
GENERAL INFORMATION

The application dossier for the commencement of a clinical trial, to be submitted to the competent authorities of the Member States and the Ethics Committees, consists of administrative information and the necessary demonstration of quality, safety and efficacy of the investigation medicinal product.

For applications submitted in accordance with Article 8 and Article 9 of Directive 2001/20/EC, applicants should clearly indicate under which conditions the application is made (competent authority or Ethics Committee).

Each volume of the dossier should be sequentially paginated throughout, in Arabic numerals, legible and suitably bound. Each volume should be clearly identified. Particular care should be given to proper and consistent cross-referencing throughout the dossier.

If spectra or photographic material are supplied in the dossier, legible copies and photographs should be supplied in each copy submitted.

Full copies of all bibliographical references should be provided, translated if necessary.