

Clinical study report [CSR]

A clinical study report is a document containing extensive detail about the plan, methods and conduct of the study so that it is clear how the study was carried out. This report should provide a clear explanation of how the design features of the study were chosen and include results of the trial. A clinical study report should also provide enough individual patient data, to allow the key analyses of data to be repeated, should the regulatory authorities wish to do so. It is a central part of any application for a new medicine to receive marketing authorisation, and it must meet the requirements of the regulatory authority that has to assess the application.