Johner Institute

Digital Twins in Medical Technology

With Dr. Simon Sonntag, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights A podcast from the Johner Institute for medical device manufacturers, authorities and notified bodies.

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One of the most important aspects that manufacturers of medical devices should consider is the „time-to-market“, because this is what determines their competitiveness.

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Now we have to consider, what does this time to market depend on?

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And one of the important factors that we have talked about many times is the issue of approval.

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So how long will it be stuck with authorities and notified bodies?

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But we are working on this problem or on the solution of this problem, among other things with the whole digitalization.

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But there are still large areas left that also have a decisive influence on this time to market.

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In particular, the development and afterwards, of course, the verification and validation.

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And there I would also quite explicitly use the

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clinical evaluation or clinical trial.

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So the question now remains, what can we do to speed up these areas as well?

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And one approach that can be pursued here is that of digital twins.

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And I asked Dr.

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Simon Sonntag, who also spoke at the Institut Tag about what possibilities we have with digital twins to accelerate the development, including testing, clinical testing of the products.

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Simon, I would say you introduce yourself briefly so that we know you and then we go straight into me-diastase.

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Great, thank you very much.

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It's great to be here and to imagine this area a little more.

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Yes, a little bit about me.

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I have been working in the field of medical technology product development for almost 15 years now, with a focus on computer-aided methods.

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In the beginning, I was still very technical, with a focus on numenic mathematics in the field of medical technology image processing.

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I then went to Aachen to do my doctorate in the field of cardiovascular technology, then worked as a manager in a consulting company for medical devices and also for my own product developments.

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That's when I experienced first-hand the difficulties of what it's like to really bring a product to market.

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Also the time it takes and the difficulties of then also carrying out certain verification and validation of the products.

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However, the focus for me was already the simulation.

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and then I got more and more involved in regulation, was then also part of the ISO Commission, and then also accompanied the process of this digitization of test methods.

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That's when I saw great potential for these simulations and digital patient twins to be used for product development on the one hand, but also to be used more and more for approval purposes and clinical trials.

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And above all,

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there is very strong support on the regulatory side from the authorities such as the FDA, but also in Europe.

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For example, in 2019 I decided to go back to Munich on the one hand and then concentrate fully on this focus on the other and then founded the company Vetronomy, where we have the mission to drive exactly this area forward.

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Excellent, so of course we still have to talk about regulation, we definitely dive into that, but maybe let's start with the question,

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Where can simulation, modeling or digital twins be used in what areas do you recommend that you use them now?

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I had only presented two very rough areas, so to speak.

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I think we should dive deeper into this in order to understand the potential.

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Yes, at first it sounds a bit futuristic, of course, such as digital patients, twins and simulation in this area.

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It is good to take a quick look at other areas, such as the automotive industry, where

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Brash tests are more and more carried out on the computer or wind tunnel studies are then carried out via such simulations, flow simulations.

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It's just everyday life with us.

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Every product, every smallest component goes to the next level, not without a computer simulation and analysis of it.

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And that's something where we are still a bit away in the medical sector, of course, but where this area will go more and more, then also in the future.

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And there are areas of application there

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two areas where the whole thing is interesting is, on the one hand, the pharmaceutical sector, one or the other may have already heard, such as Drug Discovery, where pharmacokinetics is extremely difficult and time-consuming to find.

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And there, computer simulation and artificial intelligence can be used to simulate a large number of parameters that are actually extremely difficult and time-consuming in the trial-and-error process.

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And thus, of course, on the one hand the finding of medication, but also then

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significantly speed up the testing of drugs.

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Another area here is also reference arms, which then also carry out placebo arms, which are extremely complex, but which can then be accelerated there via virtual studies artificial intelligence and also carried out genetically in order to be able to use it for different drugs.

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Here, for example, a US company Unlearn is quite far along, which is already active in this area and has already shown there that the whole thing

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immense advantages.

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The other area where these digital patient twins or Insilico methods, as they are also called, are used is the medical device industry.

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On the one hand, the device itself can be simulated there, i.e. it can then be examined how it then relates to structural mechanics, fluid dynamics, but also the combination with anatomy is possible.

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That's also what we do at Vetronomy, through a

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A large data set of patient models is then also used to test how the implant really behaves in the body in the interaction, in order to then carry out certain safety and effectiveness analyses, which can later lead to problems in the clinical trial or even then really in clinical application, in order to predictively minimize the risk in this whole process.

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It can also be used to study physiology and hemodynamics,

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But other application methods are also to be optimized, monitored and then also predictively found out whether the product will have any signs of wear or fatigue problems at some point, for example in production.

