

Further Use of Clinical Trial Data Consent Should Not Be Mandatory in All Cases

EU lawmakers adopted the General Data Protection Regulation¹ (“GDPR”) in May 2016. With that, they also aimed to close a prolonged and intense debate regarding the lawful use of personal data for scientific research. Much of this discussion focused on whether or not it should be a requirement to obtain new consent for such scientific use. Ultimately, as we will discuss below, the outcome of this debate under the GDPR is crystal clear.

Notwithstanding this fact, we must remember that the GDPR is no island unto itself. It is a regulatory framework that affects and interacts with many other frameworks. Furthermore, the political reality is that EU Member States were not ready for a general regulation in this space. For example, in other important and more sensitive areas (such as health and genetic data), they clawed back the power in order to self-regulate, despite their commitment to a harmonizing EU “regulation.” The end result is a complex web of EU and national rules that allows for different interpretations and substantial regulatory disparity across the EU. This complexity is particularly evident in the case of further use of clinical trial data.

This article addresses the interaction (and, in some cases, conflict) between the GDPR and the Clinical Trials Regulation² (“CTR”) in relation to the further use of clinical trial data. By “further use” (or “secondary use”) we mean uses of clinical trial data that go beyond the initial intended purpose of the trial, as described in the trial protocol.

Interacting rules

EU lawmakers adopted the CTR on April 16, 2014 – more than two years before the GDPR.³ The CTR sets out a modernized regulatory regime for clinical trials in the EU, regulating virtually all aspects of clinical trials. However, when it comes to the handling of personal data, the CTR generally defers to the GDPR.⁴ Article 93 CTR, for example, provides that Member States must apply EU data protection law to any personal data, which requires processing pursuant to the CTR. Similarly, Art. 28(1)(d) CTR provides that clinical trials must be conducted while respecting the privacy rights of individuals “in accordance with the GDPR”.⁵

It is not uncommon for literature to qualify the CTR, as opposed to the GDPR, as the *lex specialis*. However, we do not believe this is accurate. The CTR does not actually address in any detail how the privacy rights of trial participants must be protected; on the contrary, it

¹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), *OJL* 119, 4.5.2016, p. 1–88.

² Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, *OJL* 158, 27.5.2014, p. 1–76.

³ The CTR does not yet apply and probably will not until 2021.

⁴ The CTR refers to Directive 95/46/EC, which now should be read as the GDPR by virtue of Art. 94(2) GDPR.

⁵ Article 28 CTR is reproduced in annex.

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consistently refers to the GDPR in this regard. We therefore submit that in relation to the protection of personal data in clinical trials, the GDPR is the primary instrument (in effect, the *lex specialis*).

The relevance of this consideration becomes clear when we analyze how the CTR addresses further use of clinical trial data. Article 28(2) of the CTR provides as follows:

“Without prejudice to Directive 95/46/EC, the sponsor may ask the subject [...] at the time when the subject [...] gives his or her informed consent to participate in the clinical trial to consent to the use of his or her data outside the protocol of the clinical trial exclusively for scientific purposes. That consent may be withdrawn at any time by the subject [...].

The scientific research making use of the data outside the protocol of the clinical trial shall be conducted in accordance with the applicable law on data protection.”

According to the plain reading of this provision, a possible interpretation is that further use of clinical trial data must be based on consent obtained from the trial participant. This outcome would be sub-optimal for many reasons, and, in our opinion, is only one of the various possible interpretations.

Consent and further use of clinical trial data – a sub-optimal solution

Lawmakers and civil society discussed the importance of further use of personal data for scientific research at length during the negotiation of the GDPR. We will not repeat those discussions in full here, but the main outcome was that consent, as defined by the GDPR, would be an overly restrictive legal basis for scientific research.

A GDPR-consent must be freely given, specific and unambiguous (explicit for health data).⁶ In relation to scientific research and further use, this required level of specificity poses a problem. The objective of scientific research is to discover connections links, patterns and correlations that are novel and often unanticipated. This means it is difficult to predict what types of research certain personal data may be useful for. As a result, relying on specific consent carries the risk of limiting other permissible uses down the road and hampering potentially promising research projects. The GDPR recognizes this in Recital 33, which allows for a broader consent to “certain areas of scientific research” and for participants to select those areas. However, this is hardly a solution given that defining those areas is precisely the problem.

A consent requirement raises another concern in that it may be very difficult to obtain a consent. If certain areas of research were not or could not have been foreseen at the time of data collection, it is often very difficult, time consuming and expensive for the sponsor of a trial – let alone other parties, such as research collaborators – to trace back the participants and obtain consent for the new research.

