



AMC Board Oversight of Collaboration with Industry: The Emergence of Innovation Centers for Digital Health

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Overview

In recent years, the healthcare sector has seen an unprecedented rise in digital health innovation, fueled by advances in data aggregation, wireless technology, and machine learning. In turn, these breakthroughs have accelerated, and have been accelerated by, more robust collaboration between academic medical centers (AMCs) and industry participants.

These collaborative initiatives take many forms,¹ ranging from largely internal AMC efforts at more streamlined decision making and processes for commercialization with third parties,² to development of new business entities that facilitate external investment in and development of digital technologies. Moreover, the potential industry partners in these AMC efforts cover the full spectrum of health sector participants,³ from corporate giants such as Google to start-up enterprises.⁴ They may be sponsored by a single AMC system, or they may also involve other AMCs, health systems, or laboratory partners.

Regardless of form, these AMC efforts in the digital health sector are being characterized as innovation centers. These innovation centers represent a sea

- 1 See, e.g., Jackie Drees, "[13 hospitals, health systems launching innovation centers in 2020](#)," *Becker's Health IT*, August 6, 2020.
- 2 Devin M. Mann, et al., "[Building digital innovation capacity at a large academic medical center](#)," *NPJ Digital Medicine*, Vol. 2, No. 13, March 7, 2019.
- 3 Ravi N. Shah, M.D., M.B.A., et al., "[The Rise of Digital Health and Innovation Centers at Academic Medical Centers: Time for a New Industry Relationship Paradigm](#)," *Jama Health Forum*, April 8, 2021.
- 4 Natasha Singer and Daisuke Wakabayashi, "[Google to Store and Analyze Millions of Health Records](#)," *The New York Times*, November 11, 2019.

change in the traditional AMC approach to commercialization,⁵ which tended to license each discrete emerging technology to a third party that then was wholly responsible for commercialization efforts. This traditional approach reflected not only the lack of commercialization infrastructure within AMCs, but also was an implicit acknowledgement of the low risk tolerance that AMCs had for financial and regulatory risk associated with these commercialization initiatives.

With an innovation center model for digital health, an AMC brings these commercialization efforts into the core strategic thinking for the academic health enterprise.⁶ Rather than offloading the commercialization and implementation of a digital health opportunity on a third party through a traditional licensure arrangement, the AMC becomes a key investor and decision maker in the development and application of the digital technology.⁷ Depending on the particular opportunity, the AMC may offer to the venture clinical expertise, robust healthcare

5 Center for Digital Health Innovation at UCSF, [“A New Model for Collaborating with an Academic Medical Center”](#) (blog), May 6, 2020.

6 Mike Miliard, [“Partners launches expansive 5-year digital health innovation plan,”](#) *Healthcare IT News*, December 12, 2019.

7 David Guez, M.D., et al., [Accelerating Early Stage Digital Patient Workflow Innovation](#), Center for Digital Health Innovation at UCSF.

→ Key Board Takeaways

- AMCs are participating in a wide array of industry collaborations focused on digital health, through innovation center development and expansion.
- AMC boards should be fully involved in strategic decision making associated with these digital health innovation center initiatives, and should have the opportunity to assess the structure, due diligence, and compliance considerations associated with these efforts.
- Certain compliance considerations are cutting edge, and technology currently may be ahead of law and regulation in arenas such as privacy protections, FDA regulation, and Intellectual Property. In addition, any cross-border digital health initiatives must be evaluated under pertinent international law.

data, technology, and potential clinical partners, along with funding. In return, the AMC may benefit from the development of and priority access to tools that enhance quality and value-based care, as well as diversified revenue streams.

As we see the continued rapid acceleration of AMC-driven innovation center activity in digital health, it is important to ensure that the AMC governing board is educated as to these developments, and is appropriately involved in the strategic decision making associated with these efforts. This requires that the board receive regular reports on innovation center initiatives; be afforded the opportunity to evaluate alternative models for digital health commercialization; and be apprised of due diligence, and regulatory and compliance risk factors, in connection with these innovation center activities.

Trends in AMC-Sponsored Innovation Centers for Digital Health

In a very real sense, the most compelling metric for AMC-sponsored innovation centers is the sheer variability in approach. Nevertheless, certain themes have emerged in terms of possible models:

- The innovation center serves as a centralized location within the AMC ecosystem for digital health development resources to be made available to external industry collaborators that can include research design, clinical validation, piloting of products, and access to faculty consultation. It may also offer collaborators access to digital tools developed within the AMC, as well as investment opportunities for these collaborators.
- Industry collaborators potentially can include companies in digital health, life sciences, health insurance, healthcare provider, technology, or other pertinent sectors. They may be large, well-established organizations, start-up enterprises, or private equity/venture capital-focused.
- Digital health can be broadly thought of to include telehealth, wearables, personalized medicine, and machine learning.
- The innovation center may be an internal division within the existing AMC infrastructure, or may entail development of one or more new entities that facilitate streamlined decision making, efficiency in commercialization, and ease of external investment.
- In the case of an innovation center model that entails development of new, for-profit entities, the AMC may have the opportunity to invest in the venture,

participate in governance, and contract with the enterprise to ensure that the AMC has a priority role in research, development, and use of the digital technology.

- It is possible for certain innovation center initiatives to focus on digital health innovation for targeted patient populations, for example medically underserved patients, oncology patients, or pediatric patients.
- For certain AMCs, the innovation center may entail cross-border opportunities with one or more global companies. These initiatives, while exciting, require specialized attention to regulatory and compliance considerations.
- For AMCs, a key strategic goal of the innovation center model is to accelerate the push to diversify traditional campus/bricks-and-mortar healthcare service approaches, facilitate value-based care, and offer patients cutting edge clinical resources.

