Biogen

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European Data Protection Board
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Guidelines 07/2020 on the concepts of controller and processor in the GDPR

Dear Dr Jelinek

Introduction

Biogen welcomes the possibility to provide comments in response to this Consultation. We are a biotechnology company, pioneering treatments in neuroscience. Since our founding in 1978 Biogen has led innovative scientific research with the goal of defeating devastating neurological diseases. We have our corporate headquarters in Cambridge, MA, USA and our international headquarters in Baar, ZG, Switzerland. We have affiliates in 17 EU countries with plans to open more.

As noted in the Guidelines, the concepts of controller, joint controller, and processor play a crucial role in the application of the GDPR. Our comments focus specifically on the following two examples provided in the Guidelines:

- clinical trials (para. 66); and
- market research (para. 42).

Clinical Trials

The Guidelines provide an example of a clinical trial involving a health care provider as an investigator and a university as a sponsor:

"A health care provider (the investigator) and a university (the sponsor) decide to launch together a clinical trial with the same purpose. They collaborate together to the drafting of the study protocol (i.e. purpose, methodology/design of the study, data to be collected, subject exclusion/inclusion criteria, database reuse (where relevant) etc.). They may be considered as joint controllers, for this clinical trial as they jointly determine and agree on the same purpose and the essential means of the processing. The collection of personal data from the medical record of the patient for the purpose of research is to be distinguished from the storage and use of the same data for the purpose of patient care, for which the health care provider remains the controller. 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."

The process followed in an interventional clinical trial for a drug, as undertaken by life sciences companies, is far more complex than the example given, involving many different actors such as a sponsoring pharmaceutical company (sponsor), a clinical research organisation (CRO), the principle investigator who is responsible for overseeing and administering the trial, trial staff and the treatment centre where the trial takes place (trial site). While an interventional clinical trial involves multiple parties involved in a common project, each of those parties has independent and separate duties that are often established by law and professional standards in their own right. The set-up of an interventional drug trial can vary quite significantly depending on the level of involvement of the trial site and sponsor, details related to the research, the medical intervention and the therapeutic area under examination.

The question of the role that the trial site plays under data protection law, usually as the employer of the principle investigator and trial staff, is an area which has caused much discussion since the inception of the GDPR and there are wide differences of opinion across Member States. Biogen believes that the trial site acts as an independent controller in the processing of personal data on two levels:

1. provision of therapeutic care to the trial participants as medical professionals; and
2. the provision/administration of the trial itself to participants.

The principle investigator and trial staff are medical professionals who are responsible for the conduct of the clinical trial at the trial site. They are chosen due to their medical (or other applicable) background. The principle investigator is subject to professional medical confidentiality or equivalent confidentiality obligations. In addition, the principle investigator's responsibilities include the following:

- providing medical/scientific expertise required for the conduct of the clinical trial;
- providing medical care for the trial subjects (including entering subjects' personal data into a separate set of medical records that is maintained solely for purposes of health care delivery);
- drafting and maintenance of the trial master file at the trial site;
- ensuring compliance with the requirements of clinical trials laws and regulations (its own direct obligations under the Clinical Trials Regulation, as well as general compliance);
- ensuring general clinical trial compliance with the protocol and Good Clinical Practice;
- ensuring compliance with the internal data procedures and policies of the trial site (which is often a public authority with very prescriptive procedures which cannot be deviated from); and
- ensuring the investigator's/trial site's own compliance with data protection laws.

The principle investigator determines what information it is necessary to obtain and process to provide medical care and properly conduct the clinical trial. This results from the fact that the principle investigator has independent obligations under clinical trials legislation, separate from the sponsor, and must comply with trial site practices and procedures, as well as professional medical duties towards the trial subjects. The principle investigator is subject to legal, professional, and ethical obligations that presuppose a level of control over the data processing operations well beyond that of a processor. Together with the principle investigator's governing ethics committee, the principle investigator evaluates the sponsor's research proposal independently and exerts real control over the way personal data of trial subjects is processed and disclosed to the sponsor.

In a clinical trial, there is a deliberate separation by law of the responsibilities of the principle investigator and sponsor as a kind of system of checks and balances to ensure the integrity of the trial and the protection of trial subjects. The principle investigator has a direct relationship with the data subjects and exercises professional judgment in the processing of their personal data. It is the independent obligations of the principle investigator and the sponsor respectively that distinguishes the responsibilities of the parties in a clinical trial from various types of joint controllerships in which the parties jointly determine, by means of a contract, what data will be collected and how it will be used, or a controller-processor situation. The trial site, as employer of the principle investigator, should be seen as an independent controller in its own right in relation to the personal data of trial subjects processed for the purposes of the clinical trial and the therapeutic care associated with this.

