



WEBINAR TOP TAKEAWAYS

Hospital and Health System Innovation Summit: LESSONS LEARNED: DILIGENCE, DETOURS AND DATA, OH MY

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Industry leaders shared first-hand lessons learned from their work on recent innovation related projects. We covered a range of case studies, highlighting lessons learned around mission alignment, conflicts of interest, diligence considerations, data ownership and de-identification, and strategies for protecting a minority investor.

Mission Alignment

1

It is essential for a hospital and health systems to adopt a formal innovation strategic plan that aligns with its overall strategic mission and vision and clearly articulates its specific innovation goals and prioritizes focus areas. Hospital and health systems pursue innovation initiatives largely to support the clinical mission and drive revenue growth and diversification.

Partnerships are Essential Partnerships Drive and Shape Innovation.

2

There is widespread recognition that today's complex, multi-dimensional and technology-driven innovation requires partnerships and collaborations among stakeholders who bring different resources and expertise to the effort. Very rarely, if ever, can any single stakeholder provide all the ingredients and resources. However, picking the right partners and the right partnership/collaboration approach is key. "I think a key step is figuring out what are the role of partnerships. And then thinking about what that portfolio looks like over time and how it contributes to innovation," said **Mai-Tal Kennedy**, Principal, Vantage Partners. "What types of partnerships you're going to want to have in your innovation center, and then how you build to be able to meet the needs of those relationships."

Understand Possible Conflicts of Interest

3

Conflicts of interest must be evaluated at the front end and continuously revisited and re-evaluated during the full life cycle of the innovation, from early research & development and design and implementation of co-investment vehicles through commercialization and deployment in the hospital/health system's clinical and operational setting. "The potential for conflicts in commercialization of home grown innovation can be particularly challenging and complex if investment interests, royalties and compensation arrangements exist between and among the hospital and health systems, its officers and directors (and/or their families), and employed and

voluntary members of the medical staff,” said **Bernadette Broccolo**, Partner, McDermott Will & Emery. Failure to properly identify, assess and manage conflicts can undermine the integrity of research data supporting commercialization, which in turn can result in denial or withdrawal of FDA pre-market approval, create research subject and patient safety risks (and associated liability), lead to false claims liability and civil money penalties in connection with the submission of claims for reimbursement for the innovation by government reimbursement programs. An equally important and very real consideration is that failure to manage conflicts is of great interest to the media and the plaintiff’s bar and can also create significant reputation and public relations risk not only for a hospital and health system but also for other stakeholders as well. Oversight of potential conflicts in innovation by an independent committee with board authority has proven to be an effective step in achieving a disciplined and effective conflict of interest management plan.

Data Strategy Supporting Innovation

4

Robust, complex data of various types is one of the most valuable assets hospitals and health systems bring to the innovation table. “Many innovation partnerships begin as a data collaboration. Contributing or licensing that data to support the innovation endeavor also presents significant privacy compliance challenges that require careful planning at the outset and throughout the entire innovation life cycle, not the least of which is the HIPAA prohibition on the sale of identifiable data,” said **Bernadette Broccolo**, Partner, McDermott Will & Emery. An essential ingredient for managing the privacy risk will be development of an effective and sustainable de-identification strategy. Key due diligence and contracting questions in that regard include what de-identification method will be used, whether it meets HIPAA and other application de-identification standards, who is going to de-identify the data, whether and how often the de-identification will need to be revalidated, who will be the cost, and who bears the risks associated with impermissible re-identification.

5

Health IT Solutions Need to Focus on Problems to Solve

Emerging health technology companies often fail to make clear what problems they are trying to solve. To be successful, it needs to be clear what problem you want to solve and you need to be adept at convincing health systems they want to buy your solution.

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