

# CONCEPT PAPER

## M8: electronic Common Technical Document

### **Introduction and Background to the Proposal**

In November 2010, the ICH Steering Committee endorsed the establishment of M8: eCTD Expert Working Group (EWG) / Implementation Working Group (IWG). Work in relation to the eCTD had previously been undertaken by the M2 EWG for the three main areas:

- Maintenance of the existing ICH eCTD specifications
- Liaison with M4Q to develop Q&As to resolve outstanding change requests associated with Modules 2.3 and 3 of the eCTD
- Development of the eCTD v4.0 in collaboration with Standard Development Organizations.

At the ICH Steering Committee meeting in Lisbon (November 2014) it was agreed that M8 would update the M4 Annex: Granularity Document based upon agreement with M4Q IWG in order to correct gaps between the Granularity Document and the eCTD Q&A.

At the ICH Assembly meeting in Jacksonville (December 2015) the eCTD v4.0 Implementation Package as well as the Specification for Submission Format were approved for Step 4.

This document describes the scope of M8: eCTD EWG / IWG and details its roles and responsibilities.

### **Type of Harmonisation Action**

The M8 IWG will produce and update the eCTD Q&A for ICH eCTD v4.0 while continuing to support the ICH eCTD v3.2.2 and STF v2.6.1 until all the ICH regions transition completely to v4.0. In the eCTD v4.0 implementation phase, the M8 IWG will also provide orientation materials to facilitate its implementation in ICH regions.

When the need of revision arises, the group will update the Implementation Package and/or the Specification for the Submission Format as the M8 EWG. The M8 EWG will also provide technical review and impact assessment of issues arising from the use of the ICH M4 CTD Guidelines within the context of the eCTD. This activity includes:

- a. Identify issues arising from the usage of CTD/eCTD specifications, consider possible solutions
  - i. Provide technical specification, where appropriate, via change control and Q&A processes
  - ii. Identify where scientific input is required (CTD Q, S or E) and raise to ICH Assembly, as appropriate, to determine mechanisms to address
- b. Liaise with scientific (Q, S and E) Subject Matter Experts, as directed by ICH Assembly, to address eCTD implementation questions and issues arising from usage of the CTD/eCTD Guidelines. This includes update of the Granularity Document in accordance with the agreement by appropriate M4 Working Group whereas the Granularity Document continues to be owned by M4.

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**Statement of the Perceived Problem**

Deliver a technical standard and Implementation Guide to facilitate the electronic exchange of regulatory information prepared in accordance with the requirements of the CTD in the ICH regions.

**Issues to be Resolved**

M8 EWG / IWG facilitate ICH regions to utilise common approaches to the implementation of the eCTD.

**Type of Expert Working Group / Implementation Working Group**

The M8 EWG / IWG would continue to be an eight-party group plus Drug Regulatory Authority (Australia) and observers (IGPA and WSMI). A Regulatory Chair and Rapporteur should be appointed by ICH Assembly.