Comments on
“Guidelines 01/2025 on Pseudonymisation”
by
Federal Association of Contract Research Organisations
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(Bundesverband medizinischer Auftragsinstitute e.V., BVMA)

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Introduction

We appreciate the opportunity offered by the EDPB to send comments on their “Guidelines 01/2025 on Pseudonymisation”. We ask the EDPB to consider for these guidelines the judgements of the Court of Justice of the European Union on the cases C-582/14 (Patrick Breyer v Bundesrepublik Deutschland) and T-557/20 (SRB v EDPS), because these judgements feature important principles for the classification of personal data as pseudonymised and these principles have an eminent impact on the workload for processing of some personal data in clinical research.

Comments

We suggest adding to section 2.5 (Transmission of pseudonymised data to third parties) or as a new section 2.8 (Anonymisation of pseudonymised data) the following content:

It has to be noted that the classification of pseudonymised data as personal data is not absolute and objective but depends on the capabilities of the recipient of the pseudonymised data to re-identify the data subjects. If the additional information for attributing the pseudonymised personal data to a specific data subject are held by another party and the access of the recipient to these additional information is prohibited by law or practically impossible on account of the fact that it would require a disproportionate effort in terms of time, cost and man-power, the risk of re-identification in reality is insignificant. In such a case, the pseudonymised data in the hands of the recipient have to be regarded as anonymised data (see the Judgements of the Court of Justice of the European Union on the cases C-582/14 (Patrick Breyer v Bundesrepublik Deutschland) and T-557/20 (EDPS v SRB)) and are no longer subject to the GDPR.

This principle is applicable to the transfer of pseudonymised data to a third party and to the export of pseudonymised data. The principle applies especially to the setting of clinical research, where the additional information for attributing the pseudonymised personal data to a specific data subject are held exclusively by study centers. The personal data collected from the study participants are associated with a subject-specific and study-specific code. A list that connects these codes with the identity of the study participants are filed only at the study centers and many parties involved in the clinical research have no access to that list. If such parties involved in the clinical research or authorities get data sets derived from the research, they usually get sets of anonymised personal data, even if the data sets are still associated with pseudonymizing patient-specific codes. These parties might be central laboratories, data management service providers, medical safety service providers and others. The authorities might be authorities that supervise the clinical research or authorities that receive applications for the authorisation of medicinal products or medical devices. If the principles that were developed by the Court of Justice of the European Union in the cases C-

582/14 and T-557/20 are applied to the transfer of data as described above, the transfer of data does not need to be supported by agreements for the transfer of personal data or by safeguards for the export of personal data into third countries, because the data are no longer subject to the GDPR.

We would like to note to the EDPB that this issue causes enormous bureaucratic workload. It concerns the necessity to implement safeguards for the export of personal data, the necessity for setting up detailed data transfer agreements, the wording of informed consent forms and is triggers discussions with ethics committees about this wording. One regular topic of discussion is the consent of study participants to the transfer of their data to health authorities outside of the EU. This might become necessary in order to obtain the authorisation for the marketing of a medicinal product years after the clinical trial has ended. While these authorities are provided with data that are effectively anonymous, ethics committees ask sponsors to inform study participants on the names of the countries that might in a far future receive their data and to implement safeguards for this export of personal data. These requests are absurd since they are applied to data that in the described context are no longer personal data.

This issue frustrates sponsors of clinical research and conveys to them that the GDPR is a burdensome and bizarre regulation and that the EU is a difficult place for the conduct of clinical research. A clear statement in the guidelines of the EDPB might provide good arguments that could help to reduce the workload triggered by the transfer and export of research data.

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