# Making sense of clinical trial data disclosure in the EU

There are now three bases on which clinical data can be disclosed in the EU. **Elisabethann Wright**, **Ciara Farrell** and **Amy Merrick** examine what each entails.

The European Medicines Agency's new policy on the publication of clinical data for medicinal products[1,2] has led to a sense of confusion in some pharmaceutical companies concerning the overall framework governing the disclosure of clinical trial data in the EU.

Following the EMA's publication of its disclosure policy on 2 October 2014, there are now three bases on which clinical data can be disclosed in the EU, although not always from the same source. The EMA may disclose data on the basis of its disclosure policy and on the basis of the agency's access to documents policy[3]. Individual companies may also sometimes disclose clinical data as a result of voluntary commitments based on industry policies. When the EU Clinical Trials Regulation[4] enters into effect – which is expected to take place in the second quarter of 2016 at latest – this voluntary commitment will, in some circumstances, become a legal obligation.

The EMA's power to provide access to clinical trial data on the basis of its policies must be distinguished from the legal requirements that the new CTR will impose on pharmaceutical companies to disclose data from clinical trials. The EMA policies are a prerogative of the EMA. Consequently, access will be provided on the basis of these policies only to information that is in the possession of the EMA.

The CTR will impose obligations on individual companies to disclose clinical data generated in trials for which they were the sponsor. As a result of the regulation, pharmaceutical companies will, in the future, have a legal obligation to proactively ensure that certain clinical data is made available to the public.

Initiatives such as the "joint principles" adopted by the EU and US drug industry bodies, EFPIA and PhRMA[5], are voluntary commitments with no legally binding effect. They demonstrate the pharmaceutical industry's commitment to transparency of clinical data in the EU.

## EMA policies

As mentioned above, the EMA may disclose clinical data on the basis of two separate policies. The agency's policy on access to documents permits third parties to request the EMA, with limited exceptions, to disclose documents – both those generated internally and those provided by third parties – that are in its possession. As a result, third parties can seek disclosure for clinical and non-clinical elements of applications for marketing authorization. The disclosure policy provides specific access by third parties to clinical data that has been submitted as part of applications for marketing authorization, or of applications for extensions to existing marketing authorizations and that the agency has proactively made available.

## EMA policy on access to documents

The EMA policy on access to documents provides that the agency may, in response to a request by a third party, provide access by such third parties to certain documents that it holds. The documents that are held by the EMA may include clinical trial data submitted as part of an application for marketing authorization.

However, as a general rule, the EMA will not disclose documents or information that contain trade secrets or "commercially confidential information" concerning pharmaceutical companies.

The term "commercially confidential information" is defined in the documents developed by the EMA and the Heads of Medicines Agencies outlining the general principles for the disclosure of documents held by the EMA in a variety of circumstances (EMA/HMA Principles)[6].

Commercially confidential information is:

*any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information.*

Before clinical data held by the EMA is disclosed in response to a third-party request, the EMA will communicate the request to the company that submitted the data to the agency. The company is entitled to submit arguments in support of a claim that the clinical data in question constitutes commercially confidential information that should not be disclosed.

## EMA disclosure policy on proactive publication of clinical trial data

The EMA's much discussed disclosure policy, unlike the agency's policy on access to documents, permits the EMA to proactively publish clinical trial data submitted as part of an application for marketing authorization, or as part of a post-authorization procedure for a centrally-authorized medicinal product. This data will be composed of clinical reports and individual patient data. The data will be published on the EMA's website.

The disclosure policy is intended to serve as a complementary procedure prior to the implementation of the proactive disclosure requirements provided in the new CTR discussed below.

As a result of the disclosure policy, clinical data that were submitted as part of an application for centralized marketing authorization of a medicinal product as of 1 January 2015 may be publicly disclosed. From 1 July 2015, clinical data submitted as part of an application for extension of a therapeutic indication and line extension applications will also be subject to the disclosure requirements of the disclosure policy.

