

DIGA – First-hand experiences

With Philipp Heimann, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

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

00:00:18 Speaker 1

A few weeks ago, we added the first digital health applications to the DiGA directory.

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and one of these manufacturers, Doctor Heimann, I have him here in the podcast today.

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The Ministry of Health and the DiGA regulation have now given us completely new opportunities here and so I would like to talk to Doctor Heimann about what hurdles he had to overcome, what tips he would give other manufacturers to overcome these hurdles well and how he perhaps also sees the further development of this whole DiGA market.

00:00:55 Speaker 1

Yes, Dr. Heimann, you are very welcome.

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Would it be possible for you to introduce yourself and your product very briefly?

00:01:01 Speaker 2

Yes, very much.

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Good morning, Professor Johner.

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My name is Philipp Heimann.

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I am the co-founder and CEO of Vivira and the Vivira app offers therapeutic training programs for pain in the back, knee and hip.

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And as you just said, we were recently added to the league directory of the B.F.A.M.

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Our Vivira program offers 4 exercises a day, which are explained and explained in great detail with audio, video and text and which are continuously adapted to their abilities through constant feedback from the patients, so that the patients always treat themselves therapeutically within the framework of their abilities and requirements.

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and thus enable better health care by closing certain gaps in care in addition to conventional therapies, such as drug therapy, physiotherapy or physical therapy.

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How do we do this in concrete terms when we follow the treatment guidelines, for example for non-specific back pain, knee osteoarthritis or hip osteoarthritis?

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or the Therapeutic Products Directive, these explicitly provide for movement therapy training in self-exercise.

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To ensure this, however, there were no really functioning programs in the past.

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That's why there is now Vivira.

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Vivira thus supports the movement therapy training component of the guidelines and guidelines and thus enables compliant health care.

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In addition, there is

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the reality of statutory health care, in which patients often have to wait several weeks for their first therapy appointment, then usually get 620 minutes, for example physiotherapy sessions, and then it ends.

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And with Vivira, not only can this long waiting time until the first appointment be bridged.

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The ongoing therapy can be supplemented in accordance with the guidelines and after completion of

the prescription,

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Secondary prevention should be actively pursued.

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And perhaps a very important last point, if people in rural regions have no access to therapists at all, then training with Vivira is often better than no therapy at all.

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Yes, that was already a passionate plea for digital health applications, which I am also happy to join.

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Because what you have described here

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these are advantages that are not only specific to their application, but that can also be transferred to many, many other digital health applications.

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Yes, there is really a very, very big congratulations that they have managed to do that, but probably also a joy that we in Germany can take on a pioneering role here.

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Yes, also thanks to our ministry, it must be said, which makes these new forms of care possible for us.

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But now I know,

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that this is not an easy path and that's why I wanted to ask you if you could perhaps briefly describe to the other manufacturers what were the hurdles that you all had to overcome so that people can appreciate what you have achieved.

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So the hurdles from the first idea until they were then included in the Diga directory, maybe on that occasion, what was particularly easy?

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Yes, first of all, we are really very happy that the D.V.G.

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and thus a suitable collective agreement basis for reimbursement for digital health applications.

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In the years before, we in SGB 5 were of course looking for suitable and by that I mean above all scalable ways into care, but we didn't really find them and so the announcement of the D.V.G.

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in the

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Summer 2019 already a huge ray of hope.

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But you will certainly remember that there were still very, very big and also quite threatening questions this summer and autumn.

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For example, will the DVG really come into force and when?

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Yes, when is the MDR coming?

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Are we all 2 A products then?

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Will there be any capacity at all at notified bodies?

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And

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And no one in the market could really answer these questions over a longer period of time.

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That was very exciting and a huge hurdle for us at the time.

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Yes, so now came the D.V.G.

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and the DiGA Regulation in fact.

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There wasn't just one M.D.R.

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Extension of the transitional period, but the M.D.R.

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Overall, it was postponed.

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and also the B.

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Farm was ready to go and we even found a notified body.

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Yes, so at first it all seemed almost too good to be true and so there were huge existential hurdles for us in 1.2.

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quarter of this year and exactly that, that was actually the one that made the trip we made there in 2019

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had to live through.

