EXAMINING SUCCESS FACTORS FOR INNOVATION IN THE MEDICAL DEVICE SPACE: A PATH FORWARD FOR FUTURE ENTREPRENEURS

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ABSTRACT

Karthik Kaundinya: Examining Success Factors for Innovation in the Medical Device Space:
A Path Forward for Future Entrepreneurs
(Under the direction of Dr. Arvind Malhotra)

The medical device industry in the United States is a complicated and dynamic business environment. This industry is characterized by some high-profile entrepreneurial successes and many failures. Although innovation and entrepreneurship are well studied in the literature, many existing theories face challenges when scrutinized within the context of medical devices. This thesis explores the determinants of entrepreneurial success in the medical device industry. Two models are considered: one that explains the ability of current medical device startups to receive funding and one that explains the likelihood that a startup will either succeed or fail. The models show that increasing the founders' LinkedIn followers, focusing on an FDA Class 3 medical device, and being embedded in a robust entrepreneurial ecosystem are all significant and positive factors for determining funding. In addition, having more founders and including a founder with a medical degree both increase the likelihood of startup success.

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INTRODUCTION

Scientific thought and achievements are spurred by entrepreneurship and competition. Tesla, led by Elon Musk, is revolutionizing the way the world views electric cars. Closer to the purview of this thesis, 23andme co-founders Anne Wojcicki, Linda Avey, and Paul Cusenza launched FDA approved genetic testing kits which could detect dozens of genetic traits that led to susceptibility to diseases. For the affordable price of $199, these kits can reveal, for example, whether one is susceptible to breast cancer on account of carrying the BRCA gene. A similar test would have cost multiple times that in 2001 (Jorgensen-Earp, 2019).

My interests in the nexus between biotechnology and entrepreneurship budded during high school. When I viewed Steve Jobs' first presentation revealing the iPhone, I noticed that he emphasized the Internet and cellular communications aspects of the device even while the crowd around him seemed more enthusiastic about the cell phone's music playing capabilities. Fast forward more than ten years later and using smartphones to browse the Internet and call other people are central to the functionality of the device. Successful entrepreneurs like Steve Jobs are able to think about what future scenarios look like, and how customer needs evolve in those scenarios.

This ability to conceptualize the future and meet the evolving needs of the world in that future excites me. Currently, I am leading Muse Biomedical, a startup that has branched out from an undergraduate pitching competition. Muse Biomedical aims to provide data-driven diagnostic tools

for those with longer term opioid prescriptions so that they can better understand the physiological effects of their medication over time while having a platform to share their experiences with their physician and loved ones. Muse Biomedical's ultimate goal is to reduce the prevalence of opioid addiction.

Most people can think of at least one problem they experience, and many may think of a few ways to get around that problem. Far fewer come out with a successful solution. According to an article by CITI I/O (2019), just thinking about problems in the world spurred university-aged students to create a self-charging car, a virtual map creator, and a protective electric jacket. However, even when interesting ideas are generated, they often are shelved somewhere along the way from initial ideation to commercialization. Understanding what factors drive the successful implementation of these ideas will allow them to design and operate their ventures accordingly, increasing the likelihood of successful commercialization. Correspondingly, the goal of my research is to inform medical device entrepreneurs and researchers about some key drivers of success in this space. I hope that my findings will provide insights to these entrepreneurs and increase their own likelihood of success, ultimately benefiting patients across the world.

As this study explores medical device entrepreneurship in the United States, some context related to medical device definition and regulation is useful before perusing this thesis.

Medical Device Definition

Differentiating the medical device industry from the pharmaceutical industry is important even though the emergence of smart drugs may blur the lines between the two. I am disregarding pharmaceutical products in this thesis as their development and regulation fundamentally differ from those related to medical devices. For the purposes of this thesis, I will use the definition of the term

"medical device" as employed by the United States Food and Drug Association (FDA). According to the FDA, a medical device is:

> An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
>
> intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. (FDA, 2018)

The last two parts of the definition are most important to the study as they dictate the functions and mechanisms of action for medical devices.

Medical Device Regulation in the United States

Products classified as medical devices are regulated by the FDA in the United States. The FDA only has jurisdiction over devices that are marketed in the U.S., implying that a company based in the U.S. can first sell their products abroad before obtaining FDA approval. The standards of rigor applied during regulatory review are also higher in the U.S than in many other developed economies. For example, FDA approval requires that a device be proven to be effective in its stated goals compared to common control treatments or be substantially equivalent to a prior approved device while medical devices in the E.U only need to perform their stated function (Maak & Wylie, 2016).

