EXECUTIVE SUMMARY

The University of Colorado (CU) Denver and Stryker collaborated on a successful acquisition due in large part to the relationship and interaction with the Bioengineering Chair and engineer at CU and an orthopedic device consultant responsible for the majority of the research activities. The relationship between the bioengineering department and its location on the medical campus also contributed to the synergy between all members. According to Mr. Kemler, “Typically, successful deals are a result of relationships already established through researchers.”

— JAMIE KEMLER, VP, Intellectual Property Business Strategy, Stryker

Best Practices

<table>
<thead>
<tr>
<th>University Strategies</th>
<th>Industry Strategies</th>
</tr>
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<tbody>
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<td>Several universities hire licensing professionals, who have the scientific background necessary to understand the technologies being licensed and the ability to facilitate discussions between the university and the company.</td>
<td>When a company has conducted due diligence, it is equipped with the necessary information on the university’s technologies. This in turn allows companies to formulate a plan when approaching universities which can be received favorably and drive productive discussions.</td>
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Points of Contact

| Industry should maintain open lines of communication by identifying a point of contact to serve as project advocate and provide insight on organizational changes. In addition, companies should consider establishing a primary executive responsible for academic relations. |
| In the course of partnering discussions, universities may benefit by identifying a member of their faculty to serve as a scientific champion. |

Business Agreements — Licensing Terms

| When taking a deeper look at form agreements and negotiations, it may be helpful for universities to approach this process in two parts by setting expectations, as well as displaying flexibility. For their part, industry should recognize the unique nature of transactions with academic institutions. |
| Both companies and academic institutions have certain priorities when negotiating agreements — these can be summarized through the “four E’s” and “four P’s,” respectively. |

Four E’s and Four P’s

Some of the most important elements of a license agreement to companies can be summarized with the following four E’s: Exclusivity, Economics, Enforcement, and Exit. Additionally, the following items have been expressed by universities as being the most important components related to licensing terms – the four P’s: Publication, Prosecution, Participation, and Protection. Remembering that the ultimate goal in medical technology licensing agreements is to provide for patient access to technologies may help each side to remain reasonable in its requests during negotiations.

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Executive Summary

The relationships between medical technology companies and university technology transfer offices play an integral role in the medical technology innovation ecosystem and impact the lives of patients. Universities are filled with enthusiastic faculty members conducting research on cutting-edge approaches to health concerns. Medical technology companies are equipped with the knowledge and resources to drive state-of-the-art solutions to market. When the two groups collaborate on novel approaches to medical technology, the results include stronger research and development pipelines with potential to improve treatment options for patients.

Given the importance of these relationships between universities and medical technology companies, AdvaMed Accel, in conjunction with Farah Gerdes and Jacki Lin of Wilson Sonsini Goodrich & Rosati, has developed the AdvaMed Accel University Technology Transfer Best Practices Guide to examine the history of technology transfer and the dynamics of collaboration between universities and medical technology companies. Over the past two years, AdvaMed has employed strategic analysis tools and qualitative research methods to explore and identify the characteristics, culture, and approach of successful academic and industry collaborators in medical technology. Additionally, a formal fireside chat and group discussion with over 40 university representatives was conducted to gain a deeper understanding on this topic from the academic perspective. Further interviews with early-stage companies, medtech investors, large medical device companies, and representatives of incubator/accelerator organizations were also held to inform the drafting of this guide.

With the introduction of the Bayh-Doyle Act in 1980, technology transfer for universities, non-profit entities, and small businesses receiving federal funding was fundamentally changed and entities were given greater flexibility and authority to commercialize federally-funded innovations and technology. The Bayh-Dole Act led to a remarkable growth in university patenting and licensing activity. There has also been significant growth in the number of start-up companies forming to develop and commercialize these technologies, pursuant to licenses from the universities, since the enactment of Bayh-Dole. However, based on a recent AUTM survey (512 responding institutions), 2017 marked the first-ever decrease in reported university invention disclosures (down 3.2%) from the previous year and there was a 7% decrease in new patent application filings in 2017 as compared to 2016.¹ In parallel, access to capital for emerging medical technology companies has declined over the past decade, and “financial pressures generated by health care reform, the transition to value-based care, and tougher insurance coverage and regulatory requirements for medtech innovations have deterred some corporate and VC investors.”² Given current trends, it is more important than ever for industry and academia to establish long-standing cooperative relationships.

We examined the strategies employed by both universities and industry partners and conducted further research on the most effective relationships in the field. The result is a best practices guide that discusses the following key factors critical to developing and sustaining effective relationships between university technology transfer offices and medical device companies:

1. **University Strategies** for Engaging with Companies
2. **Industry Strategies** for Engaging with Universities
3. **Points of Contacts** (Gaining Access to Points of Contacts, Scientific Champions)
4. **Business Agreements** – Licensing Terms

By applying best practices in these key areas, universities and medical technology companies will develop productive relationships and more effectively translate academic innovation to commercial products that positively impact patients lives.

AdvaMed Accel is the division within AdvaMed dedicated to addressing the unique needs and challenges of smaller medical device and diagnostics manufacturers—the lifeblood of the medical technology industry. The only organization of its kind focusing specifically on the needs of the medtech industry’s emerging growth companies, AdvaMed Accel works to create a policy environment more conducive to capital formation and innovation.

For a full version of the University Technology Transfer Best Practices Guide and for more information on AdvaMed Accel, visit www.advamedaccel.org.