Trial results: modalities and timing of posting

As per Commission Guideline 2012/C 302/03

Version: 28 September 2020

Interventional Clinical Trials that ended on or after 21 July 2014

Trial category	What is in scope of EudraCT	Composition of results	Timing of posting
Non-paediatric trials	 Non-paediatric trials conducted in at least one EEA country Non-paediatric trials included in an agreed PIP, whether conducted inside or outside the EEA 	Full data set mandatory; summary attachment(s) optional	\leq 12 months after the end of the trial ¹
Paediatric ² trials	 Paediatric trials conducted in at least one EEA country Paediatric trials included in an agreed PIP, whether conducted inside or outside the EEA Paediatric trials involving the use of a medicinal product covered by an EU marketing authorisation and sponsored by the marketing authorisation holder, whether or not included in an agreed paediatric investigation plan (PIP) and whether conducted inside or outside the EEA³ 	Full data set mandatory; summary attachment(s) optional	≤ 6 months after the end of the trial (exceptionally ≤ 12 months after the end of the trial if justified and if trial not sponsored by marketing authorisation holder for involved product(s)) ⁴

 $^{^{1}}$ Commission Guideline 2012/C 302/03 para 4.3 2 A paediatric trial is a trial that includes at least one subject below 18 years of age.

³ Studies within the scope of Art 46(1) of Regulation (EC) No 1901/2006 ⁴ Commission Guideline 2009/C 28/01 para 2.2.2

Interventional Clinical Trials that ended before 21 July 2014

Trial category	What is in scope of EudraCT	Composition of results	Timing of posting ⁵
Non-paediatric trials	 Non-paediatric trials conducted in at least one EEA country, and not included in an agreed PIP, ended before 21 July 2013 	Summary attachment(s) mandatory; full data set optional	Trials ended between 21 July 2013 and 21 July 2014: full data set to be posted by 21 July 2015 Trials ended before 21 July 2013: summary attachment/full data set to be posted by 21 July 2016
	 Non-paediatric trials conducted in at least one EEA country, and not included in an agreed PIP ended after 21 July 2013 Non-paediatric trials included in an agreed PIP, whether conducted inside or outside the EEA 	Full data set mandatory; summary attachment(s) optional	
Paediatric ⁶ trials	 Paediatric trials conducted in at least one EEA country Paediatric trials included in an agreed PIP, whether conducted inside or outside the EEA Paediatric trials involving the use of a medicinal product covered by an EU marketing authorisation and sponsored by the marketing authorisation holder, whether or not included in an agreed paediatric investigation plan (PIP) and whether conducted inside or outside the EEA⁷ 	Full data set mandatory; summary attachment(s) optional	

Additional information provided in our **Frequently Asked Questions**

Instructions on how to post results provided in the <u>Tutorials on posting results</u>

 $^{^5}$ Commission Guideline 2012/C 302/03 para 4.6 6 A paediatric trial is a trial that includes at least one subject below 18 years of age. 7 Studies within the scope of Art 46(1) of Regulation (EC) No 1901/2006