Medical devices regulated under the FDA fall under three categories: Class I, Class II, and Class III. These three classes are named in order of lowest risk to highest risk. For example, tongue depressors used in a hospital fall under Class 1 regulation as they pose almost no risk to the patient

while most high-risk implants, such as pacemakers and invasive surgical tools, typically fall under Class 3 regulation. Class 2 devices can range from mildly invasive but well-established products such as sutures to wearable sensors (Van Norman, 2016).

Research Questions

Tapping into the potential of the medical device industry requires a detailed knowledge of medical device startups. These startups differentiate themselves from incumbents and large corporations through prototyping new technologies (Nelson et al., 2019). In that context, my two research questions are as follows: First, what are the key factors that determine the level of funding that medical device startups receive? Second, what are the key factors that determine whether a medical device startup succeeds or fails?

The thesis is structured as follows. In the literature review, I examine multiple perspectives on entrepreneurship and innovation and their relation to the medical device industry. I then discuss the theoretical development, which leads to a set of hypotheses. Following that, in the methodology section, I discuss my variable selection, data collection, and model structure. In the findings section, I present the findings from statistical analysis. Finally, in the discussion and conclusion sections, I cover the implications of my findings, discuss the limitations of my research, and summarize my thesis.

LITERATURE REVIEW

Theories of innovation have evolved over time. Further, thinking about innovation is inherently interdisciplinary, unconstrained to a specific business or technical discipline. From a macro-perspective, theories of innovation have evolved from the linear innovation models – that proceed through the stages of invention, commercial application, and diffusion – and the concept of creative destruction (Schumpeter, 1934) to more recent approaches that view innovation through the lens of knowledge management (Shujahat et al., 2019) and Technological Innovation Systems (Bergek et al., 2008). On the other hand, in terms of topics considered, the literature on innovation spans numerous micro-perspectives ranging from creativity (e.g., Fischer et al., 2019) and risk taking (e.g., Mao & Zhang, 2018) to firm competencies (e.g., Souitaris, 2002) and market disruption (e.g., Schmidt & Druehl, 2008). Covering every studied perspective in this review would be a daunting task. Therefore, I draw from specific theoretical aspects that are particularly relevant to my analysis of medical device innovation. I begin with the concept of disruptive innovation because it is central to the entrepreneurial startup perspective I adopt in this study.

The theory of disruptive innovation

This theory was first introduced by Clayton Christensen and popularized in his book *The Innovator's Dilemma* (Christensen, 1997). He developed the theory from his research on the computer disc-drive industry, where companies iterated on previous designs by decreasing drive size. Christensen described disruptive innovation as something that "introduce[ed] simplicity,

convenience, accessibility, and affordability where complication and high cost are the status quo." (Christensen Institute, 2020). Since then, the theory of disruptive innovation has been expanded upon and critiqued even as technology and innovation have been redefined and reframed in the 21st century. I will discuss disruptive innovation more broadly and then the theory's conceptual application to the medical device industry.

In *The Innovator's Dilemma*, Clayton Christensen differentiated disruptive technologies from sustaining technologies. He argued that the latter was more common and was characterized by improving upon a previous existing technology (Christensen, 1997). These improvements could be incremental or radical in nature, but they were improvements nonetheless compared to existing market solutions. In contrast, he characterized disruptive technologies as those that result in a lower level of performance on introduction compared to existing solutions. Examples of disruptive technologies that he listed included sports motorcycles manufactured by Honda and Kawasaki outcompeting larger on-road Harley Davidson bikes, and hydraulic excavators overtaking conventional mechanical excavators in construction. When first introduced in the late 1940s, hydraulic excavators lacked the range and the capacity to compete with mechanical excavators for industrial applications, so they were relegated to residential and small public infrastructure use, where they became popular. Technological progress over the next 20 years fixed the mobility issues and increased the storage capacity past what industrial consumers required. Thus, an innovation that had underperformed its intended audience at first, exceeded expectations over time.

Disruptive innovation has arguably existed in some form across human history. The nature of technological progress dictates that what was once new and expensive becomes common and affordable over time. Accelerating innovation has created situations where short-term events have made new technologies obsolete in a few years, such as when camera-equipped smartphones made

digital cameras obsolete within a few years of the former's introduction. Thus, the need to study the disruptive technologies that push incumbent solutions out of the market only grows.