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And then, of course, the catalogue of requirements of the Digaf itself is also a hurdle, but in my opinion, a very constructive and good hurdle.

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Because in our opinion, of course, digital health applications only have a future if we achieve absolute top quality in all dimensions of these requirements, which I consider to be absolutely justified.

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For all the notified bodies and authorities and ministries that may be listening right now, they notice the effects of their actions.

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So on the one hand, what stress, what burden they create when they have things in the dark and on the other hand, how they can support manufacturers with clarity to go down these paths.

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And as Doctor Heimann has just pointed out, who is very happy to meet this requirement.

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Well, there is no discussion here about the fact that they are not justified.

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I thought I heard the opposite even here now, but we need clarity and everything that leads to ambiguity leads to unnecessary obstructions.

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And I think that should be avoided as much as possible in all the activities we have.

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What did you get from the side of the B.

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Farms as particularly helpful, but perhaps also something

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as disabled beyond what you have just reported.

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Yes, first of all, to briefly respond to your comment from just now, you are absolutely right, this ambiguity, this room for interpretation, which was sometimes given in texts, was incredibly difficult for us.

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And we have in the phase

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Consultants have to be hired, lawyers have to be hired, a wide variety of experts have been interviewed and have always received different answers from different directions.

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And that's why I can very much agree with the plea you have just made, for a clear, clear definition of the requirement.

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Yes, so now to your question, the cooperation with B.

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Farm.

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I might want to

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First of all, I would like to briefly say that I would like to thank the teams in the B.M.G., in the Health Innovation Hub, and of course also in the B.

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Farm, so I really appreciate it and think that they have done an absolute great job in all these months.

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Yes, the cooperation with these different teams was sometimes quite intensive,

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as a DiGA manufacturer was really fun and we felt at all times that this is about innovation, this is really about the future, this is about new beginnings in the healthcare system and that was a special moment and a special magic.

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And I would like to express my thanks to these teams, which I just mentioned.

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Yes, there was really hard work.

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and from the time when, of course, the B.F.RM portal was open and the D.G.A.F.

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was clear and the B.F.M.

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guideline, our full focus was on listing in the D.G.A.

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List, compliance with the D.G.A.F.

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Requirements.

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That was during the first Corona wave, we were all working from home, so it was all really a very, very intense time and the cooperation with the B.F.RM team was really excellent.

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We had

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We started our BfArM consultation very early on and came across an incredibly competent, well-informed team from the first impression.

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Totally competent, fast, friendly.

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So the whole process was constructive for us, yes, and above all it professionalized us as a company very much.

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Yes, we are a young company and the BfArM has already helped.

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to get back on a more solid footing.

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Yes, and that's absolutely how it should be.

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I also found the intensive cooperation within the umbrella association for digital health care, the S.V.D.G.V., very, very helpful during this time.

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There are absolutely great people in there and the work is very entrepreneurial, very collaborative between the different members of the association.

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And so to become a member there and actively participate, I can really recommend to every Diga manufacturer.

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I think I would be very, very happy about that, because I believe that authorities and ministries are not the ones who are overrun with praise.

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But I think we all agree that it was a great job they did, because they now had to pay attention to various aspects of their Scrutiny.

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There we have the topic

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Positive care effects, if on the other hand you look at topic I.

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T.

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Security, let's talk about both.

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What approach did you choose, probably also in consultation with the B.

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farm to prove the positive supply effects of your product.

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Before I go into the positive aspects of care, may I make a point regarding the B.

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Farm?

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I just remembered it when you were already formulating your question.

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There was

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A special challenge for us, we can also give good advice to other DiGA manufacturers who are still in the process.

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So, although the BfArM has always communicated very clearly that the DiGA manufacturers are responsible for the correctness of their information when applying, it was only after some time in the application process that it really became clear to us that the BfArM, for example, in the area of information security

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We would not be able to carry out our own examination of our data, yes, while the BfArM examined us in great detail in the area of positive care effect and also asked many questions.

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And that only became clear to us late, although the BfArM has actually always communicated this clearly.

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Yes, but that's how it is sometimes when you're in such a complex process.

