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Q&A on the use of UUID in eCTD

What is a UUID?

The Universally Unique identifier (UUID) was introduced with the eCTD specification v3.0, and all eCTDs must from then have a valid UUID, linking the sequence to the eCTD application to which it belongs.

It is also clearly stated in section 2.9.1. of the published *Harmonised Technical Guidance for eCTD Submissions in the EU*, that a UUID should be defined for each eCTD lifecycle.

The identifier must be defined with the first sequence of a new dossier (or the first sequence using EU eCTD M1 specification version 3.0 or later), and it must from then on be consistent throughout the eCTD lifecycle.

Should I use the same UUID during the eCTD lifecycle?

The UUID should be kept for the eCTD for its entire lifecycle. The only exceptions to this are when the eCTD is split or merged (see Q&A¹) or the eCTD is re-baselined by submitting a new 0000 sequence for that eCTD (see details in section 2.12.3 of the *Harmonised Technical Guidance for eCTD Submissions in the EU*).

If the eCTD sequence in question does not yet contain a UUID it should be included in the first eCTD sequence submitted in accordance with EU eCTD M1 specification version 3.0 or above. However, the UUID **cannot** be added to the earlier submitted eCTD sequence created prior to the introduction of the UUID, since there is no placeholder for the UUID in earlier envelope.

Why is the UUID important?

The UUID is used by the authorities to facilitate archiving the sequence with the correct eCTD lifecycle and some authorities also use it for automated sorting of incoming eCTD submissions to the correct eCTD lifecycle.

It is important that the UUID for each eCTD lifecycle is unique and it should therefore always be machine generated, i.e. be created by the eCTD building tool or, if not possible, by using an online UUID generator such as <https://www.uuidgenerator.net/>. Creating the UUID with uppercases or lowercases is not restricted but needs be kept as chosen during the full lifecycle.

¹ Q&A on merging or splitting eCTD lifecycles for different strengths and/or forms of medicinal products

Will the eCTD sequence be invalid if there is no or incorrect UUID?

The validation criteria includes tests for UUID to confirm the format, that it has the same UUID as the previously submitted sequence of that eCTD and is identical in all the envelopes of that eCTD lifecycle.

Validation criteria v.7.1

9.7	EU regional XML	The UUID is well formed according to ISO/IEC 11578:1996 and ITU-T Rec X.667 ISO/IEC 9834-8:2005	P/F		This criterion will test whether the UUID is well formed.
9.8	EU regional XML	If the sequence already submitted numerically preceding the incoming sequence in the eCTD lifecycle contains a UUID (i.e. was submitted using v3.0 of the EU m1 Specification or higher), then the UUID in this incoming sequence must be identical to the one in the previous sequence.	P/F	Y	This rule checks that the UUID is correct and the sequence is being loaded into the correct eCTD Application.
9.9	EU regional XML	The UUID must be identical in all envelopes.	P/F		

What happens if the UUID in an eCTD sequence is already used in another existing eCTD lifecycle?

Beside the technical validation checking the correct UUID, some authorities can also check that the UUID is not the same as in *another already existing eCTD lifecycle* in the authority's eCTD repository. Although extremely unlikely, this has been experienced, probably by copying a UUID from somewhere. Since the UUID is used by some authorities in the automatic processing of eCTD sequences, it is important that each UUID in the eCTD repository is unique. Therefore, even if this is not part of the eCTD technical validation criteria, in such cases, the authority will contact the applicant/MAH and request an updated eCTD sequence with a new UUID.

If this is not the first sequence of the eCTD lifecycle, the applicant/MAH must also update all previously submitted sequences in the eCTD lifecycle that have been assigned this same UUID. In case the eCTD lifecycle includes a large amount of sequences with this UUID, the NCA and the applicant/MAH might agree on a pragmatic solution to fix the problem.

The updated eCTD sequence(s) should be submitted with a new UUID to all authorities concerned by the eCTD sequence/lifecycle using the same sequence number(s). A comment should be included in the CESP delivery file that the eCTD is a technically corrected sequence (corrected UUID) that is re-sent. The sequence(s) should not include any other changes to the earlier submitted sequence(s) than just the new UUID.

Where the identical UUID would be the same as in another already existing eCTD lifecycle for eCTD sequences within the Centralised Procedures, EMA will contact the applicant/MAH with specific instruction of the handling, since this cannot be handled within the normal Gateway delivery.