An important and interesting question that arises here is: How does an inferior technology manage to overthrow the superior, incumbent technology? As successful incumbents increasingly focus on serving their existing customers and keeping them from being poached by competitors, they focus on a series of incremental innovations that steadily improve their products. Ultimately, this results in their products overshooting the needs of the low-end customers, who are no longer well served. These customers – who are ignored by the incumbents that are focused on the higher end, more profitable customers – welcome the new, simpler technologies that the disruptive innovator offers. After establishing a presence at this low end, the disruptive innovator steadily improves the capabilities of the new technology and at some stage overtakes the capabilities of the incumbent, and displaces the incumbent from the market. This sequence, tellingly, is relevant to the application of disruptive thinking in the medical device space – a point I discuss later.

Debates around disruptive innovation

One criticism of Clayton Christensen's work is that his use of the term "disruptive innovation" is so broad that it impedes meaningful conclusions (Markides, 2006). To address this, Markides argues that disruptive innovation should be subclassified into disruptive technologies, disruptive products, and disruptive business models.

According to Markides, business model innovation involves changing the value proposition and supporting operations of an existing company to attract more customers or cause customers to increase spending. For example, traditional business schools, which emphasize in-person education and long-term benefits of deep and broad learning have been challenged by online knowledge providers such as Coursera that emphasize flexibility, highly contextual learning structured in

discrete and digestible chunks, and low prices. Disruptive product innovation happens when firms offer a variant of the product that mainstream customers will buy. He points to a few of Clayton Christensen's examples of disruptive innovation in *The Innovator's Dilemma* such as Honda motorcycles and Canon copiers as being more traditional product innovations (Markides, 2006; Christensen, 1997). Finally, disruptive technological innovation happens when a totally new product is developed for the first time. Markides further argues that established companies are better at fostering disruptive product innovations than entrepreneurial firms while the latter are usually better at producing disruptive technological innovations – this point is particularly relevant in my study context.

As such addendums to and critiques of the disruptive innovation concept amassed over the years, Christensen tried to clarify what his theory did and did not address. His main argument was that people often used the term disruptive innovation imprecisely to refer to any event wherein there was a shake-up in the market with existing market incumbents ending up on the losing side (Christensen et al., 2015). Distinguishing between disruptive innovation and other forms of market shake-ups is important because the business strategy that goes into being disruptive or guarding against disruptive market entrants is different than that applicable to other types of innovation.

For example, Christensen et al. (2015) contended that app-based ride-provider Uber was often termed as a disruptive company simply because it dramatically transformed the taxi industry. However, they conclude that Uber's rise in the mid-2010's was not an example of disruptive innovation because Uber began by appealing to the same mainstream consumers in San Francisco that used traditional taxi services (Christensen et al., 2015). They argue that, in contrast, and as described earlier, a disruptive innovation first appeals to fringe, low-end consumers at first and then transitions over time to displacing the dominant incumbent and serving mainstream customers. As

opposed to Uber, Netflix's rise and dominance over Blockbuster in the mid-2000's qualifies as a disruptive innovation. Netflix originally appealed to movie buffs, a fringe segment that was not satisfied by Blockbuster's mainstream offerings. Over time, Netflix was adopted by mainstream movie watchers. The theory of disruptive innovation itself does not explain how an entrepreneurial firm can succeed in a market with better-resourced incumbents. However, a point of note is that, because an entrepreneurial firm that adopts a disruptive innovation approach naturally focuses on low-end or fringe customers to begin with, this can help avoid destructive head-on competition with the well-resourced incumbent (Christensen et al., 2015).

Measuring disruptive innovation

In applying the theory, an interesting question arises as to what counts and what does not count as a disruptive innovation. Christensen and Raynor (2003) count disruptions as either being new market disruptions, which create a new customer segment entirely, or low-end disruptions, which cater to the more price-sensitive customers in an existing market. Govindarajan and Kopalle (2006) use these two categories as a framework to create a specific set of five criteria that disruptive innovations encompass: "the mainstream market does not value the innovation's particular package of performance attributes at the time of product introduction", "the innovation performs poorly on the attributes mainstream customers value", "the innovation is first introduced in an emerging or insignificant niche market", "there is not necessarily a word-of-mouth effect, or opinion leadership, or respect among peers at play for the niche customer segment that finds disruptive innovations attractive", and "the disruptive product offers a lower margin and may therefore be ignored by incumbents who are serving larger and more attractive segments" (Govindarajan & Kopalle, 2006, p. 191).