The EMA will disclose clinical data in two phases. In the first phase, only clinical reports will be published. In the second phase, the agency plans to make individual patient data available. However, this disclosure shall be preceded by an assessment of the most appropriate way to make disclosure of such information compliant with applicable data protection laws.

Reflecting the EMA policy on access to documents, clinical data containing commercially confidential information will not be proactively disclosed on the basis of the disclosure policy.

The EMA's assessment of commercially confidential information in the context of its disclosure policy is similar to that conducted as part of the agency's approach to requests based on its policy on access to documents. Moreover, access by third parties to the clinical data will be conditional on acceptance by visitors of "terms of use". There are two separate terms of use depending on the intended purpose of which data accessed will be used: (a) terms of use concerning access for general information purposes; and (b) terms of use concerning access for academic and non-commercial research purposes.

Users must complete a registration process and agree to the related terms of use. Users requesting access for general purposes have access to information as a "view-on-screen-only" mode. Users requesting access to data for academic and non-commercial purposes are able to download, save, cut and paste, and print the data.

No clinical data accessed under either terms of use may be used to support an application for marketing authorization for a medicinal product or an application for an extension or variation to a marketing authorization.

## Requirements imposed by the new CTR

The current EU Clinical Trials Directive does not require pharmaceutical companies to publicly disclose clinical trial data. However, the new CTR, which will replace the CTD, requires the public disclosure of clinical study reports on a publicly accessible database. The regulation is expected to enter into force no later than the second quarter of 2016.

The CTR provides that the EMA, in cooperation with the European Commission and the EU member states, must establish and maintain a publicly accessible and searchable EU database of all approved clinical trial data relating to medicinal products.

The new EU database will include the following information:

- detailed summaries of the results of authorized clinical trials, including a summary drafted by the trial sponsor in plain language which must be submitted to the database within one year of the termination of the clinical trial; and
- the final clinical study reports that were submitted to support an application for marketing authorization. These should be uploaded onto the EU database within thirty days of the authorization, rejection, or withdrawal of the marketing authorization of the medicinal product.

Trial sponsors may be subject to penalties if they fail to adhere to these transparency obligations. The exact penalties will be determined by the national laws and regulations of the individual member states.

In recognizing the legitimate economic interests of sponsors, the EU database shall be publicly accessible unless, for all or part of the data and information contained therein, confidentiality is justified on any of the following grounds:

(a) protecting personal data in accordance with the EU legislation on access to documents, Regulation ((EC) No 45/2001[7];
(b) protecting commercially confidential information, in particular through taking into account the status of the marketing authorization for the medicinal product, unless there is an overriding public interest in disclosure;
(c) protecting confidential communication between member states in relation to the preparation of the assessment report; or
(d) ensuring effective supervision of the conduct of a clinical trial by member states.

## Voluntary commitments by trade associations and industry

Pharmaceutical companies and trade associations in the EU are increasingly adopting voluntary commitments concerning the disclosure of clinical trial data to demonstrate their dedication to increased transparency. These voluntary commitments are not legally binding on pharmaceutical companies. Nor is compliance with any voluntary commitments required by any EU laws or regulations.

The joint principles adopted by EFPIA and PhRMA concern the sharing of clinical data with patients and healthcare researchers. They entered into force on 1 January 2014. The joint principles applies to all EFPIA member companies and EFPIA member associations.

These disclosure requirements are established on the basis of the following principles:

- enhancing data sharing with researchers;
- enhancing public access to clinical study information; and
- sharing results with patients who participate in clinical trials.

A number of member companies of EFPIA have begun to include clinical data on their company websites.

## Conclusion

Each of the four policies discussed above have the same basic aim. This is the dissemination of clinical data to interested third parties. Once the CTR enters into force, companies will be required not only to comment on third-party requests to the EMA for access to data that they submitted and that is held by the EMA, they will be required to create detailed summaries of the results of clinical trials that they sponsored. The protection of commercially confidential information is a right that is common in all four procedures. The scope of this term and the context in which it should be applied would, however, benefit from guidance and clarification.



**References**


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