Revised Implementation guide for
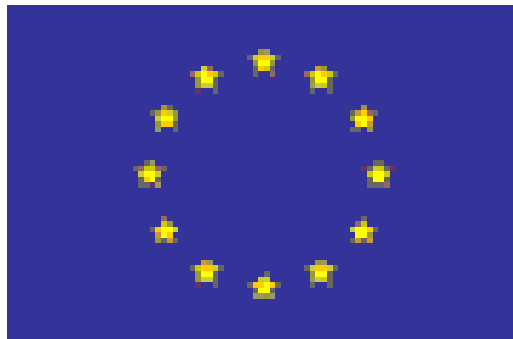
EU Module 1 Specification, version 3.0 and 3.0.1

and

EU eCTD Validation Criteria, version 6.1

EU NeeS Validation Criteria, version 4.1

EU eCTD M1 Specification v3.0 and v3.0.1

A new version of the EU eCTD M1 Specification, version 3.0, was published on 19 October 2015 on the [eSubmission website](#). The version 3.0 sees the introduction of a new submission attribute containing a Universally Unique Identifier (UUID), introduction of the concept of 'submission unit' as well as a number of new regulatory activities among other updates. As a result of the need to correct pick list values, errors in the published stylesheet and subsequently an update of the associated checksum, a revised version of the specification, EU eCTD M1 v3.0.1 was issued in May 2016.
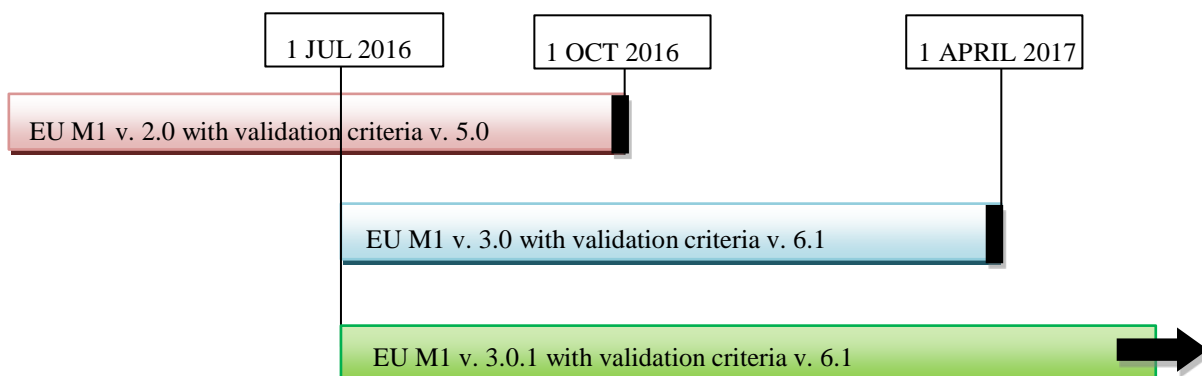
EU Validation Criteria

New versions of the validation criteria have been published on the [eSubmission website](#). They are mainly related to the EU Module 1 Specification version 3.0 and should be used in case of submitting a new sequence according to EU M1 specification v3.0 or v3.0.1after **1 July 2016**. The new validation criteria will be used for the technical validation for <u>all</u> electronic submissions received **as of 1 October 2016** to the NCAs and EMA.

The earlier version of the criteria version 5.0, will be withdrawn by close of business on 30 September 2016. Therefore, it is important that applicants plan their submissions very carefully around this date to prevent problems in the validation.

Transitional period

During a transitional period from **1 July 2016 to 30 September 2016**, applicants can submit eCTD format submissions compliant with EU M1 v2.0 and validation criteria version 5.1 *or* compliant with EU M1 v3.0 or EU M1 v3.0.1 and validation criteria version 6.1.

From **1 October 2016** *only* eCTDs compliant with EU M1 v3.0 or EU M1 v3.0.1 and validation criteria v6.1 are accepted. From **1 April 2017** only eCTDs compliant with EU M1 v3.0.1 and validation criteria v6.1 are accepted.

eCTD submissions starting regulatory activities using EU Module 1 eCTD specification v3.0 or v3.0.1 as of 1 October 2016 at the latest

Sequences in eCTD format must contain a new attribute called **Universal Unique Identifier** (UUID). A new 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

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. 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.

The **extended list of submission types** and the usage of the submission unit types will allow defining more precisely the content and intention of the submission. The submission types and submission unit types have to be carefully selected to ensure the presentation to the assessing agencies is correct and time consuming re-processing can be avoided.

NeeS submissions

The timelines and transition arrangement stated above for technical validation of eCTD submissions are applicable also for NeeS submissions within the EU. NeeS submissions can be submitted in accordance with the new EU NeeS Validation Criteria version 4.1 from 1 July 2016 and **have to fulfil** the new criteria version 4.1 from 1 October 2016. *(Please note that NeeS submissions are not accepted within the centralised procedure.)*