As the health industry evolves to meet consumer expectations for better quality, lower-cost and more convenient health care options, the demand for technology-driven innovation is accelerating as is the level of interest and investment among stakeholders or all sorts.

Health systems and other institutional providers are playing a more active investment role in the commercialization of biomedical, digital health, and other important health care discoveries in order to remain competitive, secure their positions as industry leaders and generate growth opportunities. This more active role also affords their internal innovators (e.g., physicians and scientists) to play a meaningful role in accelerating the commercialization of home-grown discoveries that may otherwise be left in "the valley of death" between government-funded basic research and later stage, industry-funded commercialization. Drug and medical device manufacturers, venture capital, private equity firms, large donors and other investors are injecting significant capital into fueling research, development and commercialization of health care technology innovation. On the one hand, health care systems and providers welcome such external co-investors who bring sophisticated expertise in product and market research, technology innovation, valuation and strategy capabilities, as well as access to networks of potential co-investors. For such external co-investors, on the other hand, joining forces with health care institutions affords much needed access to the expertise and thought leadership of clinicians, scientists and health technology innovation; a ready-made proving ground and "anchor customer" for the product; and the halo effect of the health care provider around the co-investor's clinical care and research reputation. The theory and the hope is that the combined capital and the different, but complementary, expertise, experience and perspectives of such co-investors provides a formula for financially successful innovation that is transformative and not merely disruptive.

As the speed of innovation accelerates, the regulatory framework is lagging behind; yet government agencies are highly interested and watching the sector closely. It is critical to proactively identify and manage regulatory risk considerations from the beginning and throughout the innovation investment lifecycle. A proactive strategy for managing regulatory risk will help to avoid creating or discovering impediments that can disrupt or fatally derail the investment and at the same time enhance the digital health innovation's potential.
The Perfect Storm of Non-Compliance Consequences