New EU directive for clinical trials

The European Parliament has adopted the new regulation on the regulation of clinical trials by a large majority. If the Council of Ministers also agrees, it shall enter into force. The aim is to simplify the application process for clinical trials and to centrally coordinate them via an online portal that has yet to be created. There, the results of the studies are also to be published in language understandable to the layman within one year of graduation.

Nothing new in Brussels

The new regulation is justified by shortcomings of Directive 2001/20/EC and the resulting decreasing number of clinical trials in the EU. From the point of view of all stakeholders, patients, researchers, payers and companies, an increasing number of projects carried out in Europe would be welcome, as the quality of the data collected, and the existing data protection standards are high. However, the present proposal does not provide any new information or clear guidelines on how to proceed after the entry into force of the Regulation. The template is mostly kept in the subjunctive and provided with well-known information, which is sufficiently represented by the generally accepted guidelines, in particular ICH-GCP. The proposal is aimed specifically at "scientific" research (40% of the projects), a clear commitment to competitive prosperity is sought in vain. If the Commission is essentially concerned with 'big data' under the pretext of greater transparency, an economically sensible adaptation of Directive 2001/20/EC would have sufficed. Whether the envisaged coordination of the national authorities will work is far from clear.

The EU regulation comes into force about 2 years after publication, a ratification by the member states is not necessary in this case and would not stand up to serious scrutiny by the Federal Council. It would have made sense to entrust the universally recognised and respected experts of the European Medicines Agency (EMA) with the task of drawing up and introducing general guidelines in order to catch up with the USA in terms of expertise, to compete and to involve all Member States appropriately – without subjunctives.

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