

Is the Data Act relevant for medical device manufacturers?

With Prof. Dr. Marc Strittmatter, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights.

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A podcast by the Johner Institute for medical device manufacturers, authorities and notified bodies.

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Medical device manufacturers certainly have no shortage of regulatory requirements.

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Now there are not only the specifications that specifically affect medical devices and medical device manufacturers, but also orthogonal regulations.

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Think, for example, of the AI Act, which is currently being hotly debated, or another act is this EU Data Act.

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And it is still quite unclear to many what that means exactly.

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Medical device manufacturers are also unclear whether they are affected by it at all.

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And if they are affected, what should they do now?

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And that's exactly what I want to discuss today.

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That's why I brought in someone who knows much, much better than I do, namely Professor Marc Strittmatter.

00:01:04 Speaker 1

Marc, tell us very briefly who you are, that the listeners know that, can sort you out and are also convinced that we have found exactly the right person here.

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Yes, hello Christian.

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Thank you for inviting me.

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Of course, you set the bar very high right away.

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with a wide variety of regulations.

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I teach IT and data protection law at the university here in Konstanz and one focus is on data law, with which the European Union is now blessing us abundantly.

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The Data Act, which we want to discuss today, is, so to speak, the keystone in the EU data strategy, although one can very well discuss whether regulation itself should be

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data economy.

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But we do not have to decide this question today, the EU has long since done so.

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And yes, last week the new Data Act was published in the Official Journal and in fact, in the Official Journal of the European Union.

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And in fact, it will also come into force in September 2025.

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When I'm not teaching or researching,

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I also didn't lazily set up a research project on the topic of the Data Act with partners from Switzerland and Austria.

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So when I'm not working on it, I'm advising companies.

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In all questions of IT and data protection law and probably also on a larger scale, I expect to see the same in the area of data law.

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Yes, especially against the background of what they have to do if this regulation is activated.

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Okay, what we might want to mention, you're a fully qualified lawyer, I think that's what you call a lawyer, someone who doesn't do anything else all day.

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And you have specialized in exactly this topic of data law, as you just mentioned it.

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And what you've already told us is when this thing will go live.

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So it's passed now and 18 months later, so what did you say?

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September, 12.

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September, next year, so it will be done live.

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So now the question is,

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Who does it actually affect?

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But maybe one more question before.

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What did the EU intend to do in the first place?

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So what did she want?

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Why do we need such a regulation?

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So whether we really need it now, you can probably argue about it.

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But what was the intention behind it?

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I think that's the easier question.

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The intention was to create access to machine data.

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There are already detailed regulations in the area of personal data.

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It was about the protection of personal rights.

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Now it's a matter of promoting the data economy, the data economy, by giving those who generate the data the opportunity to have access to this data.

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So access is a central term, you can remember it.

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Perhaps the best way to explain this is with a constellation.

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There are 3 parties.

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So the first party is the party that generates the data.

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Let's imagine that there are networked medical imaging systems, such as CT or MRI now.

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They are connected to cloud platforms and data is generated during the operation of these systems.

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Yes, so party 1 generates data.

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So the patient estimates in our very specific case.

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The patient or, above all, the practice, the

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operates this device and has thousands of records, ultimately in their systems.

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Then there is the second party, namely the one who actually has the data with him, who has data sovereignty.

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If this is a cloud system, it is the cloud provider and the practice itself may have access, but possibly not the full extent of the data treasure itself.

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And then maybe there's another one

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third party, always called a third party in the regulation, which could have an interest in offering a service from it and cannot offer it because the data holder does not know exactly how to deal with the data and the user is the one who now has no de facto sovereignty.

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And this third party could make something out of it, namely by offering a connected service,

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If I were to go to an example in the field of industry, we would think of predictive maintenance or something similar.

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And here in the field of medicine you can actually think of the examples yourself, what you could do with many data sets, diagnostics and so on.

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So you can say, I'll put it very briefly, breaking up the data goals so that others can generate new business with this data.

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Absolutely, absolutely that's the idea and

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Maybe it's a bit of a reaction to the lost battle over personal data.

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There, the EU is still mourning the fact that the major American providers of social media and other platforms have actually lost this data battle.

