Resolving trade disputes involving medical devices

With Dr. Siegfried Raith, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights.

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

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After more than a year of the pandemic, the lights are increasingly appearing at the end of the tunnel.

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On the one hand, this certainly includes the

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Vaccination rate, which is going up significantly, but on the other hand also the rapid tests, with which we can ensure that we are not infectious and that we can use before we meet with other people.

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Of course, this presupposes that these rapid tests are also on the market and have the appropriate approval.

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We at the Jona Institute have also made a contribution to this, among other things in the field of usability studies and so that you know,

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How to do something like this and how to proceed with it, I had invited two of my colleagues.

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Once Sophia Schweppe and then Dr.

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Nils Becker, who tell us what they did there.

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Sophia Nils, can you introduce yourselves very briefly, so that our listeners know who they have in the podcast.

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Yes, thank you Christian.

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Just like I said, my name is Sophia Schweppe.

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I've been at the Jona Institute for almost two years, now in the area of usability.

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I previously studied psychology, specialized in the field of human factors and thus also came across the usability area and conduct usability studies for the Jonah Institute, but I also accompany our customers in the entire usability engineering process and also help and create the files in accordance with standards.

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You think of.

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Yes, I studied molecular neurobiology and then worked for an IVD manufacturer in the field of regulatory affairs and quality management, where I also gained my first experience with usability tests.

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I enjoyed it so much that I wanted to focus on the topic of usability and fortunately I have been able to do so at the Jona Institute for almost more than 3 years now.

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And my tasks are actually the same as Sophia's.

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So, we advise customers on all usability topics.

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This starts with the implementation of usability engineering processes, with the documentation and creation of the usability file for the technical documentation.

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And then, of course, there is also a lot of planning, carrying out and evaluating usability evaluations, such as usability tests.

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And I think in the 3 years since I've been here, we've also done more than 3 dozen usability tests as a team.

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But we also create.

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Fuse, i.e. instructions for use and review them too.

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Yes, and now the rapid tests came to you.

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How would you assess that?

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What were the big differences between all the products you have evaluated so far and now the rapid tests, which are also a separate product class.

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Yes, it all started with the fact that Jens Spahn or the B.

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Farm announced at the end of January, beginning of February that there would be special approval for the Corona rapid tests for laypeople

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users.

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And that got the ball rolling, so that we could hardly save ourselves from customer inquiries.

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And everyone wanted to bring their product to market as quickly as possible.

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And yes, according to the BfArM, this required proof of safe usability, which was to be provided by the usability test.

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The difference here was that 100 participants were required for these tests.

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And this has presented us and we also the manufacturers or importers with enormous challenges.

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Well, you have to think of it this way: For regular admissions, tests with 5 to 20 participants per user group are sufficient and yes, we usually have a few weeks lead time for planning and recruitment.

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And it is usually the case that we then conduct the usability tests with a moderator and a minute-taker.

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And this time we were faced with completely different conditions.

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So, in order to be able to fulfill the wishes of our customers in the best possible way, we then had to

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sometimes prepare a test with 100 participants in one week and carry it out and evaluate it within another week.

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So a completely different time management was required here.

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Yes, and that was only possible through the commitment or full commitment and cooperation of our entire usability team.

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So we have concentrated fully on the Corona rapid test studies and

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Yes, we then worked very closely with the manufacturers, but also with the importers, because the Corona tests, which were already approved for professional use, but so you can also look at the I.F.U.

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They were then directed more as specialist personnel and were then not quite as usable in that sense, apart from only a few unfortunate translations and that is simply not for the layman users

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would have been practicable.

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And then we tried to redesign the Ifos with the customers in the shortest possible time in order to avoid the occurrence of use errors in the tests as much as possible in advance.

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I would say that these were the biggest differences and challenges we had to create for ourselves.

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Yes, thank you very much.

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Now, you've already hinted a bit at where the sticking points were, but maybe let's take a step back.

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what exactly have you done now, how have you proceeded to evaluate these rapid tests?

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Nils, could you give us an insight?

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Yes, of course.

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So during the planning, the first thing to do was to whip the instructions for use into shape so that they are really understandable even for laymen.

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We had to recruit 100 participants within a very short time and we had to make sure that we recruited a cross-section of society.

