Johner Institute

Clinical evaluations

With Dr. Bettina Martin, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

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

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Recently, we have been repeatedly asked to revise and improve clinical evaluations, because the

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Have become conspicuous or during the review of the technical documentation.

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And because we want to help ensure that these problems do not exist or exist less, I invited my colleague, Doctor Bettina Martin, today, who, together with her team, the Clinical Affairs team, takes care of precisely optimizing such clinical evaluations.

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And let's see that she can give us some tips on how to write clinical reviews.

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Hello Bettina, maybe if you could introduce yourself very briefly, so that our listeners know who I am allowed to talk to today.

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Hello Christian, yes, nice to have me there.

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My name is Bettina Martin and I am the head of our Clinical Affairs department.

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We take care of the clinical evaluation and I have been writing clinical reviews myself for several years and supporting manufacturers in

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development of the clinical strategy for their medical devices.

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Now I just said in the introduction that there are always problems with exactly this central document.

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What are these typical problems, problem classes that you encounter?

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In other words, things that you obviously do wrong over and over again.

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Most manufacturers don't know how to generate clinical data themselves

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and they are not aware that it does not always have to be a clinical trial, but that data can also be generated in other ways.

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Furthermore, the problem is that the equivalence route is often confused or similar products are used instead of equivalent products.

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And these are the points of criticism that come from the notified bodies, I suspect.

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Exactly, there are always very hard deviations in the clinical evaluation.

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Mhm, and of course we can then also prevent the approval.

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Are there certain product classes or certain types of manufacturers that you notice where this occurs particularly frequently?

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Yes, so there are mainly problems with class 1 manufacturers, because of course they have an extreme problem that they usually have no scientific literature or clinical data themselves, because it is simply considered unsuitable to do a clinical study with these products.

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Well, I don't necessarily need to

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a sling or surgical scissors that has been on the market for years, carry out a new clinical study and very often questions or problems arise when it comes to collecting one's own clinical data and also looking for equivalence products.

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Most of the time, it is smarter not to choose these routes at all, but to go on the performance data route or the performance route.

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Now we have just talked about the

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Problems you encounter, including the special product classes where they occur more frequently.

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What are you doing now to solve these problems?

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So, can you solve them in all cases and which of these problems can you support particularly well?

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Yes, for example, if we find in a gap analysis that an equivalence product has been considered that is simply not likely to be equivalent

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and thus the clinical data cannot be used, we usually advise to take this equivalence route with caution and rather to go over the performance data or performance route, where the conformity with the basic safety and performance requirements is checked in the clinical evaluation and here an alternative is available.

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Now you have already given us an example, a problem class, namely the

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Products for which the sufficiently equivalent products are missing and therefore their clinical data may ultimately not be used.

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Do you see any other problem classes, perhaps also of a formal nature?

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Yes, so there are usually a lot of problems of a formal nature.

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It is simply the case that through the M.D.R.

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which has changed the structure of the clinical evaluation and because many adjustments also have to be made.

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For example, it is also quite clear that the qualifications of the authors must be presented.

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That will.

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also in the M.D.C.G.

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Dokumente 2020 13 that the qualification of the authors must be demonstrated.

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This is what most manufacturers lack in their clinical evaluation.

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In the field of literature research, there are also classics that are done wrong again and again.

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Yes, literature research is usually not systematically documented, especially the state of the art.

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So you always think you just have to document the literature for performance and safety.

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However, it is actually the case that the entire systematic literature search for the state of the art as well as for one's own product must be documented and presented.

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Then, if I understand correctly, you even have to do several literature searches.

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Exactly,

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So, you should do several literature searches.

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One is to determine the state of the art first.

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This can also be done within the Clinical Evaluation Plan.

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This is also very good for further technical documentation, for example to assess risks for risk management.

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And on the other hand, you have to carry out a literature search on the product or equivalent products.

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or similar products.

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These could be, for example, the generic product group, just to classify my product first.

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What is the state of the art at the moment?

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What are the latest methods?

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Am I still in line with that?

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Now we have discussed some of these problem classes.

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Do you see a dependence on the notified bodies?

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In other words, that different notified bodies have different priorities or are perhaps more likely

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Differences within the notified bodies.

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Yes, some notified bodies interpret the guidelines more strictly than others.

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But it's also the case that there is an inconsistency within the notified bodies.

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This is also simply dependent on which reviewer audits the clinical evaluation, so to speak.

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If, of course, it's a subject matter expert, what it means

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should always be, a much stricter sense of proportion is required here, as if someone is doing it now, for example, who has already worked less in this field.

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This means that the state of the art in the field of Techfile Review is not yet completely homogeneous, but it is possible that this will level out a bit over time.

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Yes, we are now in October, in May next year the M.

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D.

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R.

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definitively entered into force,

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What would you recommend to the manufacturers now, what should be done in the remaining months, maybe even in what order?

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So in any case, they should carry out a gap analysis to see whether the clinical data that they have now collected for their product is also available under the M.

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D.

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are still valid and, above all, whether they can still be used.

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This means that this clinical evaluation should be planned now with, for example, the Clinical Evaluation Plan, which provides this, because the clinical evaluation is not a document that is simply ready in a few weeks, but it takes several months to collect this data.

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It also takes several months to write a clinical evaluation and most importantly

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clinical follow-up, such as P.M.C.F., must also be planned now, so that it can simply be carried out under M.D.R.

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these clinical data are already available.

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So, I'll try to summarize this again so that you can check if I understood it correctly.

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So, the first thing you recommend is to immediately check whether the clinical data is sufficient and whether it also comes from sufficiently equivalent products.

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if this is not the case, use the remaining time immediately in the second step to collect this missing data as much as possible.

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And then, while this collection is running, question marks, then continue to write the clinical evaluation and also after that then create the Post Market Clinical Follow-up Plan.

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Is that true?

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Exactly.

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Yes, I think it was relatively short what we have discussed here, but we have written more tips in our articles, which you will find linked below.

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So there are specialist articles, for example, on the subject of clinical data.

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We have a technical article on the topic of equivalence, so that goes mainly to this M.D.C.G.

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document 2020 05.

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We have articles on the

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clinical evaluation overall and also on MedEv 271 Revision 4, which we have not discussed now.

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So there is still enough literature for you.

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If you would like us to submit your clinical evaluation, your clinical data, to a quick check, then let us know and we will help.

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And I think both of our tips, Bettina, is to get to work right away, use the remaining time to collect your

clinical data in order to improve your clinical

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To bring the review up to date, so that when it comes to the Techfile Review next year, everything will run smoothly.

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Bettina, thank you very much for joining us.

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Thank you.