Hang et al. (2011) argue that a simpler method is more useful to aspiring innovators. They propose a framework centered around market positioning, technology, and other drivers, including life-style changes associated with the innovation and helpful legislation. They develop a short yes/no questionnaire related to these factors; the results of the questionnaire can be used to determine whether an innovation will disrupt the market successfully and whether it will be better suited for a low-end market, a new market, or both as described by Christensen and Raynor (2003). When applying the framework to Nucor's minimill steel and Seagate's 3.5-inch disc drive, two famous examples of disruptive technology, the questionnaire correctly predicts that both technologies would be successful disruptors and that the minimill steel would be successful in the low-end market while the new disc drive would create a new market (Hang et al., 2011). However, the model casts doubt on whether Google Drive web applications, including Google Docs, would be able to disrupt Microsoft Office. As of 2018, Google Drive had succeeded with almost one billion active users (Lardinois, 2018), suggesting that the model did not account for either the allure of simple cloud-based systems or that Google Drive and Microsoft Office could both serve the same customer in different ways. Other researchers such as Guo et al. (2019) have created more detailed models to measure the disruptiveness of an innovation, and its likelihood of success.

Knowledge-based perspectives of innovation

Today's managers are knowledge workers who can be most innovative when the knowledge they possess can be increased and then leveraged in multiple directions. This calls for an explicit management of managerial knowledge. Knowledge management has been defined as the cumulative set of activities associated with the acquisition, creation, transfer, storage, and application of knowledge (Inkinen, 2016).

Knowledge management processes can be divided as follows. First, *knowledge creation*, related to the development of new knowledge through one or more of four pathways (Nonaka and Takeuchi, 1995; Yeh et al., 2011): Socialization, wherein tacit knowledge held by individuals is shared through observation, imitation, practice and participation in communities; Externalization, wherein tacit knowledge is converted into explicit concepts – which is key to learning; Combination, wherein different concepts often sourced from different individuals are integrated into a knowledge system; and Internalization, wherein explicit knowledge is transformed into tacit knowledge. Internalization can lead to lower levels of knowledge usage because that knowledge is once again resident in the mind as opposed to being documented on paper or coded into a shared procedure.

Second, *knowledge sharing* relates to the widespread dissemination of existing knowledge across individuals and business units (Dyer & Nobeoka, 2000). Knowledge sharing increases the productivity of the existing knowledge within the network because more individuals are able to put that knowledge to work. Further, in the context of innovation, knowledge sharing increases the likelihood that the knowledge is acquired by a person who can leverage it to come up with a new idea.

Finally, *knowledge utilization* relates to the application of knowledge to solve problems and improve existing systems, or otherwise respond to the different types of knowledge possessed by an individual (Gold et al., 2001).

As we transit into an economy anchored by knowledge and information, innovation is increasingly seen through the lens of knowledge management. Implicit in this view is the notion that innovation is a socially embedded initiative, driven by the power of collective knowledge embedded in a social network.

System-based perspectives of innovation

System-based perspectives acknowledge the complex, multi-stakeholder environment within which an entity innovates (Greenacre et al., 2012). For example, the OECD's Oslo Manual describes an Innovation System Frame to capture four conditions that can influence innovation (OECD, 1997): *Framework conditions*: these include the educational system, communication infrastructure, macroeconomic factors, market accessibility, and other such influences; *Science and engineering base*: this refers to the science and technological institutions that develop the technical talent and partner with firms; *Transfer factors*: these control knowledge transmission to, and absorption by, firms; and the *Innovation dynamo*: the innovative capabilities inherent in the entity that generates and commercializes innovative ideas, which is usually the firm.

This system perspective has been applied at the national level to understand how a nation's policies and investments can ultimately increase its National Innovative Capacity (NIC) and lead to an innovative economy – or not (Furman et al., 2002). The argument that a national perspective is overly broad has been advanced – this is where a narrower application of the National Innovative Capacity (NIC), i.e., the regional or cluster-based capacity, enters the picture (Riddel & Schwer, 2003).

Silicon Valley is considered by many to be the most productive and influential innovation cluster in the world. To understand the emergence of such a phenomenon, theories focusing on national or even regional structures of innovation systems may not be sufficiently effective or complete (Meijer et al., 2006). Instead, the concept of the Technological Innovation System (TIS) has been proposed as an improvement (Bergek et al., 2008).

The TIS focuses on a smaller set of stakeholders and influencers than the national system. Specifically, the TIS focuses on the convergence of research institutions, production capabilities and

capacity, users, sympathetic societal groups, and supportive public authorities to create an environment wherein innovative firms and entrepreneurs can thrive (Geels, 2002). Interestingly, these helpful conditions could nurture "innovation clusters" within a limited geographical area even if the national policy is not particularly conducive to innovation. A single firm can rarely influence national policy. What the firm can influence is its own location, and choosing to locate within a TIS can increase its likelihood of success.

