

Pivotal Study

A pivotal study is normally a Phase III study of a new intervention which is designed to provide the necessary data for a decision by a regulatory agency.

For example, the European Medicines Agency (EMA) requires specific safety and efficacy information about new medicines before it can issue a marketing authorisation. A pivotal study will be conducted to Good Clinical Practice standards. It will generally be randomised and controlled (an RCT). It will be of adequate size and, whenever possible, double-blind.