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Yes, and today it is clear to me that as a DiGA manufacturer, I am in the application process

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In all areas of DiGaf where I am not quite sure whether I am compliant, that as a manufacturer I have the responsibility to organize audits by service providers myself in order to have my conformity confirmed again before I finally submit this application.

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And that it is not the task of the BfArM to verify my information again.

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That all went well for us, but at the time I wished I had understood it earlier and would like to give this as a tip to all DiGA manufacturers who are still in the application process and have not yet submitted their application.

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Yes, I think that's a very important addition that you have given us.

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Maybe also a little explanation for why there was also I.T.

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security issues.

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because there is just a lack of examination and the others have not checked it with the same care, accuracy or have not had it checked as they had just described, as they have done.

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If we come back to the question of the positive supply effects, I think this is one of the really big hurdles for many manufacturers, because now we come from the area of M.

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D.

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R.

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to a certain extent also out

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of this evaluation concept, which are also very specific to the individual products.

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How did you manage to prove it?

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Yes, so the evidence of the positive effects of care is very, very important to us.

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Yes, our entire future at Vivira and I think I am also speaking here and can also speak for other DIGA manufacturers, depends on us providing a positive benefit in healthcare.

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And we are now

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based on our already available retrospectively controlled study on pain reduction and, of course, on the basis of our evaluation concept for an R.C.T.

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Study that is already underway.

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And one point that is very, very important to me, especially in the context of the public discussions that we can currently follow in the media, is

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With this already available and the current study by Vivira, we are using the Vivira app to bring clinical evidence to an area, namely the field of physiotherapy, physiotherapy, exercise therapy, which is neither standardized nor verifiable in today's reality of care and in which there is therefore a lack of any evidence so far.

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And that's an important point, because what I'm trying to say is that the DiGAs are able to provide evidence in completely new areas, which is important, and I'm also not at all concerned about the positive supply effects of the DiGA manufacturers as a whole, because all the DiGA manufacturers I know are either already R.C.T.

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studies available

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or have them running.

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And I therefore hope that the discussion on this will become more and more constructive and positive.

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Because there is great potential here for improving health care at the highest level of clinical evidence.

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I think that is very, very important, what you have added here, because I believe that it will also make it clear to the listeners once again what double

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The challenge that all other DIGA manufacturers have to overcome, namely on the one hand to help improve health care with a new product class, namely digital products, and at the same time to define a state of the art, at the same time to provide evidence that competing processes have never provided before.

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And of course, these are already high hurdles that

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which are given to the manufacturers, but which, overall, and this is how I have just understood it, will contribute to the fact that we will then have exactly this evidence, against which other methods may then have to be measured again.

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If we look at the second major area that DIGA manufacturers have to address, in addition to the positive inheritance effects, we come to I.

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T.

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Security.

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What did you do to make the

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initially, but also to make the I.

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To ensure security on an ongoing basis.

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Because, as we have seen from 2 not so nice examples, there were problems.

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How do you do it better?

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What would you recommend to other DiGA manufacturers?

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So, of course, we do in Area I.

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T.

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Security very, very much and what I would definitely recommend to every other DiGA manufacturer is

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work with suitable service providers at an early stage and undergo early and regular pen tests and thus become sensitive to the topics in the area and the possibilities and necessities to address them.

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Not only do we regularly undergo pen tests, we also continuously monitor our system landscape very closely in all its dimensions, such as the dimension of the soups used.

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And so information security is an ongoing project for us, as it should be for everyone else.

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And the exact requirements for the information security of the DiGA are still being worked out in part by the authorities and are not yet clear.

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And that is also an important part of the work we do in this area.

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We are following this discussion very closely.

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and of course implement all requirements, as soon as they are clear, as quickly as possible.

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That is wonderful and I would also like to agree with the point you just mentioned, that sometimes there is not yet clarity everywhere.

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Yes, what is really to be done here now?

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On the one hand, we have this DiGA catalogue or the checklist points in the DiGA regulation, but nevertheless it often gives out doubtful things exactly or what else do I have to consider.

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Here might be a tip for the manufacturers.

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Here at the Institute, we have published the Guide to I.

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Security, which has exactly this goal, to compile all these standards, best practices that we also have internationally.

