Post Authorisation Safety Study [PASS]

A post authorisation safety study is a study carried out after a medicine has been given a marketing authorisation. Its purpose is to obtain further safety information or to assess how well risk-management measures are working. The information from a post authorisation safety study is used in regulatory decision making.

A post authorisation safety study might be a clinical trial or a non-interventional study, and can be created voluntarily by the MAH, or can be required by the regulator (‘imposed’). The Pharmacovigilance Risk Assessment Committee (PRAC) at the European Medicines Agency (EMA) is responsible for assessing the protocols of imposed studies and for assessing the studies’ results. The EMA publishes the protocols and abstracts of the final study reports online.