Entrepreneurial perspectives of innovation

Schumpeter has referred to the "gales of creative destruction" unleashed by entrepreneurs that upend the prevailing status-quo in markets and industries (Schumpeter, 1934). Entrepreneurs have been identified as the sources of numerous innovations ranging from calculators to the turbojet engine (Scherer, 1980) and even as key sources of national competitive advantage (Baumol, 2002).

The entrepreneurship literature has focused primarily on behaviors and outcomes at the individual, team, and the venture levels; as a result, there is only limited insight into how the context influences entrepreneurship and its outcomes (Autio & Acs, 2010).

The *industry and technological context* is the most studied area related to the entrepreneurial environment. Entrepreneurial innovation is more intense at the early stages of industry formation where different product designs are being formalized and introduced (Goethner et al., 2012). An important, emerging influence in this area is the effect of technological platforms on entrepreneurial innovation (Garud et al., 2008). These platforms – for example, Apple's IOS – can force entrepreneurs to focus their innovation to a narrower area, and constrain the range of innovation, but also offer the opportunity to quickly access a wide market that subscribed to that platform.

Next, the *organizational context* subsumes influences typically internal to the organization, including culture, practices, previous experiences of the employees, knowledge bases, and the inventory of skills (Nanda & Sorensen, 2010).

In contrast, the *social context* acknowledges the fact that the entrepreneur does not innovate and operate in a vacuum; instead, they are embedded in a network of entities that include partner firms and entrepreneurs, advisors and financers, customers, competitors, and knowledge and resource providers (Amin & Cohendet, 2000; Hoang & Antoncic, 2003).

The *temporal context* and the *spatial context* overlay the three contexts discussed above (Autio et al., 2014). The temporal context acknowledges that things change over time, and sometimes in a systematic manner. For example, an industry that has no large players and is inherently friendly to entrepreneurial ventures may become inhospitable even as the initial entrepreneurial entrants become dominant and the technical standards narrow and crystallize. An entrepreneurial firm that has not established itself by then can be frozen out. In the spatial context, an innovation cluster can become increasingly attractive to entrepreneurs as the network of available talent, financiers, technology providers, and partners builds on itself over time. However, as limited available area for commercial expansion, high rents, and long travel times all result from the growth of the innovation cluster over time, many firms can shift to and seed alternative innovation clusters. For example, within the United States, many entrepreneurial startups are choosing to locate in Austin, TX, and the city is also the choice for relocation for many existing firms from Silicon Valley. Looking into the future, the rapid growth of virtual collaboration as the result of the COVID-19 pandemic has the potential to redefine the conceptualization and impact of "space" in the context of entrepreneurial innovation.

Innovation in the medical device space

Innovation in the medical device space has some special characteristics. First, consider disruptive innovation in this space. While many of Christensen's initial examples focused on consumer and industrial products, he later studied disruptive innovation in the healthcare industry. Christensen is broadly critical of the state of innovation in healthcare and argues that a major reason for rapidly escalating healthcare costs is the dominance of sustaining innovation in health-related technology (Hwang & Christensen, 2008). This relentless focus on increasingly sophisticated devices and procedures has led to a situation where the level of treatment often overshoots what is needed by most patients. Correspondingly, there has been a lack of focus on simple but highly effective devices and techniques that would solve patient problems.

As a result, existing healthcare business models often fail to deliver value to their customers. Hospital systems are still acting as solution shops, meaning that they vertically integrate and overly personalize care at the expense of efficiency and cost (Hwang & Christensen, 2008). Against this backdrop, affordable and frugal medical device innovation is crucial for mitigating the health care disparities that minorities face (Harderman & Kahn, 2020).

Consistent with Christensen, Rosenwasser et al. (2017) define a disruptive technology as one that cannot meet mainstream demand when first released to the public but overtakes incumbent technologies through rapid improvements. They characterize neuroendovascular surgery as a major disruptor in neurovascular operations. Removing an aneurysm historically required open surgery, wherein the surgery itself posed significant risks and, despite being highly invasive, did not always provide a clear route to the aneurysm. Neurosurgeons would clip the aneurysm permanently to block blood flow (Ahmed et al., 2019). In contrast, new neuroendovascular surgery techniques allow surgeons to insert a catheter in a patient and use a magnetic coil that would detach to form a blood

clot, also occluding the aneurysm. Furthermore, even newer flow diversion capabilities in endovascular surgery have disrupted traditional endovascular surgical methods as flow diversion allows surgeons to redirect blood flow around an aneurysm (Rosenwasser et al., 2017). This new development is especially helpful in the context of large aneurysms in clinically complicated neural regions.

