Cross-border considerations for privacy in clinical trials

[00:00:00] **Paula Gonzalez:** Welcome to today's podcast on Clinical Trials and Data Privacy. I am Paula Gonzalez De Castejon and I'm here with James Clark and David Kopans. I'm a partner of DLA Madrid office, and I define myself as a regulatory and privacy life science lawyer. I have developed my career at DLA - very proud of that - and during the past years, I've been to conduct in major pharma and medical device companies. This has given me the opportunity to understand the challenges of the industry.

[00:00:32] **James Clark:** Hi everyone, I'm James Clark. I'm based in the UK. And like Paula, I'm a data privacy expert who focuses on the life sciences sector. So, I work with life sciences sector clients of all shapes and sizes, from big pharma all the way down to biotech startups. I really love my work. And I think this area is particularly fascinating at the moment. David?

[00:00:59] **David Kopans:** I'm David Kopans. I am a partner at DLA Piper in the Washington DC office. I am part of the firm's healthcare regulatory group. In addition to advising healthcare clients on value-based digital health and other innovative healthcare arrangements, I advise clients in both the healthcare and life science industries on transactional, regulatory, and compliance matters related to health information, privacy and security.

[00:01:27] **Paula Gonzalez:** Thank you, James and David, and welcome everyone.

[00:01:31] Privacy matters in clinical trials is a hot topic, especially with GDPR and the US regulation [at your tpa]. As an international law firm in DLA, we have developed a cross border guide on privacy matter in clinical trials. James, please, can you tell us a little bit about it?

[00:01:49] **James Clark:** Yes, of course, Paula. Our guide was really generated out of client demand. And that's because, in theory, we have a harmonized data privacy law in Europe, the GDPR. In practice, the way in which it applies to clinical trials varies greatly from member-state to member-state. And that's partly as a result of local laws which apply in addition to the GDPR. But it's also a result of historical and cultural differences

between different European countries and also the different approaches that local data privacy and medicines regulators take to the interpretation of GDPR in the context of clinical trials.

[00:02:33] And so what that means is that if you are conducting, say, a multisite clinical trial in Europe that may be taking place in five or six different European countries, what you'll find is that in practice, the privacy requirements associated with that trial, and the rules and regulations you have to comply with, vary from country to country, even though in theory we have a harmonized law.

[00:02:56] And that's something that clients often struggle with. So, we decided to produce a guide for clients, a cross-border guide. With input from our colleagues and from local council in all key European jurisdictions, and actually a couple of non-European jurisdictions as well, where we look at some of the key privacy issues in a clinical trial. It allows clients to compare the position on a topic in country A versus countries B and C.

[00:03:27] And we think that's something that's very useful for our clients. Paula?

[00:03:35] **Paula Gonzalez:** Yes, definitely. This is really useful and that's why we thought it was a good idea to provide clients with this general overview, as you said, James. Sometimes they struggle with the different interpretations. So David, could you tell a little bit about how this works in the US?

[00:03:58] **David Kopans:** Yes, definitely.

[00:03:59] Just like the need for the guide in the EU to show how the interpretation of the laws and the like can vary from jurisdiction to jurisdiction. The United States, still lacks a national comprehensive data protection law similar to the GDPR. HIPAA largely remains the primary law governing clinical research, but even then, it has very limited application, especially if the trial is not being conducted by a HIPAA covered entity, or the records being used as part of the trial do not belong to a HIPAA covered entity. A number of states have fairly recently passed comprehensive data protection laws, but most of those laws, specifically exclude not only data subject to HIPAA but also data generated as part of clinical trials.

[00:04:53] So in the case of the United States, the specific laws that may apply to a particular trial can vary quite a bit. And they must always be carefully assessed.

James and Paula, I think the extra territorial application of privacy laws tends to be another big issue facing life science companies operating internationally. To the extent they apply HIPAA and other US data protection laws will continue to protect data when transferred overseas. For example, if a HIPAA covered entity uses an overseas vendor,

even if affiliated, to store or analyze data, HIPAA would generally continue to protect that data. But this is a very fact-specific analysis. Could you talk about what you are seeing regarding the applicability of EU privacy regulations extra territorially?

