Johner Institute

Get to market faster with Phantoms!

With Dr. Paul Jahnke, 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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From one of the last podcasts, you know how much German manufacturers in particular have lost market share in the German market.

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This means that they have dramatically lost competitiveness.

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And

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this raises the question, what can we do to regain this competitiveness?

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And one way to achieve this is to achieve a faster time-to-market.

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And for this, in turn, it is very helpful if you can use phantoms, for example, to speed up certain steps in development and approval.

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And we had already talked about the topic of simulation during the Institute Day and another podcast.

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Today we dive more into this area of phantoms.

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so I asked Dr.

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Janke, who manufactures such phantoms exactly in his company.

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And in the podcast, we now want to shed light on how medical devices can help manufacturers shorten this time to market.

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But before we start, Mr. Janke, if you briefly introduce yourself, so that we can get to know and assess you all.

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Yes, thank you very much for the introductory words.

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I am a radio volunteer at the Charité and lead a working group there.

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And in this context, I have been researching for about ten years

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Methods for the evaluation of radiological image data quality.

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In the first few years, the focus was primarily on data quality for classic radiological diagnostics, i.e. by humans, and in recent years the focus has clearly shifted towards data quality and reliability of AI diagnostics in radiology.

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As a central element of our work, we have developed technologies to produce highly realistic reference test specimens for imaging procedures, which are also called phantoms in radiology

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By highly realistic phantoms, we essentially mean phantoms that accurately reproduce the characteristics of human tissue, anatomy and pathology.

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This work then resulted in the Phantom X, which manufactures and sells such phantoms, but is also active in the provision and evaluation of radiological image data and in the automation of quality analyses and, in particular, in the quality assurance of diagnostic AI applications.

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So you have already learned, so this also serves quality assurance, if we now surf a little closer, now of course there are different forms of imaging in the radiological field, could you give us an overview of the imaging methods for which you produce these phantoms and perhaps also how they work?

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Yes, we use a manufacturing process in which we extend image data on the computer, which in the end can

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all possible image data, including real image data, for example CT data sets of patients.

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At the end of the day, you can think of what we do in a similar way to a printout to a high-performance printer that you plug into your computer.

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In a similar way, we then print phantoms based on this image data, which transfer the information from the image data set to the phantom on the computer without loss.

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We actually use printing technology for this and print

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the information from the images on the computer first with special materials on the carrier material.

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In the case of CT and X-ray imaging, these are materials that interact with X-rays.

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In the case of MRI imaging, these are paramagnetic materials and in the second production step, these printed carrier layers are then merged into stable objects that increase the shape size and, in the case of CT, radiation attenuation properties, for example.

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that are stored in the original input record.

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This means that afterwards you have real phantoms in mind, i.e. bodies that behave magnetically or in terms of X-ray density in the same way as a patient from whose data they were obtained, or possibly also from a simulated patient for whom he has generated the corresponding images.

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That's exactly how you say it and you already have

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This gives us a relatively high degree of flexibility to produce phantoms that realistically reproduce the clinical characteristics of patients for specific applications, and we also have the possibility of optimally designing phantoms and, for example, combining certain pathologies in one phantom in order to simplify quality assurance or validation work at the end of the day.

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So I think that's exactly what you will now

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because most of our listeners are not operators, i.e. hospitals, which would need this for quality assurance in their hospitals, but most of our listeners are medical device manufacturers.

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That means we should briefly look at how these phantoms help with development, approval and perhaps later also with post-market surveillance.

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Can you give us an insight into what you see as the benefit of your phantoms, especially for manufacturers?

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So far, we have been in the world in which

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Evaluations of imaging systems or software applications can essentially take place in two overarching ways.

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On the one hand, there are phantoms that have the advantage that they are readily available, that they can be exposed to unlimited radiation, that they provide reproducible examination conditions and, above all, that only provide a known basic truth with which one can compare whether the result is compatible with the

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expected result.

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On the other hand, there are patients who mirror real clinical imaging but do not have exactly the advantages of phantoms, i.e. they are poorly available, cannot be exposed to unlimited radiation or contrast agents, provide little reproducibility and usually have no knowledge of the untruth.

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What we do is ultimately bring the best of both worlds together by combining the advantages of phantoms

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with the benefits of patients.

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And this is becoming more and more relevant because the systems we use and develop today are becoming increasingly complex and there is an increasing need to ensure that the systems for their clinical purpose are accurate and reliable.

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So I'll try to rephrase that so that you can check if I really understood it.

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So in development, for example, you see the advantage in

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for example, if you

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AI algorithms can train, ensure, on the basis of this very ground truth that you have imprinted with it, whether the algorithm can actually detect, for example, some lesion or a mass, a cancer.

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So you have reference images, so to speak, with which you can check the performance, number one.

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And number two, you also see the possibility that we can use it to evaluate patient populations, yes, clinically that we would otherwise be able to

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or do not evaluate them in sufficient numbers, or where it would perhaps even be unethical to drive the study population so high, so to speak, and then actually have certain borderline cases in the population.

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So I have now understood these as two concrete advantages.

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Am I right about that?

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That's exactly how it is.

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At the moment, when you develop a product,

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at a certain point in time, they often have to go to an examination on patients, and that is of course subject to restrictions.

