Johner Institute

Fast international approval thanks to usability

With Dr. Philipp Schleer, 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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Most companies have managed the changeover to the MDR or are perhaps still in the middle of it and know what hurdles are.

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So, examples of these 3 hurdles that we often see, and also 3 innovations of the MDR and IVDR analogously, are the clinical evaluation or the requirements for clinical data, which are simply much higher.

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It is the area of traceability, i.e. post-market is part of it, but also the whole topic of UDI and the topic of usability, where the

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and I.

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V., who has now become a bit more granular about what is required.

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And that's exactly why we're taking a closer look at this area of usability today.

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And I once invited Philipp Schlayer, an absolute expert on this topic, who also works for us, but who now introduces himself best and also explains what exactly he does with us.

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Yes, good day Christian, thank you very much for the invitation.

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I am also welcome to simply report briefly about myself.

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I have a PhD in mechanical engineering with a special focus on medical technology.

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The whole thing developed back then, so during my studies I discovered the field of medical technology for myself and was really enthusiastic about it from the beginning and then just took a look at the various areas.

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This was both textile technology and biomechanics.

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and also mechatronics.

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And in the end, that motivated me to do my doctorate in this field as well and then I studied at R.

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I did a doctorate in the field of surgical robotics.

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In particular, I was concerned with how to design assistance systems for surgical robots.

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You can imagine it a bit like driving assistance systems in cars, only for surgical robots.

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That means, of course, I also had to worry a lot about it

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deal with communication between humans and machines.

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And that's when I really discovered my passion for the topic and, on the one hand, of course, I implemented this function, but also did scientific studies on whether what we really implemented really helps users in the end and whether they really get better with it.

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And I've done a lot of studies on that.

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And a second focus at our chair was the approval of medical devices and it was exactly the combination that naturally brought me to the Johner Institute, where I am now dealing with exactly the two areas, i.e. both usability and approval, and on the one hand I do usability seminars that I hold at manufacturers on site, or even an official usability seminar, where you can learn in practice how the whole thing really looks like and is implemented in practice.

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but I also introduce such processes to companies or simply support the entire usability process during development or also carry out formative studies, i.e. studies accompanying development, or summative studies.

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And this can be in our laboratory in Germany on the one hand or elsewhere in the world, on the other hand in the U.S.A.

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or in the rest of Europe, i.e. in Spain, Sweden or any other

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Country in Europe.

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And in the future, China will also be particularly interesting here, because there are now also new requirements that studies must also be carried out there.

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Yes, cool, so you've already introduced the topic with it and actually suggested the next questions.

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But maybe half a step back, why do you need these usability studies and what would be a motivation to carry them out internationally?

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So you have a lot of experience, you also reach a lot through the world,

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what is the reason why manufacturers also commission you or us to carry out studies internationally?

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Yes, so basically the usability studies or the summative study, which many people are familiar with, is also part of the validation of medical devices.

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This means that it must be proven that the product I have now developed can ultimately be used safely by the intended users in the intended application environment.

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This means that you have to take a look in advance at what risks are associated with the application and, above all, what would be possible damage if a user here makes some mistake on the device or enters a wrong input or maybe not at all.

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And if such damage is irreversible on the one hand or could lead to medical intervention, then I as the manufacturer have to provide objective proof that my user interface, i.e.

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my product can be used safely and it is precisely for such objective proof that summative studies are often done.

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Now you have mentioned 2 motivations, namely the topic of patient safety.

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So you want to make sure that there is no damage due to a lack of usability.

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You helped lead the regulation as a motivator.

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But now back to the question, why international?

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So we have differences that a product is safer in one country than in another.

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Exactly, so for the motivation to do this internationally, there are different, let's say, motivations among the manufacturers.

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On the one hand, this can be regulation, as I have just mentioned, that is, special countries such as the F.D.A.

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or China have very special requirements.

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The F.D.A.

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would like summative studies with U.S.

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American citizens.

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This means that they often have to be carried out there on site in America and China

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is planning or has just recently issued a guidance, where they also stipulate that from the 8.

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October of this year insofar as you have a so-called High Use Risk Device, that studies in China may also be necessary if I do not have sufficient data from the Chinese market of a comparable product.

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So then it's the regulatory reason to do the studies in other countries.

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Now you've spoken of

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Spain, Sweden and many other countries.

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So companies now choose Sweden or Spain, to name these two examples, to simply have a country representative in Europe, or do they go to several countries in Europe and in any case the question is, what motivates them to choose a certain or several certain countries?

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Exactly, so yes, we now had the regulatory requirements.

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The second is often the primary sales market.

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of the products.

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So even if I want to test a product in Europe, I'm usually relatively free in which country I test it.