[00:05:48] **James Clark:** Yes, absolutely. David, this is another very common question we get from clients. Say, for example, you're a US pharma company and you want to conduct some clinical trials in Europe, even if you don't have any establishment in Europe, you don't have any offices there, and you don't have any affiliates or subsidiaries in Europe.

[00:06:08] You're just kind of conducting the trial, almost certainly with the help of a local CRO. It's important that you understand the GDPR data privacy laws in Europe are still going to apply to you as the sponsor of that trial. And that's because the GDPR has an extra territorial effect in two circumstances.

[00:06:28] In one case, where you are offering products or services to individuals in the EU, but the other is where you are, what they call monitoring the behavior of individuals in the EU. And there's very clear guidance from the European data protection regulators.In the context of a clinical trial, one of the things that the sponsor is doing is monitoring the behavior of the participants in that trial.

[00:06:53] And for that reason, the GDPR will apply to you even if you are a non-EU sponsor of the trial. But this whole question of extra territoriality, that's one of the topics that we cover in the guide. So, clients can go and look and see what the position is and the local guidance in each member state. Another topic that we cover, and one where there's much more variance between jurisdictions, is the question of, what is the correct lawful basis for processing patient data in the context of a clinical trial? I don't know, Paula, if you maybe want to talk a bit more about that particular topic?

[00:07:34] **Paula Gonzalez:** Yes, certainly. James, thank you. Because as you said, this is something that varies a lot from country to country and is a very interesting matter. Actually, there is a bit of confusion on whether consent should be the law basis for the data processing activities in clinical trials, especially taking into account that, from a regulatory perspective we have so-called informed consent, which is the consent the patient has to grant after having been properly informed about the pros and cons of participating in a clinical trial.

[00:08:11] There was a tendency to think that consent could also be the lawful basis for such data processing activity. But actually, at least in Spain, it's considered, at least in Spain, that consent should not be the lawful basis for such data processing activity. It should be something like complying with legal obligations or performance of the appointment with the patient. It sometimes could be a legitimate interest, but this is

something to discuss. And again, clients can go into the guide and see how it is regulated. So, David, please, can you tell us how this works in the US?

[00:08:53] **David Kopans:** Certainly. I think for clinical trials in the US, the concept of a lawful basis, doesn't really exist at this point. But as you were mentioning, the focus is largely on obtaining a research subjects informed consent in the US. And so that would not only cover participation in the trial, but also how their data will be used or disclosed. However, this informed consent is generally also tied to some type of HIPAA compliant authorization. So, you have the informed consent and you have the HIPAA authorization together, all of that would cover how the data of that subject could be used or disclosed.

[00:09:35] But the authorization needs to carefully define who is authorized to use and receive that data. And the informed consents, the authorizations, at least on the US side, largely dictates how that data can be used or disclosed, including as part of any subsequent M&A transactions, future clinical trials, publications, and the like.

[00:09:58] James, in the US, the law is typically applicable to clinical trials, including maybe HIPAA. They do not generally distinguish between de-identified data, key coded data or other pseudonymous data. It's either de-identified or it's not. I understand that it's generally not the case under the GDPR. Is that correct?

[00:10:24] **James Clark:** Yes, so that's right, David. Under the GDPR it is a little bit different. We really have two kinds of personal data. So, we have personal data, which is information that can be linked to an identifiable individual. But then we also have this slightly gray area in between personal data and fully anonymized data, which is what we call pseudonymized data. And it's very important to remember that pseudonymized data is still personal data, but it does benefit from a slightly different regime under the GDPR. And pseudonymized data is data where it can only be linked to an individual with the use of additional information, which is kept separate from the pseudonymized dataset.

[00:11:12] And this has direct relevance in the context of clinical trials. When we think about key coded data, which is nearly always, or at least in the opinion of most European countries, nearly always what you would call pseudonymized data, and that's because the direct identifying information in that data set has been removed and replaced with a pseudonym.

[00:11:36] So that if you just look at the data set, you couldn't directly identify anyone, but you always have the ability to go back and replace the pseudonym with the directly identifying information, which is kept separately. And for that reason, it's what we call pseudonymized data,and it's still regulated by the GDPR, still treated as personal data,

albeit there are some additional concessions that you benefit from versus normal personal data.