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The General Data Protection Regulation was set against it in order to protect personal rights at least then and thus establish a kind of gold standard of data protection.

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And now they might want to be faster here.

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by opening the factual conditions on the area on the machine data page.

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And this is done by creating so-called access claims.

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This is called Access by Design.

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And if you don't have access by design, then there is a legal claim of those who generated the data against those who have it.

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I will try to summarize this very briefly.

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So we are now trying to enable this access, because it actually comes directly into the next question, what is being demanded?

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And what I have already heard, i.e. the demand to create access.

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Now maybe two sub-questions about it.

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When do you need which access or when do you have to grant this access as someone who is sitting on this data?

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That is perhaps one of those questions.

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And the second question is, what other requirements does this Data Act impose

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except for the obligation to provide this data now.

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I'll be happy to go into that right away.

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Maybe a remark before that, so that you can classify it well.

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Or two, even.

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One is that the lawyers have been discussing for at least 15 years whether there should be such a thing as ownership of data.

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And one could, malicious tongues could say, we have lost 15 years of scientific discussion.

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I still found them useful.

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They decided against it.

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So there is no ownership of data.

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So, what's the alternative?

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You make it one size smaller and that's just what we just heard.

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This is the so-called access.

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The second remark, so that there is no impression of incompleteness here, although that should actually arise, because the whole Data Act has, I think, explanatory memorandum and text, 200 pages.

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Which is nothing, by the way, compared to the final text on the AI Regulation that we saw this morning, was 182 pages in the mediation document.

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I don't know if you've seen it.

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So in the Data Act there are also regulations on cloud contracts, which are extremely important in practice, because they provide for so-called switching rights, i.e. mandatory short termination and switching periods and regulations on technical interoperability.

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This means that the transition of a cloud user from one cloud to another or from one cloud provider to another provider should be facilitated.

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I could go on and on about that now.

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But that goes beyond the scope of today.

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So these two points, no property, but access.

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Secondly, Cloud Switching Rights, there is also a whole chapter in the Data Act, which is also worth reading.

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What does the

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Owner, i.e. the data holder, what does he actually have to do now?

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There are 5 prerequisites that you could remember abstractly in advance, so to speak.

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The first is transparency, then accessibility by design, then access claims, interoperability, and finally data security and protection.

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These are the 5 main duties,

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Requirements.

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In my view, the two key points are the possibility of designing the products, the services in such a way that the user, the one who operates a device, is able to access the data.

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And if this is not technically possible or conflicts, we will come back to the topic of trade secrets and personal data protection later, if that conflicts, then he must at least have access claims

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And in addition, the lawyer is pleased, there is a very elaborate data contract law behind the scenes.

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So the Data Act contains regulations on what data contracts should look like.

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I have a personal opinion on how sensible it is to intervene in the autonomy of the contract in this way.

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And if you look at the level of detail in the Data Act, yes, you know that there is a lot of work ahead of you.

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but these are the obligations for the time being, which means that the data holders must become active.

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K., so we have, I have now learned, we have 2 major demands, so to speak, one is to grant access and the other was to enable the change.

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Of course, this also includes or is a prerequisite for appropriate interoperability.

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And now you have also said that now there are another five points, so to speak, that are necessary or prerequisites to meet these two main demands.

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And it was a suggestion that maybe you could go through this with an example, these five points.

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And you had given the first example earlier, so that was a medical case, i.e. where image data is generated, CT, MRI or whatever.

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And the assumption was that this data would be stored with a cloud provider

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For example, the hospital uses the services of a cloud provider to be able to store exactly these images that are created.

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And if we now assume this scenario, then I understand, so you need a right under certain conditions that you can then continue to work with this data.

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You have already mentioned that there will of course be restrictions when it comes to personal rights or data secrecy.

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But

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That's there for now and secondly you said, must be able to access it somehow.

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And I can understand that quite well.

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And we have a lot of interoperability standards in medicine as well.

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But now these five points, that is not quite clear to me yet.

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Could we now go through them again using the example?

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Yes, you are not alone.

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In fact, I think very few people have understood them so far.

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The Data Act has been published in its last form for a good week, but you can give it a try.

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The first requirement would be transparency.

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How do I create transparency?

