CTD and eCTD services

- Your older dossiers are still in the old format according to "notice to applicants" 1998 available?
- Some of the parts exist only as paper copy?
- You would like to update your regulatory data base to be ready for the future?

- The EU heads of med agencies decided and stated publicly in April 2006:
  from January 1st 2009, all national authorities and EMA are ready to accept electronic CTD dossiers only!
  This means from this time, no paper copies are necessary, when filing electronically.

- we scan your old (NTA 1998) dossiers and safe them automatically into an electronic CTD structure
- we provide, where necessary, transformation of old documents into CTD conform modules
- we compile your new dossiers directly in an eCTD structure
- we transform older EDMFs (drug master files) into CTD format
- eCTD in the Centralised Procedure

In centralised procedure the EMA now only accepts submissions received in eCTD format. We understand that there may be occasions when applicants are unable to comply with this electronic requirement and in those circumstances we will accept paper submissions.

Since January 2013 and "**Mandatory from March 2014**" all eCTD submissions must be sent using the dedicated submission channels: eSubmission Gateway or the related eSubmission Web Client

To facilitate the use of eCTD as the highly recommended submission format in the MRP and DCP, a Best Practice Guide is published by the CMDh (see the link below). Any change requests to the document should be handled through the Change Control Process.