**Posting of clinical trial summary results in European Clinical Trials Database (EudraCT) to become mandatory for sponsors as of 21 July 2014**

As of 21 July 2014, it will become mandatory for sponsors to post clinical trial results in the European Clinical trials Database (EudraCT), managed by the European Medicines Agency (EMA). This date corresponds to the finalisation of the programming of the database as referred to in a [European Commission guideline[External link icon](http://ec.europa.eu/health/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf)](http://ec.europa.eu/health/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf), in application of the current [clinical trials Directive 2001/20/EC[External link icon](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF)](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF) and the [Paediatric Regulation](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000068.jsp&mid=WC0b01ac0580025b8b). Under these frameworks, since the result-related information is fed into the publicly accessible European Union Clinical Trials Register, summary results of clinical trials will become available to the public as sponsors start to comply with their legal obligations.

**What this means for clinical trial sponsors**

Sponsors will now be obliged to post results in EudraCT for any interventional trials registered in EudraCT and that have ended within a certain period of time:

* For any interventional clinical trials that ended on or after 21 July 2014, sponsors will have to post results within six or twelve months following the end of the trial, depending on the type of trial concerned;
* For trials that ended before that date, sponsors will need to submit the results retrospectively, in accordance with the specific timeframe laid out in the above-mentioned European Commission guideline on the posting and publication of result-related information on clinical trials.

EudraCT already contains protocol-related information submitted by sponsors for interventional clinical trials conducted in European Economic Area (EEA) countries, as well as clinical trials conducted in third countries, when the clinical trial is part of an agreed Paediatric Investigation Plan (PIP). Information on these is already made public in the European Union Clinical Trials Register.

Clinical-trial sponsors were encouraged to start uploading summary results on a voluntary basis, when new functionalities were made available in EudraCT in October 2013. This was intended to enable them to get used to this new feature and be ready to comply with the legal requirements.

A further iteration of EudraCT was launched at the beginning of May 2014 with improved functionalities. The scope of the information to be posted in EudraCT has also been extended to include marketing-authorisation holder sponsored clinical trials conducted in third countries that involve the use in the paediatric population of a medicinal product covered by an EU marketing authorisation.

As of 21 July 2014, with the launch of a final iteration of EudraCT, all functionalities will be in place to enable the posting of results by sponsors on a compulsory and systematic basis.

**What this means for public access to information on clinical trial results**

A subset of the data included in EudraCT is made available to the public in the European Union Clinical Trials Register. The content and level of detail of these summary results is set out in the European Commission guideline and in its technical guidance. A number of summary results can already be viewed on the European Union Clinical Trials Register website. A typical set of summary results provides information on the objectives of a given study, explains how it was designed and gives its main results and conclusions.

In addition, information on paediatric studies that ended before the Paediatric Regulation came into force in 2007, which used to be accessible through the EMA website, is now available through the European Union Clinical Trials Register. This improvement allows a greater and richer approach to the search and greater public access to clinical trial related information.

It is foreseen that access to summary results will be an essential feature of the European Union Clinical Trials Register for interventional clinical trials conducted in EEA countries, as well as clinical trials conducted in third countries which are linked to European paediatric drug development.

**Notes**

* Guidance on the content of protocol-related and results-related information is available here:
  + [Guideline on the data fields contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC to be included in the database on medicinal products provided for in Article 57 of Regulation (EC) No 726/2004[External link icon](http://ec.europa.eu/health/files/eudralex/vol-10/2008_07/c_16820080703en00030004_en.pdf)](http://ec.europa.eu/health/files/eudralex/vol-10/2008_07/c_16820080703en00030004_en.pdf).
* [Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006[External link icon](http://ec.europa.eu/health/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf)](http://ec.europa.eu/health/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf).
* [Technical guidance on the format of the data fields of result-related information on clinical trials submitted in accordance with Article 57(2) of Regulation (EC) no 726/2004 and Article 41(2) of Regulation (EC) no 1901/2006[External link icon](http://ec.europa.eu/health/files/eudralex/vol-10/2013_01_22_tg_en.pdf)](http://ec.europa.eu/health/files/eudralex/vol-10/2013_01_22_tg_en.pdf).
* For further details on the modalities and timing of posting see [Trial results: Modalities and timing of posting[External link icon](https://eudract.ema.europa.eu/docs/guidance/Trial%20results_Modalities%20and%20timing%20of%20posting.pdf)](https://eudract.ema.europa.eu/docs/guidance/Trial%20results_Modalities%20and%20timing%20of%20posting.pdf).