Johner Institute

Interoperability

With Prof. Dr. Sylvia Thun, Prof. Dr. Christian Johner

Transcript

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Medical Device Insights, a podcast by the Jona Institute for medical device manufacturers, authorities and notified bodies.

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One of the big trends, additional features, is also digitization and of course this also means networking

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of medical devices with each other, but also the networking of medical devices with other systems, such as IT solutions.

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And it is therefore clear that the topic of interoperability is playing an increasingly important role.

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And that's exactly why I have the interoperability pope today, I don't know if there is such a thing, if not, be it invented, with the podcast, namely Professor Silvia Thun.

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Silvia,

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could you briefly introduce yourself who you are and what you do all day long as an interoperability pope?

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Yes, hello Christian, thank you so much for letting us find the time here to discuss this important topic together.

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Yes, what do you do all day as a professor?

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You know that well yourself, don't you?

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So, we have lectures, of course we have to teach or are allowed to teach and first and foremost

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But do I do projects, i.e. projects that promote interoperability and, above all, bring patient benefits.

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And here I am responsible for the technical part, i.e. the translation of the medical requirements into technical language.

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So not only into a programming language, but into a programming language, which is a technical language for the healthcare sector.

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And which can then also be understood worldwide and there is extensive work and a huge community with an insane number of tasks.

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And here, for example, I am also elected to international committees of H.L.

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Here in Germany, I even manage the H.L.

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7 user group in Germany.

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And now you imagine that I'm on committees all the time.

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But that's not the case, that's really how we work.

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Directly together with the Charité, of course, and the Medical Informatics Initiative.

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Wow, anyone should say that the life of a professor is not varied.

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So a lot is happening there and I think that will now also hear us directly into the next question.

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So that we might go in the direction of concrete projects as an example, but maybe also answer the question of what has contributed to the fact that this topic of interoperability is so important again

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has gained in importance, because for almost decades, I would have said, we have also had this telematics infrastructure and that was tough in some cases.

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But somehow I at least have the impression that it's really picking up speed again and the question is, how does it come about, probably because you're also there, but you were also there the whole time.

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What would you see as the main drivers for this interoperability and perhaps also in the example,

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as you have already indicated.

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Yes, of course there are extensive things that contribute to this.

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First of all, I would like to say that of course, and we all know this, we have the smartphone at our disposal and know how to deal with IT and, above all, with interoperable health IT, because we can do that every day, for example, we can track ourselves or record an ECG and see it directly.

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So we know, so the citizen knows,

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That is possible.

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I think that's the most important thing.

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And I want to have that and I want to have more of it.

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And I know it has a use.

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This is certainly the most important thing in all projects, that patient benefit is in the foreground here.

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The second is the software.

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The software is now ready, as are the technologies behind the software, so that we can work with web services right here, with modern technologies, with security mechanisms that perhaps didn't even exist a few years ago, especially for mobile applications that are now ready for use and allow us to do so.

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And the third thing is people, the people who

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Behind all these organizations, I say of course female doctors, then perhaps also a K.B.V., the National Association of Statutory Health Insurance Physicians, also Gematik, who are suddenly pulling together here and, above all, the scientists, of course, and say, we are doing this now and we want it now and it really benefits everyone and the fears are no longer so in the foreground, but really

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the goal, what you have in mind, first of all the patient file, of course, which is now being expanded, modernized, is also now being designed on the basis of modern technologies and of course, I mean, I don't have to say this here, the pandemic, which has shown how important data is.

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Mhm, so I'll summarize very briefly again, so you once said, through technical development and the associated expectations, then the technology itself,

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You've now talked about web services, probably now also the whole fire context you're alluding to, then the attitude in a certain way of the people who are now also promoting it, who are working together, you just said, and then this and the pandemic.

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Would you also see the political framework as favorable or rather obstructive?

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I would say quite neutrally that every party has exactly that in mind and of course there are ministers who push something and get it on track quickly and those who do it slowly.

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And I think we just had a very fast minister.

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Mhm, i.e. the number of

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Regulations that have come out of his house speak a relatively clear language, I think, and interoperability was also an issue all the time and over and over again.

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And I think we should come back to that right away, also to current regulations, but maybe another step ahead.

