

Post-authorisation efficacy study [PAES]

A post-authorisation efficacy study (PAES) may be voluntary or imposed by regulatory authorities. Post-authorisation efficacy studies take place after marketing authorisation is granted and the medicine is in general use. They are Phase IV studies, intended to complement efficacy data that are available at the time of the initial authorisation, and gather long-term data about how well the medicine works when used widely.