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Professional Perspective

Guidance Regarding Interaction Between GDPR and EU Clinical Trials Regulation Leaves Several Questions Unanswered

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On January 23, 2019, the European Data Protection Board (the "EDPB") **adopted an Opinion of the Board** (the "Opinion") in response to a question-and-answer ("Q&A") document issued by the European Commission regarding the interplay between the European Union Clinical Trials Regulation (the "CTR") and the European Union **General Data Protection Regulation** ("GDPR"). This new guidance discusses significant questions faced by sponsors, sites and investigators in clinical research seeking to comply with GDPR. Most notably, the Opinion recommends that consent, although it must be obtained for participation in a clinical trial pursuant to the CTR, generally should not be the basis for processing personal data in the context of a clinical trial. Alarmingly, this recommendation conflicts with the approach of certain European Union ("EU") member states, as well as with the historical practice in the clinical research community of obtaining participant consent for both clinical trial enrollment as well as use of personal data.

While the Opinion provides guidance on some open questions facing the research community, it leaves other issues unresolved, particularly around use of clinical trials data in secondary research. Unfortunately, the underlying Q&A document in response to which the Opinion issued appears not to be publicly available, making it more difficult to evaluate the proposals fully and accurately.

I. The EDPB Distinguishes Between Processing for Safety Purposes and Processing for Research Purposes, Presenting Challenges for Providing Notice to Data Subjects.

Under Article 6 of GDPR, a data controller requires a legal basis for each activity it undertakes that involves the processing of personal data. If the personal data processed include "special categories" of personal data, such as data concerning health, genetic data and race/ethnicity, the processing activity additionally must fit within an exception to the prohibition on processing such data found in GDPR Article 9. Because clinical trials almost always involve the processing of "special categories" of personal data, most clinical trials will require both an Article 6 basis for processing and an Article 9 exception. One challenge faced by sponsors of clinical research and clinical trial sites under GDPR has been determining the proper basis under GDPR Article 6 and exception under GDPR Article 9 for processing personal data collected during the course of a clinical trial. The choice of the basis of processing is important because it must be included in notices provided to data subjects under Articles 13 and 14 of GDPR, which in the case of a clinical trial are typically included in the trial's informed consent form or accompanying patient information sheet. The choice also affects the rights of data subjects under Articles 15 to 22 of GDPR.

The Opinion divides processing that occurs in a clinical trial between (1) processing for "reliability and safety purposes" and (2) processing that is "purely related to research activities," identifying different legal bases for processing in each instance. According to the Opinion, processing operations required by the CTR, i.e., processing for "reliability and safety purposes," should be based on "legal obligation(s) to which the controller is subject" under Article 6(1)(c) and "processing necessary for reasons of public interest in the area of public health … such as ensuring high standards of quality and safety of health care and of medicinal products" under Article 9(2)(i). The EDPB points to the CTR as the legal obligation that permits this processing.

On the other hand, the Opinion takes the position that processing operations "purely related to research" conducted as part of the primary trial protocol cannot, in the view of EDPB, be derived from a legal obligation. Instead the controller must rely on either (1) a data subject's consent (for purposes of Articles 6 and 9) or (2) a task carried out in the public interest or legitimate interest (for purposes of Article 6), and either "processing necessary for reasons of public interest in the area of public health … such as ensuring high standards of quality and safety of health care and of medicinal products" (Article 9(2)(i)) or "scientific … purposes in accordance with Article 89(1)" (Article 9(2)(j)).

The EDPB discusses in the Opinion several reasons why it does not consider consent as the appropriate basis for the processing of personal data in the context of a clinical trial, including notably that the EDPB believes consent is not "freely given" if the participant is not in good health condition. Participants in a clinical trial often have adverse health conditions, as studies frequently involve the evaluation of safety and efficacy of a product for participants with a certain disease or other health condition. Therefore, following the logic of the Opinion, it is hard to see how the consent for trial participation, which the EDPB notes is required for purposes of the CTR, would be freely given, if at the same time, these subjects cannot give consent to the use of their personal data because of the disadvantage presented by their health conditions. The Opinion further notes that if consent is the basis for processing, then following a participant's withdrawal of consent, one must delete the participant's data unless there is another lawful basis for processing. Overall, the EDPB's position on use of consent is not surprising given that it reflects statements by the EDPB's predecessor, the Article 29 Working Party, in that body's April 2018 guidance on consent.

