

CTD General Questions and Answers

Date of Approval		Questions	Answers
23	June 2004	<p>Amendments and variations in CTD format</p> <p>Is there a separate format for amendments/variations submitted in CTD format or should applicants use the CTD format as it is now? If used as it is now, is it enough to simply indicate whatever modules are not used?</p>	<p>The CTD structure is suitable for amendments and variations (refer to regional guidance for applicabilities). The applicant should not submit the modules that are not used i.e. it is unnecessary to include “not applicable” pages against unused CTD headings.</p>

CTD-Efficacy Questions and Answers

Date of	Questions	Answers
18 June 2004	<p>According to ICH E3 Structure and Content of Clinical Study Reports, the case report forms should be located in Appendix 16.3, the individual patient data listings in Appendix 16.4 and the publications and literature references in Appendices 16.1.11 and 16.1.12 respectively. The CTD organization provides locations for case report forms and individual patient data listings in Module 5.3.7 and for literature references in Module 5.4.</p> <p>Can clarity be provided as to where these items should actually be placed in CTD and the eCTD submissions?</p>	<p>For paper submissions, case report forms and individual patient data listings should be located in Module 5.3.7, identified by study.</p> <p>For eCTD, PDF files for case report forms and individual patient data listings should be organised by study in the folder for Module 5.3.7. However, in the <i>index.xml</i> file the leaf elements for the case report forms and individual patient data listings should be included under the same heading as other study report files with additional information included with any accompanying study tagging file. In addition, a repeat of the leaf element <u>can</u> be placed under the heading 5.3.7 Case Report Forms and Individual Patient Data Listings. Datasets, if required by the region, should be organised according to regional guidance.</p> <p>For paper submissions publications and literature references should be located in Module 5.4.</p> <p>For eCTD, the files for publications and literature references should be located in the folder for Module 5.4. However, in the <i>index.xml</i> file the leaf elements for the publications and literature references should be included under the same heading as other study report files with additional information included with any accompanying study tagging file. In addition, a repeat of the leaf element <u>should</u> be placed under the heading for 5.4 Literature References.</p>