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So, you said that technology has evolved, standards have also evolved.

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What would you currently consider to be the most important trends and standards in

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in the area of interoperability in healthcare, which advance the cause and that companies could or should really know and use, I would even say in order to achieve the goals.

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Of course, this is the standard that has now been set for Germany and also Europe via various road-maps in Europe, but also here also regulations in Germany and decisions by Gematik and that is the so-called

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FHIR Standard, Fast Healthcare Interoperability Resources Standard, which enables us to find a uniform language, i.e. interface language, on the one hand, but also to design entire systems, i.e. database systems, on the basis of these findings of this standard.

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And there are now very innovative companies in Germany that work very quickly and efficiently with this standard, and can also create products very quickly.

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and above all, the mobile applications, including the so-called digital applications of the DiGAs, enable us to connect to traditional applications, such as a HIS.

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No, and this is certainly the most important standard of all and it then uses international and national terminologies.

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And here, of course, it must also be said that we are now taking the big

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Have the freedom and joy to use the SNOMED terminology in Germany.

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So this was not a matter of course, we have only had it since this year and with this SNOMED terminology we finally have a language that we really need for any application in the healthcare sector.

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Mhm, I can absolutely understand that and as a technician, of course, your heart always laughs when you come across well-known

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Yes, technologies in this case are now bumping into web services, JSON or XML-based yes formats that simply anyone can handle, where there are libraries that you have long known from other contexts and know how to deal with.

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This FHIR standard, as you just described it, is of course a huge monster and

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That's why there are always these suitable profiles, so to speak, to be able to bundle and tap into the corresponding resources for a very special use case, I don't know if the term is the right one here, so to speak.

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What would you recommend to companies that feel that the profile for their specific situation is not yet there?

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because you are also at the same time as half past 7 chairman, probably the person who knows that particularly well.

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What would be the steps you would recommend to these four?

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Yes, it's not so much a monster as it is more of a fairy from whom you can wish for something if you also participate.

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So that means we can actively help shape it here in Germany and internationally, because many of the resources, so in principle they are modules, they are not yet normative, that is, they are not even finished yet

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Or they or we don't want to finish them at all because they can't and don't want to internationalize them.

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Accordingly, I have the 8020 approach.

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So 80% I use and is also interoperable.

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And about 20% I have to think about it together, best, I say, nationally.

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How would I map this in a country and not just in a project, such as the person or the encounter, i.e. the case or the diagnosis?

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If you have that and get it coordinated in one country, then the software manufacturers have it relatively easy.

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So, of course, it's still difficult to create software, but the specification, which can then also be found in a so-called implementation guide, i.e. the one we call H.

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7, the basic profiles, on the basis of which you can then build your projects, your applications

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So the more agreement is reached and the more there is national coordination here, especially with regard to terminologies, the more interoperable a country becomes and the faster the software manufacturers can act.

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And consequently, on the one hand, of course, become a member of the HL7 association, actively participate here.

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So the developers, please, not the politicians.

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And then also follow up on what the basic profiles, for example, like the ones now for the new one, we were able to bring in a lot of news this year and updated and coordinated with K.B.V., Gematik, the Medical Informatics Initiative, so that actually there is already a relatively well-rounded thing.

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You just have to know where it stands.

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I'll try to summarize this again so that you can make sure that I understood it.

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So, you would recommend the companies.

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First of all, look at what is there at all, because you say, that's certainly 80% and I believe that immediately, because you have thought about what is needed for decades and have already modeled it accordingly.

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For the rest of the part, your recommendation, if I understood you, is to coordinate.

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In other words, avoid going it alone, companies going it alone if possible, but at least coordinate at the national level.

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And you invite that just content 7.

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Germany, for example, and then you signaled a very high openness to push things forward there and then perhaps there is still a very small remainder left, which may then be really company-specific or use-case-specific, which then does not have to be regulated at all because it is simply too specific.

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Does that fit like that?

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Ah, exactly, perfect.

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Yes, that brings us to the topic of limiting standard wild growths that we can achieve in this way.

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Now there was a new regulation, this Interoperability Regulation or GIGV, there are now a lot of names that the thing has again.