The Opinion states that in place of consent, one may rely on the alternative exceptions to the prohibition on processing of special categories of personal data found under Articles 9(2)(i) and 9(2)(j). Notably, however, these provisions require, respectively, that processing be based on "reasons of public interest in the area of public health … *on the basis of Union or Member State law*" or "scientific … research purposes in accordance with Article 89(1) based on *Union or Member State law*." *[emphasis added]* Thus both provisions arguably require a specific, explicit basis under Union or Member State law. The Opinion notes that the CTR will not supply the applicable law to process information for research activities, and thus in most cases the law in question would need to be that of the relevant EU member state. Significantly, this guidance does not clarify the source of applicable member state law and whether, for example, the relevant EU member state must enact implementing legislation to permit reliance on this basis. If compliance relies upon member states' implementing legislation, the availability of these exceptions will vary across member states, as some have not implemented relevant provisions. These inconsistent obligations could force sponsors to adopt differing approaches across the different EU member states.

As noted above, under GDPR Articles 13 and 14, a controller must provide notice to the data subject regarding the nature of the controller's processing activities, including the purpose and legal basis of processing and categories of recipients of personal data. Because the EDPB divides processing in the primary trial between processing for "reliability and safety purposes" and processing that is "purely related to research activities," informed consent documents explaining this information to data subjects will need to explain these multiple bases of processing. This will cause consent forms to become more complex and potentially difficult for participants to understand.

II. The EDPB Acknowledges But Does Not Resolve Basis for Secondary Research.

The EDPB helpfully recognizes that the appropriate basis for processing personal data for purposes of secondary research use outside of an interventional clinical trial protocol is an important topic for the research community. One approach to such processing is to rely on Article 5 of the GDPR, which suggests that further processing may be carried out without an independent legal basis if such processing is compatible with the initial purpose of processing. The Opinion helpfully recognizes that the text of the GDPR supports reliance on compatibility for secondary research, stating that "… further processing for archiving purposes in the public interest, *scientific … research … purposes* shall, in accordance with Article 89(1), not be considered *incompatible with the initial purposes*." (Article 5(1)(b)) *[emphasis added]*However, the Opinion concludes its discussion of secondary research without describing the extent to which one can rely on compatibility for further processing, and instead provides the following statement suggesting the need for further guidance:

> These conditions, due to their horizontal and complex nature, will require specific attention and guidance from the EDPB in the future. For the time being, the presumption of compatibility, subject to the conditions set forth in Article 89, should not be excluded, in all circumstances, for the secondary use of clinical trial data outside the clinical trial protocol for other scientific purposes.

This language may suggest some internal disagreement amongst the EDPB members regarding the extent to which one can rely on compatibility with the initial purpose of processing when conducting secondary research. Such internal division, if it does indeed exist, would not be surprising given that processing of personal data for scientific research purposes is one area in which GDPR provides several opportunities for derogations by member states, presumably because of the differing approaches taken by the member states to research issues.

III. Despite the EDPB's Recommendations, EU Member State Variation Remains.

Since the GDPR enforcement date of May 25, 2018, EU member states have demonstrated varying preferences regarding the appropriate Article 6 basis and Article 9 exception for processing of personal data in the context of a clinical trial. For example, we understand from prior experience working with multiple sponsors that Germany has advocated for consent and explicit consent as the legal basis and exception for processing personal data and special categories of personal data, respectively, in this context. In contrast, two United Kingdom ("UK") research bodies, the **National Health Service Health Research Authority** and the **Medical Research Council**, have advocated for use of the scientific research exception for processing special categories of personal data under Article 9 for prospective research. Depending on whether the entity conducting research is a for-profit or not-for-profit entity, these bodies have proposed legitimate interest or public interest, respectively, as a legal basis for processing under Article 6. Note that the approach of the UK research bodies is similar to the approach recommended by the EDPB, though there are some slight differences: (1) the UK research bodies do not seem to emphasize the distinction between processing for safety and processing for research

use discussed by the EDPB; and (2) the UK research bodies emphasize reliance on the scientific research exception rather than providing a choice of the scientific research or public health exceptions.

The EDPB issued the Opinion pursuant to GDPR Article 70(1)(b), which authorizes the EDPB to "on its own initiative or, where relevant, at the request of the Commission … advise the Commission on any issue related to the protection of personal data in the Union, including on any proposed amendment of [GDPR]." It is unclear at present how in response to the Opinion the EU member states and individual ethics committees should or will change their approach to the proper basis for processing personal data in the context of a clinical trial.

IV. Conclusion.

The research community has been seeking resolution of the questions considered by the EDPB in the Opinion, and any guidance from the EDPB is welcome. Although the recommendations from the EDPB may conflict in certain situations with the approaches of different EU member states, the Opinion may pave at least the beginning of a move toward greater pan-EU uniformity regarding the processing of personal data for research purposes.
