



EU Module 1

v1.3

Transition Guidance
May 2008

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1. Introduction

This document provides guidance to applicants and tool vendors regarding the implementation of EU M1 specification v1.3, including:

- Information on timelines for implementation of the new EU M1 version, and;
- Technical guidance regarding the inclusion of new information required by legislation (i.e. paediatrics data) whilst using a previous version of the EU M1 during the defined transition period.

2. Timeline for Implementation

The Specifications and DTD of the eCTD EU Module 1 v1.3 include several changes to v1.2.1 (see Release Notes for EU M1 v1.3), but the principal change is alignment to the 2008 updated version of the CTD guidance, specifically to include section 1.10 for the information relating to paediatrics. The CTD M1 guidance and eCTD EU M1 specification are published simultaneously.

Applicants are given **6 months** from the date of publication to implement EU M1 v1.3 for all European procedures, and eCTD applications submitted after 31st December 2008 using any previous version of the EU M1 specification (i.e. v1.0, v1.1 or v1.2.1) will not be accepted.

The 6 month deadline applies not only to new applications, but also to all lifecycle sequences/submissions for applications ongoing at the time. Please note that, for existing applications, it is *not* expected that all existing submissions will be updated to EU M1 v1.3 and re-submitted; it *is*, however, expected that authoring and review tools will allow for a change in DTD mid-lifecycle.

3. Provision of Paediatrics Information

From the date of publication of the CTD guidance, applicants are required to submit information relating to paediatrics with each submission (electronic or otherwise).

During the transition period, it is accepted that applicants may need to continue for a time to use a previous version of the eCTD EU M1 specification (i.e. v1.0, v1.1 or v1.2.1), where the new section 1.10 'Information relating to Paediatrics' does not exist in the DTD.

In this case, information relating to paediatrics should be placed in the existing eCTD section 'Additional Info' (see EU M1 Specification v1.3 Appendix 2, row 70).

Additional Data is a country-specific folder (i.e. the element "specific" with a country attribute should be used), and therefore a leaf cannot be attached directly below the Additional Data section.

Depending on the submission procedure, the following country attributes should be used:

- Centralised Procedure: 'emea'
- Decentralised Procedure: 'common'
- Mutual Recognition Procedure: 'common'
- National: 'cc', where 'cc' is the country code of the country where the application is being submitted.

A dedicated 'specific' element for paediatric information should be created, if using an EU M1 DTD version other than v1.3. As there is no title element at the level of a 'specific' element, the only way to identify the paediatric information within the additional data section is via the use of the leaf title, and this leaf title should be used to describe the document(s) being included. The leaf title should correspond to the title of the new section being introduced. In this instance the following is suggested:

- 1.10 Information relating to Paediatrics

The file name should be compliant with the standard convention for the additional data section, namely m1/eu/additional-data/CC/CC-additionaldata-VAR.EXT. The variable part of the file name should be consistent with the file name used in the new section of the eCTD EU M1 v1.3, namely 'paediatrics-VAR.EXT'. This would therefore give the following order and file paths, dependent on the submission procedure (note that a hyphen is not allowed within the variable part of the file name):

- Centralised Procedure:
 - m1/eu/additional-data/emea/emea-additionaldata-paediatricsVAR.EXT
- Decentralised Procedure:
 - m1/eu/additional-data/common/common-additionaldata-paediatricsVAR.EXT
- Mutual Recognition Procedure:
 - m1/eu/additional-data/common/common-additionaldata-paediatricsVAR.EXT
- National Procedures:
 - m1/eu/additional-data/CC/CC-additionaldata-paediatricsVAR.EXT, where 'CC' is the country code of the country where the application is being submitted.

Please note that certain authoring tools may be designed to gather all information attached to the same country under the same root element, and due to the repeatability of the element "specific" with the same country attribute value, this may cause difficulties with such tools.

4. Future Replacement of Documents

If, after transition to a later version of the eCTD EU Module 1, there is need to update the document previously submitted under the Additional Data section, the replacement document should be located in the new, correct location of the hierarchy, namely '1.10 Information relating to Paediatrics', and the new, correct filename should also be used, namely 'paediatrics-VAR.EXT'. The replacement document should not be placed again under Additional Data. The 'current' view of submissions utilised by tools should provide a view that is based upon the latest specification, rather than an earlier one.