Trial protocols: Modalities and timing of posting

Version 2 (1 September 2017)

Note: Only third country protocol files are posted directly to EudraCT by third country data providers (i.e. PIP addressees), 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 paediatric investigation plan (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]

[1] Commission Guideline 2009/C 28/01 para 2.2.1