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On the other hand, there are also methods that are more clinical applications, for example, the simulations can also be used as a medical device, such as Heartflow also from the USA, where the whole thing is used, or

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medical device, e.g.

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for diabetes, for the dosage of medication, where artificial intelligence or simulation are being used more and more, and then to create the optimal therapy for the patient.

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So we now have several areas that are being simulated.

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Once the product, then once the patient and then once the interaction of product with patient.

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If you perhaps take these three things into account again,

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I seem to remember that you once reported on a case that also went very well with the FDA, it was about the topic of 3D mammography.

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Yes, so they simulated the product once, then they simulated patients, even in the sense that they generated artificial mammography data, and then they simulated how the product behaves with these simulated data, how it behaves with each other.

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Will we perhaps be able to take a very short look, i.e. what can be done on the product, for example

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i.e. which properties?

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Exactly, the properties of the product are then all the physical effects that can really be considered there.

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This means that you have, for example, a stent, a vascular system that is inserted.

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Of course, they want to investigate how the product behaves under certain conditions when the whole thing is then primed and expanded in certain vessels, whereby fatigue strength analyses, for example, are a major factor.

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Whether the

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product then also behaves positively over a longer load state or whether it holds the whole thing negatively somewhere in the context of design adjustments or even then of framework conditions.

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And typically the whole thing is then carried out via such accelerated tests, where the whole product still has to be tested for half a year to a year over 400 million cycles, for example, and then to determine

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At some point the whole thing didn‘t work, where of course you don‘t know why the whole thing didn‘t work.

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If you then adapt the whole thing to the design, you have to do these tests again on this product.

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This means that many parameters can then be played through in the computer.

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This means that it is then possible to examine exactly where there are high stress curves, strain curves, in order to then perhaps adapt the design at an early stage in order to then also

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to foresee exactly such defects in the product and to act accordingly to investigate it.

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Another example can then also be hemodynamics, e.g.

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a blood pump to reduce blood damage there, hemolysis, thrombi administration and so on, but also in many other areas.

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I think you once showed EMC in a slide, i.e. electrical safety, electromagnetic compatibility, so we can even simulate that, the

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you said earlier, there were the patients, so you said, there were different morphologies, anatomies, physiologies, so you can try out virtually everything, which has the great charm that you can ensure it again, especially in such peripheral areas, where there are few patients in the population, and thus actually achieve a higher level of safety.

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So not only a speed advantage, but also a safety advantage, if I may call it that.

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Now you have mentioned another case, namely that as a service.

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So

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So help us to understand very briefly, simulation as a service, i.e. what is offered to the companies, what are the products and what do the manufacturers who use these services get out of it?

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Yes, so also our users of these services, of our software come from many different phases of product development.

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Some are very early, i.e. in an early phase, where you haven't really developed the design yet or then have the rough understanding of it.

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For this purpose,

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really methods to understand the patients well, to understand the pathology, to understand the orpho-

logy, the anatomy, just like you just said, then also to see how are peripheral areas, because it is often the case that product manufacturers then want to develop „one size fits all“ or „fits most“, but what does this „most“ from the patients really mean?

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And then to see, where are the really limitations, where are the difficult areas then?

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And that‘s what where

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conventionally it is very difficult to get this diversity in these data situations, where, for example, the FDA is also very much in focus on investigating diversity in clinical trials, in clinical evaluation, but also in the population that is to be considered.

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Because if the product doesn‘t work later in the patient, in a certain population, that‘s of course a disaster, a catastrophe to help shape it.

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And here we have

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who use it in various areas preclinically, but also clinically, preclinically, for example animal experiments.

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We also have a large dataset of animal models because there is still a lot of trial and error used here.

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Finding the right animal model, the right size and then also using that, the transition from the animal model to the human patient, because it‘s just not the same to get there a lot of animals that are then used in the iteration and the goal here and that‘s also the goal of the

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European Commission, for example, is to reduce more and more to animal experiments or even to do without them completely in the future via special in vitro methods, but also such Insilico methods, which can be used more and more there.

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And then the whole thing can also be used in clinical trials.

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Yes, and this means that we not only have fewer animal experiments, but also fewer human experiments.

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Yes, exactly.

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Now we've talked a lot about pre-market.

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We also have this simulation in, I'll call it in the

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Post-market area.

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That is, when the products are on the market, for example, in order to be able to select a suitable implant.

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Can you say a few words about this post?

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I don't know if post-market is the right term, but after products are more or less approved, how simulation can still support there.