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At least that's how it was done in the General Data Protection Regulation.

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Data protection notices have been painted.

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Es gibt das böse Wort ‚No one has ever read a data privacy notice unless being paid for‘.

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I think that's relatively close to reality, but that's how it is in the imagination.

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In other words, transparency, hints, who does what, what data we collect, what

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and with whom are they shared.

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That would be the first thing that both the device manufacturer and the operator have to do.

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Then, in order to map the accessibility-by-design point, I think you would have to work with technical solutions.

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You can certainly give better answers than I can.

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Maybe by memory separation

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through compatible standards, access options.

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We have a huge construction site with patient data protection, that is immediately clear.

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But in principle, a technical solution would be or is a technical solution preferred to the legal solutions.

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The legal ones would then actually be contractual, to name a third prerequisite, to map the possibility of depicting the

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certain data can be accessed under certain conditions.

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We can also talk about this in detail again.

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I imagine it in practice that even if you didn't need it now, but in order to implement the standard, which is also sanctioned, we can talk about that again, in order to implement the standard, you will have to make a kind of supplement Machine Data Handling to the contract.

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Yes, that's a facility then,

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This can also be relatively simple and straightforward, but you have to do it.

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Yes, it has to be mapped at the contractual level, both on the part of the manufacturers and on the part of the users.

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The Data Act also benefits consumers, so it is also a B2C and B2B Act, the end users don't have to do anything for the time being.

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They will probably be asked for their consent and transparency will also be created towards them by adding even more paper.

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which is then also not read.

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But I try to hold back the irony a bit.

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So that would be the third prerequisite for access.

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The last two prerequisites: interoperability and data security, data protection.

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Interoperability must be achieved technically, via standard interfaces, technological neutrality if possible, and data security and data protection.

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This is similar to data protection, the so-called TOMs.

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technical-organizational measures.

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This is where practice will develop.

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This seems to me to be a solvable problem.

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Okay, so I'll summarize it again briefly for the sake of the example, so our radiology example.

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So the first thing is the operator, i.e. the hospital and, if I understand you, also the data owner, which can then be a cloud provider.

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First of all, we have to say, what am I saving, perhaps also for what purposes.

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We also have a parallel story to the GDPR.

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then the next step is to ensure accessibility of the products at all.

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That's what you just mentioned at Accessibility by Design.

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I see this as relatively closely linked to the fourth requirement, namely interoperability, namely you have to get your turn somehow.

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You said that this can be done technically, i.e. via a data interface that has to be interoperable or just second-best case, you somehow regulate it by law.

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Then the third thing was,

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And once you've done all that, you also have to make sure that people really get access, which is not just a technical story.

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We have just talked about interoperability.

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I think that's the least trouble for the manufacturers, because they have to, that's anyway, so these products are networked with each other anyway.

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And we know the topic of data security and data protection from other areas.

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So those would be the five points that we have just gone through from very concrete use cases.

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Now we were already in a use case for medical devices.

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Now the question arises, i.e. which companies are generally affected?

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So I've already learned that companies that store data, so that's probably also going against them or affects these hyperscalers we're talking about.

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But now a very concrete one, i.e. which medical device manufacturers, for example, must now or are subject to this EU Data Act?

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Yes, that's a good question.

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The Data Act had above all.

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the I.O.T.

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Product operators, manufacturers, users in mind.

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In other words, everything that produces masses of data that is not primarily personal.

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After an E.U.

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Investigations or estimates, 80% of these data treasures are lying around unused somewhere.

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So manufacturer of I.O.T.

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products, manufacturers of products that use I.O.T.

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Devices verbauen,

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vendors, landlords, lessors, companies that have control over IoT data, providers of IoT services, connected services, those that use the products and services.

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And finally, this is a bit off the main topic, such companies that offer cloud services themselves, for them this chapter is cloud contracts

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relevant, you just have to look at it separately, I would like to separate it mentally to a certain extent, but all those I have mentioned here, all those I have named here, should look at it.

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But before a kind of depressive mood arises here, it must also be said that there are also opportunities in the Data Act and that one should not lose sight of them.

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This right of access

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of the actual data generators, i.e. those who have participated in the data creation process, yes, they should also have the fruits of it.