It is precisely due to these concerns that the GDPR contains specific language permitting the further use of personal data for scientific research without consent.

⁶ Art. 4(11) GDPR.

Secondary use of health data for scientific research under the GDPR

EU lawmakers recognized the concerns set out above and inserted a regime in the GDPR that allows for the further use of health data for scientific research without a new consent. The basic provision supporting this regime is Art. 5(1)(b) GDPR:

“Personal data shall be [...] collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; *further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes* (‘purpose limitation’).” (emphasis added)

This subsection states that, subject to certain safeguards expressed in Art. 89(1) GDPR, personal data, which has been legally collected for any primary purpose (e.g., health care or a clinical trial), can be used for scientific research. This scientific research is by default compatible with the primary use and therefore does not require a new legal basis, such as consent. Recital 50 GDPR is particularly clear about this:

“The processing of personal data for purposes other than those for which the personal data were initially collected should be allowed only where the processing is compatible with the purposes for which the personal data were initially collected. *In such a case, no legal basis separate from that which allowed the collection of the personal data is required.* [...] Further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be considered to be compatible lawful processing operations.”⁷ (emphasis added)

Article 5(1)(b) GDPR is an exception to Art. 6(4) GDPR which sets out a number of parameters to assess the compatibility of different uses of personal data. For scientific research, the Art. 6(4) parameters are irrelevant because this use is, by default, compatible.

Interplay between GDPR and CTR

So how can the GDPR and CTR be reconciled? The more recent GDPR has a dedicated regime for further use of personal data for scientific research, whereas the older CTR appears to impose consent. Below we set out three arguments in favor of an interpretation that is favorable to scientific research, i.e., the interpretation, which avoids a mandatory consent requirement in every case.

1. *GDPR is the lex specialis*

As indicated above, when it comes to the protection of clinical trial data, the CTR consistently refers to the GDPR. In fact, Art. 28(2) CTR (referring to the further use of clinical trial data) specifically states that it is “without prejudice to” the GDPR. In other words, where

⁷ Note that the use of the word “should” does not affect this analysis. EU laws always use “should” in the recitals.

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the GDPR contains different provisions, the GDPR prevails. This has three possible consequences.

First, it could be the case that the GDPR prohibits or restricts further use on the basis of consent and essentially prevents trial participants from consenting to such further use.⁸ In this case, Art. 28(2) CTR could not apply, but we are not aware of a Union law imposing such a prohibition in the research space.

Second, the GDPR may contain derogations from the need to obtain consent for further use, in which case the consent obligation of the CTR should also not apply. This is the logical corollary of the first point. Article 28(2) CTR is without prejudice to the entire GDPR, including the derogations it contains, especially if those derogations relate specifically to scientific research. As set out above, the GDPR does contain a specific derogation, which was adopted more recently than the CTR and was the result of extensive parliamentary debate. There is no reason, legally or politically, why this derogation could not and should not supersede the possible consent obligation in Art. 28(2) CTR.

Finally, where the GDPR imposes requirements going beyond the CTR, such as for transparency, participant rights, restrictions on international transfers and security, these requirements apply in addition to any other obligations imposed by the CTR.

2. Article 28(2) CTR does not in fact impose an encompassing consent obligation

There is a risk that a strict reading of the CTR could lead to the conclusion that further use of clinical trial data is only allowed with consent. Looking more carefully at the CTR's wording, however, it appears that the regulation only sets out the *option* for sponsors to acquire consent at a given time. It says sponsors “*may* ask the subject [...] at the time when the subject [...] gives his or her informed consent to participate in the clinical trial” for consent to further use. In other words, sponsors have the option to obtain such consent when the trial participant enters the trial, but they are under no obligation to do so, and the provision does not exclude options other than consent.

Additionally, the CTR does not seem to regulate unanticipated further use when consent could not have been obtained at the time the trial participant entered the trial (simply, because it was not anticipated). The CTR only speaks to consent obtained “at the time when the subject [...] gives his or her informed consent to participate in the clinical trial.” As a result, if the CTR were read on its own and as superseding the GDPR, sponsors would not even be allowed to obtain consent to further use from participants *after* they consented to join a trial. Clearly, this cannot be the intended outcome. As set out above, in such case, the GDPR and its derogations should apply, unless the lawmaker wanted to completely prohibit potentially valuable research.