Overall, the theory of disruptive innovation provides an important lens to evaluate innovation in the medical device space. At least, from a forward looking perspective, an increased focus on disruptive innovation can help reduce cost and complexity, and increase accessibility of underserved customer segments to healthcare.

Next, the calculus of benefits delivered by medical device innovations is complicated (Provines, 2010). On the one side, there are at least 12 stakeholders who may be directly or indirectly impacted by the innovation, including payers, health technology assessors, healthcare providers, caregivers, intermediaries, physician societies, industry advocates, utilization controllers, patient advocates, employers, patients, and patients' families. On the other hand, there are a range of potential benefits that can be classified under: functional benefits pertaining, for example, to improved effectiveness and lesser pain; economic benefits, pertaining, for example, to quicker cycle times and lower operating costs; and psychological benefits, pertaining, for example, to a lower probability of procedure failure and a lower probability of infection. Correspondingly, communicating the relevant benefits of medical device innovation to the appropriate stakeholder can be challenging.

Further, innovation in the medical device space is an inherently interdisciplinary endeavor (von Roth et al., 2011). Such innovation combines knowledge from areas where building expertise calls for different types of training. For example, it is not uncommon for medical professionals who

deeply understand human biology and anatomy, biomedical engineers who deeply understand the human-machine interface, computer engineers who deeply understand coding, and mechanical engineers who deeply understand robotics to work together on medical device innovation.

Finally, the regulatory hurdles to be cleared can be challenging, especially for certain kinds of medical devices. This is particularly the case for Class II and Class III devices, where the device is implanted within a patient, or where device failure or malfunction can have significant negative consequences for the patient's well-being (Guerra-Bretaña & Flórez-Rendón, 2018).

Having discussed multiple relevant streams in the literature, I now proceed with the model development.

THEORY DEVELOPMENT

This research aligns with my future career interests in biotech entrepreneurship. Correspondingly, the goals of this paper are to provide research insights into the drivers of success related to medical device innovation and to provide practical guidance to entrepreneurs working on designing and commercializing medical devices. In building the theory, I will draw from multiple strands of the reviewed literature. Given the large number of potential independent variables that could be considered, I will frame the model with the objectives of the study as a backdrop.

Success factors internal to the firm

I begin by considering success factors that are internal to the firm. As discussed in the literature review, these factors relate to specific qualities of the founders and their influence on the company. For example, Lazear (2005) focused on how an individual's background, experiences, and skills of influence whether they are apt to be entrepreneurs. He creates a theory of entrepreneurship which hinges on the prediction that individuals, who have a wide variety of skills or are "jacks-of-all-trades", are more likely to be entrepreneurs compared to those with a more specialized skillset.

The internal success factors measured in this study include the number of founders, whether one of the founders had a medical degree (MD), the average number of prior full-time jobs before founding the medical device company, and the average number of followers they have on LinkedIn as of Spring 2021.

Number of founders

Entrepreneurial firms with founders who have an internal locus of control tend to be more innovative and operate in stable environments while those with founders who have an external locus of control tend to focus on low-cost strategies and operate in dynamic environments (Wijbenga & Witteloostujin, 2007). This juxtaposition presents an interesting conundrum in the medical device space as medical device entrepreneurship relies on innovation in a dynamic environment. Therefore, a single founder is unlikely to embody the distinct and somewhat contradictory leadership characteristics that are required in this space.

Second, an internal locus of control is positively correlated with opportunity recognition among aspiring entrepreneurs (Assante & Affum-Osei, 2019). Having more founders and which act as additional pillars of support can increase both the likelihood of specific opportunity recognition and the confidence that the opportunity space has been fully explored.

Third, as discussed in the literature review, the calculus of benefits provided by a medical device is complicated because the implications are spread across a range of stakeholders with different priorities and interests (Provines, 2010). It is unlikely that a founder who is familiar and able to work closely with healthcare providers and caregivers is able to work equally well with payers and utilization controllers. Having founders with different backgrounds on board helps with socializing the new medical device and pushing acceptance and adoption across the different stakeholder groups. Based on these arguments:

Hypothesis 1: A medical device startup is more likely to succeed as the number of founders increases.

Having a founder with an MD degree

Both formal education and previous professional experiences work together to bolster entrepreneurial skills (Kurczewska et al., 2020). These skills directly translate to entrepreneurial success. Analyzing the medical device industry presents a unique opportunity to study the effects that a certain type of formal education, a medical degree, has on entrepreneurial success. During their medical training, doctors learn about human physiology and disease states in great detail. In addition, they develop patient interaction skills and develop a deep understanding of medical procedures and possible shortcomings through clinical internships. This knowledge, which is difficult to build through other formal or informal learning programs or experiences, could prove important for assessing and developing products that patients really need and hospitals can effectively use.

Second, having a medical professional with an MD deeply involved with the entrepreneurial venture will also help implement the credo of "do no harm." The regulatory process for approving medical devices can be long and complicated, especially for Class II and Class III devices (Sorenson and Drummond, 2014). The founder with the MD brings skillsets that are relevant to ensuring safety and designing medical trials to generate data related to efficacy and safety. In addition, that founder will also add credibility to the team by signaling to regulators, investors, and potential customers that the product design incorporates not just engineering knowledge, but also the patient and care provider interests. Based on these arguments:

Hypothesis 2: A medical device startup is more likely to succeed if one of the founders holds an MD degree.

Average number of previous jobs held by founders

Experience matters to entrepreneurs because it provides them with a practical touchstone for decision-making. Experience informs decisions in the context of risk versus return. Every entrepreneurial venture involves some risk taking. Learnings gained from previous work experiences hold back entrepreneurs from being overly optimistic and taking undue risks, while yet taking on a measured amount of risk in uncertain settings (Schwer & Yucelt, 1984).

Second, medical device design is an inherently interdisciplinary field that integrates disciplines such as medicine, anatomy and human biology, chemistry, mechanical engineering and computer science. Therefore, the variety of discipline-spanning and function-spanning experience that the founders bring to the table is important. In addition, research has shown that the manager's variety of experience can help them think more innovatively in any focal domain (Argote, 1999). Based on these arguments:

Hypothesis 3: A medical device startup is more likely to succeed if the founders have prior experience across a number of jobs.

Founders' social network strength

The ability to build and maintain a network of business relationships is a critically important ability for entrepreneurial founders. Increased social capital in interpersonal networks enhances entrepreneurship (Hsiao et al., 2015). The role of social and business networks in determining entrepreneurial success has been widely studied (Turkina, 2017). Tello and colleagues (2012) specifically follow medical device entrepreneurs in a startup incubator in the United States. Through longitudinal observations and interviews, they determine how these entrepreneurs form their networks and subsequently leverage their networks for valuable resources.

While measuring an entrepreneur's social network may have been difficult twenty years ago, the rise of social media and especially of business focused social media platforms such as LinkedIn now allow an exploration of a founder's business network. Specifically, Banerji and Reimar (2019) found that out of 129 companies measured, entrepreneurial funding was strongly linked to the average number of LinkedIn followers of the company founders. Further, an international study revealed that entrepreneurial participation is significantly increased by just knowing someone who has started a business in the past two years (Klyver at al., 2007). Johannisson (1990, p. 40) argues that "when the potential and creditworthiness of a small firm is calculated, its social resources or 'network equity' should be included as the most valuable asset."

First, a robust social network for the founders can speed up learning and knowledge transfers that are focused on solving the startup's problems (Schilling & Phelps, 2007; Yli-Renko et al., 2001). Given that entrepreneurs are boundedly rational, they do not have the knowledge or capabilities to resolve all problems independently in the increasingly competitive and complex business environment (Singh et al., 2000). The entrepreneur can purposefully probe the network for responses to specific problems. The growth of electronically connected social networks has made such focused search increasingly efficient and productive.

Second, social contacts between entrepreneurs and social network members can often be a source of new venture ideas. A survey of 65 entrepreneurs in several industries found that half of their ideas were sourced from social contacts (Koller, 1988). Hills and colleagues (1997) report a similar split; in addition, they found that networked entrepreneurs identified significantly more ideas than solo ones. Based on these arguments:

Hypothesis 4: A medical device startup is more likely to succeed if the founders are embedded in stronger social networks.

Success factors external to the firm

We next consider drivers of success related to the environment of the medical device startup, as opposed to the founders.

Regulatory scrutiny

The healthcare and medical device industries are subject to intensive regulation. Even experienced medical device entrepreneurs fumble when navigating the financial and regulatory hurdles present in the U.S. medical device industry (Russell, 2015). NeuroPace had to wait four years for the FDA to approve its Class III medical device, which was a surgical implant that stimulated the brain in epileptic patients to reduce the occurrence of seizures (Russell, 2015).

