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5x5 series: Insights and actions

Digital health risk management

A new health care consumer continues to emerge: Patients are better informed, and they want the ability to manage their health via tech-enabled solutions. Many life sciences organizations are exploring or expanding digital platforms—such as wellness applications and fitness trackers—to help meet these consumer demands. While these platforms **present many benefits to patients**, digital health assets introduce a new risk profile for life science companies. This quick summary provides insights and actions you can use today to help you determine whether your assets are developed and deployed within the "guardrails" of this highly regulated industry.

5 insights you should know

The power of digital health assets largely comes from their ability to collect, store, analyze, and visualize data about patients and their health. But as the capabilities of digital health assets expand, so do the associated risks, particularly for organizations that also act as "traditional" drug or device manufacturers.

A key variable to an asset's risk profile is its anticipated regulatory pathway, as well as how the asset will engage in the marketplace. Speed and agility are crucial to successful design, development, and deployment of digital health assets; therefore, active engagement of risk advisers able to partner with product teams is critical.

Regulatory and compliance frameworks have not necessarily been developed or updated to reflect the digital revolution. However, regulatory and enforcement agencies are aware of and attempting to respond to the proliferation of such assets.

Many consumers have embraced digital assets to assist in the management of their health. The security and privacy implications are substantial, as significant amounts of patient data are recorded and monitored by these assets. Protecting and managing personal health information is a significant challenge posing both regulatory and reputational risk.

Because digital assets reach individuals in all facets of their life, these products present an opportunity to engage with patients and other stakeholders across the health ecosystem on a deeper level. Therefore, protecting patient and stakeholder information and trust is paramount.

5 actions to take now

1. **Conduct a rapid risk assessment.** For companies considering the development or enhancement of a digital health asset, it's critical to quickly confirm the intended use and capabilities of the asset and assess potential risk across regulatory, cybersecurity, privacy, safety, and more.
2. **Evaluate existing infrastructure and talent.** Manufacturers should understand where existing control structures can manage risk and where controls are either not fit for purpose or insufficient. Digital health assets challenge organizations to evaluate and evolve their infrastructure, requiring personnel who can advise on the related risks.
3. **Engage regulators proactively.** Having proactive, transparent discussions with regulatory bodies regarding the envisioned functionality of assets can be critical to ensuring that both parties have a common understanding of an asset's regulatory pathway. Engaging enforcement agencies regarding novel market strategies can be informative where precedent doesn't exist.
4. **Strengthen enterprise security and privacy.** Organizations should consider their enterprise cyber security and privacy capabilities before considering development of a digital asset. Beyond mandated compliance requirements, organizations may also want to consider more proactive measures that could become a key competitive advantage.
5. **Maintain and increase trust in the health ecosystem.** As companies dive into the digital era, they should look to protect, and even enhance, trusted relationships across the health ecosystem. Privacy, security, and compliance are key responsibilities of asset developers. Not only is the company's reputation at stake, but so is the trust of patients and providers.

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