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But even within Europe, user groups or the distribution of roles at hospitals differ.

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That is, what a nurse or a paramedic might do here in Germany.

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is perhaps also distributed quite differently in Spain, that a paramedic may be allowed to take on tasks that he is not allowed to take on here in Germany and vice versa.

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This means that if my primary sales market for my product is not Germany at all, but 1 of the other European countries, it makes sense to use this study to test in the respective country and then get direct feedback from the market that is most important and yes, then

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quasi direct hands-on experience together.

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K., that is, the decision is actually based on the specific user groups, of which you just said that they can differ in the countries and there you will naturally or obviously, as you have just described, go to the country where you will expect a lot of sales, so because then this user group is particularly relevant.

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Are there any other reasons that a manufacturer then says, I go into different

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do my studies in different countries at the same time or in addition.

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Yes, I mean, on the one hand it's the ways of working, the distribution of roles, but there are still much more fundamental cultural differences.

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So, if I now take a look at the color distribution, for example,

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what the color red means, for example, in Germany or in European countries, is rather something that goes in the direction of danger.

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But when I go in the direction of Eastern cultures, red is often more associated with happiness and celebration and joy, which of course can also result in a completely different evaluation of the user interface.

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Or even a color like white, for example, which here stands for purity, is more associated with mourning and death in Eastern cultures, which of course

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could then result in contradictory interpretations.

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And that's exactly what I don't want for my product, but I want my product to be well perceived by users and of course I get that best from the people who actually use it in the end.

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Absolutely.

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So what we just learned were the different reasons to use usability studies in

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different markets in different countries, now completely independent of whether you do it in one or more countries in parallel and at the same time.

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If we could now briefly tap into your experience, how do these studies or the approaches differ from the regulations is of course clear, but perhaps how they are carried out, how people react,

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What are your practical experiences that you have gained in the different countries so far?

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What are the particular difficulties?

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Yes, a common difficulty, but one that is probably known to everyone, is customs.

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This means that you always have to take this into account when you ship the products to the different countries.

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In some cases, the countries also have local requirements and you always have to look, because of the distribution of roles, of which we already had it earlier,

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that you really recruit the right users in the respective countries and also make sure that you are well ac-

quainted with it yourself with your user group in the countries beforehand or that you

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at least otherwise information from other places and sometimes depending on the country you don't speak your own language either.

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That means you have to think about whether you want to work with simultaneous translators and then think about the setup, how to set up the whole thing.

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Mhm, and you just touched on the topic of recruiting, what are the things you've already experienced or maybe things you should pay attention to?

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Yes, so in recruiting, as I said,

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It is very important that you are in close contact with the recruiters, who really take over the recruitment in the end, also during the entire recruitment process, because here and there it is perhaps not so well known how the roles are distributed in another country and that you are really in close exchange with the recruiters there, during the entire recruitment process, which starts several weeks before the study,

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and also specifically perhaps already has individual questions in the screening questionnaires to find out whether the users I invite are really performing the tasks that I ultimately want to test with them in the study.

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Not that you will experience unpleasant surprises during the study.

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Who have never done that before.

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Yes, so you basically called them recruiting, you mentioned customs.

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I also remember topics such as compliance, which are sometimes regulated differently.

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Because they are also paid for participating with it.

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I think we also have different requirements, difficulties that you have.

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If you go from the difficulties to the solutions, so what are you doing to overcome this challenge, when are points reached where you would say, yes, maybe you will get help before you try it yourself?

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So

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I mean, when it comes to customs, which we had first, it's of course just important to start really early and send the products on their way really early, because in a wide variety of countries it always leads to products getting stuck in customs.

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It doesn't have to be that there are really problems with the import, but because there are simply questions and then you should really plan enough time.

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With regard to the local requirements, you had already mentioned that there could be problems here and there because of the incentives.

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And there is in the U.S.A.

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there is, for example, the Sunshine Act, which could be mentioned, which you should definitely deal with beforehand if you want to conduct studies there.

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As far as the user groups are concerned, we had just said a bit more precisely that you really have to look at each other there and should be in close contact with the recruiters to see whether the participants you invite are really the ones you need in the study.

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Otherwise, with regard to the planning of the last study or the implementation of the study, you should of course translate all materials into the respective national language in advance.

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And here you should pay particular attention to the fact that you really use the right medical terms, if necessary also local expressions, which may simply be so, so, let's say, clinical jargon, which are then used in the individual countries.

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where it is best to work with translators who may also be familiar with the clinical context.

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Of course, you should also translate your product so that users can understand it in the end.

