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The Influence of General Data Protection Regulation on Patient Engagement

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Abstract: The new European General Data Protection Regulation – also known as GDPR – has raised the awareness among the private business entities regarding the protection of data subjects and the usage of personal data in their trade operations. In the present study, we aim at identifying and assessing the impact the new Regulation mainly on the life science sector, with a particular focus on clinical trials. Besides the subjects of the clinical trials, patients as the data subjects and the protection of their rights, when conducting scientific research in the medical-pharmaceutical field, we seek to define concepts such as sensitive data and data concerning health, data processing in scientific research and roles of all parties involved through the definitions of data subject, controller, processor or recipient given in the GDPR. The scope of the present research is represented by the analysis of the impact of the GDPR provisions on the derogations relating to processing for scientific research purpose on the rights of the clinical trial subjects.

Keywords: *clinical trials, general data protection regulation, clinical subject, patient engagement, GDPR.*

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Whatever, in connection with my professional practice or not, in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret. (Hippocratic Oath)

Introduction

Privacy has become particularly relevant in the past years as personal data is being used in various areas of activity, raising several issues that need to be addressed. Various legal instruments have been developed in order to create a framework for the usage of such data that establish a connection between the protection of the data subject and the activities of entities that process data, as well as the trust of the natural persons in the legality and fairness of the processing of their data.

The initial role of these legal instruments was harmonizing the data protection legislations of the member states of international organizations. Most of these soft laws provided sets of principles and recommendations on how to lawfully process data, paying a particular attention to sensitive data[1] (World Medical Association, 1964), (World Health Organization, 1995),(World Health Organization,2016), (Commission Directive, 2005), and therefore to health data and the necessary information for clinical trials and studies.

At the European Union level, data protection has been under the auspices of the Directive 95/46/EC of the European Parliament and the Council[2] (Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995) that has been transposed into the national legislations of the member states. Yet, this act did not provide specific rules

[1] Such as: (1) World Medical Association - Declaration of Helsinki on Ethical Principles For Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, (2) World Health Organization, Guidelines for clinical practice (GCP) for trials on pharmaceutical products in WHO Technical Report Series, No. 850, 1995, Annex 3, (3) European Union Guidelines for clinical practice (GCP) - Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products, published in Official Journal of the European Union no. L91/13, 9 April 2005.

[2] 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, Official Journal L 281, 23rd of November 1995.

regarding the processing of any kind of sensitive data and, even more, it proved to be insufficient for ensuring the protection of data, given the advanced technological progress. Therefore, a new act has been adopted at the European level enlightening the perception of what exactly data represent to the EU citizens and entities and the necessity of having common rules to protect such data. The Regulation (EU) 2016/679 of the European Parliament and of the Council[3] (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016) also known as the General Data Protection Regulation brings new rules on how data is used and more importantly, enshrines and develops the rights a data subject has with regard to his personal information.

The concept of *patient engagement* designates the ideal situation in which the natural person, acting in any capacity (patient, subject in clinical trials and so on) which is in contact with the health system will be properly informed of his / her rights and obligations in any medical intervention so that he / she can make informed decisions. The implementation of patient engagement measures in any action in the medical sector, particularly in clinical trials, will increase the confidence of subjects, improve the quality and safety of the medical act, streamline the research and development process and marketing of new treatments. Moreover, patient engagement prioritizes the patient's experience in the medical act, without any limitation. (World Health Organization, 2016)

2. General considerations on the data related terminology used in clinical trials and the legal ground

According to the new provisions of the General Data Protection Regulation, article 4, para. (1), personal data is *any information relating to an identified or identifiable natural person*. This definition is vague and covers a wide range of information. (Ungureanu, 2017, p.138) As a novelty, General Data Protection Regulation also defines special categories of data, namely sensitive data that determines the guaranteed identification of a certain natural person due to its primary, original and unique character: data concerning health, biologic data and genetic data. In this study, we shall refer mainly to the data processed in clinical trials, necessary for obtaining the authorization of merchandising pharmaceutical products.

[3] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, Official Journal of the European Union L 119/1, 4th of May 2016, applied stating the 25th of May 2018.

