

JOINT DECLARATION

Mutual recognition of Good Clinical Practice and inspections relating thereto

For medicinal products, the results of clinical trials carried out on the territory of the Member States are currently accepted for inclusion in applications for marketing authorisations and their variations or extensions. In principle, the Member States agree to continue to accept these clinical trials for the purpose of marketing authorisations applications. They agree to work towards an approximation of Good Clinical Practice, namely by implementing the current Declarations of Helsinki and Tokyo and all guidance relevant to clinical trials adopted in the framework of the International Conference on Harmonisation. However, due to legislative developments concerning inspections and authorisations of clinical trials in the European Community, detailed arrangements for the mutual recognition of the official supervision of these trials will have to be considered in the near future and laid down in a specific Chapter.
