LEGAL PROCESSING OF PERSONAL DATA

DURING A CLINICAL TRIAL

On 23 January 2019, the EDPB1 adopted an opinion2 dealing with the relationship of the Clinical testing3 and the General Data Protection Regulation4.

Despite the fact that the application of the clinical trial regulation has been postponed and is expected the beginning of application only in 2020.5 in the Slovak legal order is a clinical trial regulated by several laws6, the Office identifies itself with the legal bases of personal data processing data for clinical trial purposes, which according to the opinion should be applied regardless on whether the clinical trial regulation applies.

Processing of personal data for the purposes of the clinical trial protocol7

According to the opinion, this is the primary use of clinical trial data. In this case differentiates between two types of processing activities that have different legal basics:

1. Processing operations, the purpose of which is to ensure reliability and security8

The appropriate legal basis for processing personal data for this purpose is Art. 6 par. 1 letter c) of the General Data Protection Regulation - processing necessary to fulfill the legal obligations of the operator.

Regarding the fulfillment of the condition for the legal processing of a special category of personal data, the condition in Art. 9 par. 2 letters i) of the general regulation on personal protection data - processing is necessary for reasons of public interest in the field of public health, such as protection against serious cross-border threats to health or ensuring a high level of quality and safety of health care and medicines or medical devices, based on the law of the Union or the law of a Member State, by which establish suitable and specific measures to protect the rights and freedoms of the person concerned, especially professional secrecy.

European Data Protection Board, learn more at https://edpb.europa.eu/edpb_sk

Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the GDPR, currently available only in English at https://edpb.europa.eu/our-worktools/our-documents/opinion-art-70/opinion-32019-concerning-questions-and-answers-interplay_en

3

Regulation of the European Parliament and the Council (EU) no. 536/2014 of April 16, 2014 on clinical trials of medicines for human use, repealing Directive 2001/20/EC

4

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons in processing of personal data and on the free movement of such data, which repeals Directive 95/46/EC (General Data Protection Regulation)

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Point 3 of the opinion

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For example Act No. 362/2011 Coll. on medicines and medical devices and on the amendment of certain laws

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More detailed information is given in part 2 of the opinion

8

More detailed information is provided in section 2.1 of the opinion

2. Processing operations related to purely research activities9

Possible legal bases of processing:

a) Art. 6 par. 1 letter a) of the General Regulation on Personal Data Protection – consent,

in connection with Art. 9 par. 2 letters a) of the general regulation on the protection of personal data

for the processing of a special category of personal data - express consent.

Informed consent under the Clinical Trials Regulation cannot be confused with (explicit)

consent according to the General Data Protection Regulation. There are two types of consent.

The legal basis of consent in terms of the General Regulation on the Protection of Personal Data, which is

decisive for the processing of personal data, according to the opinion, does not appear to be the most appropriate,

as it is disputed whether the sponsor or the examiner and the participant of the clinical trial are not

in the same position, and thus it may appear that consent was not freely given.

b) Art. 6 par. 1 letter e) or f) of the General Regulation on Personal Data Protection -

fulfillment of a task carried out in the public interest or legitimate interests

operator.

According to the opinion, these legal bases appear to be more appropriate compared to the one mentioned above

option. However, processing is only possible if one of the conditions is met

for processing a special category of personal data

i. Art. 9 par. 2 letters i) of the General Regulation on the Protection of Personal Data -

processing is necessary for reasons of public interest in the public domain

health, based on Union law or the law of a Member State, or

ii. Art. 9 par. 2 letters j) of the General Regulation on the Protection of Personal Data -

processing is necessary for the purposes of scientific research according to Article 89 paragraph

1 on the basis of Union law or the law of a Member State.

Processing for purposes not specified in the clinical trial protocol, exclusively for scientific purposes

purposes10

Regulation on clinical trials in Art. 28 par. 2 requires the consent of the person concerned for these purposes.

Again, we emphasize that informed consent under the Clinical Trials Regulation is not the same

as (express) consent according to the General Data Protection Regulation.

More detailed information is provided in section 2.2 of the opinion

More detailed information is given in part 3 of the opinion

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