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On the one hand, it is time-consuming, expensive, time-consuming, and on the other hand, it is accompanied by the restrictions associated with examining patients and

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We ultimately solve these problems with the phantoms that we provide, and on top of that, we can deliver things, just as you mentioned, that are not possible at all in patients, for example, to generate very broad data, across different settings, on CT systems, for example, different doses, the design methods,

etc., which would never be possible in patients entirely.

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Okay, I have now added a third advantage, which is of course very important and with which I had started the introduction, namely a faster time-to-market.

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So it's not about us getting patients who we wouldn't otherwise be able to get hold of so easily.

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It's not just about making it really verifiable what the performance data of the corresponding products are, but all this can also be done even faster, thus helping us to develop faster, hopefully also to approve it faster.

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so perhaps also a look at the area after placing on the market, i.e. the post-market surveillance phase, where I see that if, for example, we had self-learning or continuing learning AI algorithms, we can always ensure that quality markers are still achieved, even if this algorithm changes.

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Do you see it that way too or do you perhaps see other advantages in the post-market phase?

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Absolutely.

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Is

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Especially with regard to AI, it is currently the case that we can use AI as a supplementary tool, which means that we are allowed to use AI, but in the end there still has to be a diagnosis by radiologists.

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What are big unresolved issues related to AI are questions of transparency and exactly what they mentioned, postmarite surveillance, so how do I make sure

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that a particular application that has been trained in a setting on a limited dataset will work reliably in my local setting, and that it will do so permanently.

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These are questions that users ask themselves, but they are also questions that play a major role for the developers and manufacturers of such AI solutions.

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This is based on the fact that it is well known that AI can decrease in performance over time, that AI applications that were developed in one setting, as already mentioned, may not be able to work in another

setting.

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work well and that it is also well known that there are currently problems to objectively evaluate the extent to which such effects are the case and to track such effects.

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And our phantoms ultimately provide a standardized reference for carrying out such evaluations objectively, reproducibly and also prospectively.

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Now we've talked a lot about the advantages

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Of course, we can only use them if our regulatory authorities and notified bodies also go along with it.

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Therefore, the question of how this is to be assessed from a regulatory point of view, what are your experiences with regard to acceptance by notified bodies and authorities, such as the FDA.

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So they actually go along with this path.

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Yes.

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So, of course, there is also an awareness there that

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Technologies that we use today in radiology are increasingly being developed and optimized to achieve the optimal result in clinical application, and that the underlying principle is that there must also be a parallel further development of the methods used to evaluate and continuously monitor these products, that phantoms play a central role as standard instruments for quality assurance

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the FDA, for example, has already made efforts to develop more realistic phantoms for such purposes.

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And at the end of last year, for example, an article was published in which, among other things, the FDA outlined its vision of healthcare and in which our work and especially the phantoms we are developing are a central element.

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Congratulations! So of course that's a great supporter, probably the most beautiful thing you can get.

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And we also have

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and many people in the FDA who are involved.

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I'm thinking of Tina Morrison and her team right now.

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It's amazing how much energy they put into it.

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And when you then see, on the other hand, that we in Europe have no one at all in these areas, regulatory science, then it is sometimes embarrassing.

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But since the FDA is leading the way and we in Europe are sometimes at least lagging behind, it's a good sign.

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Maybe others

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a regulatory-relevant document is this ASME 40VNV Guidance, where there is a lot of talk about simulation and the requirement for simulation and validation of models.

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So the FDA was also involved in this and you are told relatively clearly what it expects from you, to really be allowed to use simulation and models as evidence instruments in approval procedures.

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Yes, what would you recommend manufacturers do?

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How could it help in concrete terms?

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Which manufacturers should perhaps also contact you in particular?

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Ultimately, of course, we are addressing the manufacturers of imaging systems on the one hand, and on the other hand, we are addressing the developers and manufacturers of post-processing software and diagnostic software, especially using AI in radiology.

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To sum up, this can be seen among all companies that

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are active in diagnostics and are dependent on objectively validating that their products can be used accurately for their intended purpose in a real clinical setting.

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What we have simplified has already been briefly mentioned, i.e. we shorten the time necessary to test and optimize new products in development for their clinical applications.

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we can then also provide data that could be used for approval.

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We help with local validation with customers for the implementation of products and new systems and we enable continuous prospective quality assurance of the products in clinical application, thus creating simplified access to data to prove the clinical performance of the products, that is what I was going to say.

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I will summarize very briefly so that I have understood everything correctly.

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So you have actually answered two things, two questions, namely who they help and how they help.

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In the case of those who they help, you said that they are mainly medical device manufacturers who produce radiology, i.e. products for radiology, i.e. for imaging procedures, and on the other hand, all those who process the data from this radiological imaging.

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It may be that it is a pure software manufacturer,

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has nothing to do with devices at all.

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So that was the answer to the question of who they help and how they help is to use phantoms, to actually go through these arguments with these phantoms, possibly also to set up the processes so that everything works in a legally clean way.

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Does that fit?

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Yes.

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Yes, all I can say is that we link your contact details.

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That is, all those who feel addressed by it,

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like to meet at Dr.

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Janke and his team from Phantom X.

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I link the e-mail or the website so that you can contact them.

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I am convinced that phantoms, models, simulations will and must gain dramatically in weight so that we can maintain our competitiveness, because the others are doing it and running after it is, I think, not a good thing.

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Mr. Janke, thank you very much for joining us.

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Gladly.

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Thank you very much for the invitation.