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PROFILING IN THE RECRUITMENT OF SUBJECTS FOR CLINICAL TRIALS IN THE LIGHT OF GDPR

1. INTRODUCTION

The importance of the contribution made by the pharmaceutical industry to the provision of new, effective drugs is an undeniable fact. Over the last decades, research and development in the pharmaceutical industry has led to the development of new treatments for many diseases, saving lives, improving the health and well-being of millions of patients¹. Further progress in this area should be expected, due to the dynamically developing technologies in the field of m-health and a greater use of patient mobile applications. S. Crossley underlines that “Traditional recruitment strategies, such as the distribution of information leaflets and placing advertisements in newspapers, appear to be ineffective strategies to recruit groups for research purposes. M-Health techniques, specifically FB is a more successful method to reach and recruit participants for

¹ A. CHOWDHURY and A. GAIGL, *The Economics of Competition Law and of Pharmaceutical Patents*, [in:] *Competition and Patent Law in the Pharmaceutical Sector: An International Perspective*, eds. G. PITRUZZELLA and G. MUSCOLO, Alphen aan den Rijn 2016, p. 9.

a clinical trial”.² Medical and technological innovations lead to better healthcare, a better quality of life and longer life expectancy³. Failure to use new technologies in recruitment may even lead to a failure in the implementation of the clinical trial, due to the insufficient number of participants⁴.

The aim of clinical trials is to test the safety and efficacy of new medicinal products before they are put on the market⁵. Clinical trials assess the risk–benefit ratio associated with the use of a new drug⁶ and help to reduce the possibility of side effects occurring once the drug is made available to a large number of patients. Usually sponsored by pharmaceutical companies, they are the only reliable way to prove the effectiveness and safety of the tested product.

EU law regulating clinical trials is highly restrictive, which discourages sponsors from running them on EU territory. One of the most neglected areas in healthcare is data processing⁷. The General Data Protection

² S. CROSSLEY, *EU Regulation on health information technology, software and mobile apps*, [in:] *Life Sciences: A Global Guide from Practical Law*, ed. S. FELLOWS, I, 2016, [https://uk.practicallaw.thomsonreuters.com/2-619-5533?transitionType=Default&contextData=\(sc.Default\)&firstPage=true&bhcp=1](https://uk.practicallaw.thomsonreuters.com/2-619-5533?transitionType=Default&contextData=(sc.Default)&firstPage=true&bhcp=1). (accessed 3 January 2019).

³ H. YU, *Achieving Proof of Concept in Drug Discovery and Development*, Cheltenham 2017, p. 3.

⁴ Such a risk has recently emerged in ISCHEMIA, a very important global study. See D. STEMPPEL, *What the ISCHEMIA Controversy Tells Us About Patient Recruitment in Clinical Trials*, *Medical Marketing Insights*, <https://www.mdconnectinc.com/medical-marketing-insights/ischemia-controversy-patient-recruitment-clinical-trials> (accessed 3 January 2019).

⁵ F. REYES, *Recherche clinique et prise en compte l'innovation*, [in:] *Traité de santé publique*, eds. F. BOURDILLOR, G. BRUCKER, and D. TABUTEAU, Paris 2007, p. 270-271.

⁶ A. WNUKIEWICZ-KOZŁOWSKA, *Eksperyment medyczny na organizmie ludzkim w prawie międzynarodowym i europejskim*, Warszawa 2004, p. 70; J. RÓŻYŃSKA, *Ocena ryzyka i korzyści badania biomedycznego*, [in:] *Badania naukowe z udziałem ludzi w biomedycynie. Standardy międzynarodowe*, eds. J. RÓŻYŃSKA, M. WALIGÓRA, Warszawa 2012, p. 70.

⁷ P. CADUFF-JANOSA, *Lost in Regulation*, [in:] *Pharmacovigilance. Critique and Ways Forward*, eds. I. EDWARDS and M. LINDQUIST, Basel 2017, p. 7-20.