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Exactly, there are two areas, preoperative planning, as I call it, and perhaps post-market surveillance, where simulation can actually help in both areas.

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For example, you have a

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Patients who are screened with complete tokenography or MRI or other echocardiography methods and the doctor does not yet know exactly which implant should be inserted, which type, which size, which positioning, for example.

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In some cases, this is actually quite difficult, for example for heart valves to find the size, but also the positioning for pediatric applications, for example Fontan patients with a cannulation,

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very often it is difficult to find the access routes correctly, where the whole thing can then be simulated in the computer beforehand pressure, i.e. really three-dimensional or four-dimensional, the patient is then reconstructed, segmented, built up and then the doctor can test there virtually, how would it behave if I implanted this or that product in this or that place, to then simply have better security,

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if you then really go into the patient and implant the whole thing in order to then reduce camping numbers, to optimize the outcome, to simply have more safety there.

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Another area is post-machet surveillance, which really means that if adverse events occur in clinical application, then also to see why it came about in the first place?

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Because if there is a stent hernia on certain fractures, in certain areas, for example, there is of course a stop from this for the time being

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Pressure on the market.

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Of course, it is a disaster for the manufacturer, even if the whole thing can then no longer be used and a claim comes from the FDA.

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And then to find out why it came into being in the first place and then to interact quickly and maybe find out because it's an isolated case or is it a case that can really happen more often, the simulation can then be used again and in combination with the data to find out what was the problem here, what can be done, can it be,

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so that this does not happen again and then to be able to use it again quickly in the clinic.

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So I think we now have a good overview of where we can use modeling, simulation, digital twins.

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Summarize very briefly again, on the one hand we have everything that happens before approval in quotation marks, to be able to develop the product in such a way that it is safe, powerful and effective and to prove that.

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So that means then we have the topic of clinical

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Evaluation clinical trial, so in this whole stack we need that.

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And the second is then also itself after it has been placed on the market, after approval, depending on the market, what it is called.

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And there you mentioned two sub-points again, namely on the one hand to find out problems, to be able to reproduce them, to be able to identify suitable measures and on the other hand to be able to use the product correctly, for example to be able to select the right product and then be able to implant it surgically, for example.

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Yes, that all sounds great and you also said that the FDA and the Commission actually like to see it and that brings us directly into the topic of regulation.

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So what is allowed here?

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Perhaps the nasty question was asked: Do the manufacturers perhaps not have less work as a result, but more, because they have to do virtually everything they have done so far and now have to provide this additional evidence or can they actually save something?

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So what do the standards and laws say about it?

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That.

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A very clear goal, also from a regulatory point of view, is to save money here and, above all, to reduce the effort on the one hand by reducing or partially replacing certain tests and thus to get to market much faster and safer.

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This is also the motivation that regulators such as the FDA and the Commission are also moving forward very strongly in this area, because the goal should not be to create even more effort here and then

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in addition to the ganging methods, to have a method to check the whole thing, but more and more really to reduce other methods.

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The FDA predicts, for example, that in the next few years more than 40% of the approval process can be sold via such simulations and digital methods.

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Simply for the reason that many parameters that cannot be examined with ganging methods can be examined more quickly and thus certain factors can then be examined.

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then into the process.

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Of course, what the FDA also asked itself from the beginning is: What about the accuracy of simulations?

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Probably many who listen or watch here ask themselves the same thing: How do I manage to set up a simulation that is so accurate to reflect reality?

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Here, the FDA then teamed up with ASME, a so-called WienV40, i.e. verification and validation on the model side.

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Guideline was created to check whether the simulation is really accurate enough or accurate enough to make certain statements in order to ensure hypotheses regarding the safety and effectiveness of the products.

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And that‘s something that has to be done on the site, as well as for reporting.

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And that‘s something that, of course, depends on other methods, if animal experiments or Invito experiments have to be carried out, you also have to make sure that there is a well-accurate

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accuracy and the same is of course necessary on the simulation side.

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Once the whole thing has been carried out, validated, verified on the numeric side, I‘ll say now, then the whole thing can really be used to run through very, very many parameters, to check them, in order to then reduce certain experiments.

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For example, in-vitro experiments that want to be carried out over a complete parameter space are sometimes

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very time-consuming or sometimes even impossible, because not 1000 different parameters can be performed.

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This means that these parameters can then be carried out simulatively and certain worst-case scenarios can then be carried out in vitro in order to check the whole thing again and have an additional factor in it.