3. The consent requirement in Art. 28(2) CTR is not a GDPR consent

Despite statements to the contrary by the European Commission, optional consent for the further use of clinical trial data is not a consent based on the GDPR (after all, the provision is

⁸ Article 9(2)(a) GDPR provides that Union or Member State law can restrict the use of consent for the processing of health data, including for further use. We are not aware of a Union law doing that in the research space.

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without prejudice to the GDPR).⁹ It is a consent derived from the CTR itself. The importance of identifying the precise legal source of a consent requirement has recently been highlighted by the EU Data Protection Board in relation to financial services regulations. The Board indicates that consent requirements imposed by other pieces of legislation must be read in a way that preserves the full effect of the data protection legal framework,¹⁰ thus including the derogations in that framework.

The consent imposed by Art. 28(2) CTR is therefore not subject to the consent requirements set out in Art. 4(11) and 7 of the GDPR. As a result, the consent for further use under the CTR does not have to meet the strict GDPR requirement of being specific, at least not to the extent generally expected by data protection authorities. A consent based on the CTR could thus be broader in scope, covering larger areas of research that can encompass unforeseen research. Finally, while the CTR provides that consent can be withdrawn at any time, the impact would not have to be the same as under the GDPR, where regulators have held that data must be deleted following a withdrawal of consent¹¹ – an unpalatable suggestion for research that requires replicability of results.

Conclusion

The GDPR reveals that lawmakers accept that consent is not always an appropriate legal basis for conducting scientific research with personal data. That said, the intersection between the GDPR and the CTR is not as clear as it could be. An interpretation that gives credit to both texts and reflects the political debate that underpinned them should not render consent the sole route to a lawful further use of clinical trial data. Such an approach would be overly restrictive and ignore the GDPR, which contains more detailed and recent rules on such use.

Consent for the further use of clinical trial data must be seen as an option that can be deployed where possible, without, subject to suitable safeguards, limiting other justifications for the use of this data for unanticipated research.

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⁹ European Commission, Discussion Paper, Meeting of ad hoc group on clinical trials on 19 February 2018, on personal data protection issues in the Clinical Trials Regulation in the light of the GDPR, p. 3.

¹⁰ Letter of the EDPB of 5 July 2018 to MEP in't Veld, available at: https://edpb.europa.eu/news/news/2018/letter-regarding-psd2-directive_en.

¹¹ Article 29 Working Party, Guidelines on Consent under Regulation 2016/679 (wp259rev.01), pp. 29-30, available at: http://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051.

Annex

Excerpt from the Clinical Trials Regulation

CHAPTER V

PROTECTION OF SUBJECTS AND INFORMED CONSENT

Article 28

General rules

1. A clinical trial may be conducted only where all of the following conditions are met:
 - (a) the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored;
 - (b) the subjects, or where a subject is not able to give informed consent, his or her legally designated representative, have been informed in accordance with Article 29(2) to (6);
 - (c) the subjects, or where a subject is not able to give informed consent, his or her legally designated representative, have given informed consent in accordance with Article 29(1), (7) and (8);
 - (d) the rights of the subjects to physical and mental integrity, to privacy and to the protection of the data concerning them in accordance with Directive 95/46/EC are safeguarded;
 - (e) the clinical trial has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects and both the risk threshold and the degree of distress are specifically defined in the protocol and constantly monitored;
 - (f) the medical care provided to the subjects is the responsibility of an appropriately qualified medical doctor or, where appropriate, a qualified dental practitioner;
 - (g) the subject or, where the subject is not able to give informed consent, his or her legally designated representative has been provided with the contact details of an entity where further information can be received in case of need;
 - (h) no undue influence, including that of a financial nature, is exerted on subjects to participate in the clinical trial.
2. Without prejudice to Directive 95/46/EC, the sponsor may ask the subject or, where the subject is not able to give informed consent, his or her legally designated representative at the time when the subject or the legally designated representative gives his or her informed consent to participate in the clinical trial to consent to the use of his or her data outside the protocol of the clinical trial exclusively for scientific purposes. That consent may be withdrawn at any time by the subject or his or her legally designated representative.

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The scientific research making use of the data outside the protocol of the clinical trial shall be conducted in accordance with the applicable law on data protection.

3. Any subject, or, where the subject is not able to give informed consent, his or her legally designated representative, may, without any resulting detriment and without having to provide any justification, withdraw from the clinical trial at any time by revoking his or her informed consent. Without prejudice to Directive 95/46/EC, the withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal.