

M2D2: a successful model catalyzing medical device innovation and development

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ABSTRACT

The Massachusetts Medical Device Development (M2D2) center offers inventors and small medical device companies coordinated access to research, engineering, and clinical investigation at the UMass Medical School (UMMS) and UMass Lowell (UML) campuses. UMMS provides clinical expertise and access to 40+ research cores, while UML contributes its world-renowned engineering expertise and plastics laboratories, business analysis and planning support, and prototyping and product development services. Corporate sponsors (e.g., Johnson & Johnson, Amgen, Boston Scientific) and service providers with interests in biomedical product development provide access to technical, regulatory, and legal advice, as well as device design and manufacturing services. With this support, M2D2 has helped 111 entrepreneurs secure ~\$152M in private investment and \$11M in NIH SBIR funding to support a broad array of medical device and biotech innovations. M2D2 has hosted 120 student interns and has provided an annual local economic impact to the city of Lowell alone of \$74 million. The success of M2D2 demonstrates our ability to form effective partnerships that allow stakeholders to provide critical input into medical need and product development, engage small companies to bring medical devices and therapeutics to the clinic, connect entrepreneurs to the healthcare system for clinical trials, and provide valuable entrepreneurship experiences for business, engineering, and medical trainees.

Keywords: medical devices, biotech, incubator, product development, innovation

1 BACKGROUND

The Massachusetts Medical Device Development (M2D2) Center is a highly successful medical device accelerator and incubator [1]. This center combines the engineering and business expertise of University of Massachusetts Lowell with the clinical development expertise of University of Massachusetts Medical School. M2D2 has helped over 111 medical device start-up companies advance their medical devices. This assistance consists of incubator space, access to the University's core research facilities, access to student interns, prototyping and product development services at UML, medical assessment

and clinical development at UMMS, and business development and start up assistance at UML. M2D2 also provides services from Sponsors that include regulatory services, legal services, and device design and manufacturing services. Among the currently supported companies, 31 are in residence in the M2D2 accelerator/incubator and the rest are virtual or rent only a desk and not lab space (Table 1). Since M2D2 has typically supported very early stage companies (many of which arose from discoveries made in academic laboratories), the companies typically exit the space once they have larger teams and manufacturing needs.

Table 1. History of M2D2-Supported Companies

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| 111 total companies |
| 53 virtual companies (use M2D2 services but not in residence) |
| 58 resident companies 31 currently in residence 27 graduated |
| Of the graduated companies 1 was acquired |
| 23 outgrew the space and raised funds for another facility |
| 8 have current products on the market |
| 5 failed |

2 ORGANIZATION

M2D2 has a team of Core Directors (the authors of this manuscript), which is a subset of the larger M2D2 Executive Board (Core Directors plus UMass faculty and staff with expertise in product development). The Executive Board includes representatives from a wide range of disciplines represented at UML and UMMS, including business, technology transfer, microbiology, lab science, nursing, engineering, and clinical and translational science. This team selects client companies for residency in the accelerator/incubator, and provides advice on development and mentoring of client companies. M2D2 Core Directors and Executive Board Members meet in person bi-weekly and confer frequently by phone or email.

The UMass team is guided by an Advisory Board, consisting of institutional leaders; experts in legal,

regulatory and manufacturing; as well as representatives from several large corporate sponsors such as Johnson and Johnson, Boston Scientific, and Amgen, all of whom provide feedback on both strategy as well as serve as mentors to client companies.

The Core Directors have administrative responsibility for M2D2 interactions and sponsor engagement. M2D2 currently manages three accelerators / incubators, two in Lowell and one in Worcester which are sustained by a combination of company rents and sponsorships. A primary role for the Core Directors is to manage the fiscal operations of the Center. The Core Directors also govern administrative policies and procedures, such as lease terms and management of non-compliance with rent payments. The Core Directors are the primary point of contact for relationship management with our Sponsors and other partners, including scheduling events with the Sponsors and resident companies.

3 RESOURCES

M2D2 offers resources in five broad categories: physical space, equipment, connections to UMass, funding opportunities, and mentoring. We describe each of these areas in more detail below.

3.1 Physical Space

M2D2 currently operates in three physical facilities, two in Lowell and one in Worcester. Our original incubator is located on two floors in the Wannalancit Mills Office and Technology Center at 600 Suffolk Street, Lowell, MA. The second floor has 9,000 square feet and includes six wet laboratory suites, two office suites, a large open office collaboration area, a conference/board room, reception area, and break room equipped with table, chairs, and kitchen equipment. On the first floor, 5,000 square feet is available and includes six individual offices along with conference and meeting space. In 2015, a fully equipped shared lab facility opened at 110 Canal Street, Lowell, MA. This 11,000 square foot center includes dedicated lab bench space, BSL2 capabilities, equipment and services, open co-working and collaboration space, and meeting and conferencing space. Our newest space opened in 2018 at the UMass Medical School, 55 Lake Ave. N, Worcester, MA. This 1,200 square foot facility includes open concept lab space along with a shared conference room and offices.

3.2 Equipment

In addition to physical space, M2D2 provides a range of common equipment for our client companies. Between all locations there are well over 60 pieces of equipment available ranging from hot plates and stirrers to large floor model centrifuges, freezers, and incubators. In the past year M2D2 has invested over \$300,000 in new

equipment for our client companies. Equipment that is not immediately contained within the lab space can be made available to companies once they receive the proper training and approvals. Biosafety cabinets and rooms along with environmental rooms are also available for use.

3.3 Connections to UMass

As a medical device and biotech incubator operated by a major research university, one of the most valuable services we provide are connections to the UMass community. We broker numerous connections to UMass faculty for clinical input, expertise, and sponsored research. UMass students are another major resource for M2D2 companies. In collaboration with the Massachusetts Life Sciences Center (MLSC) Internship Challenge [2], we have placed over 120 students at our client companies, and over 20 have converted to part- or full-time employees. Companies enjoy multiple benefits as they gain access to eager students and have the intern stipend reimbursed by the MLSC. Finally, M2D2 companies receive preferred rates and access to nearly 50 state-of-the-art research core facilities at the UMMS [3] and Lowell [4] campuses.

3.4 Funding Opportunities

M2D2 offers several funding opportunities throughout the year to help our client companies access the capital they need to bring their technologies to market. Our signature event is the “M2D2 \$200K Challenge”, an annual start-up competition hosted by M2D2 focused on identifying and rewarding disruptive companies in the medical technology and biotechnology industries. Every year we receive scores of entries from entrepreneurs worldwide (over 140 applications in 2019). Selected finalists present their technology at a pitch and networking event to be eligible to win a share of \$200,000 of sponsor-provided, in-kind services. These services include lab and office space; engineering, product development, legal, regulatory, clinical, and business services. Past winners have been empowered to bring their innovations to life—and to market.

Another popular event is an annual “Barracuda Bowl”, a panel-style venture pitch event resembling a popular television show. Several entrepreneurs representing M2D2 start-up companies pitch their venture and face questions from a panel of investors regarding their technology, current stage of development, and financial projections. Over the past five years we have sponsored 35 pitches to 37 investors in front of over 650 attendees.

Over the past year M2D2 has received two peer-reviewed grants from the Federal government to help entrepreneurs move their products to market. The first, called the Center for Advancing Point of Care Technologies in Heart, Blood, Lung, and Sleep Disorders (CAPCaT – U54HL143541), will support development, deployment and testing of promising late-stage, point-of-care technologies

that can be rapidly used to enhance the diagnosis, monitoring, management and treatment of heart, lung, blood and sleep disorders. Through the center, CAPCaT award winners will have access to resources at the National Institutes of Health Point of Care Technology Research Network [5] as well as those from M2D2.

A second grant will allow M2D2 to scout for innovative technologies and products being developed for health security indications such as pandemic influenza, sepsis, and bioterrorism. As one of only eight centers in the USA, this opportunity allows M2D2 to help businesses that create these technologies by connecting them with our network of corporate sponsors, mentors, and vast set of university resources. Funding is provided by the Biomedical Advanced Research and Development Authority (BARDA) DRIVe initiative [6].

3.5 Mentoring

M2D2 currently partners with over 15 sponsors to provide financial support to M2D2 operations and the \$200K Challenge. More importantly, these sponsors support emerging companies through access to core research facilities (such as the M2D2 accelerator/incubator), educational programs, experienced entrepreneurs, and company expertise in deal-making, therapeutic and technology areas, product development and commercialization. Long-standing relationships include Mintz, a law firm specializing in intellectual property and corporate structure; MPR Associates, a product design/development/manufacturing services firm; and Johnson & Johnson, who selected M2D2 as its first academic J Labs site [7].

4 CONCLUSION

The M2D2 accelerator provides strategic, regulatory, and business development and support services to medical device and biotechnology innovators. By concentrating resources and expertise, client companies have access to what they need to successfully commercialize their technology.

REFERENCES

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