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And together the whole thing can then be submitted to the regulatory authorities and thus the whole thing can then be taken up in the report, as is the classic case.

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So you have already mentioned one thing about regulation, namely this V&V guide with the number 40, which describes the process of ultimately proving the evidentiary reliability of this method and thus pro-

ving that the simulation, i.e. the results of the simulation, are representative of reality.

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Then there is this guidance document, which then says in what format and with what content you then submit this evidence.

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Then we at the FDA have this

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area of the MDDT, can you say a word about that?

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Yes, MDDT, that's called a Medical Device Development Tool, because such methods of simulation for development and approval processes are not a medical device in themselves, they don't have to be approved in this way, which is a support.

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And the FDA has developed a program here, which is a voluntary program, so to speak, but which then shows, if you have gone through it, that the quality of the simulation is also ensured there,

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for this application.

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This means that MDDT can then be used for certain applications.

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For example, there is an MDDT for radiation therapy.

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That is, if there is an implant in the body and you are in an MRI, how the whole thing behaves, which of course can then lead to problems there.

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And the whole thing cannot be done experimentally.

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It can be done in phantoms, but only in limited quantities.

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You can't do that with human patients or with animals, because of course

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ethically unjustifiable to expose someone there to this risk.

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Therefore, simulation is a method to evaluate the whole thing.

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And the MDDT is then simply a factor that the manufacturer of the product can then use the whole thing in such a way that it can then also have the acceptance of the FDA that the whole thing can really be used in the approval process without having to investigate such a validation of the simulation methodology again.

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That means it's just a

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a quick process for FDA acceptance.

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Without MDT, the whole thing can also be used, but then it has to be checked again simply in one process.

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This is simply an accelerated voluntary procedure for such simulation methods.

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So that means for very specific use cases, we have a kind of module, like a kind of macro, that you can use and thus have the proof

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, so the proof is already proven and you just use it and it doesn't have to be checked again.

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Exactly.

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So that means that FDA has once again been able to observe an effective regulatory science in action.

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Then perhaps we will bend our gaze towards Europe.

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What do we have there?

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What is going on?

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What guidelines or possibilities do we have there?

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Yes, Europe has to be said that it is still lagging behind.

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There is also the

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Prioritisation of the Commission, including the EMA, for example, which has on the plan to really work in depth in this area and to create methods there as well.

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The challenge in Europe that we have is simply this decentralization, that we have many units.

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We have the Commission, we then have the notified bodies in the area of medical structures, we have various

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Areas to pick up everyone, even for such new application methods, is always a challenge.

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The advantage of the FDA there is, of course, that you have a centralized unit that also has a very high level of expertise.

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Within the FDA there are about 200 employees who deal with and deal with this digital patient area, this in silico area.

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That means there is a very high level of expertise and if you talk to the FDA, there too, they simply have the understanding of this methodology on

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European side still lacks this understanding in some cases.

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We are also part of certain societies such as the Avicenna Lions, where we then work together with various other industries, companies, but also academic areas to do educational work in order to move notified bodies forward.

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However, certain notified bodies, including the Commission, are also very open.

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They absolutely see this as the next important step

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also want to join the FDA here.

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The same applies to other areas such as Asia, South America and so on, where the whole thing also has this focus more and more.

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Yes, I always hope so.

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You get what you pay for and the USA invests in the matter with 200 people.

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The EU Commission will be exactly zero.

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So they don't just have zero regulatory science in the digital sector, but overall and you shouldn't be surprised then.

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Let's move on to the next topic.

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Maybe, where do you see where this market is going overall?

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Yes, I think this digital patient market is natural, which has a lot of potential.

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This can, as we have already seen, a development of medical devices can be used, it can be used in the approval process, even after approval for marketing, training,

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There are also many applications here in the field of virtual reality, for example, where the whole thing can be supported, but then preoperative planning and post-market surveillance can also be used.

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Where the whole area still has potential to really develop.

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That's something that might not be in the next two to five years, but more like that in the next ten years is all the predictive medicine.

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That is, where we are going away more and more is from this sick care, that is, you have symptoms, you go to the doctor, you get medication or therapy procedures and

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then somehow has an influence on the symptoms afterwards.

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Where the whole thing is going is really predictive medicine.

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And that's something that's incredibly exciting, of course.

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This means that you may have a digital twin of yourself.

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Of course, this depends on many factors.

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Of course, you first have to create the data infrastructure so that all certain factors come together, because, for example, the result of dental examinations can also have an influence on the cardiovascular system.

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This means that all this data has to be put together.