Processing, according to article 4 para. (2) of General Data Protection Regulation, *means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.* In clinical trials, (i) genetic data is the *unique information about the physiology or the health of that natural person* [according to article 4 para. (13) of the General Data Protection Regulation] that results in particular from an analysis of the biological material harvested from the data subject in question, such as the information obtained from collecting the biological and genetic material and its analysis by profiling which results in the determination of a representative sample of patients and potential clinically-tested patients, (ii) the biometric data [according to article 4 para. (14) of the General Data Protection Regulation] results from *specific technical processing relating to physical, physiological or behavioural characteristics of a natural person*, allowing or confirming the unique identification of the data subject, *e.g.* facial images or the dactyloscopic data (Jain *et al.,* 2003, p. 1494) collected during the monitoring period of the subjects during the clinical trials and (*iii*) data concerning health [according to article 4 para. (15) of the General Data Protection Regulation] that takes into account the information that relates to *the physical or mental health of a natural person including the provisions of health care services, which reveal information* about the health status of the person whose data is being processes, *e.g.* the data obtained from laboratory analyses, the medical history of the person of concern and the monitoring of the vital functions of the body of the data subject.

3. Clinical trials. Definition and classification

According to the Regulation (EU) no. 536/2014 of the European Parliament and of the Council[4] (hereon, Regulation no. 536/2014), article 2 defines the clinical studies as investigations in relation to humans that intend to discover or to verify the *clinical, pharmacological or other pharmacodynamic effects* of medicinal products or *to identify any adverse reactions to one or more medical products* or *to study the absorption, distribution, metabolism and excretion of one or more medicinal products*, the main objective being the one of establishing whether the studied medicinal product is safe and / or efficient. The same article also

[4] 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, Official Journal of the European Union L158/1, 27th of May 2014.

defines the clinical trial as the *clinical study* that fulfils either of the provided conditions: *a) the assignment of the subject to a particular therapeutic strategy,* decided in advance and not falling within the clinical practice of the state concerned, *b) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study or c) diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects*. Having this into consideration, in the present study, we shall refer to clinical trials as clinical studies that are any investigation related to humans that aims at discovering or verifying the clinical effects of certain medical products or identifying potentially adverse reactions to said medical products or assessing the safety and / or efficacy of the concerned medical products through studying the absorption, distribution, metabolism and so on of the products on the human body.

The Romanian legislation provides, according to the Order no. 904/2006 (Order no. 904/2006 of the Minister of Health of Romania)[5] of the Minister of Health for approving the norms on the implementation of good practice rules in the conduct of clinical studies using medicinal products for human use, the clinical studies refer to any investigation of human subjects that intends to discover of confirm the clinical, pharmacological and / or other pharmacodynamic effects of one of more medicinal products for clinical investigation[6] (Order no. 904/2006 of the Ministry of Health) (and / or to identify any adverse reaction to one more clinical investigational medicinal products, for the purpose of assessing their safety and or/efficacy, carried out in a single or multiple centres in one or more countries.

Having into consideration the importance of data usage in relation to the purpose of the clinical trial or study, we aim at clarifying to what extent the clinical trials are included into the scientific research category according to the provisions of the new legislation on data protection at European level

[5] Order no. 904/2006 of the Minister of Health of Romania for approving the norms on the implementation of good practice rules in the conduct of clinical studies using medicinal products for human use, published in the Official Journal of Romania no. 671 from the 4th of August 2006.

[6] By medicinal product for clinical investigation, we refer to the pharmaceutical form of an active pharmaceutical ingredient or placebo which is being tested or used as a reference in a clinical trial, including medicines that already have been authorized for marketing but are used, presented or packaged differently with regard to the authorized form, or used for an unauthorized indication or for obtaining wider information on the authorized form (*transl.* article 21 letter e) of Order no. 904/2006 of the Ministry of Health).

and whether the Regulation distinguishes between the purpose of the research, profit and development of medical knowledge and science.

The data protection regulation does not define the concept of scientific research, yet we appreciate that this notion has a broad scope that also includes the clinical trials that, by their nature, aims at developing and researching pharmaceuticals, contributing to technological, medical and academic progress. The inclusion of clinical trials in the concept of scientific research is most relevant as the General Data Protection Regulation provides safeguards and derogations relating to data processing for scientific research purposes, having a heavy impact on the effective protection of the personal data of concerned subjects and the subjects of the clinical trials.

The clinical trials can be classified into (i) interventional studies – where, for example, the subject receives a dose of researched medicine in order to have its effects monitored and studied and (ii) non-interventional studies – referring to the monitoring independent from any intervention on the human body.

Also, with regard to the purpose of how the study is being organized and conducted, we can distinguish between (i) commercial clinical trials initiated by the pharmaceutical industry for the purpose of developing new products and (ii) non-commercial clinical trials conducted by researchers, without the participation of pharmaceutical companies and aiming at the testing of previously authorized medicinal product for marketing.