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And if I'm really testing in a country where I have to use simultaneous translation because I don't speak the language myself, it's always advisable to really take a native speaker as a moderator and just use simultaneous translation, because that

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It's just a lot easier for participants to give feedback when they can give feedback in their own language and otherwise you just lose a lot of information if you don't do it.

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And here you should also make sure that you don't use too many simultaneous translators, preferably only one about a study, because then he is also familiar with the terms.

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Perhaps you should also send terms to the translator in advance.

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that may be very product-specific or are medical terms.

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Maybe you also have your own instruction manual in several languages, that you can perhaps also make it available to the simultaneous translator, that he can simply familiarize himself with all the terms beforehand in order to be able to translate better.

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When the study is finally due, then it is also very important that the

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translator that he should really translate as well.

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There is also the English term interpreter and depending on the translator, he takes this term interpreter very literally and interprets more.

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But in usability, we ultimately want to evaluate as usability specialists how the user is to evaluate a certain situation with the user and not let it be done via the translator.

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In addition, you should also plan enough time for the sessions, as it always takes more time if you have any questions, perhaps from the respective experts, then from the company, because you then have to translate these questions from German or English back into the national language and the answers have to be translated back.

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And depending on the language, even the duration can depend on the study.

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Depending on which countries you may have already traveled to, you may have already noticed that some languages are much faster than others.

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This means that this should also be included in the calculation of the studies or test times.

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These are all things that require a lot of experience, as I am just realizing, which not everyone necessarily has when companies

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also come to this conclusion and want to be helped.

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What should you pay attention to when choosing your service provider?

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Yes, when choosing a laboratory, you should definitely make sure that the laboratory is also able to recruit real medical staff, because this is also different from now, for example, with marketing or market research institutes, which then rather, let's say, recruit general lay users.

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And you should also

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make sure that it is possible to recruit from different institutions, that the participants are not only invited by one hospital in the city, because there are also differences between the individual hospitals in the individual countries and that one does not run the risk of really developing for only one hospital.

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In addition, you should also make sure that

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they also have suitable simultaneous translators who are also familiar with the medical field.

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Because such a simultaneous translation in the medical field is much more demanding than one that is not in the medical field, where you simply have to be more familiar with the technical terms.

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Yes, otherwise the laboratory should also have knowledge of the medical device context in general, because there are also regulatory requirements on how such studies are to be carried out or should be conducted.

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And

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there must also be such a basic expertise in any case, so that it can be involved in the planning.

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So, these are 2 dimensions that can be used to narrow down the choice of service provider.

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Namely, one we need this, this medical, this medical knowledge and the other is the legal, yes, dimension.

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Through the standards, it comes together to a certain extent.

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So a 62 366 stroke 1 for example.

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You talked about China NMPA requirement earlier, you talked about Human Factors requirement.

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So of course a laboratory has to bring all that with it.

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This means that the usual market research usability study laboratories are certainly not the right place to go.

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Of course, your team does it too or they do it all day, you don't do anything else.

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How do people get to you, what is the best way to get in touch with you?

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Exactly, so

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Of course, you are also welcome to contact us.

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We also have partner laboratories in the different countries, i.e. both in the U.S.A.

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as well as in different countries in Europe, be it the U.K., Spain, Sweden, Italy, we can also support everywhere and in the future also in China, if studies are pending in China.

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And we even have the opportunity to act as the organizer of a larger study and

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in order to make it possible to carry out the same study in several countries, in order to then also see to what extent the differences between the users are in the individual studies and so then to really develop and adapt one's product specifically for the individual countries, so that it can then really be used safely by everyone.

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So that there is no duplication of work, I think that's a very important aspect.

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In other words, that you don't just do work that you can do in one fell swoop.

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just do it well.

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I think that's 1, where you have a look at it.

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A second thing, as I know from another conversation with you, is to make sure that the probability that these usability studies will lead to success is also sufficiently high, namely through formative evaluations, which you also take part in, because such a study, which I think you have now also noticed well in the interview, is a time-consuming thing.

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The more countries, the more participants there are, the more expensive this thing becomes, more complex and expensive it becomes.

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And

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and of course you want to minimize any risk and that's exactly what you do with the formative evaluations.

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Philipp, thank you very much, that was again a lot of insights that you gave us here and I think that's exactly what makes it so special.

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One thing is what is in norms, what is in legal texts, and the other is the practice that you then see.

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I still remember a usability study, where the recruiter then drew my attention to it,

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that some participants see it more as a business model to participate in such studies and that there is an important filter to sort out exactly that.

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So you don't have that, as you said several times earlier, not the representative users in the representative context of use, and so of course the results are not so valuable.

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Philipp, thank you very much.

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Yes, thank you, Christian.