COLLABORATIVE TRANSFORMATION

FOCUS ON INNOVATION CENTERS

FOCUS ON INNOVATION CENTERS: DUE DILIGENCE FOR COLLABORATIVE VENTURES

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Hospitals and health systems (HHS) are increasingly acting as the catalyst for growth and expansion through technology and data innovations. Through their centralized innovation initiatives, HHSs not only drive internal innovation, but also allow HHSs to explore external investment opportunities and collaborations with third parties. As HHSs diversify beyond brick and mortar, these innovative ventures are opening up new paths to improve healthcare and tackle population health goals.

As noted in our previous installment in the Focus on Innovation Centers series, HHSs are taking a more integral role in the development and commercialization of new inventions and products. Rather than simply licensing an innovation to a partner, such as a large biotech company, HHSs are increasingly making investments to take an equity position in a start-up company and actively pursuing the development and commercialization. Click here for our discussion of various funding mechanisms for these investments .

As an HHS considers these funding opportunities, it must also ensure that it is conducting appropriate and thorough due diligence. These innovative partnerships naturally incur new risks for HHSs, such as the still-evolving regulatory landscape (for example, around digital health and FDA regulation), compliance considerations and complex questions on issues such as data ownership. HHSs have historically prioritized risk avoidance as key part of their business strategy—but low risk tolerance can quickly stifle innovation. To minimize risks without sacrificing the strategies driving today's novel

advances, HHSs should build out the corporate, legal and management infrastructure necessary to vet these new investments and opportunities. Particularly when investing in start-up companies to develop and commercialize innovative products, HHSs need to tackle due diligence through a fresh lens.

While HHSs may be well versed in diligence processes for ventures involving hospitals, physician practices or established companies, diligence for start-ups involves different issues—particularly when that start-up will be manufacturing a medical device regulated by the US Food and Drug Administration (FDA). In an innovative venture, diligence should include ample interviews with the principals to help you understand the vision and pathway for the company and its product(s). Start-ups rarely have compliance or legal staff, let alone full departments or robust infrastructure, so an HHS will want to thoroughly vet these issues independently of its partner. These investments require a different diligence style and skillset than many HHSs may be used to, so careful attention to certain additional areas is important. For example,

- Due diligence efforts should include a thorough **evaluation of all co-investors**. For HHSs, reputation is paramount, so it is important to understand who your partners are in owning and managing this innovative company. Understanding compliance "IQ" and risk tolerance are important considerations. Background checks on key individuals can help you avoid potential headline grabbing issues or problems down the road.

- Regardless of whether your innovation is a digital health product, a medical device, or a pharmaceutical or biotech product, it is vital to consider its potential **FDA approval pathway**. If the innovation is a pharmaceutical or biotech product, it is also helpful to consider what a global approval pathway might look like. For example, many drugs are launched in Europe before the United States, so understanding that international pathway can help you plan for future funding and research needs.

- Another critical component of start-up due diligence is **intellectual property** (IP). Does the target company have an IP position that is defensible and will create future value for the investment? If competitors come onto the market with better IP, they may push your innovative company out of the market, preventing your innovation from reaching patients and delivering its clinical benefit. Before you invest dollars, ensure that the proper IP protections are in place.

As you explore these important diligence areas for collaboration with a start-up, keep in mind that the diligence process itself will look different than it would for a well-established business or a traditional acquisition. With the right infrastructure in place to evaluate potential opportunities and careful due diligence, HHS' participation in innovative collaborations will accelerate bringing game-changing products to market, to the benefit of patients and healthcare consumers.

Read the full series on Innovation Centers at mwe.com/InnovationCenters