stable data point in the regulatory evaluation and authorisation process. For this new regulatory activity a new submission type to address 'Clinical data for publication' has been added.
   A considerable number of new submission types have been added based on the pharmacovigilance legislation as well as "rup" for repeat use procedures in line with the controlled term list for CESP.

2. Another new submission type is added to support application on Certificates of Suitability being submitted to the EDQM. The addition of the submission type as a new regulatory activity as well as introducing EDQM as an additional receiver would sufficiently support the processing at EDQM.

3. To support automation of processing at all agencies it a new attribute containing a Universal Unique Identifier (UUID) was added. This UUID should be generated when the first sequence using the revised specification version 3.0 or 3.0.1 is published. This UUID will

be kept as a reference for all subsequent submissions related to the application (also known as dossier).

- A UUID is a hexadecimal number in the form of 8-4-4-4-12, including 32 digits and 4 hyphens. UUIDs are formally defined by ISO/IEC 11578:1996 and ITU-T Rec X.667 | ISO/IEC 9834-8:2005. UUIDs are represented as follows:String of digits separated by hyphens: 25635f23-a3a4-4ce0-9994-99c5f074960f 596

4. Following the same intention to support process automation and to provide more clarity in regard to relationships between sequences the concept of "submission unit" will be introduced as already foreseen in the CESP delivery note and as well as currently implemented by FDA. The existing attribute of the "submission type" will then solely describe a regulatory activity. The "submission unit" will describe actions within that regulatory activity like an initial submission of an application, an update due to validation issues, responses to questions from agencies, any additional information or consolidating submissions after closing a regulatory activity. In the same way "reformat" will be used as a submission unit together with submission type "none" as it is not a regulatory activity, but just a reformatting of the dossier.

5. Based on the public consultation and to support some ways of ordering sequences by regulatory activities and related sequences, the related sequence element has been set mandatory and rules have been added to guide the user in case of initial submission units.

6. Finally, the abbreviated name of the Danish agency will be corrected in the controlled term list (the name will most likely remain; the outstanding correction of the DTD is no longer necessary, the name of the Irish agency will be updated and the EDQM will be added.

7. Some more examples how to use the specification correctly have been added.