

AstraZeneca



JUN 20 2002

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Sir or Madam:

Re: Docket Number [01D-0435]
Response to ICH Draft e-CTD Specification

Reference is made to the International Conference on Harmonization (ICH) Step 2 Document, "ICH Technical Requirements for Registration of Pharmaceuticals for Human Use – Electronic Common Technical Document Specification [e-CTD]," released by the M2 Expert Working Group (EWG).

AstraZeneca fully supports the concept of establishing criteria that will make an electronic submission technically valid, understanding that the Step 2 document does not dictate CTD format. Achieving such a technical solution would provide the ability to transfer the registration application electronically from industry to a regulatory authority. These achievements would support the laudable objectives of CTD as established by the ICH Steering Committee in 1997. AstraZeneca supports the following principles, each one of which the company relates to meeting the CTD original objectives via the eCTD delivery mechanism:

- The eCTD must be accessible to all territories. The eCTD may not eliminate the need for paper review.
- The eCTD must not present a technical burden to any territory.
- The eCTD must be consistent with and facilitate CTD review. The eCTD must not lead to or drive toward any negative change in review process.
- The eCTD must not lead to a longer review time in any territory.
- Change control procedures, post approval, should be significantly and noticeably improved
- The eCTD should result in one set of summary technical documentation (relating, where applicable to the Common Technical Document), not bigger than the current requirements.
- The eCTD should not require any legacy documents, previously filed in paper, or electronic format to be reworked.

AstraZeneca eagerly awaits the Step 4 document, and the readiness of agencies to work with the company on eCTD. We recommend that the Step 4 document reflect an assessment of the perceived benefits against the effects on current regulatory processes.

AstraZeneca has extensively reviewed the Draft Step 2 document and our comments are attached.

01D-0435

CS

US Regulatory Affairs
AstraZeneca LP
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Please direct any questions or requests for additional information to me, or in my absence, to Sandra L Bihary at (302 886 2192).

Sincerely,



David S. Ross

Global Publishing and Templates Manager

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/dsr

Table 1: General Comments

Reference in ICH Draft eCTD Specification	Comment
Appendix 3, General Considerations for the CTD Modules ; Appendix 6, eCTD XML Submission Page 1.	We suggest that folder and file naming conventions should be prefixed by their equivalent CTD reference number in order to more easily navigate around the structure without using a browser. This is so that folders and files within a particular level in the structure match the CTD order.
General Comment	Please provide a glossary of terms (Volume, Section, Sub-Section, Cross-Referencing).
General Comments	Please provide any recommendations as to where fields such as Report Number, Date, Compound Name should be placed in individual reports.
General Comments	Please provide confirmation regarding whether each appendix within a Clinical Study Report should be page numbered independently.

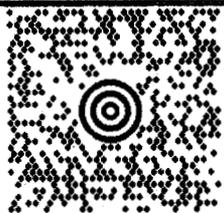
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SHIP

TO:

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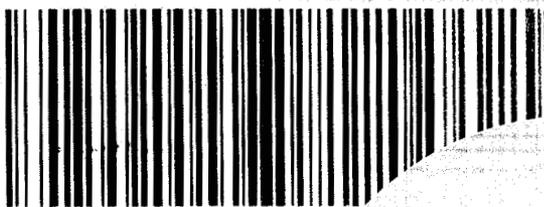


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