Regulation (GDPR)⁸ and the EU regulation on clinical trials⁹ have opened the door for the proper processing of patients' personal data in line with privacy standards.

Recital 1 of the EU regulation on clinical trials says that the interests of the subjects should always take priority over all other interests. Furthermore, in a clinical trial the rights, safety, dignity and well-being of subjects must be protected and prevail over all other interests; and it must be designed to generate reliable and robust data. Under the GDPR, the new provisions are designed to strengthen the rights of data subjects¹⁰. However, the Regulation underlines that a certain restriction of these rights is necessary¹¹. It seems crucial to ensure a balance between the reliability of data used to ensure the safety of medicinal products and the protection of persons (particular patients) whose data are processed¹².

⁸ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1-88).

⁹ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1-76).

¹⁰ The study *How the GDPR changes the rules of scientific research* emphasizes that the way data subjects' rights can be strengthened is to reconcile the requirement for specific, informed and free consent in the GDPR with the need for broad consent in scientific research, and to reconcile its definition with the requirement of consent in associated instruments. See European Parliamentary Research Service, *How the GDPR changes the rules of scientific research*, Brussels 2019, p.72.

¹¹ Facilitating access to data for research and development purposes is becoming crucial. See F. LAURIE, *L'innovation et l'échange de données numériques*, [in:] *L'innovation a l'épreuve de la mondialisation*, ed. P. CERVETTI, Marseille 2015, p. 90 ff.

¹² The requirement to strike a balance between the interests of the data subjects and the public interest is not new and has always been the foundation of the protection of privacy. See P. BLUME, *Data Protection and Privacy – Basic Concepts in a Changing World*, «Scandinavian Studies in Law» 56/2010, p. 151-164; L. Bygrave has written at length on this issue; see his *Data Protection Law: Approaching Its Rationale, Logic and Limits*, The Hague 2002, and *Data Privacy Law: An International Perspective*, Oxford 2014. On the conflict between innovation and protection, see M. GAYO, *Protección de datos personales e innovación: (in)Compatibles?* Madrid 2016, p. 161-162.

Ensuring a balance and protecting the rights of data subjects also applies to data profiling¹³.

2. PROFILING

According to Art. 4 Point 4 of the GDPR, “profiling” means any form of automated processing of personal data intended to evaluate certain personal aspects relating to a natural person or to analyse or predict that natural person’s performance at work, economic situation, location, health, personal preferences, reliability or behaviour.

One of the issues giving rise to misgivings is whether any form of automated processing refers to data processing of the solely automated type and at the same time also to partly automated processing. It should be noted that already in its opinion on the data protection reform proposals¹⁴, the Working Party pointed out that the scope of the provisions on profiling should not be limited to exclusively automatic processing but should also include partly automated processing methods.

Any other interpretation could lead to an unwarranted restriction of the catalogue of situations in which profiling takes place. It is also problematic to qualify the processing as solely automated, because in most cases human participation will occur at some stage, e.g. when the data is fed into the system which will process it. However, in a situation where manual (non-automated) processing occurs, we cannot consider it profiling within the meaning of the GDPR, even if the rules of assigning profiles and making the assessment were the same as in the case of automated processing.

¹³ N. HÄRTING, *Big Data und Profiling nach der DSGVO*, «ITRB» 2016, p. 209-211.

¹⁴ Article 29, Data Protection Working Party, *Opinion 01/2012 on the data protection reform proposals, adopted on 23 March 2012*, https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2012/wp191_en.pdf (accessed 6 January 2019), p.15.

The definition of profiling contains various terms referring to what is being evaluated¹⁵. In the final version, the term “personal aspects” is used. One can only assume that the distinction of the concept of “behaviour” in the definition of profiling coincides functionally with the concept of “personality.”