Depending on the type of medicine as object of the research, the clinical trials are being classified into (i) clinical studies of new and innovative medicinal products, including orphan medicines and (ii) bioequivalence studies for generic medicinal products. (Tataru, 2017, p. 726-737) This classification is overlapping with the one regarding the clinical studies with or without therapeutic benefit – clinical studies in Phase I, to which we shall refer later in the present study and bioequivalence studies.

In order to conduct a bioequivalence clinical trial, it is necessary to fulfil the prerequisite for accessing the clinical study data of the innovative medicine that it refers to. It is worth mentioning that, through the concept of data exclusivity, the legislation protects the information regarding the clinical studies used to authorize the marketing of the medicinal product. Therefore, the entities interested in developing generic medicines cannot use the information processed during the clinical studies for the innovative medicinal product until after the moment when the data exclusivity period comes to an end.

4. The parties to the clinical trials

The clinical trials are initiated in order to fulfil the interest of pharmaceutical companies of obtaining the necessary authorizations for merchandising the medicines they produce. The studies are organized either within the respective entities as in-house activities or outsourced to other institutions specialized in this type of activity and accredited for this purpose, also known as Contract Research Organizations. The processing of the data provided by the individuals selected to participate at these studies is based on a protocol[7] (Regulation no. 536/2014).

The natural person that takes part in a clinical research is referred to as a subject, according to article 2 para. (2) point 17 of the Regulation no. 536/2014. The subject of a clinical trial can be either a healthy individual or a patient who is suffering from a disease relevant to the study. Regardless of its status, according the General Data Protection Regulation, the natural person is a data subject, based on the article 4 point 1 of the aforementioned European act. The information provided for the purpose of participation in the study and also the data obtained during and after the clinical research identify or could identify the data subject – the subject of the research. Being a data subject according to the Data Protection Regulation entails the attainment of the rights that the new legislation enshrines. The issue that arises in this situation refers to the derogations provided in article 89 of the General Data Protection Regulation and the confusion created between the informed consent provided by the legislation on clinical trials and the consent and the conditions for obtaining it envisioned in the General Data Protection Regulation.

The clinical trials are conducted for the purpose of authorizing pharmaceutical products by a natural or legal person, *institution or organization which takes responsibility for the initiation, for management and for setting up the financing of the clinical trials*, also known as sponsor, according to article 2 para. (2) point 14 of Regulation no. 536/2014. Considering these facts, we notice that the activities of the initiation, the management and the setting up of the financing of the clinical studies are included in the definition given to the controller who, according to article 4 point 7 of the General Data Protection Regulation, is *the natural or legal person […] which […] determines the purpose and means of the processing of personal data.* Similar to the aforementioned situation,

[7] The protocol is a document that describes the objectives, the project, the methodology, any statistics needed and the logistics of organizing a clinical research. The notion of protocol covers, besides the original document, also its updated versions. [Article 2, para. (2) point 22 of the Regulation no. 536/2014].

relevant for the data subject as subject of the clinical trials, it is important to mention that the General Data Protection Regulation qualifies the sponsor as a controller and therefore, certain provisions oblige him to comply with the newly-provided obligations. the General Data Protection Regulation also makes him accountable for the processing of data due to the rigorous procedures that need to be follow in order to not be fined.

When the clinical trial is initiated and conducted by the sponsor, he is also the investigator. (Guideline for Good Clinical Practice, p. 8) However, if the clinical study is outsourced, the individual responsible for conducting it, according to article 2 para. (2) point 15 of the Regulation no. 536/2014, is the investigator. Yet, this investigator can also be an accredited entity (Guideline for Good Clinical Practice, p. 6) that may contract sub-investigators as staff of the research. (Guideline for Good Clinical Practice, p. 8) Referring to the General Data Protection Regulation, we find that in the aforesaid relational scheme, the sponsor-investigator retains the status of a data controller, while the investigator and / or sub-investigator acquires the status of processor who, according to art. 4 point 8 of the General Data Protection Regulation, is a *natural or legal person […] which processes personal data on behalf of the controller.*

As regard to the outsourcing of the clinical trials, the investigator must be a licensed entity to offer such services, such as the CROs - Contract Research Organizations, medicine assessment centres or specialized laboratories for pharmacokinetic determinations and others.

5. Phases of the clinical trials

Life-sciences sector is seeking to develop new medicinal products through processes that are not invasive to the human body and also protects the personal data of the research subjects. Therefore, only after tests are being done in laboratories and on animals, the most promising active pharmaceutical ingredients or combinations of such ingredients will be used in the research phase of the clinical trials on human subjects.

