

Final Concept Paper
M8 : Electronic Common Technical Document
dated 8 November 2010
Endorsed by the ICH SC on 11 November 2010

Introduction and Background to the Proposal

For several years the workload of M2 has necessitated the separation of activities into sub-groups which have met in parallel at Expert Working Group meetings. The eCTD sub-group has had six-party representation and participation of all M2 observers. The sub-group has taken responsibility for three main areas:

- Maintenance of the existing ICH eCTD specifications;
- Liaison with CTD-Q to develop Q&As to resolve outstanding change requests associated with Modules 2.3 and 3 of the eCTD;
- Activities associated with the development of the requirements for the eCTD Next Major Version.

The ICH Steering Committee (SC) has previously sanctioned the development of the Next Major Version of the eCTD in collaboration with Standards Development Organisations to ultimately produce an ISO/CEN and HL7-approved standard. Development will commence with HL7 and then proceed to an ISO standard.

At the ICH Steering Committee meeting in Tallinn (June 2010) it was agreed that M2 should be restructured and that its eCTD subgroup should be established as an independent Expert Working Group reporting directly to SC.

This document describes the scope of this new EWG and details its roles and responsibilities.

Type of Harmonisation Action

The eCTD EWG will produce a *Step 4* Implementation Guide for the Next Major Version of the Electronic Common Technical Document (eCTD NMV) while continuing to support the current ICH eCTD v3.2.2 and STF v2.6.1 standards as the eCTD IWG.

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

Agreement at ICH to utilise common approaches to the implementation of the eCTD unless regional needs direct otherwise.

Type of Working Group

The eCTD EWG/IWG would continue to be a six-party group plus observers (WHO, EFTA and Health Canada) an Interested Parties (IGPA and WSMI). A Rapporteur and Co-Rapporteur should be appointed by SC and a new 'M' number assigned to the EWG/IWG.

Scope of the eCTD Expert Working Group & Implementation Working Group

The primary purpose of the eCTD EWG is to 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. The ICH Steering Committee has already sanctioned the implementation of the next major version of the eCTD. This activity involves:

- the development of the ICH requirements for the eCTD;
- liaison with HL7 to clarify details of the requirements;
- conducting the testing of the draft standard;
- assessment of testing results and provision of ballot comments to HL7;
- development of an ICH Implementation Guide;
- guiding the standard through the ISO process.

The secondary activities of this working group are to continue as the eCTD IWG for the current ICH eCTD Specifications. This activity involves:

- the maintenance of the current ICH specifications for eCTD (v3.2.2) and Study Tagging File (v2.6.1) including change control and Questions and Answers (Q&A);
- identification of CTD issues raised either by use of the current eCTD or in the development of the eCTD Next Major Version, and the progression of resolution of these issues, with appropriate Steering Committee assistance:
 - Current activity in this area involves development of Questions and Answers associated with CTD-Q;
- establishment of a timeline for adoption of eCTD NMV in all regions and retirement of the current ICH eCTD specifications.

The remit of the eCTD EWG should continue until the following major milestones have been achieved:

- the delivery of an HL7 normative standard (target date: May-2012) and ISO standard (target date: TBD) that are deemed to meet the requirements of the ICH eCTD EWG;
- the delivery of an ICH *Step 4* for the eCTD Implementation Guide (target date: Nov-2012);
- implementation of ICH eCTD NMV in all regions and retirement of the current eCTD specifications (target date: TBD).

Once these milestones have been achieved, the remit of the eCTD EWG and IWG should then be reassessed in line with best practice for maintenance of ICH standards which will be determined by M2.

eCTD EWG & IWG Roles and Responsibilities

The detailed roles and responsibilities should be:

1. Provide business and technical expertise for the development of the Next Major Version of the ICH eCTD
 - a. Maintain business and technical functional requirements for ICH and ICH Regions
 - b. Continue to liaise with SDOs, according to the working practices defined by the current SDO Relationship Management Group (or successor to be defined), for the technical development of the eCTD Specifications based on the approved ICH requirements
 - i. Ensure fidelity of ICH-Global and ICH-Regional requirements are maintained through SDO process
 - ii. Evaluate new requirements brought into SDO process from outside of ICH and review for utility in ICH regions and that they do not contradict ICH requirements
 - c. Develop test plans and test protocols for the testing of ICH-Global and ICH-Regional requirements to maintain global harmonization, where feasible, on the implementation of the ICH eCTD Specification
 - d. Develop ICH Implementation Guidance(s) to support usage in each region
2. Provide business and technical expertise to maintain the current version of the ICH eCTD and STF specifications until they are retired by ICH
 - a. Provide Change Control processes for global enhancements or modifications to the specifications taking into account the need for appropriate assessment of regional impacts
 - i. Continue to maintain the ICH Change Control and Q&A document
 - b. Develop a timeline for the full implementation of eCTD NMV in all regions and sunseting of the current ICH eCTD Specifications
3. Provide technical review and impact assessment of issues arising from the use of the ICH M4 CTD Guidances within the context of the eCTD
 - a. Identify issues arising from the usage of CTD/eCTD specifications, consider possible solutions
 - i. Implement technical solutions, where appropriate, via change control and Q&A processes
 - ii. Identify where scientific input is required (CTD Q, S or E) and raise to SC, as appropriate, to determine mechanisms to address
 - b. Liaise with scientific (Q,S and E) Subject Matter Experts, as directed by SC, to address eCTD implementation questions and issues arising from usage of the CTD/eCTD Specifications