Evaluation is an important element of profiling, and may be manifested through the analysis of the past and present state, on the basis of which the person is qualified for a particular profile. An assessment may also involve a prognosis that includes the person’s particulars relating to future events. The profiling referred to in Art. 4 Point 4 of the GDPR need not be effective. Only its assessment aspect is relevant. If a decision is made as a result of profiling, ordinary profiling becomes the qualified type of profiling referred to in Art. 22 of the GDPR. Qualified profiling requires that certain conditions (including legal grounds) must be met¹⁶.

The definition of profiling does not mean that it must affect only one person, it seems that it can also relate to a group of people¹⁷ (e.g. patients with a specific disease), provided that the aspects which are to be assessed are common to these people, and they are not a whole group which could

¹⁵ C. RUSTICI, *GDPR Profiling and Business Practice*, «Computer Law Review International» 2/2018, p. 36-43.

¹⁶ P. VOIGT and A. VON DEM BUSSCHE, *The EU General Data Protection Regulation (GDPR). A Practical Guide*, Cham 2017, p. 180.

¹⁷ V. FERRARIS; F. BOSCO, G. CAFIERO, E. D’ANGELO, Y. SULOYEVA, and B.J. KOOPS, *Defining profiling*, (11 December 2013). Available at SSRN: <https://ssrn.com/abstract=2366564> or <http://dx.doi.org/10.2139/ssrn.2366564> On p. 6-7. the authors divide group profiles into distributive and non-distributive group profiles. Distributive profiles involve a group of people with the same attributes. In this case, the profile can be applied to the group as a whole and any of its members, because it is also an individual profile. A non-distributive group profile identifies a certain number of people who do not share all the attributes of the group’s profile. For example, a group of individuals with a higher risk of cardiovascular diseases is profiled by the occurrence of a certain number of risk factors (e.g. specific lifestyle habits, occurrence of particular diseases in members of the family, stressful conditions at work, etc.). A person may be identified as a member of this group without having the same attributes as other members of the group, and without sharing all the attributes. This kind of profiling has a higher probability of erroneous identification of members.

be made subject to the profiling (Ince, Cuijpers, Hof & Riper, 2014)¹⁸. The ICO (the UK supervisory authority) has adopted a similar position, that profiling means gathering information about people or groups of people and analysing their characteristics and behaviour patterns¹⁹.

Therefore, it seems reasonable to consider the profiling of a small group of patients to test drug effectiveness and then compare the results of treatment with the results of other patients as profiling in the sense of the GDPR. However, the group should be relatively small, and each of its members should have the same characteristics within the scope of the profiling.

However, the question arises whether all the data that has been collected for analysis or a prognosis, for instance data relating to health, must be the personal data of a particular person, or whether some of it may be the data of other persons²⁰. This interpretation is admissible and not in breach of the definition in Art. 4 Point 4) of the GDPR, which does not say that the personal data used for the assessment must always be the personal data of a given individual. On the other hand, one could claim that it would be pointless to create a profile based on the data of just one individual and assess it against the data of another individual. However, it may be assumed that there are situations in which the data of the person who is evaluated may be compared with the data of a member of their family, e.g. their mother, and a prognosis regarding their health could be made on this basis. This approach may, on the one hand, support the fact that the data subject to profiling does not necessarily have to be the personal data of the individual subject to the assessment, or on the other hand – that the data is actually data relating to the evaluated person (not third parties), thus excluding the use of third party data from profile creation. Regardless of the approach

¹⁸ B. INCE, P. CUIJPERS, E. HOF, and H. RIPER, *Reaching and recruiting Turkish migrants for a clinical trial through Facebook: A process evaluation*, «Internet Interventions» 1.2/2014, p. 74, 74-83.

¹⁹ Information Commissioner's Office, *Feedback request – profiling and automated decision-making*, <https://ico.org.uk/media/2013894/ico-feedback-request-profiling-and-automated-decision-making.pdf> (accessed 3 January 2019).