[00:12:05] But this whole issue of pseudonymized data and personal data, this also kind of plays into another very common issue that clients struggle with under the GDPR, which is the whole regime around international transfers of data. Paula, maybe you want to expand on that a little bit?

[00:12:26] **Paula Gonzalez:** Yes, James. Thank you. Yes, what we see is that there are many sponsors based in the US which carry out clinical trials in Europe. And getting back those data results from the clinical trials to the US poses some challenges from a data protection perspective. From what you have discussed previously, James, about whether data is pseudonymized or not, here in Spain, it has been considered that provided that sponsoruses only coded data, it is not necessary to implement a specific safeguards measure as it won't be considered the international data transfer of regular data or personal data that allow for the identification of someone. David, if you could please provide us the perspective under US regulation.

[00:13:30] **David Kopans:** You know, I think from the US side, we don't generally see the same complications in transferring clinical trial data overseas, including to the EU. But that being said, from time to time, there may be limitations on offshoring data. Such as, some states have rules that restrict the transfer of certain healthcare data, especially for state Medicaid, the government healthcare programs at the state level.

[00:14:00] Transferring that Medicaid data sometimes has significant restrictions. And of course, the data, if subject to a US data protection law, would still remain subject to those laws, but they don't necessarily impose an impediment to transferring the data overseas. How and where that clinical trial data is stored or transferred is still, on the US side, largely a matter of private contracting, including with respect to the applicable informed consent forms and other authorizations that I mentioned earlier. Now, in looking at the larger picture of of privacy and clinical trials, from everything I've been seeing, privacy continues to play an increasingly important role in clinical trials.

[00:14:46] How data is being processed can significantly impact whether a subject's informed consent has been sufficiently obtained. For example, if a trial involves the use of third-party digital technologies, whether medical devices, mobile applications, e-diaries, and the like, you need to be careful that those technologies do not come with terms of use or privacy policies that conflict with the informed consent or other authorization.

[00:15:20] And likewise, there are a lot of M&A deals happening in this space. If the proper consents and authorizations regarding clinical trial data are not properly obtained, it could mean that data rights can't be transferred as part of the deal. And in

some cases, the data might be a significant motivation for the deal, which means the target company loses significant value.

[00:15:45] So, privacy considerations, the way I'm seeing them, can pose a pretty significant risk in this space. James, I don't know if you have similar thoughts on this or other kind of closing thoughts for us?

[00:16:00] **James Clark:** Yeah, David, I suppose I echo everything that you've just said. The data that is generated during a clinical trial is the key value, the key asset, associated with that trial. And what is apparent is that the use, the sharing of that data, is being increasingly regulated. And regulated in increasingly different ways as well, just to kind of complicate matters further. From a European perspective, we do have some hope that there may be some further harmonization in this area. The European Data Protection Board, which is the body of all European data protection regulators, has promised to produce some detailed guidance on the processing of personal data for scientific research, which would also include clinical trials.

[00:16:58] That guidance was supposed to come out in 2021. We're still waiting for it. But hopefully when that guidance is published, it will help different countries align a bit more on a common position on some of these issues, which is something that'll be greatly welcomed by organizations operating in this space.

[00:17:18] I suppose until that day comes when we do get harmonization, I would encourage clients to check out our guide. If they go to DLAPiperIntelligence.com, you'll find a link to the Privacy and Clinical Trials guide. And there's a number of topics that we haven't had time to discuss today. For example, reuse of personal data, secondary use, And what are the roles of the sponsor and the PI and other parties in the clinical trial. So, there's lots to explore in the guide and I just encourage people to check it out. Paula, do you have any closing comments?

[00:17:56] **Paula Gonzalez:** Well, I believe this is all the time that we have for today but thank you very much David and James for the very interesting conversation. Definitely DLA Piper's cross-border guide will be a help for many clients. Thank you very much everyone for listening.

This publication is for general information only. The information presented is not legal advice, and your use of it does not create an lawyer-client relationship. All legal matters are unique and any prior results described in this publication do not guarantee a similar outcome in future matters. DLA Piper is a global law firm operating through DLA Piper LLP (US) and affiliated entities. For further information, please refer to dlapiper.com. Attorney Advertising. Copyright © 2022 DLA Piper LLP (US). All rights reserved.