

In preparation for the IPMPC-MedTech Europe Workshop with Data Protection Authorities on Data Protection in Health Research we are issuing a series of Briefing Papers. This is the third in the series. Please visit <https://www.surveymonkey.com/r/SBBCJG9> to register for the 27 November Workshop in Brussels, Belgium.



IPMPC
International Pharmaceutical &
Medical Device Privacy Consortium

IPMPC Briefing Paper #3

CLINICAL TRIALS AND FUTURE RESEARCH

***Issue:** The GDPR provides at least two pathways for researchers to be able to reanalyse data collected in prior clinical trials to answer new scientific questions. The express consent of the data subject provides one pathway. The derogation for processing for scientific research purposes is another pathway. This paper explores the requirements of each approach and the resulting implications.*

BACKGROUND

Data collected in clinical trials can be useful to answer scientific questions that arise after study completion. Clinical trial participants are typically informed at the point of enrollment of the potential for data collected about them to be used in future medical research.

All clinical trials must be conducted in accordance with a protocol that has been approved by a research ethics committee. A clinical trial 'protocol' is a document that describes the objectives, design, methodology, and organization of a trial. The trial sponsor analyses the data collected during the trial and prepares a clinical study report which details the methods and results of the trial. This clinical study report is submitted to regulatory authorities when seeking marketing approval of a new product.

Scientific research is often an iterative process in which the results of one study are used to design future studies. In the course of a clinical trial, researchers may notice results that were unexpected and require further investigation. They may wish to analyze the data collected in ways that were not originally envisioned in the clinical trial protocol. More generally, as scientific understanding evolves, researchers' questions may evolve as well. Analysis of existing clinical trial data sets may enable researchers to answer these new questions without having to design and run entirely new clinical trials. This is important not only for purposes of efficiency but also to avoid exposing research participants to unnecessary risks.

When individuals enroll in a clinical trial, they may be informed that the data collected about them may be used in future research projects, such as research relating to the same test article or research relating to the same disease or condition in question, or more broadly to research relating to disease mechanisms generally. Such 'future research' usually cannot be described with the same level of specificity as the information in the clinical trial protocol itself because the details of the future research are unknown at the time of data collection.

The GDPR recognizes the importance of being able to analyze clinical trial data sets for purposes that may not have been described with as much detail as the original clinical trial protocol, and it provides several pathways for researchers to be able to do so lawfully.

PATHWAY #1: CONSENT OF THE INDIVIDUAL

In response to concerns of health researchers that new consent requirements could limit their ability to obtain consent to the use of health data for broad categories of future medical research, EU legislators provided clear guidance on how consent requirements should be interpreted in the context of scientific research.

GDPR Recital 33 states that ‘It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.’ The language of GDPR Recital 33 accords with Article 28 of the Clinical Trials Regulation, which states:

Without prejudice to Directive 95/46/EC [i.e., the Data Protection Directive], 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. 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.

GDPR Recital 161 makes clear that the GDPR is not intended to alter the separate requirements established under the Clinical Trials Regulation for participation in clinical trials: ‘For the purpose of consenting to the participation in scientific research activities in clinical trials, the relevant provisions of Regulation (EU) No 536/2014 of the European Parliament and of the Council¹ should apply.’

While GDPR Recital 33 suggests a more flexible approach to consent in the context of the collection of personal data for future scientific research, the Article 29 Working Party has opined that a restrictive reading of Recital 33 should be adopted in the context of sensitive data like health information. The Working Party suggests that alternative safeguards should be used in such instances to protect the rights and interests of data subjects. The Working Party indicates that these safeguards could include data minimization, anonymization, and data security, and providing data subjects with a means to obtain further information on the research purposes as they develop and evolve over time. The Working Party emphasizes that ‘where consent is being used as the lawful basis for processing there must be a possibility for a data subject to withdraw that consent.’

The Working Party’s recommendations are largely consistent with practices in the pharmaceutical and medical device industries for research using clinical trial data that is outside of the original protocol. First, in all cases, this research, while not described with as much detail as included in the original protocol, is still described with sufficient detail to enable the individual to make an informed choice. Second, the practice of key-coding data before it is reported by clinical investigators to trial sponsors protects the identities of participants. Third, trial sponsors maintain the confidentiality of all identifiable data through technical, physical, and administrative controls.