²⁰ C. RUSTICI, *op. cit.*, p. 36-43.

adopted, it seems reasonable to use third party data, considering it as data that indirectly concerns the person subject to the evaluation.

Another question is whether the obligation relating to information has to be fulfilled, and if so, who is to be informed. Arts. 13 and 14 of the GDPR do not make it necessary to inform anyone that ordinary profiling is to be applied.

Nonetheless, Recital 60 of the GDPR stresses the general requirement to inform the subject about the profiling and the consequences of such profiling (without making a distinction whether it is the type of profiling defined under Article 4 Point 4) or under Art. 22 of the GDPR). This information obligation reflects the principles of fairness and transparent processing of personal data. It seems reasonable to meet the information obligation only with respect to the person involved in the evaluation (if the third-party data is indirectly the data of that person).

It is disputable whether profiling should be considered as a separate purpose for data processing or as a means to achieve other objectives. In our opinion, profiling is not the goal of processing itself, but a specific processing activity, serving for the implementation of other goals, e.g. research or scientific needs. In Recital 24 of the GDPR, profiling is defined as the *technique* of profiling a natural person, particularly for *decision-making*. The aim is not to profile patients, but to make decisions, for example, ones regarding the patient's qualification for the further stages of recruitment for clinical trials. On the other hand, the controller has to show that he has the right legal grounds for profiling. For ordinary profiling, the controller's justified interest will provide the grounds, but in the case of qualified profiling, the legal grounds will be one of those defined in Art. 22 of the GDPR.

3. QUALIFIED PROFILING IN RECRUITMENT FOR CLINICAL TRIALS

Unlike ordinary profiling, qualified profiling entails solely automated profiling. It is difficult to assess when we have solely automated, and when partially automated profiling. In clinical trials, the final stage of recruitment should always involve the participant's direct contact with

the doctor or researcher who makes the final decision on the participant's qualification for the study.

In Case C-212/13 (*Ryneš v Úřad*), the ECJ ruled that “surveillance in the form of a video recording of persons, as in the case before the referring court, which is stored on a continuous recording device – the hard disk drive — constitutes, pursuant to Article 3(1) of Directive 95/46, the automatic processing of personal data”²¹. Moreover, in Case C-101/01 (*Lindqvist*), the Court considered it necessary to determine whether this processing of personal data took place “wholly or partly by automatic means”²².

As we see, these judgments do not give a clear answer what kind of processes may be considered wholly (solely) automated data processing, which means that controllers must make their own assessments and consider whether their profiling activities fall within the scope of Art. 22 of the GDPR. It seems we will never have solely automated data processing for the whole recruitment process for clinical trials, if it is to be carried out in accordance with the standards adopted in the EU regulation on clinical trials. However, the question arises whether the preliminary stage of recruitment (particularly inviting prospective subjects to join the study, which usually involves advertising in the social media) should not be treated as a separate process in the light of the GDPR, which would mean that it could be solely automated.

Automated decision-making under Art. 22 of the GDPR is permitted if the conditions for such processing are met²³. Art. 22 should be interpreted as a prohibition, not as a right. This means that individuals are automatically protected against the potential effects of this type of

²¹ Case C-212/13 *František Ryneš v Úřad pro ochranu osobních údajů* (ECLI:EU:C:2014:2428).

²² Case C-101/01 *Bodil Lindqvist* (ECLI:EU:C:2003:596).

²³ The aim of the far-reaching protection described in Art. 22 is to reduce the asymmetry between the data subject (patient) and the institution (research centre) accessing information for the subject's profile and aspects of its creation. See M. HILDEBRANDT, *Profiling and the rule of law*, «Identity in the Information Society» 1.1/2008, p. 63.

processing. The Working Party clarified that Art. 29 implies that under Art. 22(1) processing is not permitted across the board²⁴.

