TO WHOM IT MAY CONCERN

For more than 9 years I have professionally focused on Pharmaceutical and Medical Law (Life Sciences) and Personal Data Protection. I have gained my experiences at both sectors, private and (European) public. As a qualified lawyer (and later attorney at law registered by the Czech Bar Association) I have provided legal advice related to a wide range of legal and compliance issues arising mostly from the area of the Life Sciences and Biotechnology in the European context, including (but not limited to) the field of Clinical Trials in Human Medicines. During this period, I worked with various types of clients and represented their interests within pharmaceutical and healthcare industry.

Following the notice published on the European Data Protection Board website, I would like to use this opportunity to comment briefly on one of the examples used in the latest proposal of the Guidelines 07/2020 on the concepts of controller and processor in the GDPR.

The example in question concerns ***"Clinical Trials"***.

From my point of view, the description of this example does not reflect precisely all practical aspects of the conduct of clinical trials and, hence, I am not completely comfortable with the provided outcome. That being said, I would like to offer you my opinion on the way how respective "main" subjects involved in the conduct of clinical trials may be considered under the GDPR in relation to the processing of personal data of patients (also so-called trial subjects):

- The subjects concerned are (i) a sponsor, (ii) a clinical site, respectively a healthcare provider operating a healthcare facility where the clinical trial takes place (as, in the Czech Republic, only the respective healthcare provider has a legal subjectivity), and (iii) a (principal) investigator who is conducting the clinical trial factually.

- Although I can understand your point regarding the determination of the data controller while depending on the fact who is drafting of the study protocol (ref. the first paragraph of Example: Clinical Trials), I cannot completely agree with the following sentence: *"In the event that the investigator does not participate to the drafting of the protocol (he just accepts the protocol already elaborated by the sponsor), and the protocol is only designed by the sponsor,* ***the investigator should be considered as a processor*** *and the sponsor as the controller for this clinical trial."* (ref. the second paragraph of Example: Clinical Trials; emphasis added)

- Hence, provided that neither the (principal) investigator, nor the healthcare provider participates in the drafting of the protocol:

    1. **Please note that nearly always the (principal) investigator is just another employee of the healthcare provider (besides other members of the study team)**.

The healthcare provider (their employer) is the one who, in fact, operates not only the healthcare facility serving as a clinical site but who also operates/maintains all databases and IT systems with patients' medical records and who uses some of the patients' data generated from the clinical trial for his own purpose – provision of healthcare for such patients-trial subjects (as mentioned similarly in the first paragraph of Example: Clinical Trials). Those databases/IT systems with patients' data are under sole (legal) responsibility of the respective healthcare provider, while the (principal) investigator or other study team member can access these databases and work with data inside them merely from his/her position of an employee who has no influence on the specific means of processing/security measures concerning such databases etc. on his/her own.

Therefore, I suppose that the conclusion about the (principal) investigator having his/her separate position under the GDPR is understandable only in a case when such investigator operates his/her own private medical practice and as such is in the position of the healthcare provider.

2. Moreover, with regard to the facts stated above, it is **the healthcare provider (instead of the investigator) who should be in the position of a subject with an assigned role under the GDPR** within patients' personal data processing in the conducted clinical trial. As mentioned above, the (principal) investigator should have no specific role under the GDPR (although this conclusion should be without prejudice to his/her specific position under laws regulating the conduct of the clinical trial according to which he/she is responsible for the medical leadership of such clinical trial at the respective clinical site).

3. In addition, I would suggest to reconsider also the assignment of the roles of data controller and data processor under the GDPR – **from my point of view, in the case of processing of personal data of patients (study subjects) both the sponsor and the healthcare provider shall be in the position of two (separate) data controllers**. None of them (not even the (principal) investigator) is in the position of the data processor.

   - In practice, it is very difficult (not even impossible) to draw a clear distinction among data which are included in the source documentation (medical records) in order to determine which part is processed for the (sole) purpose of the clinical trial and which part is processed for the (sole) purpose of the provision of healthcare.

   - The situation should be rather seen as following – the sponsor and the healthcare provider process basically the same set of patients' data, respectively the healthcare provider processes the same data which are collected on the basis of the protocol for the purpose of the conducted clinical

study also for its own purpose which is provision of healthcare to the specific patients (trial subjects).

- Also, it should be noted that, according to the respective Czech law applicable on the storage of patients' medical records, the data concerning incidence of adverse events in the clinical trial on which the patient participated as well as other clinical-trial-relevant data shall be stored (processed) *by the healthcare provider* as a part of medical records of participating patient for at least 15 years following termination of the respective clinical trial (i.e. it is the healthcare provider's legal obligation to store these data for, de facto, both purposes).

- Moreover, some data processed by the healthcare provider even specifically for the purpose of the conducted clinical trial shall not be disclosed to the sponsor and are solely under control of the provider (resp. investigator who is its employee) – this is the case of, for instance, key-coding of patients as trial subjects.

- Regarding the way, how the sponsor gains the coded patients' (trial subjects') personal data for the purpose of his clinical trial – it is trough a tool named a Case Report Form which is, basically, a paper or electronic questionnaire filled in by the (principal) investigator and/or other study team member with such coded data. **I believe that this use of the CRFs should be understood as the use of a tool enabling *transfer/transmission* of data between *two separate data controllers* (as, for instance, in a case of data transfer between an employer and a tax authority)** and not as a data processing operation by which the sponsor entrusted healthcare provider/investigator**.**

Naturally, this topic is a lot more complex then indicated briefly above. Should you have any questions and/or comments in this context, I will be very happy to discuss anything further.

Kind regards

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