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And the notified bodies have adapted this guideline, so that now, I think, we have a relatively precise, precise list of verifiable requirements, which I do.

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Security and also data protection, these are actually another 2 aspects, as much as possible.

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They have already begun to

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first tips, the manufacturers or other manufacturers, what else would you have to recommend to them?

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What else would you say, should they perhaps do or perhaps not do it?

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Adding a DiGA to the directory is a complex undertaking and so I can advise the other DiGA manufacturers who are still in the process: Look for top service providers early on with whom you can achieve the

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discuss the GAF requirements and implement them hand in hand.

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Yes, don't save money in the wrong place.

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There are an incredible number of consultants in the market and in my experience there is a huge difference in quality between the very best and the second best.

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And yes, we have also tried some and had good and not so good experiences.

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but now we have a great network and a great team of service providers who support us and have also worked intensively and very well with the Jona Institute, for example.

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Yes, that would be my first tip: Seek support from the right service providers at an early stage.

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And second tip, at least as important, network with other DIGA manufacturers.

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Yes, for example through the umbrella association for digital health care, the

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Diga manufacturers are all asking themselves the same questions and overcoming very similar challenges, and the exchange, which is very, very open and collaborative between the manufacturers, is priceless.

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Yes, and that would be my second very important tip.

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What can not only the manufacturers, but perhaps also the ecosystem around it, so I don't know, authorities, notified bodies, maybe also us at the Jona Institute, health insurance companies, so all those who are now

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who are involved as stakeholders in the broader sense.

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What can we all do to further promote the use of secure, high-performance DiGAs?

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Yes, this is a mega important question and I actually have 3 very, very specific requests to all market participants who have an interest in the success of the DiGA.

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So first, I'll summarize it first.

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First of all,

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clear communication, please continue, yes, continue to communicate so well and so clearly in the direction of DiGA manufacturers what the requirements are.

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My second point is that we need to inform the doctors throughout Germany.

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And third point, I'll go into the details in a moment, we need a fully digital activation code process for the DiGA without media discontinuity.

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Now maybe to go into the 3 points a little more in detail.

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A request to the B.

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Farm and to the notified bodies: Continue to communicate the requirements to us DIGA manufacturers so clearly that we can continue to understand, know and meet the existing and all future requirements.

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You have already done us a huge service in the last few months.

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But the topic goes on and on and

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DEFAM guide, and so on and so forth.

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These are all very, very helpful, great means.

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Please keep it up, yes.

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My second point, very important, is the information provided to doctors in Germany.

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We know from numerous representative surveys that doctors in Germany are very, very open to including digital elements in their care.

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Yes, the openness is great and it is there.

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The information and knowledge level of physicians about DiGA

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but it is still vanishingly small.

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And if no one knows that DiGA exists and no one knows when and how to prescribe them, then of course there will be no prescriptions and then there will be no positive care effects.

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Yes, that means that the medical profession in Germany must be informed nationwide.

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In this respect, if you are a platform where you can inform doctors, do so.

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Spread the good news to the medical profession.

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We have to communicate to the outside world, we have to inform the doctors, we have to take the doctors with us so that everything doesn't get stuck halfway.

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And the third point, also a very, very important point, we can already see this in the first weeks since the listing.

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There is this currently still terribly cumbersome process of how the insured then use their prescription to access the DiGA activation code from their insurance company

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and then use it to unlock the DiGA.

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This process should be possible as quickly as possible fully digitally and without media disruption, because otherwise we may generate many DiGA prescriptions in Germany, but this will not translate into actually activated DiGAs and thus the positive supply effect will of course fail to materialize and in this respect

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I know that this is not a new topic, but we should really all give 8 that this digitization of the activation process is implemented as quickly as possible.

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Thank you very much for this very valuable plea.

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So, I can promise that we here at the John Institute will do everything we can to get this message out there.

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I know that you are doing the same in the umbrella association for the digital digital health industry.

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So I think we all have a common big goal and I am really very, very proud and happy with you to have had someone on the podcast today who is helping to really bring this new form of care to the market.

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It is the task for all of us to support this.

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Dr.

00:26:24 Speaker 1

Heimann, thank you very much for being there.

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Thank you very much too.