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What AMC Boards Need to Know: Due Diligence and Compliance Considerations for Digital Health Innovation Centers

AMC boards clearly play an essential oversight role in the development and implementation of innovation centers. In broad terms, the board as a whole, or a key board committee, should be informed of, and have the opportunity to weigh in on, the following:

Structure. The AMC board should be involved in ongoing decision making regarding the innovation center approach, including whether it is entirely internal in infrastructure or entails development of one or more new entities. Assuming the innovation center will sponsor one or more new, for-profit entities, the AMC board should be in a position to evaluate the ownership structure, due diligence adequacy, AMC governance participation, AMC investment opportunity, and contractual relationships between the new entity and the AMC.⁸ Aside from corporate form,

8 Douglas A. Hastings, “Increasingly Common Bedfellows—Collaborations between Academic Medical Centers and Investor-Owned Health Care Companies,” *AHLA Connections*, September 1, 2013.

this could include an assessment of percentage ownership and reserved/approval powers held by the AMC, along with an evaluation of the AMC's participation in the governance structure through designated board members or member reserved powers.

If the AMC is making a financial investment in the new enterprise, thought should be given as to whether this is an up-front equity investment or a loan structure such as a convertible note that allows for a deferral of valuation. The contractual relationship between the AMC and the innovation center entity should be explicit as to intellectual property ownership; access to and control of patient data; the AMC's priority access to research, development, and use opportunities; and the means by which the new entity will assure legal and regulatory compliance.

Due Diligence. Before embarking upon a digital health industry partnership through an innovation center model, the board should ensure that due diligence thoroughly assesses the background of the prospective partner, particularly those that are start-up or early stage entities, or private equity/venture capital partners that may have limited experience in healthcare. While partner background checks are always a good idea, the imperative to undertake them in the context of digital health is especially important, in light of the reputational consequences to the AMC and the proliferation of new entrants in the sector.

From a regulatory and compliance perspective, the board should ensure that certain cutting-edge digital health regulatory issues are addressed and planned for in the structure of the innovation center initiative. In many ways, digital health technology is running ahead of the capacity for regulatory bodies to keep up. As a result, the innovation center structure needs to acknowledge that future law and regulation may impact digital health technology being developed today. Several key areas should be evaluated:

- Access to patient data typically is central to these innovation center arrangements. At the same time, this access raises significant compliance considerations,⁹ under HIPAA and other federal and state law. Is the data adequately de-identified,¹⁰

9 Robert Belfort and William S. Bernstein, et al., *A Shared Responsibility: Protecting Consumer Health Data Privacy in an Increasingly Connected World*, Robert Wood Johnson Foundation and Manatt Health, June 2020.

10 *Matt Dinerstein v. Google, LLC*, No. 19 C 4311, U.S. District Court, N.D., Illinois, Eastern Division, September 4, 2020.

or is it subject to future re-identification? Have patients given truly informed consent? How will patient rights be addressed if, in the future, the data is used for a purpose not contemplated today? Similarly, how will these issues be handled if applicable law changes in the future to afford greater protections to patients regarding use of their data in digital health applications? While these questions cannot be fully answered today, the structure of the venture and the related agreements should acknowledge this uncertainty and provide a means for these issues to be addressed and resolved in the future.

- The Food and Drug Administration (FDA) is in the process of developing an approach to regulation of healthcare digital technologies, including wearables and machine learning tools. Through its [Digital Health Center of Excellence](#), for example, the FDA has articulated a framework for regulating machine learning and artificial intelligence technologies in healthcare, from pre-market development through post-market performance. While certain FDA compliance requirements are in place today for development of healthcare digital technologies, it is clear that the FDA will continue to issue guidance in this arena. Development of an innovation center initiative today must allow for this expanded FDA oversight in the foreseeable future.
- A key consideration for AMCs embarking on innovation center initiatives is to have clarity on ownership of intellectual property¹¹ and the right to use technologies resulting from the venture. While this is not a new issue, it is a rapidly-evolving one, and therefore it is imperative that the board ask focused questions about these issues in order to assure that the AMC is receiving appropriate current and future value from the arrangement.
- As indicated above, innovation center initiatives often entail cross-border transactions that are evaluated under the foreign corporate, privacy,¹² tax, and intellectual property laws that may apply.
- While not a new issue, not-for-profit AMC boards should assure that innovation center initiatives have been deemed Section 501(c)(3) and charitable organization legal standards, and that robust conflict-of-interest and transparency protocols are in place.

11 Patrick J. Silva, Ph.D., M.B.A. and Kenneth S. Ramos, M.D., Ph.D., [“Academic Medical Centers as Innovation Ecosystems: Evolution of the Industry Partnership Models beyond the Bayh-Dole Act,”](#) *Academic Medicine*, Vol. 93, No. 8, August 2018; pp. 1135–1141.

12 European Commission, [“Europe fit for the Digital Age: Commission proposes new rules and actions for excellence and trust in Artificial Intelligence”](#) (press release), April 21, 2021.

Conclusion

There are a wealth of opportunities for AMCs and their related systems to bring digital health development into the center of the enterprise's strategy through development or expansion of innovation centers. These models are expanding and diversifying at a rapid pace, and will play a pivotal role in the AMC's future. AMC boards should be involved in innovation center decision making, including structuring considerations, and should ensure that appropriate due diligence and compliance measures are taken. Within this, particular attention should be paid to emerging legal and compliance considerations that may require future adjustment to the innovation center's organization and activities.

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