Trial protocols: Modalities and timing of posting

Note: Only third country protocol files are posted directly to EudraCT by third country data providers (i.e. PIP addressees and Article 46 data providers), or their agents. For trials conducted inside the EEA, protocol files, i.e. Clinical Trial Applications (CTAs), are uploaded to the database by the National Competent Authorities.

Interventional Clinical Trials that include at least one investigator site outside EEA (i.e. in 'third countries')

Trial category	What is in scope of EudraCT	Protocol format	Timing of posting
Trials included in an agreed PIP[1]	Paediatric or non-paediatric trials that are included in an agreed PIP	Third country file	≤ one month after either the EMA decision agreeing a PIP, or the first approval/positive opinion of the trial by a 'third country' competent authority and/or 'third country' ethics committee, whichever is the latest[1]
Paediatric[2] trials in scope of article 46[3] that are not included in an agreed PIP	Paediatric trials completed after 26 January 2007 which involve the use of a medicinal product covered by an EU marketing authorisation and are sponsored by the marketing authorisation holder	Third country file	Prior upload of a protocol file to EudraCT is necessary to complement the required trial results. Please see separate document for "Trial results: Modalities and timing of posting".

[1] Commission Guideline 2009/C 28/01 para 2.2.1
[2] A paediatric trial is a trial that includes at least one participant < 18 years of age
[3] Art 46(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use (2006) Official Journal of the European Communities L 378/1