Trial results: Modalities and timing of posting

Version 1.0 (18 April 2016)

1. Interventional Clinical Trials that ended on or after 21 July 2014 (i.e. the date of finalisation of the programming according to Commission Guideline (2012/C 302/03))

| **Trial category** | **What is in scope of EudraCT** | **Composition of results** | **Timing of posting** |
| --- | --- | --- | --- |
| Non-paediatric trials where regulated by Directive 2001/20/EC | All non-paediatric trials conducted in at least one EEA country, whether or not included in an agreed paediatric investigation plan (PIP) | Full data set mandatory, summary attachment(s) optional | ≤ 12 months after the end of the trial[[1]](#footnote-1) |
| Paediatric[[2]](#footnote-2) trials in scope of article 46[[3]](#footnote-3) | 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, whether or not included in an agreed paediatric investigation plan (PIP) | Full data set mandatory, summary attachment(s) optional | ≤ 6 months after the end of the trial[[4]](#footnote-4) |
| Paediatric trials in scope of article 41(1) which are not in scope of article 46 (where regulated by Directive 2001/20/EC) | Paediatric trials completed after 26 January 2007, conducted in at least one EEA country and not being marketing authorisation holder-sponsored  | Full data set mandatory, summary attachment(s) optional | ≤ 6 months after the end of the trial, or≤ 12 months after the end of the trial if justified[[5]](#footnote-5) |
| Paediatric trials in scope of article 41(1) which are not in scope of article 46 (investigator sites are all outside EEA) | Paediatric trials completed after 26 January 2007, conducted completely outside the EEA, not being marketing authorisation holder-sponsored and included in an agreed PIP | Full data set mandatory, summary attachment(s) optional | ≤ 6 months after the end of the trial, or≤ 12 months after the end of the trial if justified[[6]](#footnote-6) |
| Non-paediatric trials in scope of article 41(1) (investigator sites are all outside EEA) | Non-paediatric trials conducted outside EEA and included in an agreed PIP | Full data set mandatory, summary attachment(s) optional | ≤ 12 months after the end of the trial[[7]](#footnote-7) |

1. Trials that ended prior to 21 July 2014 (i.e. the date of finalisation of the programming according to Commission Guideline (2012/C 302/03))

| **Trial category** | **What is in scope of EudraCT** | **Composition of results** | **Timing of posting** |
| --- | --- | --- | --- |
| Paediatric trials in scope of article 46[[8]](#footnote-8) | 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, whether or not included in an agreed PIP | Full data set mandatory, summary attachment(s) optional | ≤ 12 months after finalisation of the programming[[9]](#footnote-9) |
| Paediatric trials in scope of article 45[[10]](#footnote-10) | Paediatric trials in respect of products covered by an EU marketing authorisation on 26 January 2007, completed by 26 January 2007  | Summary of study submitted to EMA and uploaded by the Agency for publication | ≤ 24 months after finalisation of the programming[[11]](#footnote-11) |
| Trials in scope of article 41(1) which are included in an agreed PIP | Paediatric and non-paediatric trials included in an agreed PIP | Full data set mandatory, summary attachment(s) optional | ≤ 12 months after finalisation of the programming[[12]](#footnote-12) |
| Other trials (where regulated by Directive 2001/20/EC) that ended < 1 year prior to the finalisation of the programming | All trials conducted in at least one EEA country  | Full data set mandatory, summary attachment(s) optional | ≤ 12 months after finalisation of the programming[[13]](#footnote-13) |
| Other trials (where regulated by Directive 2001/20/EC) that ended ≥ 1 year prior to the finalisation of the programming | All trials conducted in at least one EEA country marketing authorisation holder-sponsored and not included in an agreed PIP | Full data set or summary attachment(s) or both | ≤ 24 months after finalisation of the programming[[14]](#footnote-14) |

1. Commission Guideline 2012/C 302/03 para 4.3 [↑](#footnote-ref-1)
2. A paediatric trial is a trial that includes at least one participant < 18 years of age [↑](#footnote-ref-2)
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 [↑](#footnote-ref-3)
4. Commission Guideline 2009/C 28/01 para 2.2.2 [↑](#footnote-ref-4)
5. Commission Guideline 2009/C 28/01 para 2.2.2 [↑](#footnote-ref-5)
6. Commission Guideline 2009/C 28/01 para 2.2.2 [↑](#footnote-ref-6)
7. Commission Guideline 2012/C 302/03 para 4.3 [↑](#footnote-ref-7)
8. 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 [↑](#footnote-ref-8)
9. Commission Guideline 2012/C 302/03 para 4.6.2, second subparagraph [↑](#footnote-ref-9)
10. Art 45(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 [↑](#footnote-ref-10)
11. Commission Guideline 2012/C 302/03 para 4.6.2, first subparagraph [↑](#footnote-ref-11)
12. Commission Guideline 2012/C 302/03 para 4.6.2, second subparagraph [↑](#footnote-ref-12)
13. Commission Guideline 2012/C 302/03 para 4.6.1, first subparagraph [↑](#footnote-ref-13)
14. Commission Guideline 2012/C 302/03 para 4.6.1, second subparagraph [↑](#footnote-ref-14)