The GDPR also uses the term “appropriate measures to protect the rights, freedoms and legitimate interests of the person” as a necessary condition to ensure the legality of such processing. Such appropriate measures recognize the subject’s right to obtain human intervention from the controller, to express his own opinion and to challenge that decision. The controller should ensure that human involvement is meaningful. It is unacceptable to fabricate human involvement in automated decision-making process²⁵.

These conditions should be implemented as appropriate, and justified by the nature of the particular processing, in order to give the human factor a real impact on the automated decision-making process²⁶.

Automated decisions cannot be made for the processing of special categories of personal data, such as data concerning patients’ health, unless the data subject has expressly consented to such decisions or if it is necessary on the grounds of important public interest provided by EU law or the law of an EU Member State. Such consent must comply with the conditions set out in Arts. 6 – 8 of the GDPR²⁷ and must explicitly

²⁴ Guidelines on Automated individual decision-making and Profiling for the purposes of Regulation 2016/679, p. 20.

²⁵ Privacy International, *Data Is Power: Profiling and Automated Decision-Making in GDPR*, p. 13 P. Litwiński concurs with this opinion; however, he observes that the human involvement should include a decision-making stage, and cannot be limited only to entering personal data into the system or overseeing this system P. BARTA, M. KAWECKI, and P. LITWIŃSKI, *Rozporządzenie UE w sprawie ochrony osób fizycznych w związku z przetwarzaniem danych osobowych i swobodnym przepływem takich danych. Komentarz*, Warszawa 2018, p. 433.

²⁶ The document *Data Is Power: Profiling and Automated Decision-Making in GDPR* is right to point out that supervision is not required if the processing itself is opaque, which is particularly important in the context of advanced processing based on computational algorithms, machine learning and large quantities of data, Privacy International, *Data Is Power: Profiling and Automated Decision-Making in GDPR*, p. 14.

²⁷ The European Data Protection Board has identified a conflict between the definition of consent under the GDPR and the prospective Clinical Trials Regulation. The EDPB has ruled that a distinction should be drawn for consent for primary purposes (that is, purposes associated with the clinical trial) and secondary purposes (that is,

refer to automatic decision-making. Therefore, the patient must be directly informed about such processing before he gives his consent.

4. PROPOSED AMENDMENTS TO THE LAW ON CLINICAL TRIALS

In view of the growing importance of recruitment for clinical trials, we consider it reasonable to introduce special provisions on profiling data of potential research participants. The best solution would be to introduce legislation by amending the EU regulation on clinical trials, especially as it contains an inadequate regulation on the protection of personal data, which does not come up to the GDPR standard. Subsequently, it may be worthwhile to introduce changes in the national regulations of the EU Member States.

The GDPR offers clear-cut legal grounds for EU Member States to clarify their legal provisions in this area at the level of national legislation²⁸. There are two key legal grounds in the GDPR for the adoption of detailed national regulations regarding data processing in clinical trials:

1. Art. 9. Par. 4, under which Member States may maintain or introduce further conditions, including restrictions on the processing of genetic, biometric, or health data. The literal wording of the provision clearly indicates that it applies not only to restrictions, but also to any subsequent “conditions” for the admissibility of

research-related purposes). With respect to the former category, a further distinction could be drawn between “safety and reliability” purposes and consent for scientific purposes (“pure research activity purposes”). For safety and reliability purposes, the EDPB holds that the processing of personal data could be justified under the Clinical Trials Regulation pursuant to Article 6 Point 1c. See European Parliamentary Research Service, *How the GDPR changes the rules of scientific research*, Brussels 2019, p.72-73 and Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR) (Art. 70.1.b).

²⁸ P. VOIGT and A. VON DEM BUSSCHE, *op. cit.*, p. 180.

processing sensitive data, since Art. 9 Par. 2 gives a catalogue of these “conditions”²⁹.

