COMMENTARY

A few remarks on the rules about personal data protection when conducting clinical trials in Italy, also from abroad

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Summary. The Italian Authority for the Protection of Personal Data has definitively adopted the Guidelines for data processing within the framework of clinical drug trials. The Guidelines are addressed to sponsors and other subjects who intervene, also from abroad, in clinical trials. The document provides practical instructions for the processing of personal data of human subject participating in clinical trials.

INTRODUCTION

The Guidelines for data processing within the framework of clinical drug trials issued by the Italian Authority for the Protection of Personal Data [1] are important for all professionals who are in various ways involved in clinical experimentations. Mention should be made of its particular importance also for foreigners who conduct clinical experimentations in Italy.

The Guidelines provide a complete picture of the provisions which have to be followed as regards personal data treatment in clinical experimentations; they form part of the framework already outlined by the Authority in the “Personal data protection code” (DP Code) [2] and in subsequent provisions on the matter, including most notably the “General authorisation for the processing of genetic data” [3, 4].

The Guidelines in question are applied to the various types of clinical experimentations, including non-profit studies.

ORIGIN AND FRAMEWORK OF THE DOCUMENT

The Guidelines have been drafted following the diffusion by the Authority of a document designed as reference material for the general public, inviting all individual and group stakeholders to participate, more specifically pharmaceutical companies and research organisations operating in the experimentation sector, hospitals or universities and public or private authorised establishments, representatives of health professionals and associations of patients concerned, ethics committees, the Ministry of Health, the Istituto Superiore di Sanità, the Italian Pharmaceutical Agency, the State-Regional Government Board [5].

The Guidelines were also drafted by the Authority as a response to critical situations encountered on the occasion of audits and checks in pharmaceutical companies and research institutions. The Authority, in particular, pursues the aim of counteracting the widespread habit of indicating as “anonymous” those personal data that are transferred, in a coded form, to those who promote the experimentation or to other professionals involved. It should be remembered that these data, though coded, still remain personal data, and as such they may lead to tracing back the personal identity of the individual subjects participating in the experimentation. In this respect, the Authority comments that “it is sometimes the case that sponsor companies request trial centres to inform the patients concerned that their data will be made available to the sponsor by the trial physician exclusively in anonymous format – as they mistakenly believe that data protection legislation does not apply to the information related to trial patients. By doing so, they actually prevent the patients concerned from fully comprehending what role is played ultimately by the sponsor company and all the other entities employed by and/or collaborating with the sponsor as for data processing operations”. The Authority

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concludes that: “therefore, the information intended for trial patients is not in line with the DP Code (section 13) if worded as above”. The data, though coded, may lead to tracing back the individual. Therefore the Authority stipulates that all professionals involved should adopt high security standards, especially as regards any transfer using telematic instruments. Among other things, it is compulsory to have: authentication systems for data access; encrypted systems for storage and filing; suitable communication protocols for data transmission between experimentation centres; the pharmaceutical company database and the subjects in charge of data monitoring.

THE POSSIBLE IMPACT OF THE DOCUMENT

The Guidelines reconstruct in a precise way the possible flows of sensitive data occurring as part of clinical experimentations. The Authority requires all players involved in the long process which characterises any clinical experimentation to adopt specific measures for the protection of sensitive data. This has led to dissatisfaction on the part of some professional categories (pharmaceutical companies in the first place). It should be mentioned, however, that the Guidelines, after a possibly difficult adjustment to current procedures, will allow professionals to have an unequivocal framework of rules. Having outlined such a framework, it will become possible to introduce the necessary adjustments favouring simplification. A useful aspect of the Guidelines consists in their suggesting a reference model for the information document and expression of consent to personal data treatment.

The latter form (which does not pertain to the controller of the study and by any other possible addressee of the data).

THE CROSS-BORDER FLOW OF DATA

In view of the fact that most of the major current clinical trials are of the multi-centric international type, an important aspect concerns the cross-border flow of data. As a matter of fact, “Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data” [6] stipulates, under article 4, that “Each Member State shall apply the national provisions it adopts pursuant to this Directive to the processing of personal data where (...) the processing is carried out in the context of the activities of an establishment of the controller on the territory of the Member State; when the same controller is established on the territory of several Member States, he must take the necessary measures to ensure that each of these establishments complies with the obligations laid down by the national law applicable”. This means that a subject or an institution based, for example, in Great Britain shall have to abide by the “UK Data Protection Act” if they are operating from an “establishment” physically located in Great Britain.

During the consultations before the publication of the document, the concern was expressed that the required provisions could go to detriment of sponsors, contract research organisations and other players established in Italy with respect to comparable subjects.
based in other Member States, thus discouraging the work of Italian or foreign institutions interested in operating from Italian premises. Future developments will show whether these fears are justified. Mention should be made in particular of two situations.

First of all, those countries which do not belong to the European Union might not guarantee the appropriate level of confidentiality protection. In such cases the Authority stipulates that the transfer is considered legitimate provided that the patients concerned have been previously informed and that they have expressed their consent in writing thereto (or, alternatively, that equivalent and appropriate measures are in place).

Secondly, as regards the United States, the Italian Authority, partially dissenting from the criticisms expressed by its European counterparts with respect to the principles contained in the Safe Harbor agreement, has considered that the latter contains sufficient guarantees [7].

STORING TIMES FOR DATA AND BIOLOGICAL SAMPLES

The general principle, already stipulated in article 11 of the DP Code [2] and highlighted in subsequent provisions, is confirmed whereby the storing must cease once the aim underlying the collection has been achieved. This approach is derived from the fundamental requirements according to Italian standards which stipulate that the data collection must be “relevant, complete, not excessive and indispensable with regard to the purposes sought in the individual cases”.

In the specific case of clinical trials, the Authority stipulates that personal data should be stored for at least seven years after the experimentation has been completed. In some cases, or following a specific agreement between the parties, such minimum period may be extended.

The Authority, moreover, stipulates that “trial sponsors may lawfully use the data and biological samples related to individual data subjects in future studies and researches, also by availing themselves of the external collaborators they had employed for performing the trial, providing the patients were informed adequately thereof beforehand and gave their specific, separate consent in writing” [1, cit. article 11].

Even though the Authority does not specify this, the restrictive statement which appears to limit the storing time of the sample to the duration of the experimentation for which it was collected, is generally interpreted in a somewhat more liberal way, with “experimentation” being intended as the “type of experimentation”, that is to say any use related, in terms of nature and purpose, to the aim for which the sample was taken and stored.

FUTURE PROSPECTS

The Guidelines set out an extremely articulate pattern which anyone who intends to start experimental activities in Italy, also from abroad, will have to take into careful account.

The extent of the work done by the Authority bears witness to the complexity of the issue. The role of the data treatment owner is especially relevant to guarantee compliance with the rules.

All professionals need to be aware of the fact that the medical/clinical data collected in the course of the experimentations are not anonymous. Indeed, such information, though it is coded, still constitutes personal data which can thus be traced back to the identity of the individuals undergoing the tests.

The standard consent form suggested by the Authority is expected to help prepare specific forms; the latter shall have to contain legally relevant information for each case.

In conclusion, this is a very complex issue and therefore one cannot fail to agree with the hope expressed by the Authority that particular attention will be paid to training, as already stipulated by the DP Code [2]: any professional involved in the experimentation needs to have the required experience, skills, reliability. In particular the Authority calls for specific training as regards functions related to monitoring, data entry, validation and statistical analysis.

References