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But maybe they don't want to and can't do it themselves, they can transfer their data access claim to third parties.

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It's such a hinge and the third parties could be all those who think, oh, there are interesting data treasures, I could offer a service with them.

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So if they manage to get the

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Data users, those who have participated in the process, who have generated the data, if they manage to contact them and get them to give them their right to access.

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And that will also happen, that you then collect this data, so to speak, then suddenly a business area arises in which you have a right to access.

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Maybe it's a bit about remuneration and participation, incentive, profit share, whatever you can imagine.

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And

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the Commission actually had these new business areas in mind, and they must not be lost sight of in the

face of the burden of what we see coming in the first step.

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You have now said again important, it is also mainly about IOT.

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So maybe we have to work out that little bit so that we can perhaps also take this issue of data protection and health data out of it to a certain extent.

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So there is data that is directly related to patients.

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Our diagnostic images that we have just talked about, from radiological imaging, are obviously with the personal reference.

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Now, however, there is a lot of other data that accumulates in the devices, such as usage data.

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In other words, how often is the device used, which images are taken, at what frequency, which image sequences, perhaps in MRIs.

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And in this data there is also a value that was used earlier as a bullet point

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The topic of predictive maintenance, that might be one, but it would also be process optimization, while such topics and this data have no, necessarily no patient relevance at all.

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So that's not where I really see the big conflict now.

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But if we now return to patient data, what stands out now?

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So

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D.S.G.V.O.

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or Data Act, so do I have to hand over patient data or does the General Data Protection Regulation apply here and say, no, they stay with them, they stay where they were and are not intended for further processing by third parties.

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So, you put your finger in the wound, data protection clearly takes precedence, so they didn't want to crack that open and

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and that always becomes exciting and relevant when it comes to hybrid data.

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In other words, those that are both machine data, but also personal data, where the person can be identified.

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There, data protection is paramount and you can of course consider whether, for example, image data could not also be released completely anonymously.

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now the owner of the data is not obliged to do so for the time being, but maybe there is an incentive to do it and just give out a lot of data and generate certain patterns.

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This has been done in some cases for a long time.

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What is new here is that there is now a legal claim to how the interface of this hybrid data is ultimately balanced.

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We have to wait and see, we have to leave it to practice

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and there will be those who courageously lead the way, who, if necessary, clarify something with the data protection authority and say, we will do this and we will create technical and organizational measures that ensure that this data is no longer identifiable.

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And we create business models in which perhaps everyone could also have an interest in it and are also incentivized to have the data or make it accessible.

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But

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as you rightly said, data protection comes first and then you have to look at it, that will lead to the fact that data protection management systems will have to be expanded to include this component Machine Data Act, that you need data data governance in the company.

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I think that's ultimately the appeal in the first round, you have to sort your data stocks more clearly, you have to sort them under the sorting mechanism of the Data Act

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and not only the previous data regulation, especially personal data protection.

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And you should also look at them as an asset and consider what potential business opportunities there are.

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These are similar thoughts to what we have also been built into SGB V.

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There is also a demand in the DiGA context that when data is generated, that the

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tend to have to be offered to others, but there was also the conflict or the tension between the protection of this personal data and this machine data.

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So what you just said, personal protection and data protection take precedence here, there is no discussion at all.

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In cases of doubt, you said, actually, too, but these are still things where it is balanced.

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And in the case of pure machine data without personal reference, this Data Act is particularly effective.

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And that's what the

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Manufacturers of such data should really also keep in mind that they enable their products to actually provide this data in order to meet the requirements of the Data Act.

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I suspect that there are again some drastic penalties that the EU has chosen for this.

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But it's 4% of sales, right?

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Before we get to the punishments, what you just mentioned, the possibilities of dealing with them and

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perhaps also the obligations to make the Data Act secure, to ensure the obligations under the Data Act, I would try to approach them above all technically, for example by treating data stocks separately from each other and also separately, by treating them with appropriate I.

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security concepts, TOMS, occupied, deposited, made available.

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In addition to personal data protection, there is always a commendable interest in the protection of trade secrets on the part of the manufacturers, the operators.

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It's not the case that the Commission or the EU is now simply reaching into trade secrets and trade secrets with the new regulation and saying, now show us what you have beautiful.

