The EMA's plan on access to raw data – transparency or commerce?

Burkhard Sträter warns that making raw data from clinical trials publically available breaches data protection law.

Drug regulators in the EU can learn an important lesson on data protection from their counterparts in the US.

Both jurisdictions require drug companies to prepare extensive pre-clinical and clinical dossiers in order to convince the authorities that their medicines are sufficiently safe and efficacious to warrant marketing authorization.

The European Medicines Agency and the US Food and Drug Administration also both make available to the public certain data from the clinical trials contained in marketing authorization dossiers. In the interest of transparency, this allows third parties and academia motivated by public health needs to access the data for their own research.

The amount and breadth of data that each regulator appears to be willing to share with the public, however, differ and there is concern that the EU might be planning to give too much away.

Trial data is accessible to the public in the US via the clinicaltrial.gov database. Trial data in the EU is provided on request to the EMA, although the agency is planning to proactivley publish data once the marketing authorization process has ended. In Germany, section 42b of the German Medicinal Products Act (AMG) obliges every entrepreneur to submit the clinical files pertinent to a marketing authorization to the higher federal authorities in a specially aggregated form. The higher federal authorities then publish these in a newly created DIMDI database. Some pharmaceutical companies have also started to publish the results of all clinical trials in their own databases.

Concerns over access to raw data

The FDA requires companies to submit all trial data, including the so-called raw data, so the agency may conduct an assessment from "bottom to top". As far as I am aware, the agency refuses to make raw data public, not least for legal reasons.

The EMA, as with EU member state competent authorities, does not routinely require the submission of raw data. The agency requires companies to submit the dossier and extensive final clinical study reports. It only requests the raw data if this proves necessary after it has assessed the final reports.

The EMA is now planning to request all raw data from all companies. During the annual European conference of the Drug Information Association in Amsterdam in March, Thomas Salmonson, the chairman of the agency's key scientific committee, the CHMP, confirmed that neither the EMA nor the authorities of the member states is in a position to comprehensively record and analyse this huge flood of raw data in the marketing authorization procedure. Therefore, only random samples will continue to be assessed. It appears, therefore, that the EMA will request the raw data not so that it can assess them, but so as to be able to pass them on to third parties on request. If these data are requested for the purpose of passing them on to third parties, then it must be asked whether this practice is admissible.

EU Directive 95/46/EC on protecting personal data and the respective data protection laws of the member states forbid the passing on of personal data without the consent of the patients concerned. The raw data are not anonymous but only pseudonymous. They may be re-individualized at any time. This applies, in particular, to data of patients who suffer from rare diseases. The patients permit access to their personal data on the standardized declaration of an informed consent form only for the purposes of inspection by the authorities and supervision by monitors checking the validity of data on behalf of companies. Passing on these data to other persons is not covered and would be illegal. Directive 95/46/EC would not apply even if the data were to be anonymized; data protection concerns would continue to exist because the duty to heed the content of the informed consent provided by patients is mandatory.

Passing on data to third parties is not compatible with the agreements made by the patients in the informed consents. Patients are recognisably guided by the purpose that medicines are developed and authorized based on the data from the clinical trials that show the products have a healing effect. The law calls for an "informed consent", ie consent after having been informed of the circumstances. If patients are not informed of their data being passed on to third parties, then it may not be presumed that they are in agreement because passing on these data has serious effects. If the data are generally available, they would be exposed to assessment by health insurance companies and life insurers as well as employers, thereby creating framework conditions for insurance rates and hiring practice. It is highly probable that most patients would not agree to their data being ultimately used for commercial purposes. If, on the other hand, a third party conducts a medically scientific analysis of the data, passing on of that data would be compatible with the circumstances of the informed consent given by patients. In this case, however, the authority would have to find a way to prevent unimpeded access for commercial purposes.

Abuse by generics rivals

It has been shown repeatedly that generics companies are using publicly available trial data for commercial purposes. Generic drug applications are only admissible once the protective periods in favor of the originators have expired. The corresponding EU provision can be found in Article 10 of Directive 2001/83/EC on medicinal products and Article 14 (11) of Regulation (EC) 726/2004 on the authorization and supervision of medicines. Some originator companies now believe that generics firms may circumvent this period by downloading published clinical trials.

It is remarkable that most of the applications to the EMA for information on clinical trials have not been filed by scientific institutions or doctors. Rather, a large part of the inquiries have been from researching drug companies wishing to obtain an overview of the status of research and of the research path pursued by their competitors. This can help a company avoid adopting the wrong approach and accelerate the development of products. Is this transparency or the promotion of unfair competition? Provisions for transparency and providing information to professional circles must not be used for commercial purposes. Rather, transparency should be implemented as far as possible while observing the restrictions imposed by the right to self-determination of the patients and the property rights of the companies concerned.

The surrender of raw data from clinical trials is a clear breach of data protection law. Even if the data are anonymized, the danger still exists that they may be re-individualized in this era of personalized medicine, at least as far as orphan drugs are concerned. Passing on permanently anonymized data for commercial purposes is not compatible with the declarations of informed consent given by patients. For so long as the protection of personal patient data is not guaranteed and abuse for commercial purposes to the detriment of the patients and companies is not ruled out, requests for data should be referred to clinicaltrial.gov or comparable databases such as the DIMDI database.

It is not surprising that the FDA refuses to release raw data. This is one lesson on data protection that the EU can learn from the US.

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