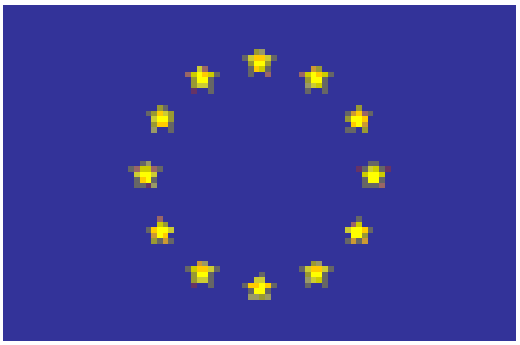
# Revised Implementation guide for

# EU Module 1 Specification, version 3.0

and

EU eCTD Validation Criteria, version 6.1

EU NeeS Validation Criteria, version 4.1



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**EU eCTD M1 Specification v3.0**

A new version of the EU eCTD M1 Specification, version 3.0, was published on 19 October 2015 on the EMA eSubmission website. The version 3.0 sees an 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.

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The EU eCTD M1 Specification v3.0 will come into force 1 July 2016 and will be required by EMA and National Competent Authorities in EU from **1 October 2016**.

**EU Validation Criteria**

New versions of the validation criteria have been published at the EMA eSubmission website. They are mainly related to the EU Module 1 Specification version 3.0 and should be used in in case of submitting a new sequence according to EU M1 specification v3.0 after **1 July 2016**. They will be used for the technical validation for all electronic submissions received **as of 1 October 2016** to the NCAs and EMA.

The earlier version of the criteria, version 5.1, will be withdrawn by close of business on 30 September 2016.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.

**Transition period**

During a transition period from **1 July 2016 to 30 September 2016**, applicants can *either* submit eCTDs compliant with EU M1 v.2.0 and validation criteria version 5.1 *or* eCTDs compliant with EU M1 v.3.0 and validation criteria version 6.1.

From 1 October 2016 *only* eCTDs compliant with EU M1 v.3.0 and validation criteria v.6.1 are accepted.

**eCTD submissions starting regulatory activities as of 1 October 2016**

Sequences in eCTD format must contain the new attribute containing a **Universal Unique Identifier** (UUID). This UUID should be generated when the first sequence in eCTD format will sent to generate a unique identifier of a dossier. This UUID will be kept as a reference for subsequent submissions.
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 supplemental 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 otherwise the presentation to the assessing agencies may go wrong and time consuming re-processing may occur.

After 1 October, only EU Module 1 v3.0 should be used in all procedures.

**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 have to fulfil the EU NeeS Validation criteria version 4.1 from 1 October 2016. *(Please note that NeeS submissions are not accepted within the centralised procedure.)*