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Therefore, data owners will always be able to invoke trade secret protection under the Trade Secrets Act and the previous EU Directive.

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Maybe this will create a bit of a game.

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If you don't want to, you say data protection or trade secrets.

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The decision in the area of trade secrets is such that access can be made subject to security measures,

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so that there will certainly be a new field of activity.

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So if you don't want to do it under any circumstances, you would find ways to make it so unattractive that you don't have to.

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Those who want access will perhaps negotiate how the interests on the other side can also be protected.

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But you had asked me something else, namely sanctions.

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Yes, before we maybe get into it right away, so now I'm amazed, because now we have on the one hand

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quasi the giant monster EU Data Act with a really big claim and serious requirements.

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And on the other hand, we have now supplied the cudgel, so to speak, on how we can put the brakes on the demand to a certain extent, namely data protection and the protection of trade secrets.

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So who benefits from it now except the lawyers?

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Yes, that's a very good question.

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So

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I can't answer your question because you don't know how these issues will be negotiated in practice and how intensively the authorities will get involved.

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Under the pressure of the sanctions, it will be the case that companies, especially data holders, will have to open up to this.

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I always take pragmatic approaches, I always think you have to be sensible

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argue that you have to make it reasonably comprehensible why you want something, what you do with it or why you don't want to give something out and why you can't give it up.

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There are always understandable interests and you have to present and argue them.

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I am very excited about the cases, I would be happy to be able to support them in this area as well and we will see the first administrative practice at some point, everything is still taking time.

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perhaps some good news, there is also an exception for small and micro enterprises.

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So, if you have fewer than 50 employees and less than 10000000€ in sales per year, you are not affected for the time being, so you don't have to implement the requirements of the Data Act.

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In this respect, we still have a year and a half to prepare for it.

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Ah, that's really good news, no, because that's what medical device manufacturers are doing.

00:28:41 Speaker 1

ecosystem is also shaped by SMEs.

00:28:45 Speaker 1

So I'll be happy to hear that.

00:28:48 Speaker 1

I would like to take up what you have just said.

00:28:50 Speaker 1

So there is not only another EU bureaucratic madness behind it, but there is also business behind it and that will never be overlooked, i.e. that there are new opportunities to earn money with data.

00:29:03 Speaker 1

And I think that's what many people have or still lack, this awareness of it.

00:29:10 Speaker 1

And

00:29:11 Speaker 1

how much we have been left behind in this area of digitalization.

00:29:14 Speaker 1

In other words, especially the use of data.

00:29:16 Speaker 1

I think the American hyperscalers have made that more than enough clear to us.

00:29:20 Speaker 1

That means that such a push can't work at all, maybe it can also work in the right direction.

00:29:26 Speaker 1

And a second thought: We have medical devices and that means we have the obligations to Post Market Surveillance, and this Post Market Surveillance needs data.

00:29:36 Speaker 1

So that means that the manufacturers themselves also need data.

00:29:38 Speaker 1

about the use of their devices and if they somehow ranked a little more elegantly, i.e. themselves via standardized interfaces, then they would find it easier to collect and evaluate this post-market data automatically and thus not only meet regulatory requirements, but also really learn something about the

use with the opportunity to improve the benefits of the products, to improve the safety of the products and thus also to be more successful in the market.

00:30:08 Speaker 2

Definitely.

00:30:09 Speaker 2

Perhaps one could also consider whether there are not business areas for data brokers, for bodies that provide data governance, that can stratify precisely these categories from each other, that master the two major legal instruments, that perhaps enforce access claims, perhaps buy them, perhaps bundle them through incentives.

00:30:35 Speaker 2

Those who make a name for themselves and in the market

00:30:38 Speaker 2

To distinguish itself as a body that can solve this problem and perhaps also provide business opportunities, you will certainly find good business opportunities.

00:30:48 Speaker 1

I hope that medical device manufacturers will also take advantage of these opportunities.

00:30:52 Speaker 2

They are explicitly mentioned, they are and they are also mentioned in the Data Act.

00:30:56 Speaker 2

So the legislator has certainly thought of her.

00:30:59 Speaker 1

Yes, especially in the automotive sector, you can see where this can lead.