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But maybe in the future you might have your own digital twin on your smartphone or on digital glasses, which will be then, and it will tell you that you have to change this and that behavior, because in five years this and this disease could set in, for example, then come.

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You should then perhaps go to the doctor to have the whole thing early.

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That really means going the whole thing regulatively.

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There are many questions here, on the one hand data basis, on the other hand technology must of course

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be at the point where what we develop can then also support in this area and also go in that direction.

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But of course there is also the question, who ultimately pays for it and is it accepted by the patient?

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Do you want to know that you will have certain illnesses in five years?

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If you can't solve the whole thing, it may be stressful at first and also additionally damaging.

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If you can change something about this disease, then of course it is something that can help the patient very much.

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Yes, now you have your gaze very far into the future.

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Let's come back to the present at the end of this podcast episode.

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What would you recommend manufacturers do today?

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So what are some very concrete steps that you would recommend to them?

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If necessary, what should they perhaps not do, so that we can get a very plot-guiding end to this podcast episode.

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Yes, these simulations themselves are a bit complex.

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Digital patient twins were of course a

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simulating the body with all kinds of aspects, blood flow and so on, is a very complex approach, a very complex method.

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This means that you can also do a lot wrong there, just as you can in the in vitro sector, in the animal testing sector, where experiments can also be carried out incorrectly, as well as in the simulation sector.

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This means that if you want to tackle this area, you should of course work with either experts in-house or with experts externally, in order to see together what

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can it help you and how can the whole thing be built up to be meaningful?

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That is, as a first step, I would recommend here, if you don't have much experience in the field, you can of course read up on the methods that are there, but then also work with companies, such as us, to see how the whole thing can also be used to really help.

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Because of course you can do a lot much, which in the end doesn't help much or doesn't have much effort, but it can also be done in such a way to really make a big difference here.

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Benefit, in order to then really see how you can speed up times there, how you can perhaps develop the product in certain areas and then set up this simulation result.

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And no one should be afraid that these are somehow methods where you need years of training time.

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This may be the case with common simulation tools, but with solutions that we offer, it is what an easy entry point is, a simple environment,

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in order not to be an expert in artificial intelligence, data reconstruction, data security or simulation, but the whole thing is then also ensured.

00:27:49 Speaker 2

Exactly this whole area of benefit and validation can then also be carried out by us, for example, to provide support here and then implement the whole thing quickly and easily.

00:27:59 Speaker 2

Of course, you should also think about the return on investment, because it is of course an investment in this area at first, but in the longer term it helps you immensely to have a return here as well,

00:28:11 Speaker 2

in order to then accelerate certain areas or minimize risk.

00:28:16 Speaker 1

So I'll summarize it very briefly.

00:28:18 Speaker 1

So the first tip is to deal with it at all, so have it on your radar because there's a lot going on and that's an important aspect of staying competitive.

00:28:27 Speaker 1

The other digitization topics that we usually talk about here.

00:28:30 Speaker 1

Second tip: First find the area

00:28:34 Speaker 1

because you have the highest return on investment.

00:28:38 Speaker 1

So that may mean the area where the most avoidable effort and pages could be saved at the moment and then to see how simulation could help in these areas in concrete terms.

00:28:51 Speaker 1

So that is, the result of the first step would be to have identified an area where this use of these tools makes sense at all.

00:29:01 Speaker 1

to have calculated what it brings economically, in what periods of time it will pay for itself.

00:29:06 Speaker 1

And once you have that, then it's time for the third step, which is to implement it.

00:29:10 Speaker 1

And you can help with this step that I just mentioned, namely to find out, to identify potential, to deduct costs.

00:29:18 Speaker 1

And afterwards, when it really goes into implementation, also with tools, of course, you have just described, with support in the verification and validation of the tools in turn, i.e. not only the products, but also the verification tools,

00:29:30 Speaker 1

be there with it.

00:29:31 Speaker 1

So I just link your contact details, your contact details in the show notes, so that anyone who is interested can contact you directly.

00:29:38 Speaker 1

Yes, with that I thank you very, very much Simon.

00:29:41 Speaker 1

That was an important insight to understand, digital transformation affects all the processes, regulatory processes, of course, but also really product development and clinical trials or the trials as a whole and

00:29:57 Speaker 1

Only if you have everything on your radar and continue to develop on all fronts, then you are the one who stays at the forefront.

00:30:04 Speaker 1

Thanks for these insights.

00:30:05 Speaker 1

I had a lot of fun.

00:30:06 Speaker 2

With pleasure.

00:30:07 Speaker 2

Thank you very much from my side for being able to be there.