2. Art. 23 permits the restriction of the scope of the controller’s and processor’s obligations. An example is his exemption from the obligation to inform data subjects, as long as the data (information) processing is related to the public interest in the field of public health and social security.

In fact, the EU legislator has enumerated many issues in the Regulation that may and sometimes need to be clarified by national law, thereby relaxing the rigour resulting from the choice of this instrument for the reform of data protection law in the EU. Although the provisions of the GDPR should be complete, in practice they may often need to be supplemented or modified under national law. EU Member States have the power to cater for matters not regulated in the national legislation³⁰. The GDPR gives EU Member States a great deal of regulatory freedom³¹. This conclusion results not only from the general nature of the GDPR, but also from a number of its specific provisions that give such authorization. In line with Recital 8, the GDPR even allows for the incorporation of its elements in national law, if such measures were to make it more coherent and comprehensible to the persons to whom they apply. An example of the type of clarification required in the provisions of the Regulation would be the introduction of legal grounds for personal data profiling in clinical law. In our opinion, such rules may and should be introduced.

This leads to the conclusion that the importance of recruitment for clinical trials calls for specific changes in the law. The legal principle which should be observed is that profiling is to be carried out in the interest of the patient and should not cause any inconvenience or any restriction of the rights or freedoms of the persons whose data is processed. Hence, researchers should implement the principles of personal data protection at every stage of their processing, starting from

²⁹ W. CHOMICZEWSKI, M. CZERNIAWSKI, P. DROBEK, et al., *RODO. Ogólne rozporządzenie o ochronie danych. Komentarz*, Warszawa 2018, p. 454.

³⁰ P. VOIGT and A. VON DEM BUSSCHE, *op. cit.*, p. 553.

³¹ A. SERVENT, *Protecting or Processing?* [in] *Data Protection and Cybersecurity in Europe*, eds. W. SCHÜNEMANN and M. BAUMANN, Cham 2005, p. 128.

their collection, through the qualification stage for research, to their use and archiving³². Therefore, we recommend that the law on clinical trials should explicitly allow profiling to be carried out for this purpose.

5. CONCLUSIONS

The main goal of this paper was to draw attention to the need of regulating profiling in clinical trials. Despite the adoption of the definition of legal profiling in the GDPR, many problems in clinical trials law still need to be clarified³³. This includes the proper classification of recruitment activity as a solely automated process, the legal assessment of non-automated profiling, the use of third-party data during profiling (also in connection with the information obligation), and the categorization of profiling as a separate purpose of processing or as a means to achieve other purposes.

To summarize our considerations, we present the following conclusions.

First of all, we believe that the current lack of adaptation of the EU regulation on clinical trials to the GDPR is an infringement both of the public interest and individual patient interests. The specifics of

³² A study which describes rules and recommendations of this kind was compiled by the Health Ethics and Policy Lab in July 2019. It includes suggestions how scientific research can find common ground with the new legal rules on data protection and how the scientific community can prepare for GDPR compliance, with special focus on delineating regulatory, procedural and educational solutions. For example, it underlines the consequences of inaccuracy in data for biomedical research projects, which may be significantly more severe than in other types of research. In our opinion, the same conclusion applies to clinical trials. Moreover, the *Ethics and data protection* document says that even when previously publicly accessible data is collected for research purposes, the researcher must provide details of the source(s) and inform users that the data is openly and publicly accessible and may be used for research purposes. (European Commission, *Ethics and data protection...*, p.13.

³³ In the context of the impact of the GDPR on scientific research, see *How the General Data Protection Regulation changes the rules for scientific research*, available at: [https://www.europarl.europa.eu/RegData/etudes/STUD/2019/634447/EPRS_STU\(2019\)634447_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2019/634447/EPRS_STU(2019)634447_EN.pdf) (accessed 20 January 2020).

patients' personal data processing in relation to the implementation of health and medicine policy are being ignored. This precludes the proper implementation of the GDPR in clinical trials and should be considered a significant legislative defect.