The issue of what ongoing responsibilities a sponsor has to provide information to data subjects as research questions are further defined is trickier. Because the sponsor only has a copy of the key-coded data, the sponsor is

¹ 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 (OJ L 158, 27.5.2014, p. 1).

not in a position to provide direct notification to former trial participants without the assistance of the relevant clinical trial investigators. Although GDPR Article 14.4 states that '[w]here the controller intends to further process the personal data for a purpose other than that for which the personal data were obtained, the controller shall provide the data subject prior to that further processing with information on that other purpose', Article 14.5(a) and (b) provide exceptions where 'the data subject already has the information' and where 'the provision of such information proves impossible or would involve a disproportionate effort'. In the latter circumstance, the controller must 'take appropriate measures to protect the data subject's rights and freedoms and legitimate interests, including making the information publicly available.' If a clinical trial participant was informed at the time of trial enrolment that his or her data may be reanalysed for further medical research purposes, the ultimate question is what additional transparency would achieve given the safeguards in place and the efforts involved in providing further information.

PATHWAY #2: RELIANCE ON SCIENTIFIC RESEARCH DEROGATION

The GDPR's provisions concerning scientific research provide an alternative pathway to be able to lawfully use health data for scientific research purposes.

The GDPR's 'Purpose Limitation' principle states that personal data must be collected for specified, explicit, and legitimate purposes, and must not be processed in a manner that is incompatible with those purposes.² The principle goes on to state that 'further processing for . . . scientific . . . research purposes . . . shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes.' GDPR Recital 50 provides that where processing is compatible with the purposes for which the personal data were initially collected, 'no legal basis separate from that which allowed the collection of the personal data is required.'

Although Recital 50 appears to make clear that, in the context of scientific research, no separate legal basis is required under GDPR Article 6 for any 'further processing', this is largely only an academic issue, for the requirements of Article 6.1 can be easily met in this context anyway. The GDPR states that processing of personal data is lawful where 'processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data.' In an opinion discussing the application of the 'legitimate interests' ground for data processing under the Data Protection Directive,³ the Article 29 Working Party noted that the interest in conducting scientific research, subject to appropriate safeguards, may be compelling and beneficial to society at large.⁴ European legislators expressly recognized the public interest in enabling scientific research in GDPR Article 9.2(j), which provides a derogation to the prohibition on processing of sensitive personal data where the processing is for scientific research purposes 'in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.'

GDPR Article 89.1 requires that when processing personal data for scientific research purposes, a controller must have in place safeguards for the rights and interests of data subjects. This must include technical and organizational measures to respect the principle of data minimization, such as the use of pseudonymization. As

² See Art. 5.1(b).

³ *Opinion 06/2014 on the notion of legitimate interests of the data controller under Article 7 of Directive 95/46/EC.*

⁴ *Id.* at 22.

noted above, data reported by clinical trial investigators to trial sponsors is key-coded, and the identities of trial participants are held confidentially at the trial site.

While the safeguards required in Article 89.1 appear to be routinely met in the context of analysis of key-coded clinical trials data, the requirement in Article 9.2(j) for processing for scientific research purposes to be grounded in EU or member state law that meets specified criteria creates some interpretive uncertainty. Does the Clinical Trials Regulation and similar EU legislation (e.g., the Clinical Trials Directive, the Medical Devices Regulation, etc.) fulfil this requirement? Or must researchers look to member state legislation to ensure that the requirements for the derogation in Article 9.2(j) are satisfied?

In any event, when personal data are processed for scientific research purposes pursuant to Article 89.1, a data subject retains a right to object to the processing 'on grounds relating to his or her particular situation, . . . unless the processing is necessary for the performance of a task carried out for reasons of public interest.'⁵ Moreover, the transparency requirements of Article 14 would apply here as well, raising the same or similar issues to those discussed above in the context of reliance on the data subject's consent.⁶

CONCLUSION

The GDPR provides several pathways for researchers to be able to analyze clinical trials data. Whether a researcher chooses to rely on consent or the scientific research derogation, the principles of data minimization and transparency must be complied with. Data minimization is routinely met in this context through the key-coding of clinical trials data. Transparency begs the question of how much information is enough, and how should this be weighed against efforts needed to provide the information? Perhaps the biggest differences between these pathways concerns (i) the data subject's unrestricted right to revoke consent versus the limited right to object to processing for scientific research purposes 'on grounds relating to [the data subject's] specific situation', and (ii) the requirement under the scientific research derogation for processing to be based in an EU or member state law that meets certain criteria.

⁵ See Art. 21.6.

⁶ Namely, as discussed above, GDPR Article 14.4 states that '[w]here the controller intends to further process the personal data for a purpose other than that for which the personal data were obtained, the controller shall provide the data subject prior to that further processing with information on that other purpose.' Article 14.5(a) and (b) provide exceptions where "the data subject already has the information" and where 'the provision of such information proves impossible or would involve a disproportionate effort'. In the latter circumstance, the controller must 'take appropriate measures to protect the data subject's rights and freedoms and legitimate interests, including making the information publicly available.'