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This means finding participants from all age groups and from all levels of education and also their dates

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within 3 to 4 days.

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In the run-up to usability tests, it is also important to determine which acceptance criteria must be met by the participants when carrying out the tests so that the application or user interface can be considered secure.

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In the tests, the moderator or the note-taker then observes compliance with these acceptance criteria and also records them at the same time.

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If an acceptance criterion is not met,

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this is considered a use error and the cause of this use error must be analysed and a risk assessment of the possible consequences must be carried out.

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The next challenge was to test the 100 participants in a few days, assuming that a team of moderator and note-taker might have 10 sessions per day.

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would have taken 10 days, which would definitely have taken too long for our customers.

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So it was clear that we couldn't run the sessions sequentially as usual, but had to run them with several moderators in parallel.

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The tests, since the tests were rather simple, the moderator could also take on the role of the minute-taker at the same time and so with a few overtime hours we were able to test 100 participants in just 3 days.

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Otherwise, these usability tests also ran like any other 62 366 struck 1 compliant usability test.

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Yes, that was the real feat of strength that you did there.

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Yes, and obviously only through parallelization.

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I mean, 3 days, that's sensational, of course.

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I think many would be happy if the usual medical devices were in place in 3 weeks or if these evaluations could be carried out.

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Yes, but let's stay with this keyword 62 366 for a very short

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Dash 1.

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You have now reported a bit about the organization, so maybe we will now dive a little deeper into the process of these usability tests.

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So, how did that happen and how do you get the norm conformity there?

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Yes, I'm happy to jump in.

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So just like I said, we also stuck to 62 366 dash 1 in the usability tests.

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This is the standard that manufacturers should adhere to in order to achieve usability engineering.

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Process including usability test, follow-up of the technology.

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And based on the Corona rapid tests now, I can also tear it down.

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In this case, the participants have now received the kids from us in the same condition as it is intended for placing them on the market.

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That is, in the original packaging with instructions for use or quick start guides.

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And yes, then the participants were given the tasks of us to carry out a corona test to check whether they were infected,

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so speak as they would have done at home.

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And in doing so, we then observed the participants and documented the implementation on the basis of previously established acceptance criteria.

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It is very important in these summative tests that the moderator or other persons do not influence or support the participant in any way.

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So the participant must, as in a real situation, take the test himself.

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to carry out outside help.

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And the result now with the Corona rapid tests was that the results usually appear after 10 to 15 minutes 10 to 15 minutes.

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And we didn't wait for this time in these studies, but we presented the results to the participants in pic-

tures and asked for their interpretation.

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And we showed pictures of all possible results, i.e. positive, negative and invalid results.

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Yes, and if use errors occurred during the test, we asked the participants about the cause at the end of each session and in the report we then described the cause of each individual use error and carried out a risk analysis.

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And that's how we would normally do it for all other medical devices.

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Well, we actually proceeded exactly in accordance with the standards.

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Yes, now of course everyone is very interested, what came out of it.

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So, you are sure you were satisfied with the results that were achieved.

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Yes, I did a calculation and about 25% of the participants did not meet all acceptance criteria, i.e. made at least one use error.

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For some use errors, this is not so dramatic at first, because it would rarely be accompanied by a risk.

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For example, many participants did not check the expiration date before taking the test.

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To be honest, this is also something that would probably rarely happen in reality and

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and with tests that you buy new, it would probably not pose a risk.

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It becomes more critical if the results cannot be interpreted correctly, for example that an invalid result is interpreted as a negative result or that too little saliva is emitted in spit tests, which could, could, lead to false negative results.

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We also observed this, which was a bit unsatisfactory, because many of these use errors could have been avoided if a little more work had been put into a really clear and understandable

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instruction manual or quick guide.

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In some cases, we pointed out corresponding deficiencies in advance and made suggestions for improvement, but these were not always implemented by the customers due to time constraints.

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The consequence was simply that the customers then had to follow the improvement after the usability test.

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Mhm, so again important, a formative evaluation.

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because your failed or partially failed has improved more and thus you then became formative by definition, only to have to do it again.

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K., but 25% is of course really a lot, if you extrapolate how many millions of tests are currently being carried out, then that's a significant amount.