Secondly, the lack of adaptation of the EU regulation on clinical trials to the GDPR also infringes the interests of entities acting as controllers of patient data (research sponsors), as well as of representatives of the medical professions (researchers). Data controllers have to resolve any conflicts that may arise between the provisions of the GDPR and the provisions of the EU regulation on clinical trials independently and on their own responsibility.

Thirdly, the GDPR contains clear legal grounds for EU Member States to clarify its provisions in individual cases related to health protection. The preamble recitals of the GDPR explain the purposes and scope of admissible changes. We think that the most urgent task is to put provisions on profiling for the recruitment of clinical trials into national law.

Fourthly, we believe that the best solution would be to amend the EU regulation on clinical trials in this respect, especially as it is incompatible with the standards provided by the GDPR. If this is not possible, then changes to national regulations should be considered.

To sum up, profiling is a challenge both to science and to the practice of clinical trials, especially when it comes to recruitment. There are many legal, ethical, and technical problems. The rule that is to be observed is that the new technologies being created, improved, and used are to serve human (patient) needs. This rule should be the paramount aim of all future activities relating to the creation of a balanced EU healthcare system.

PROFILOWANIE W REKRUTACJI DO BADAŃ KLINICZNYCH W ŚWIETLE RODO

Streszczenie

W naukach medycznych od dawna stosowane są wysoce wyspecjalizowane metody selekcji uczestników do badań klinicznych. Przykładem

jest pre-profilowanie onkologiczne polegające na wykorzystaniu biomarkerów genetycznych do wstępnej identyfikacji pacjentów onkologicznych do badań klinicznych. Należy spodziewać się dalszych działań w tym obszarze, ze względu na dynamicznie rozwijające się technologie w dziedzinie e-zdrowia i większe wykorzystanie mobilnych aplikacji pacjentów. Brak zastosowania nowych technologii w rekrutacji może nawet doprowadzić do niepowodzenia w realizacji badania klinicznego z powodu niewystarczającej liczby uczestników.

Kwestia profilowania do badań klinicznych jest ważna ze względu na ramy regulacyjne dotyczące profilowania przyjęte na mocy ogólnego rozporządzenia o ochronie danych („RODO”). Celem artykułu jest określenie zasad RODO, które ułatwiają korzystanie z narzędzi profilowania w celu rekrutacji uczestników do badań klinicznych. W artykule zaproponowano zmiany unijnego prawa farmaceutycznego w celu wprowadzenia ustawowych podstaw profilowania.

PROFILING IN THE RECRUITMENT OF SUBJECTS FOR CLINICAL TRIALS IN THE LIGHT OF GDPR

Summary

Highly specialized methods of selecting participants for clinical trials have been in use for a long time in the medical sciences. An example is offered by oncological pre-profiling, which involves the use of genetic biomarkers for a preliminary identification of oncological patients for clinical trials. We should expect further developments in this area, due to the rapid progress being made in e-health technologies and patients' growing use of mobile applications. Failure to use new technologies in recruitment could even lead to failure in carrying out a clinical trial due to a shortage of participants.

This issue is particularly important due to the regulatory framework for profiling adopted under GDPR (the General Data Protection Regulation). GDPR is of crucial importance for the R&D activities pursued by the pharmaceutical industry and in personalized medicine, and one of the biggest challenges is the practical application of its rules

in profiling activities. The same applies to the use of data obtained during clinical trials at the stage when the medical product is about to be launched on the market.

The aim of this paper is to present the GDPR rules to facilitate the use of profiling tools for the recruitment of participants for clinical trials. It includes a proposal for the amendment of the EU pharmaceutical law to introduce statutory grounds for profiling.

Słowa kluczowe: badania kliniczne; dane osobowe; profilowanie, rekrutacja; RODO.

Keywords: clinical trials; personal data; profiling; recruitment; GDPR.

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