

With the heightened scrutiny under EU MDR, global regulatory bodies are intensifying their scrutiny of medical device claims and marketing materials. Many medtech companies manage claims using a complex web of disparate solutions and manual processes supplemented with marketing trade knowledge. But, in the evolving regulatory landscape, coupled with market trends, these siloed systems and processes will no longer work, demanding a change.

In response to these challenges, many medtech companies are embracing the concept of a centralized claims library to minimize compliance risks, reduce duplicate reviews, and elevate their marketing strategies. Jessica Pavic, project manager at Fresenius Medical Care, joined Daniel Milliken, vice president of marketing at Philips, at Veeva MedTech Summit to share how their companies have started to transform end-to-end claims management. Here are the highlights:

## Modernizing claims management

Claims are essential to the commercialization of products, yet medtech companies often treat them as an afterthought. Dealing with this mismatch led Milliken to create a claims library." We live or die by claims. They allow us to get the price points we need for our products," said Milliken. "But, we didn't even know where our claims were. They were sitting in Excel spreadsheets and personal computers across multiple teams." Milliken knew that an organization of Philips' size – with over 74,000 employees – could not continue to manage claims this way.

Claims play a pivotal role in shaping the "perceived value" of a product to customers. The nature of the claim not only influences the price point a product can command but also holds strategic implications. Robust clinical evidence supporting a claim not only justifies a higher price but also enhances market access by increasing the likelihood of reimbursement from payors.

Similar struggles led Fresenius Medical Care to rethink its claims management processes. "We wanted our system to be auditable and stay in line with industry standards," said Pavic. It was also important for Fresenius Medical Care employees to understand what goes into substantiating a claim. "One of our goals was getting everyone to see that every claim always needs to have a reference, because this is integral to our company being compliant, but also contributes to product credibility, patient safety and even competitive advantage" she said.

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- Daniel Milliken, vice president of marketing, Philips

## Incentivizing organizational change

Medtech companies often hesitate to change long-established processes. For Milliken, highlighting the compliance risks of not having a claims library was the key to gaining organizational buy-in. "We had sales reps in different markets creating their own materials and saying things about our products," he said. "You risk getting penalized by regulatory bodies for making claims that you don't have evidence to support," said Milliken. Phillips was aiming to also foster global-to-local consistency in content development. So, approving and managing claims on a global scale became pivotal in achieving this uniformity.

Pavic took a slightly different approach to buy-in at Fresenius Medical Care. "Compliance is crucial, but when engaging marketing teams, the focus shifts towards speed and efficiency. While compliance remains a key driver, showcasing additional benefits becomes essential to ensure their commitment to the digital journey with claims management."

## The claim-to-clinical connection

Starting the claims management process early in medtech development is crucial to ensure regulatory compliance, substantiate product efficacy, and establish a strong foundation for marketing strategies, thereby maximizing product success in market. However, this doesn't always happen.

"Claims was almost an afterthought...we'd make a product, and then think, 'Okay, what can we say about it?" said Milliken. Pavic shared a similar experience. "As we developed marketing campaigns, we'd realize that we don't have a reference for a claim. That's when we'd start doing research," she said. Having to conduct thorough research right before going to market slowed down both companies' commercial efforts.



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Instead, Pavic and Milliken advised medtech companies to think about claims management much earlier in the product development lifecycle – even at the clinical trial stage. "The sooner you can start generating evidence, the better. Remember: it can take anywhere from one to three years to substantiate a claim," Milliken said.

They also suggested bringing cross-functional teams together across R&D, marketing, and clinical to invest in claims management. "Your value proposition for your product, claims, and evidence all need to be part of one story. If you keep them separate, it's difficult for stakeholders to understand the value," Milliken explained. Pavic added, "This is something technology can support you with, but you should also have those discussions with your colleagues at the very beginning. Otherwise, a digital tool will not work."

## The future of end-to-end claims management

Fresenius Medical Care and Philips are in distinct phases of establishing a claims foundation, but both are exploring avenues for further optimization, including asset review and approval process by the involved functions (regulatory, medical, clinical, legal), automation, and enhancing system connectivity.

For Pavic, having a centralized claims library opens up the possibility for omnichannel and modular content. For example, Fresenius Medical Care uses Veeva Vault PromoMats to store approved claims and pre-approved content components (such as images or illustrations) called content "modules. Teams can use these modules to quickly create new assets across different regions and channels. "Taking a modular approach gives local teams much more flexibility when creating assets. It also speeds up time to market," said Pavic.

Ultimately, Milliken emphasized the importance for medtech companies to recognize the significance of managing claims effectively: "You only get one chance to launch a product successfully, so you need to do it right," he said. "That means having efficient processes in place before you go to market. Otherwise, it becomes a never ending game of catch-up."

Request a demo of Veeva Vault PromoMats for Medtech to learn more, or read more about the importance of centralized claims management.

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