00:31:03 Speaker 1

So we as Europeans should not be those who

00:31:06 Speaker 1

who now only supply the hardware for some hyperscalers.

00:31:09 Speaker 1

And a data broker is someone who continues to work directly with data and does not just mutate into a hardware data supplier.

00:31:17 Speaker 1

And that's a bit of a fear that I have and I hope that it will drive things in the right direction.

00:31:23 Speaker 1

Yes Mark, so for the manufacturers very briefly now the summary.

00:31:27 Speaker 1

So the thing is passed, it will come, that's for sure.

00:31:31 Speaker 1

We said, just a moment ago

00:31:33 Speaker 1

May, September 2025.

00:31:36 Speaker 1

We knew that we had to do it because there are sanctions on it.

00:31:40 Speaker 1

Say very briefly again, how much was that or have you not yet mentioned it?

00:31:43 Speaker 2

Yes, fines according to the General Data Protection Regulation pattern up to 4% of global annual turnover, so spare me the comment.

00:31:54 Speaker 1

So that's what we've learned, so we have to take care of it, especially if we're a company that we call

00:31:58 Speaker 1

that is not even such an SME style, i.e. more than 50 employees or

00:32:02 Speaker 1

more than 10 million in sales.

00:32:04 Speaker 1

If you belong to this group, we have just learned, then it is a matter of thinking about how we can approach things in design, in development, for example by separating technical data, IoT data from personal data from the outset.

00:32:20 Speaker 1

So that would be the first thing to do.

00:32:23 Speaker 1

Then the second, think about which interfaces can be offered for this.

00:32:27 Speaker 1

the third plant to actually develop business models with it and thus ultimately be successful in the market.

00:32:36 Speaker 1

So those are a few recommendations that we would like to give here.

00:32:40 Speaker 1

For all those who want to go deeper now, how can you or how can they contact you, how can you help with these questions?

00:32:52 Speaker 2

So I'm easy to find, even with an e-mail address via

00:32:56 Speaker 2

Pages of the University of Applied Sciences Konstanz or the law firm I advise is an IT boutique in Stuttgart and Karlsruhe, Vogel und Partner is the name of it.

00:33:07 Speaker 2

I have just started a research project with partners from St. Gallen, Zurich and Vorarlberg, called Data Act Pioneer.

00:33:16 Speaker 2

We are always looking for cooperation partners, associated partners who have to

00:33:21 Speaker 2

pay nothing, do nothing, except perhaps contribute their know-how and their problem.

00:33:26 Speaker 2

The project will run for three years and we intend to issue initial recommendations for action before it comes into force, i.e. before September 25.

00:33:38 Speaker 2

Those who do not want to wait for this would have to switch to the counselling track and could certainly receive more specific advice there.

00:33:47 Speaker 2

I would recommend that if there is a real

00:33:50 Speaker 2

The right topic is the data economy, the data economy in connection with products or services or cloud services.

00:33:58 Speaker 2

Otherwise, I think we can wait a little longer.

00:34:02 Speaker 1

So Mark, how else can you help, except in this research project and outside of direct commercial consulting?

00:34:11 Speaker 2

We offer through the law firm actually companies that think that they are based on what we have said here.

00:34:20 Speaker 2

together fall within the scope of the Data Act, at least once free of charge as to whether the Data Act is actually relevant to them in concrete terms.

00:34:32 Speaker 2

So we would do a first assessment, if only because I am personally interested in it.

00:34:37 Speaker 1

Yes, because it's just you collect a lot of evidence, all right.

00:34:40 Speaker 1

So everyone who is interested in getting a free assessment, just to get an assessment, a first, how is the data

00:34:48 Speaker 1

whether and how this Data Act is relevant.

00:34:50 Speaker 1

Just get in touch.

00:34:51 Speaker 1

As always, contact details can be found in the show notes below.

00:34:55 Speaker 1

I thank you from the bottom of my heart for giving us an insight into this completely new world.

00:35:01 Speaker 1

We look at it with horror and perhaps also with many opportunities.

00:35:07 Speaker 1

So thank you very much again.

00:35:09 Speaker 2

Yes, thank you very much, Christian.

00:35:09 Speaker 2

It was a pleasure, a pleasure.