Home »Practice» CPDP opinions for 2019 »CPDP opinion on determining the figures“ administrator ”and“ processor ”when conducting clinical trials CPDP opinion on determining the figures“ administrator ”and“ processor ”when conducting clinical trials OPINION OF THE PERSONAL DATA PROTECTION COMMISSION Reg. Commission for Personal Data Protection (CPDP, Commission) composed of - Chairman: Ventsislav Karadzhov and members: Tsanko Tsolov, Tsvetelin Sofroniev, Maria Mateva and Veselin Tselkov, at a meeting held on 29.05.2019, considered a request for an opinion (ent. № NDMSPO-01-190 / 22.04.2019) by SB EOOD (“S.”), UIC ******, which raises questions concerning the determination of the legal figures “administrator” and “processor” when conducting clinical trials. The company is established on the territory of the Republic of Bulgaria, and for part of its activities has the status of "contracting authority" within the meaning of § 1, item 8 of the Additional Provisions of the Law on Medicinal Products in Human Medicine (LLPHM) and participates in initiated by him clinical trials. As a client, S. may have relationships with hospitals, mental health centers, skin and venereal disease centers, complex oncology centers, dialysis centers, diagnostic and counseling centers, medical centers, dental centers and medical and dental centers, as well as and in individual and group practices for primary and specialized medical care, received an activity permit / registration certificate under the Medical Establishments Act, where S. conducts the initiated clinical trials. The company also interacts with others in clinical trials, namely the principal investigator and researchers, as well as members of the investigator's team - collaborators, observers and trial auditors. In carrying out clinical trial activities, the categories of persons whose personal data are processed are: - Participants in the clinical trial - within the meaning of § 1, item 78 of the Additional Provisions of LLPHM, processing data on the identity and health of the person, received during the performance of the therapeutic activities of the clinical trial, contained in the medical records of the patients, participants in the trial and necessary for the performance of the clinical trial; - Researchers - within the meaning of § 1, item 21 of the Additional Provisions of the LMPHM, as well as the members of the research team, processing data on their identity and necessary for the performance of their duties in the clinical trial; - The observers and auditors appointed by S. to carry out monitoring of the activity and subsequent verification during the performance of the clinical trials, by processing their identity data in the performance of the contractual obligations. S. conducts the largest share of clinical trials in medical establishments for hospital care, where the activities of the clinical trial are carried out in the specialized clinics by doctors with the respective specialty, who are trial researchers. The same doctors are also employees of the respective medical institution. In order to settle the relations with the medical establishments, S. concluded a written contract, where it is stipulated that the medical establishment

provides qualified and instructed staff and appropriate equipment available for the examination and authorizes the monitoring and audit of the examination. On the other hand, the company enters into written contracts with the principal investigators on the studies to settle the rights and obligations of the commissioned clinical trial. S. provides information to the medical institution about the persons, researchers in the clinical trial, as well as who are the persons included in their team. Based on the above, the company asks the following questions: 1. Whether during the clinical trial the medical institution processes personal data of the participants in the clinical trial for the purposes of the trial. 2. In case the medical institution processes personal data of the participants in the clinical trial, in what capacity (administrator or processor) the medical institution processes the personal data for the purposes of conducting the clinical trial. 3. Is it considered to be the processing of personal data by both the sponsor and the medical institution that the contracting authority informs the medical institution about the researchers and their teams involved in the study, insofar as they are employees of the medical institution and already have their personal data. Legal analysis: Knowledge of the figures of "administrator" and "processor" is key to the proper implementation of current legislation in the field of personal data protection and privacy. The General Data Protection Regulation (Regulation (EU) 2016/679) provided legal definitions identical to those of repealed Directive 95/46 / EC, but nevertheless the figure of the processor underwent a significant legal metamorphosis, with a number of obligations did not exist until now. According to the legal definition referred to in Art. 4, item 7 Regulation (EU) 2016/679 "controller" means a natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union law or the law of a Member State, the controller or the specific criteria for determining it may be laid down in Union law or in the law of a Member State. The quality of administrator is a direct consequence of the fact that a particular person has chosen to process personal data for their own purposes or for purposes that are regulated by law. In this situation, except where legally required, the controller decides on the need to collect personal data, the categories of personal data, whether to change it during processing, where and how to use this data and with what the purpose of whether the data will be disclosed to third parties and what they will be, as well as for how long they will be stored, and when and in what way they will be destroyed. In addition, the Regulation imposes a certain range of obligations on the administrator. It must take appropriate technical and organizational measures relating to data security, taking into account the nature, scope, context and objectives of the data processing, as well as the existing risks to the rights and freedoms of data subjects. In addition, according to the provision of

