JOURNAL OF CLINICAL RESEARCH BEST PRACTICES
Vol. 15, No. 6, June 2019 "Happy Trials to You"

What's New in GCP?
European Commission Answers Questions on Trial Data Protection

The European Commission Directorate-General for Health and Food Safety released 11 questions with answers on the interaction between the European Union's Clinical Trials Regulation (CTR) and General Data Protection Regulation (GDPR). The Q&As, which reiterate the European Data Protection Board recommendations issued in January, discuss the general obligations of the CTR with regard to personal data; who is responsible for determining the correct legal basis for personal data processing in the context of a clinical trial; the legal basis for processing personal data of trial subjects; and the differences between the CTR and GDPR in the meaning of informed consent.

Data processing operations purely related to clinical trial research activities must fall under one of three legal bases: public interest; legitimate interest; or consent.

The guidance noted "EU law provides the legal basis for the processing of personal data gathered in the context of clinical trials. The processing of personal data in the context of clinical trials can thus be considered as necessary for the performance of a task carried out in the public interest when the conduct of clinical trials directly falls within the mandate, missions and tasks vested in a public or private body by Union or national law."

In situations where the conduct of a clinical trial cannot be considered as necessary for the performance of the public interest tasks vested in the controller by law, "the processing of personal data could be 'necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject,'" the guidance said.

The guidance also noted that under the GDPR, "consent must be freely given, specific, informed, unambiguous, and where consent is used as a justification for processing special categories of data, such as health data, such consent must be explicit. Data controllers should pay particular attention to the condition of a 'freely given' consent," the guidance said. "This element implies real choice and control for data subjects. Besides, consent should not provide a valid legal ground for the processing of personal data in a specific case where there is a clear imbalance between the data subject and the controller."

"Consent will not be the appropriate legal basis in most cases, and other legal bases than consent must be relied upon," the guidance concluded.

In addition, if the other two legal bases are used, "the withdrawal of consent to participate in a clinical trial under CTR may not necessarily affect the processing of personal data gathered in the context of that trial. The personal data may continue to be processed where there is an appropriate legal basis for such processing under GDPR," the guidance said.

When consent to the trial is withdrawn, "the personal data of that person gathered before the withdrawal shall be kept for the purposes and in the conditions defined by the protocol and the legislation."

However, if consent is used as the lawful basis for processing data, "there must be a possibility for individuals to withdraw that consent at any time, and there is no exception to this requirement for scientific research," the guidance said. "As a general rule, if consent for data processing under GDPR is withdrawn, all data processing operations that were based on consent remain lawful in accordance with the GDPR; however, the controller shall stop the processing actions concerned and if there is no other lawful basis justifying the retention for further processing, the data should be deleted by the controller. In cases where personal

data are processed on the basis of consent under GDPR, it is appropriate for the investigator to determine with the trial subject whether their withdrawal of consent under CTR relates solely to participation in trial activities or whether they also withdraw consent to the processing of their data.'

Secondary Use Addressed

"Secondary use of data, which is anonymized, does not fall within the scope of the GDPR," the guidance said. However, the processing of personal (including pseudonymized) data outside of the clinical trial protocol must consider:

- If a sponsor/investigator would like to use the personal data gathered for any other purposes than the one defined by the clinical trial protocol (e.g., medical data collected to conduct a clinical trial on breast cancer used to run a study aiming to identify new biomarkers, but which was not foreseen in the clinical trial protocol), it would require a valid legal ground under the GDPR. And "the chosen legal basis may or may not differ from the legal basis of the primary use."
- When further processing is carried out for purposes of scientific research, the GDPR provides for a presumption of compatibility of purposes. "Even when the presumption of compatibility is found to apply, the scientific research making use of the data outside the protocol of the clinical trial must be conducted in compliance with the relevant legal basis and all other relevant applicable provisions of data protection law. Therefore, the controller is not exempt from the other obligations under data protection law, for example with regard to fairness, lawfulness, necessity and proportionality, as well as data quality."

When GDPR consent is sought to be used as a legal basis for the processing of personal data for secondary use, the following considerations should be taken into account:

The GDPR requires that personal data be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes. "Further processing for scientific research purposes shall not be considered incompatible with the initial purposes," the guidance said.

Consent of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.

An individual has the right to withdraw his/her consent at any time during the conduct of the clinical trial. "Data subjects should be given this information prior to giving consent to participate in the clinical trial," the guidance said.

"It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognized ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose."

There is "some flexibility to the degree of specification of consent" and the purpose may be described at a more general level. "Yet it must be interpreted in a strict manner and requires a high degree of scrutiny. It should be noted that the obligations with regard to the requirement of specific consent still apply, despite the flexibility. This means that, in principle, scientific research projects can only include personal data on the basis of consent if they have a well-described purpose," the guidance said.

Sponsors may seek consent of subjects for a secondary use at the beginning of the clinical trial (the first use). "It is important to note that this form of consent must strictly be distinguished from the informed consent in the context of the CTR. The sponsor must ask separately for consent of data processing within a secondary use (using different consent sheets) and has to indicate the specific research purposes of this use," the guidance said. However, if the need for the secondary use "arises after the clinical trial has been completed, the sponsor must go back to the data subjects for specific consent. In any case the sponsor/investigator must inform the subject on the legal basis and the right to withdraw consent."

Other Recent Developments in the Guide to Good Clinical Practice

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