Clinical trial authorisation [CTA]

Before a clinical trial can start, the sponsor must apply for and be given clinical trial authorisation (CTA). Each European country has its own regulatory authority that assesses applications for clinical trial authorisations. For clinical trials that will take place in more than one European country, there is a ‘Voluntary Harmonisation Procedure’ which allows one application to be submitted to the authorities in all the relevant countries.

As well as clinical trial authorisation, a positive opinion from an ethics committee (or institutional review board) is needed before a clinical trial can go ahead.