We shall analyse the clinical studies and the impact of the General Data Protection Regulation on these referring to three distinct moments of this kind of researches.

The *incipient phase* dwells with the pre-selection and the selection process of the subjects. This is the moment when the sponsor and / or the investigator firstly makes contact with the personal data, mainly the sensitive data of the subjects. The selection of volunteers that will later take part in the study is made by using the inclusion criteria and exclusion criteria, these

being expressly and exhaustingly prescribed in the protocol underlying the clinical trials. The inclusion criteria refer to the conditions the subject needs to meet in order to be enrolled in the study – age, gender, affection and so on. The exclusion criteria refer to those conditions that, if not fulfilled, will result in the subject not being selected for the trial. As examples of the exclusion criteria, we mention homelessness and alcohol and narcotics addictions. In view of these facts, we consider that the retention of personal data of the subject that have not been selected for being part of the clinical trial is not justified neither by the argument that the controller has to keep the data in order to prove the transparency of the selection procedure of subject to be included in the clinical trial nor by the building of a database that can facilitate further selection of potential participants for other studies.

The actual course of the study, through the tests and monitoring carried out during this phase, generates new data concerning health of the subject or the outcomes of the treatment that has been applied. The newly generated data fall under the General Data Protection Regulation if they lead to identifying the person the data belongs to.

The final phase refers to the processing of the generated data in the previous stages and to the results obtained by the end of the clinical research, with respecting the confidentiality and the security of the stored data.

The most extensive clinical studies are those that are conducted for the purpose of analysing the effects of a new and innovative medicinal product on the human body. These types of clinical trials are being divided into four phases.

In the Phase I studies, the effects of the medicinal product on the human body are being analysed for safety and tolerance to such ingredients. Such studies are being performed on a small number of participants, fifteen to thirty healthy volunteers or ill patients who will be closely monitored to observe the occurrence of possible side effects and the medicine efficiency. (Cingi, *et al., 2017,* p. 107-108)

Phase II studies are initiated once the safety and tolerance to the applied treatment has been confirmed in Phase I trials. These studies are performed on larger groups of subjects, up to 300 persons, in order to evaluate the efficiency of a possible future medicine, based the applied dosage. This shall determine the optimal dose to maximize the efficiency of the medical product. (Cingi, *et al., 2017,* p. 108-109)

Usually, in the Phase III trials take part a large number of patients, up to 3000, for the purpose of confirming the benefits and the efficiency of

the treatment in ma documented and definitive manner. The data collected in this stage is processed in such way that it determines he best way of prescribing the medicine in the post marketing authorization of the clinical practice. (Cingi, *et al., 2017,* p. 110)

The process of developing and researching a medicinal product will usually go through all the four phases during a long period of time – up to several years. If the medicine successfully passes the first three phases and the research results are positive, it can be approved by the competent authorities to be made available to the patients and to be merchandised.

The Phase IV studies, also known as post-marketing monitoring studies, are performed after the authorization the merchandize the medicinal product is obtained. These studies also have the purpose of providing detailed information on the safety and the efficiency of the medicine or the incidence of adverse effects on a large number of persons – subpopulations of patients.

We believe that the General Data Protection Regulation has a great impact on each phase of the clinical studies, giving the fact that a different number of subjects is involved in the respective stages, as mentioned above. We note that the first phase takes place with a small number of data subjects and therefore, it should no issue for the controller – the sponsor to comply with the new data protection provisions. The scenario changes as the study reaches advanced phases, where the controller must process the data obtained from a larger number of subjects. In this case, the guarantees and derogations provided by the General Data Protection Regulation are welcome.

6. The consent of the subject in the clinical trials

The main condition that need to be met in order to include a subject in a clinical trial is obtaining his consent. According to Regulation no. 536/2014, article 2 para. (2) point 21, the informed consent refers to *a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical trial.*

In researches conducted on human subjects in the medical-pharmaceutical sector, we can also come across the concept of open consent that refers to the consent given by the volunteers to unrestricted redistribution of data obtained in a confidential relation, namely data

concerning health. It may also refer to the unrestricted disclosure of the subject's genetic data that will result from any future research whose outcome cannot be predicted. The open consent excludes anonymity and confidentiality. Even if the clinical medicine implies the veracity and credibility of data, the doctors justify the processing of personal data of their patients by invoking the importance of the public health through identifying new treatments. (Lunshof, *et al.*, p. 5)

According to the General Data Protection Regulation, the consent of the data subject is the key factor that determines the legality of the processing of any personal data. Therefore, the new legislation determines the sponsor to comply with the obligation of obtaining the free and unambiguous agreement from the subject of the clinical trial. The subject must accept the terms of the processing of his data through an unequivocal statement or action and thus consenting to the process of his personal information. The sponsor has the obligation to inform the subject about the purpose of the data processing in an explicit and comprehensible manner.

