

## A data-driven era: Why digital tools are critical to life sciences players

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The recent proliferation of digital health tools such as wearable remote monitoring devices and smartphone apps is leading to major changes in health management. While the streams of user data generated by these tools gives manufacturers, providers, and patients new insights into product efficacy and treatment adherence, their adoption also places manufacturers in uncharted legal territory. Dr. Jörg Schickert, partner in the Munich office of Hogan Lovells, says that despite these challenges, digital health tools are becoming a permanent part of the healthcare landscape, and a way forward for life sciences companies.

“Digital tools, when offered alongside a product, provide physicians with really exciting new insights into patient care,” he says. “Physicians now have the ability to see whether a product is working and whether the patient is following the prescription on a daily basis.”

Schickert says these tools can also help manufacturers stay competitive in the face of cutthroat competition from generic products. “When a drug’s patent expires, (offering a) digital tool alongside the product may be a way to further prolong its life cycle if there are a large number of active users,” he says. “It may also prevent patients from shifting from the originator product to a generic. Generic products aren’t likely to offer these digital tools because they are costly to develop and maintain.”

Questions around patient privacy and data security present the most significant legal challenges for manufacturers, but are unknown territory for many of the companies hoping to compete in the market. “Companies need to have a digital strategy in place to handle this data internally, and most aren’t set up to do that,” says Schickert. “Since a lot of sensitive patient data is involved, this can present major risks.”

Companies must also navigate a legal and regulatory framework that hasn’t kept pace with advances in digital health. “The legal provisions we deal with in order to assess digital tools are frankly outdated,” says Schickert. “These old provisions don’t reflect any awareness that these types of opportunities [around data] would evolve. Therefore the law needs to be interpreted in a very innovative manner.”

Despite the many legal questions still to be answered, Schickert believes that digital health —

and digital tools — will become an increasingly important part of doing business in the healthcare space. “Many companies out there are already gearing up... to introduce digital tools. They’ll be on the market soon, (and those early entrants) will be at a competitive advantage,” he says.

“Although we don’t know how the space will continue to develop, I’d urge any company looking to launch a digital health tool to start soon and involve their legal team from the very beginning. They’ll be operating in a space that’s moving quickly, and within a legal framework which still has some catching up to do.”

Watch the [video](#) for more insights from Schickert about how companies can navigate the rapidly evolving digital health space.

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