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WEBINAR - Q&A

Unveiling Impactful Methods to Strengthen Device Claims

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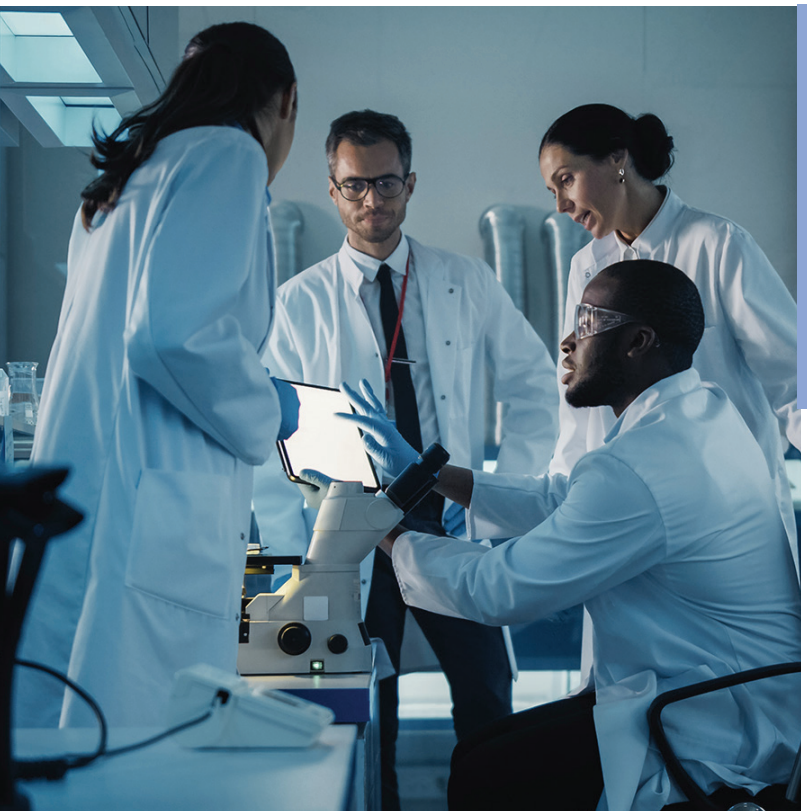

Q: Does the classification of claims become specific to a region or is it in general?

A: The classification of claims presented is a general practice worldwide, it is not specific to a particular region. There are other ways of classifying claims as well, for instance competitive claims, efficacy related claims etc.

Q: Do you see a difference between clinical claims made by marketing, which may be specific and numerous, versus benefits in the CER? If so, how do you see the relationship between specific clinical claims used by marketing versus broader benefit claims in the CER?

For example, a wound dressing where the benefit is healing wounds, but marketing wants to differentiate based on multiple, more specific claims, such as reduces damage to wound during removal.

A: So usually what we've seen is if the marketing team wants to split it into multiple benefits, they can do that, provided it maps to one umbrella claim within the CER. So, in this case say you're talking about different types of wounds that can be healed by certain dressings or in different locations, that type of claim is fine. You can call out different locations within your marketing material and just say heals wounds within the CER. But like I said, all claims should map to a specific umbrella claim and you should have proof within the umbrella claim that supports all of these individual claims as well. If it does not support one particular statement within your marketing material or within your literature provided with the device (Brochure/ IFU) then that must be taken off because we have seen instances where the notified body has pointed out claims in the marketing material that aren't a part of the CER and since it isn't a part of the CER where is the proof that you have clinical data that supports it, and we want you to change it.

Q: Can you explain the differences between claims and clinical benefits with an example?

A: Example - you are claiming lesser revascularization procedures when you use a Device under evaluation- which is a stent. That's a claim and your benefit to the patient is that they will have less time under general anesthesia, which means less surgeries, less risk, and less reoperations. That'll be the benefit to the patient. Similarly, for a device, which is a bone hemostat, my claim would be that it is completely re-absorbable by XX amount of time (say within 6 hours, within 16 hours or within a day). The benefit would be that the risks associated with the non-resorbable hemostat such as granulomas or infections are reduced. So that is the benefit. And your claim is that it's resorbable.

Q: Is there an overlap between intended use claims and clinical benefit?

A: Intended use is what your device does. In many cases the intended use itself translates to a claim - "my device performs XX without any unacceptable adverse effects". There are also scenarios where claims are what enable your device to achieve its intended purpose, for example a radiation device where you are calling out the dose accuracy or dose rate as one of the claims. The clinical benefit is related to the clinical claim and intended purpose in the sense that it is the effect that the intended purpose or the specific claim has on the patient or the user.

Q: Is there an example or guidance with an example of the type of performance or safety claims?

A: The MedDev 2.7.1 Rev 4 gives you very detailed guidance on what type of claims you should have and what the nature of the claim should be, what are measurable and quantifiable, but it doesn't have examples. It gives you pretty detailed guidance on what you should consider for claims. The MDCG document does give you very few examples on direct and indirect benefits, but not claims.

Q: During an annual update of a CER can we use the clinical literature data for a particular safety or performance as a claim?

A: Yes, your clinical literature data can be used to supplement safety and performance claims within a CER.

Q: Will all diagnostics devices have indirect claims?

A: Not really. There are cases where a diagnostic device can have a direct claim. If the diagnosis is directly resulting in identifying or a life-threatening condition or a disease that requires immediate treatment, then it is a claim with a valid clinical outcome. For example, a device that measures heart rate, and it identifies arrhythmia. So that is a diagnostic device, but with a direct claim. You can say that identifying the arrhythmia helps you prevent any sequelae from having prolonged arrhythmia.

Q: On websites and in marketing material, we often refer to the latest publications with data on our device including off label, will this no longer be allowed unless it is included in clinical evaluation report first?

A: It's not disallowed. You can have data on your website that supports an off-label use, but you ideally should not be claiming it until you have enough proof for that particular off-label use. You cannot use it as a part of the intended use, and you cannot claim it as something your device does. You can say that these are publications that support the use of the device in different situations, with a disclaimer that it is not recommended for this purpose but there are papers which demonstrate that it has been used favorably in these situations. To sum up, unless you have supported a claim in your clinical evaluation, and it has been approved by the notified body, it cannot be used as a direct claim in your marketing material either. You can mention that it is an off-label use, which is supported by these publications.

Q: Is it mandatory to cite claims in every CER or CEP?

A: The objective of having the CER is to show that your device is useful and does something. So, it is mandatory to demonstrate clinical benefit, either direct or indirect and without that the notified body would come back with questions regarding the purpose of your device. We have earlier submitted documents that said we have no claims, to which the notified body came back and said, if your device doesn't have a purpose, if it doesn't have a benefit, then why is it even in the market? So, identifying the purpose of your device, and identifying what it does for patients or for users is mandatory. You must have it as a part of the CEP and the CER for it to make sense to have your device in the market. Your claim can simply be that your device performs as intended and at par with the state of the art, you have to demonstrate this in your CER and show what benefit is associated with the intended purpose.

Q: Can you create claims which are not in CER using literature for marketing purposes?

A: I would say no, again. Somebody must be validating these claims. Somebody must be saying that there is sufficient evidence for these claims. So, if you are using it in your marketing literature on your website, and you're saying these are literature supported, somebody has to say, this amount of literature is enough. So, if it's not in the CER, who is going to verify if that data is enough, who's going check if the amount of clinical evidence is enough? So, anything that is used for your marketing should be approved by the notified body, by the regulatory authority, before it goes on there as a valid claim. AS mentioned earlier you can mention it as an off-label use that requires further evaluation but no concrete statements unless they are approved by the notified body through your clinical evaluation.

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