We can notice that the concept of open consent used in the clinical research goes beyond the notion of consent provided by the General Data Protection Regulation as it is necessary to obtain it only once in order to use the data in an unlimited way, without mentioning or specifying subsequent data processing purposes and becoming this way an open source for future researches. The new data protection legislation limits and obliges the controller to get the consent for each purpose of data processing. At first glance, the issue lies in the fact that the controller, in our case the sponsor, could also use the data for a different purpose than the initial one that has been made known to the subject and that has been given consent for in a limited and explicit manner.

In order to be included in the clinical trial, the subject must express his consent, both for the participation in the research stages and for the processing of his data by the controller. If the first form of consent is mandatory, being the essential and eliminatory condition for participation, the second form may suffer exceptions. Thus, the question arises whether the public interest is more important than a person's interest in protecting his or her personal data, and in this regard, we take into account the following situations: the data subject - the subject of the clinical trial gives his consent to the processing of his data for the purpose that has been communicated before the beginning of the clinical trial and for using the results of the research based on the processing of his data for the authorization of merchandizing a particular medicinal product; can the

public authorities or research centres use the existing clinical trial data in order to identify a treatment that responds to the public needs in certain circumstances of public interests, such as epidemics and pandemics? According to article 6 of the General Data Protection Regulation, the processing of data is lawful if at least one of the provided conditions is met. Therefore, if the circumstances are of public interest, the first condition provided by the aforementioned article at point a) refers to the data subject that *has given consent to the processing of his or her personal data for one or more specific purposes*, which may be contrary to the data processing urgency or public interest. Yet, the processing is valid according to point e) that mentions the necessity of processing in order to carry out a task that serves the public interest of results from the exercise of the public authority vested in the controller.

7. The rights of the subject in the clinical studies

The rights provided by the new data protection rules are nothing but the expression of the control the General Data Protection Regulation seeks to grant to the data subject with regard to the processing of his personal data. We remark that, regarding the data processing for scientific research purposes, the General Data Protection Regulation provides special provisions on derogations from certain rights of the data subject. In the present study, we seek to establish which are the rights that the clinical trial subject has as a data subject, to what extent are these respected in clinical trials or if the data subject can make use of them in certain situations related to clinical studies. The rights of the data subject are the right to information and access to personal data, the right to rectification and erasure, the right to object and the portability of data. According to article 89 of the General Data Protection Regulation on data processing for scientific research purpose, national or European Union law may provide derogations from certain rights, if the rights in question may render impossible or seriously impair the achievement of the abovementioned purpose. The derogation is applicable only if required to achieve the purpose.

The data subject, through the right of access and information, has the possibility to request the access to the information the controller has regarding him, as well as information about the purpose of the processing, the necessary and processed data categories, the period for which data storage is necessary, and others (in this respect, see article 15 of the General Data Protection Regulation). Considering that for the participation in the clinical trial the subject has to provide the data to the controller, sponsor or

investigator, in order to conduct an accurate and efficient study with genuine results, we can appreciate that the subject can benefit from the right of access and information until the completion of the research, meaning access to the result of personal analyses. From the incipient phase of the clinical trial, subject's data are pseudonymized, so that individual's personal characteristics are no longer relevant, the most important being the response to treatment and the observations collected from the study. Through pseudonymisation, we are referring to *the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information*, according to article 4 point 5 of the aforementioned Regulation. Therefore, the person of concern - the subject, discloses medical record information to the investigator in the incipient phase, containing data such as the extensive medical history, including genetic data and medical information of family members, the data received from the family doctor, the results of medical analyses done before study and others. The subject will be assigned a code number, making it difficult to identify the person without the additional information found in the allocation sheet issued by the investigator in order to record the subject names and assigned code numbers. The investigator is the only person who will be knowledgeable about the code assigned to each subject. Nevertheless, the investigator will provide the sponsor with all the data on the subject in the study, always using that code, never directly identifying the subject by the name. However, there are exceptions, given that the authorities have access to the subject's personal and medical data, but only to check whether the research was conducted in accordance with the GCP and legal norms. (World Health Organization, 1995) By authorities, we refer to those institutions that have competence in the field of human medicine, medical devices and medical technology assessment[8]. Authorities' inspections may include the audit of all documents related to the clinical study. During the control, the authority should have easy access to all patient documents and to the raw information used for or generated during the study, while maintaining the confidentiality over the information it has access to. (World Health Organization, 1995)

We note that the abovementioned data sheet also includes health data of the subject's family members. The reasoning is obvious: in order to conduct an accurate study, the mentioned data has relevance and the information on medical history will generate viable and robust data.