Art. 30, § 1 of Regulation (EU) 2016/679, the administrator shall maintain a register of the processing activities for which he is responsible. This commitment stems from the principle of accountability and the need for the administrator to be able to demonstrate at all times that he complies with the requirements set out in the Regulation. "Personal data processor" is "a natural or legal person, public authority, agency or body which processes personal data on behalf of the controller" (Article 4, item 8 of Regulation (EU) 2016/679). The main difference between the controller and the processor is that the latter does not act alone, but on behalf of the controller of personal data, ie. the consequences of the processing of personal data occur directly in the legal sphere of the controller. The Regulation provides that their relationship is governed by a contract or other legal act under EU or Member State law, which regulates the subject matter and duration, the nature and purpose of the processing, the type of personal data and the categories of data subjects and the rights and the obligations of the administrator, incl. to carry out inspections (audits). The General Regulation also introduces specific obligations for the data processor, which are not limited to data security. For example, he is obliged to process personal data only on a documented order from the administrator / arg. Art. 28, § 3, b. "A" in conjunction with Art. 29 of the General Regulation. In cases where it is necessary to include another data processor, this is done only with the express written permission of the administrator. Like the administrator, according to Art. 30, § 2 of the General Regulation, the processor is also obliged to keep a register of the processing activities for which he is responsible. In addition, for the sake of even greater clarity, the provision of Art. 28, § 10 of the General Regulation explicitly provides that if the processor begins to determine the purposes and means of processing himself, he automatically begins to be considered an administrator. The principle of accountability referred to in Art. 5, § 2 of Regulation (EU) 2016/679, requires participants in trade and civil turnover, taking into account their activities, to determine for themselves what is their legal relationship in relation to personal data processed by them - independent controllers, controllers and processors. the meaning of Art. 28 or joint administrators under Art. 26 of the General Regulation. Their choice should ensure not only formal but also substantive compliance with the requirements of Regulation (EU) 2016/679 and therefore effective protection of the rights of data subjects. Also, it should be borne in mind that the provision of services in which personal data are usually exchanged between the contracting authority and the contractor does not automatically lead to the emergence of a relationship between administrator and processor within the meaning of Art. 28 of the Regulation. Initially, the controller of personal data may "assign" to a processor processing activities for which he himself has a legal opportunity to perform, but for various reasons of organizational, technical, financial or other nature has determined that it is more

-appropriate to be carried out by the figure of the so-called. processing.The regime for conducting clinical trials is detailed in Regulation (EU) 536/2014 of the European Parliament and of the Council on clinical trials of medicinal products for human use and in the Law on Medicinal Products for Human Use. Moreover, the law comprehensively defines the functions and tasks of all subjects involved in a clinical trial. In the present case, the activity of processing personal data in connection with the conduct of clinical trials could not be carried out "on behalf" of the sponsor of the trial, due to the fact that they can not be performed by him, but only by authorized the respective order organization, having the quality "medical institution".

On the other hand, and last but not least, the special legislation in the field of healthcare envisages a number of obligations, measures and mechanisms for protection of health information containing personal data, which cannot be derogated from by a contract within the meaning of Art. 28 of Regulation (EU) 2016/679.

In the specific case, there are arguments for considering the figure of joint administrators, according to which when two or more administrators jointly determine the purposes and means of processing, they are considered joint. They should define in a transparent manner their respective responsibilities for the performance of their duties, in particular as regards the exercise of data subjects' rights and their respective obligations to provide the information referred to in Articles 13 and 14, by mutual agreement. , unless and to the extent that the respective responsibilities of the administrators are determined by Union law or the law of a Member State applicable to them. In addition, the data subject is provided with the possibility to exercise his rights in respect of each and against each of the controllers (Article 26, § 3 of the General Regulation).

Moreover, in Opinion 1/2010 of the Working Group under Art. 29 (now the European Data Protection Board) on the terms "controller" and "processor" explicitly states that in clinical trials, participants process personal data as joint controllers, as illustrated (p. 30). of the Opinion).

In view of the above and on the grounds of Art. 58, § 3, b. "B" of Regulation (EU) 2016/679, the Commission for Personal Data Protection states the following

OPINION:

1. When conducting clinical trials, medical establishments shall process the personal data of the participants in them for the purposes of the respective clinical trials. In these cases the medical establishments and the assignor of the clinical trial have the quality of joint administrators in the sense of art. 26 of Regulation (EU) 2016/679.

2. All actions of the sponsor and the medical establishment related to the conduct of a clinical trial, including the exchange of

information between them, shall be processed for that specific purpose.

THE CHAIRMAN:

MEMBERS:

Ventsislav Karadzhov

Tsanko Tsolov

Tsvetelin Sofroniev / p /

Maria Mateva / p /

Veselin Tselkov / p /

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