On a practical level, trial sites generally act in practice as controllers, making compliance with Art. 28 GDPR obligations impractical or impossible. Sites set up and use their internal IT systems as controllers, for example. A trial site is highly unlikely to allow a sponsor to dictate its technical and organisational security measures. It is also legally unable to delete the personal data it stores in the trial master file if requested by the sponsor, because it has legal obligations under clinical trial legislation to retain those files. In the event of a data breach, a site is unlikely to allow a sponsor, potentially in a different country or even outside the EU to dictate to it how a data breach should be managed.

Pursuant to Art. 40 GDPR, the European Federation of Pharmaceutical Industry Associations (EFPIA) is in the process of developing an EU code of conduct on scientific research, including clinical trials. The code will holistically address the roles of the parties in a clinical trial of a medicinal product and the obligations of each party. We appreciate the EDPB's efforts to develop harmonised EU guidance on the roles of the parties in a clinical trial. However, given the complexity of the issues, we believe that including a clinical trial example in these more general Guidelines may lead to further confusion. Therefore, we encourage the EDPB to refine the example to include recognition of possible alternative characterisations of the role of the trial site, depending on the set-up of a trial, as set out above, or, alternatively, to delete the example and wait to address these issues in its consideration of EFPIA's proposed code of conduct.

Market Research

The Guidelines explain that "*It is not necessary that the controller actually has access to the data that is being processed. Someone who outsources a processing activity and in doing so, has a determinative influence on the purpose and (essential) means of the processing (e.g. by adjusting parameters of a service in such a way that it influences whose personal data shall be processed), is to be regarded as controller even though he or she will never have actual access to the data.*" The Guidelines then provide an example of the application of this statement to a market research scenario:

"*Company ABC wishes to understand which types of consumers are most likely to be interested in its products and contracts a service provider, XYZ, to obtain the relevant information.*

Company ABC instructs XYZ on what type of information it is interested in and provides a list of questions to be asked to those participating in the market research.

Company ABC receives only statistical information (e.g., identifying consumer trends per region) from XYZ and does not have access to the personal data itself. Nevertheless, Company ABC decided that the processing should take place, the processing is carried out for its purpose and its activity and it has provided XYZ with detailed instructions on what information to collect. Company ABC is therefore still to be considered a controller with respect of the processing of personal data that takes place to deliver the information it has requested. XYZ may only process the data for the purpose given by Company ABC and according to its detailed instructions and is therefore to be regarded as processor."

The above example would suggest that in most circumstances, a provider of market research services will be a processor on behalf of the organisation that has retained it. However, market research in the life sciences sector is often more complex than the example given. The commonest scenario is that a pharmaceutical company commissions a market research company to conduct independent research into a broad topic, for example prescribing habits of physicians in relation to a particular disease. The pharmaceutical company gives the research company a broad overview of what it hopes to find out, however, in order to guarantee unbiased and independent research, does not dictate outcomes and provides minimal input into the formulation of the questions which will be put to the respondents. The pharmaceutical company does not direct the research company as to which individuals to interview or even how many to interview. It merely commissions the research company to provide it with a report on a required topic. That report does not contain any personal data and substantial decisions about the purposes and means of the processing of personal data to formulate the report are left to the research company.

In that scenario, the pharmaceutical company does not collect or process personal data to conduct the research, and it can be argued that it does not determine the purposes and means of processing either. These decisions are made solely by the research company as a controller. The research company has a direct relationship with the respondents and has complete autonomy as to how the personal data is processed. Whilst the pharmaceutical company has commissioned the research company to conduct the research on its behalf, it does not determine the purpose and means of processing personal data in order to conduct the independent research or compile the final report. On a practical level, if the pharmaceutical company were a controller it would have to identify itself to the respondents and

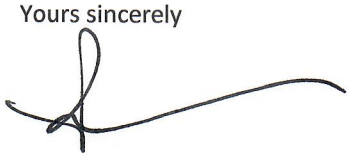
provide them with a privacy notice explaining how it processes their personal data as a controller (or ask the research company to do this on its behalf). This poses difficulties for truly independent research (known as "blinded research"), as the respondents' answers may be biased by their knowledge of the pharmaceutical company's identity or even that the sponsor of the research is a pharmaceutical company.

We do however accept that there are instances when the pharmaceutical company may well have a greater level of input into formulation the questions for respondents and may even provide lists of respondents to the research company to choose from, still leaving the research company to decide if it uses those lists or uses its own lists of respondents or a mixture. In this case it is indeed inescapable that the pharmaceutical company moves to the position of joint controller. Our point is simply that it all depends on the facts and this area is very complex for companies in our industry.

Conclusion

Biogen fully supports and welcomes the EDPB's endeavours to provide further guidance on the concepts of controller and processor, and we appreciate the EDPB's efforts to apply the guidance to real-world scenarios. However, due to the range and complexity of clinical trial and market research scenarios for the life sciences industries, we are concerned that the examples provided may lead to misunderstanding and confusion. Therefore, we ask that these examples either be: (a) deleted from this document and addressed more thoroughly in separate guidance and industry codes of conduct; or (b) amended to foresee the possibilities of different conclusions based on changes in the fact patterns as we set out in this letter.

Yours sincerely



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