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Could you tell us about it, because I've already heard that you know it particularly well, i.e. what it demands, what might have been the meaning behind it.

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Yes, the health I.T.

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Interoperability Governance Regulation, which is now

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, i.e. entered into force.

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And that's something we've wanted for many years.

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So, who are we?

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These are the experts from medical informatics, but also many bright minds and physicians who have recognized that there is a need for a coordination office in Germany, which is not Gematik to begin with, because it is of course very technically oriented.

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This coordination office is to consist of experts who know the technology on the one hand and the medicine and care requirements and processes in hospitals on the other.

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There are people who are then appointed, who come over to a committee.

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That's 7 people for now.

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There is then also a spokesperson or a leader or a national coordinator, coordinators who then manage the

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yes, whether they are wishes or whether they are specifications or whatever it turns out to be, then evaluate and also get the power to coordinate things.

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Yes, and above all not with the aim of interacting politically here, but with the focus on patient benefit.

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Yes, and this regulation is nothing new.

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This is also something that exists in many countries, namely a coordination office for these important issues and it will now come into force relatively quickly, so I have heard, as early as November and the people will be named.

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That means, and I think this was also important for our listeners, that this is not an encroachment on the part of politicians, who somehow want to control even more, but that was actually a desire and bottom-up to have an institution that also contributes to the standardization of standards in a certain way, and because too many standards are not conducive to interoperability.

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This Regulation now contains, in addition to

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these expert groups that you have just described, and there is also an obligation with the working groups that are still part of it, to use these standards, at least if you want to participate in the statutory reimbursement.

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This means that this in turn results in requirements for the manufacturers.

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How do you assess that, the effort they have with it?

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How would you possibly criticize

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who say, yes, now we have to follow even more, and that drives us up the costs even further or perhaps even brings us into problems with the transitional periods that have now resulted from the Medical Devices Regulation, because every change at an interface ultimately leads to the collapse of grandfathering, so to speak.

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What would be important arguments for you?

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Yes, I would turn the tables, it's not like it's new, that something like this is coming in Germany

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and that it would not have been possible to adapt to the standard and that the ISIG procedure, which is the exchange procedure for information from hospital information systems, is also being developed and controlled by Gematik in a very transparent process.

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So, that is, manufacturers have had time to adjust to the changes and also to the fact that at least at the interface here things are required of

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Those who have the power, yes, and that's something not, that's nothing new.

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This also exists in many countries and this is how interoperability is established.

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I mean, we've seen it for many years now that it didn't work because no specifications had been made.

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I would like to give a small example here.

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More than 15 years ago, I brought the Leuk and Juckum system to Germany to Dimdi at that time, which is now BfArM.

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And no manufacturer, not a single one, has actually implemented these systems, even though they are extremely important for patient safety.

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Yes, you have to imagine that the units of measurement are not correct or are not interoperable, and that is actually the case today.

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So, nothing happens if it is not really demanded and perhaps tied to other things, yes, such as fines.

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Well, I would say that innovative software manufacturers know what's coming anyway, maybe even the big international ones, because they know it from other countries.

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The traditional German software manufacturers who don't want to change, they have a problem with that, right?

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And they will certainly shout very loudly now, I assume so.

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But on the one hand, we as H.

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7 also help here, so I'll say teach in the sense that we

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Going through these difficult times together with the software manufacturers and then things going better.

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And on the other hand, we also want to educate and show what the benefits are.

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And if you just look at this pandemic situation again and realize what was going on, we had no way to read the PCR tests from a laboratory information system.

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Now it's possible, because we have helped, from Nalsim, what damage this does and there is even

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many, many deaths because of it and I think a software manufacturer has an ethical duty to do these things that are coming now.

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Yes, that's a really great thought and I don't think we need to add it anymore.

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So that was a great conclusion, not to see interoperability as a burden, but actually as the only chance we have to digitally transform our healthcare system and how necessary that is,

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And you have now brought in the aspect of patient safety, we all know that.

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But it's also about safety, but of course it's also about performance, effectiveness and, last but not least, affordability, which will not be given if we don't go along with this transformation.

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Silva, that was a pleasure to be able to talk to you.

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Thank you very much for your time.

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With pleasure, Christian.