

Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (Text with EEA relevance)

CHAPTER 6

INSPECTION PROCEDURES

Article 24

Member States shall make publicly available within their territories the documents relating to the adoption of good clinical practice principles.

They shall establish the legal and administrative framework within which their good clinical practice inspections operate, with definition of the powers of inspectors for entry into clinical trial sites and access to data. In so doing they shall ensure that, on request and where appropriate, inspectors of the competent authority of the other Member States also have access to the clinical trial sites and data.