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THE ROLE OF CONFIDENTIAL INFORMATION AND PERSONAL DATA PROTECTION IN CONTRACT RESEARCH ORGANIZATIONS (CROs)

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Abstract. The aim of the article is to study the regulations and policies for the protection of confidential information and personal data in a contract research organization. Pharmaceutical manufacturers, as well as outsourcing organizations providing services in this area, are subject to extensive regulatory requirements in the field of confidential information and personal data protection. Accordingly, pharmaceutical manufacturers, contract research organizations develop, implement or refine compliance elements that address areas of potential problems or high risk and are applicable to their own companies. In this article, we review the General Data Protection Regulation (GDPR) as the best practice for protecting confidential information and personal data in contract research organizations, as well as laws that regulate this industry. As an object, the standards and policies on confidential information and personal data in force have been analysed. Having conducted the research, we can conclude that the implementation and compliance with GDPR-based data protection policies and standards helps to solve the following issues: maintaining the sustainable companies' operation and improving the patient data security.

Keywords: contract research organization; confidential information; personal data; clinical trials; data protection policy; data protection regulation; data security; compliance elements.

JEL codes: D82; C81.

References

1. Gambarelli, G.; Gangemi, A.; Tripodi, R. (2023) Is Your Model Sensitive? SPEDAC: A New Resource for the Automatic Classification of Sensitive Personal Data // IEEE Access. Vol. 11. P.: 10864-10880.

2. Chaika, V.K.; Vustenko, V.V.; Morozova, N.A. (2022) On the risks of digitalization of healthcare // Medico-social problems of the family. Vol. 27. No. 4. P.: 64-74.

3. Chassang, G.; et al. (2017) The impact of the EU general data protection regulation on scientific research.

4. Zhang, D. (2018) Big data security and privacy protection / 8th international conference on management and computer science (ICMCS 2018). Atlantis Press. P.: 275-278.

5. Regulation, P. (2018) General data protection regulation // Intouch. Vol. 25. P.: 1-5.

6. Baishev, N.P. (2021) On the issue of state-legal regulation of the protection of personal data in medicine // Rostov Scientific Bulletin. No. 2. P.: 9-11.

7 Romanosky, S.; Acquisti, A. (2009) Privacy costs and personal data protection: Economic and legal perspectives // Berkeley Tech. L.J. Vol. 24. P.: 1061.

8. Averchenkov, V.I. (2016) Protection of personal data in the organization. M.: Flinta. P.: 17-20.

9. Babash, A.V.; Baranova, E.K.; Melnikov, Yu.N. (2018) Information Security. Tutorial. Moscow: KnoRus. P.: 10-15.

10. Ponomareva, O.N. (2020) Features of personal data protection in medicine // Vestnik USMU. No. 4. P.: 53-54.

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