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Yes, now you described earlier, it's kind of funny, so they do Corona tests, so you didn't wait for the results.

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Or to put it another way, you only let them do the test, so to speak, after they were already there before you carried out the test.

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How did you manage to do all this in a corona-compliant way?

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Well, you somehow have this exaggerated or very frequently used term of the hygiene concept.

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So, what do you have in this one?

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context so that you are safe, but that the participants are also safe.

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Yes, we had already thought about this in the team relatively at the beginning of the pandemic, because it was clear to us that this would be with us for a longer time now and we still wanted to make it possible for medical devices to come onto the market with the help of usability tests.

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And that's why, I think, we had already worked out our hygiene concept last year in April and also carried out studies based on this concept in advance.

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It is very important that we all disinfect our hands, and all participants regularly receive hand disinfection from us before they come to our office or labs.

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Only a maximum of 2 people may be in a room at any one time.

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We always try to keep the distance of at least 2 meters, and even in winter we have the windows open and ventilated them.

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We all have FFP2 masks and also provide them to our participants.

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Now with the Corona rapid tests, we always had a plexiglass separation between moderator and test subject and, of course, the FFP2 mask of the person to be tested was briefly removed during the sampling and we then tried to solve it that way.

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The windows were open and that was really a very short period of time and.

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We had the FFP 2 mask on the whole time.

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Yes, then of course it is very important that we do not have any participants in the study who show symptoms.

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They had to confirm this beforehand in an in with the help of a form.

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We have contact forms from the people and we disinfect all surfaces and all objects after each session and this was really meticulously taken care of.

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Mhm, that's a lot.

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You've already had a

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article on how he does it.

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So I'll link it in the show notes so that all those who want to understand exactly what this hygiene concept looks like can read through it.

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Yes, maybe let's leave the area of Corona rapid tests.

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I said that it is relatively similar to these other products, but if you were to ask very briefly, what are these products that you usually take a closer look at?

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And these are actually all kinds of medical devices and I.V.D.s that exist.

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It starts with C.

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Arches of X-ray machines, so really large devices too, or heart pumps, a lot of software, of course.

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For example, we recently tested dermatology software, and there are also a lot of apps, such as apps that can be used to create nutrition plans for hospitals, individually for patients, but also blood glucose meters, syringes

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and everything you can ultimately imagine.

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Mhm, so the whole range of M.A.C.

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products and E.V.D.s.

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I, you said earlier that you smuggled through 100 people per Corona rapid tester, you almost have to say.

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Where did you do that?

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Yes, what was the equipment with which you operated.

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So in this case, our lab in Frankfurt simply didn‘t have the capacity to test so many people at the same time.

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And that‘s why we worked with market research laboratories and institutes, sometimes in parallel with different ones.

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And they had large rooms, where of course there was also a mirror glass separation.

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Camera system, with camera systems it was aligned and they could actually adapt it to our needs.

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So everything we needed was provided or of course we took our equipment with us.

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But you also have your own labs, you may have mentioned that.

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That‘s exactly right, so normally we do the studies in our laboratory in Frankfurt and we also work internationally.

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So we work with partner laboratories in the U.S.A.

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and yes,

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only now, I think last year, also with a simulation lab from a hospital, where you can really let off steam if you have to have a very special setting.

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And exactly, but usually in Frankfurt in our own lab.

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Yes, that means you can help with the planning and implementation of usability evaluation, formative and summative.

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Nils, you said earlier that you also help with the creation and improvement of the

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Instructions for use, what I forgot, where you like to be there.

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We actually like to be involved at the very beginning of development, where we really get to the point where we can help design the user interface or at least give ideas.

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This is also very important for the formative evaluation process, where you can then test your prototypes on the

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test bench to see where are the strengths, where are the weaknesses and, of course, always the very important question, can the product be used so safely?

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And thus achieves that mistakes can be found early, as you showed earlier or as you have shown, and thus expensive rework.

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Yes, I think all those who want to have their products optimized for usability, who want to check it, from the product to the instructions for use, they can turn to you.

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We link your contact details below in the show notes.

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And all that remains for me to do is to thank you very much.

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Thank you too, Christian.

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Thank you very much, too.