[8] For example, the medicinal product regulatory authority in Romania is ANMDM, the National Agency for Medicines and Medical Devices, https://www.anm.ro/en/.

(Mathers, 2010) We question ourselves what impact the new General Data Protection Regulation will have on this practice since, according to the new rules, the data controller should obtain the consent to process this information and if the practice changes in the sense of changing the procedure for informing the subject during the process of obtaining the informed consent of the subject and his / her family.

Another right of the data subject refers to the possibility to modify the data that concern him by a request addressed to the operator, according to art. 16 of the General Data Protection Regulation. We consider that the use of this right by the patient - subject of the study may have significant implications for the development of the research in the sense that the following situations may arise in practice: (i) the data subject modifies the existing data or adds new information before the beginning of the research, therefore, he may or may not determine, depending on the rectified information, the change of the circumstances of the study or treatment application, or (ii) the data subject alters the data during the study - which may cause the treatment to be applied incorrectly or ineffectively and determine the subject exclusion from the research process. If after the investigation has been completed, the data subject wishes to rectify the data given to the investigator, the right of rectification would be inoperable in this case because, as we have shown in the present study, the outcome of the research is already determined and the data obtained during the study cannot be altered as it results from the analysis made during the study and not from the information originally provided. It is of the essence of the sensitive data not to be altered.

The new General Data Protection Regulation establishes the possibility for the data subject to request the erasure of his or her data. The person of concern has the right, according to art. 17 of the Regulation, to ensure of the deletion of the data if they have lost relevance or have withdrawn their consent to their processing. (Şerban, 2017, p. 336) In the case of clinical trials, the controller - sponsor, at least as a general rule, will have to erase the information and will take the necessary measures in order for the recipients of the study to do the same, if the data subject of the research expresses this request. (Dickinson *et al.*, 2017) As a matter of fact, being an area of public interest in public health, according to article 9 para. (2) point (i) of the General Data Protection Regulation, the data erasure does not apply because processing is necessary to ensure high standards of quality and safety of medicinal products, but also to provide new medical treatments.

The right to data portability, according to art. 20 of the General Data Protection Regulation refers to the possibility for the data subject to transmit his data originally provided to the controller to another controller without encountering any difficulties from the former one. In the field of clinical research, the right to portability of data translates into the possibility of the data subject of the research to receive his or her personal data and to transmit them to another entity. Nevertheless, the realization of this right is limited by the obligation of confidentiality regarding the intellectual property rights or the know-how of the operator, on the study carried out by the sponsor and the violation of which could affect the entire research.

Another right of the data subject is to object, for reasons related to the particular situation in which he or she is, the processing of the personal data concerning him, according to art. 21 of the Regulation. In clinical trials, if the controller - the sponsor, demonstrates that he has legitimate and compelling reasons to justify the processing and which prevails in the interests of the data subject, the processing may be legitimate.

Conclusions

Having into consideration the personal engagement of the subject to the clinical trial, we consider to be relevant the inclusion of stricter obligations that the controller – sponsor has to comply with in order to have the data of the trial subject protected according to the General Data Protection Regulation as part of the Guidelines to Good Clinical Practices recognized by the entities conducting such researches.

We can note that the principle of data minimization regarding the processing of personal data does not prove to be particularly efficient in clinical trials as it is necessary for the sponsors and / or investigator to process a large amount of sensitive data of the subject in order to have verisimilar and effective results that could improve the life science sector.

The successful results of any clinical study are largely determined by the quality of the selection procedure of trial subjects. Therefore, we propose the improvement of present clinical trials practices and related legislations so they comply with the new data protection provisions. An additional guarantee for protection the personal data could determine and open and transparent relation between the subject and the sponsor / investigator.

Under no circumstances should the new data protection provisions hinder the technological development and the initiation of scientific research in the life science field. The general and imperative nature of the General

Data Protection Regulation should be adapted to serve the European general interest regarding public health policies.

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