The MDR: Navigating Europe's New Standard for Medical Device Safety

Europe's new medical devices regulation (MDR) is four times longer than the previous medical device directive (MDD), and it has raised the bar for clinical evaluations. It's imperative that manufacturers proactively identify the gaps in their data and take the necessary steps to fill them—from pre-clinical through post-market.

Kim van Noort
Senior Medical Writer
Avania

ACT: Under MDR, what are the most important steps for companies to take when attempting to compare their medical device to benchmark devices?

VAN NOORT: Before starting to compare your medical device to your benchmark device, you need to establish performance and safety objectives first as well as the intended clinical benefit of your device. Ask, what are the performance requirements for your device, and what safety requirements belong to your device? Additionally, it is important to establish a quantifiable clinical benefit, which might depend on your performance and safety objectives. This can be tricky because the clinical benefit needs to be measurable, not a vague statement.

For example, is the performance or safety of your device at a 30-day follow-up sufficient, or would you prefer these outcomes periodically or at a one-year follow-up? This depends on the risk classification of your device. Once you have that information, sufficient benchmark devices need to be identified. This is less difficult, as the manufacturer is often aware of who their direct competitors are. And lastly, the performance and safety objectives that you established earlier need to be compared to each other to see if they meet the acceptance criteria you set for your devices, depending on the benchmark device data you collected.

ACT: Can you explain how the process of device equivalence is different now that MDR is in place?

VAN NOORT: Under MDR, you need to establish an equivalent base on the biological, technical, and clinical equivalence, and this must be done within one equivalent device—you can't use different devices. In practice, this assessment is strict in that you cannot claim equivalence when your device is roughly comparable to another device. As such, you need to establish equivalence to all technical characteristics, i.e., you need documentation for the device you want to claim equivalence to. Further, you must have a contract in place with the other manufacturer of that equivalence device or you can own the device yourself. Therefore, in practice, this is often only possible to claim equivalent to a predecessor device of your own device. This is different from MDD when you could have a roughly comparable device that was equivalent to your device. So, if your device was heavily dependent on an equivalent device from competitors, you now have to fill a huge gap in clinical evidence. Additionally, a previously equivalent device may now fill the gap as a benchmark device instead of an equivalent device.

ACT: What do companies need to do under MDR to provide evidence for a device that has more than one intended use or will be used in several different anatomical locations?

VAN NOORT: Under MDR, the intended use must be specific, including anatomical locations. This means that a lot of devices on the market under MDD need to change their intended use to also include specific locations or specific patient populations that need to collect or have clinical evidence on those intended uses. As such, the clinical data you had under MDD will now be divided over more intended uses, or you may have no clinical evidence on part of that intended use. These gaps need to be filled by doing, for example, post-market clinical follow-up activities, which are largely dependent on the risk classification of the device and what gaps are identified in the clinical data during your clinical evaluations. In extreme cases, when there's no data on specific intended uses, your CE mark can be withdrawn or not certified to you, or you are required to adjust the label of your product to, for example, specify the intended use more clearly and include different patient populations or less anatomical locations.

ACT: Can you give us an example of how MDR guidelines for post-market clinical follow-up (PMCF) help companies identify long-term issues early on?

VAN NOORT: PMCF actively collects data, which makes it possible to have a closer eye on trends happening with your device and identify problems early on before they become big, such as training your physicians or excluding patient population from your intended use or adjusting instructions for use before larger complications emerged.

A good example of this is the adverse effects of breast implants—they were largely unnoticed and only after logging thousands of complaints, steps were taken for regulatory changes. If, however, you have sufficient PMCF in place, you could see the trend in adverse events, and it could have triggered earlier changes to the device. This is why MDR exists: to catch outcomes as early as possible to mitigate risk for the patients.

ACT: Under MDR, what are the most common pitfalls or setbacks that device manufacturers encounter when preparing clinical evaluations on their own, and how can a medical partner help avoid them?

VAN NOORT: First, a manufacturer needs to clearly define the intended use, associated performance, safety objectives, and intended clinical benefit. Second, you need to assess whether you can claim equivalence to another device. If you can, you need to perform an equivalent assessment on the biological, technical, and clinical equivalence. Additionally, you need to perform a systematic literature search for the identification of benchmark devices and associated literature on your device itself and whether it's applicable on equivalence devices.

As long as you have a rationale and a design for your PMCF activities, you can ensure that you remain on the market or get access to the market on the MDR. All this information will assess your clinical evaluation where the gaps in the clinical evidence will be assessed.

All this info is input for the clinical evaluation itself. Next is risk assessment, which is also dependent on the safety and performance objectives and intended clinical benefit. You may or may not identify gaps in the clinical evidence that you'll need to do PMCF activities. One thing we often see is that a manufacturer says they don't have any gaps in clinical evidence, but they are going to do PMCF activities to gather more information. This is a bit counterintuitive because why would you do PMCF activities if you don't have any gaps? So, it's not wrong to say that you have gaps in your evidence. As long as you have a rationale and a design for your PMCF activities, you can ensure that you remain on the market or get access to the market on the MDR. All this information will assess your clinical evaluation where the gaps in the clinical evidence will be assessed. With these gaps, PMCF activities will be performed again and again.

This circle has a lot of pitfalls and difficulties, and often we experience a lot of uncertainties and questions from a manufacturer, as they often skip important parts of the circle of the identification of clinical evidence, so I think we are a good partner to help you guide through that.