Regulation can strongly impact innovation outcomes, but the impact is not unidirectional. For example, one study examining the effect of a U.K. regulatory guideline recommending the measurement of nitric oxide in the breath of patients presenting with shortness of breath found that it had little effect on innovation in precision medicine approaches to treating asthma (Rushforth & Greenhalgh, 2020). In contrast, rapidly evolving FDA vaccine regulatory guidelines in 2020 in response to the COVID-19 pandemic, including approvals of "Fast-Track Status" for companies with early-stage research and acceptance of human challenge studies, led to the shortest novel vaccine development times in history (Goldman et al., 2020).

Within the United States, the extent of regulatory scrutiny a device is subject to is based on whether it is classified as a Class 1, Class 2, or Class 3 device. Each of these classifications faces a sequentially higher degree of scrutiny. Most medical devices fall under Class 2 or Class 3, with Class 3 products requiring much more clinical data and safety testing than Class 2 products. Increased regulatory time and cost can create a strong disadvantage for entrepreneurs who do not have access to much capital. Further, because Class 3 devices are evaluated more critically on account of their

serious implications for patient health and well-being, the risk of failing the approval hurdle is likely to be higher for these devices. Building on these arguments:

Hypothesis 5: A medical device startup is more likely to succeed if it focuses on a Class 2 device than on a Class 3 device.

Location within an entrepreneurial ecosystem

The location of the startup within an entrepreneurial ecosystem can influence innovation outcomes. For example, the burgeoning San Diego biotech entrepreneurial ecosystem creates and circulates entrepreneurial knowledge, leading to San Diego's entrepreneurial dynamism (Sang-Tae, 2015). Within the United States, Stephens et al. (2019) classify Silicon Valley, Boston, and Austin as the three largest technology-focused entrepreneurial ecosystems measured by producing the most technology startups.

First, according to the theory of Technological Innovation Systems (TIS) reviewed earlier, the convergence of research institutions, human talent, production capacity, users and institutional support can lead to the creation of dynamic innovation clusters within a region (Speirs et al., 2008). Once that happens, that cluster also draws the attention of venture capitalists and other sources of corporate financing that can benefit the entrepreneurial startup.

Next, such entrepreneurial ecosystems can potentially create a spirit of "coopetition," where firms that compete against each other also find ways to expand the market by working with each other within the bounds of antitrust law (Nalebuff & Brandenburger, 1996). Firms in a "coopetitive" network can share knowledge and help fill gaps in each other's capabilities. This expands the size of the pie sought by the firms and increases their profitability, sometimes at the cost of firms embedded on other innovation clusters. Building on these arguments:

Hypothesis 6: A medical device startup that is located within an innovation ecosystem is more likely to succeed than one that is not.

Control variable

Startups arrive at an end state over time. A start up that has been in business for a while could have a stronger likelihood of making it through, all else being the same. Therefore, I include time since existence to control for this effect when explaining the success versus failure likelihoods, when those likelihoods are known.

METHODOLOGY

I first detail the data collection procedure and the measured variables. To find potential medical device companies for my database, I searched for "medical device startups" and related terms using Google. For each company, I searched for the product that was the focus of the startup and determined whether the product is or would be regulated by the FDA.

Independent Variables

I used the business information website Crunchbase to determine the number of founders in the company. If the information was not provided, I searched through news articles for the list of founders. I determined whether a founder had an MD degree using the business networking website LinkedIn. If the educational experience was not provided, I searched their history until I found their educational background. The number of prior full-time jobs before founding the medical device company of interest was also primarily recorded by searching through their work experience history on LinkedIn. If the information was not present on LinkedIn or obviously incomplete, I searched for other biographies that provided an employment history. If I could not find one, that founder's number of prior jobs was marked NA. For each company, I calculated the mean of the number of prior jobs among the founders who I had information for, given that the number of founders was already included as an independent variable.

To measure the strength of the social network, I measured LinkedIn followers for the entrepreneurs using the "Activity" section on their LinkedIn page. If founder did not have a

LinkedIn profile, their number of followers was marked NA. I chose to examine followers as opposed to primary LinkedIn connections as LinkedIn provides the connection number up to 500, at which point the connection number reads "500+." Though being a LinkedIn connection requires mutual action from both individuals and being a LinkedIn follower requires one-sided action from the follower, I will assume a 1:1 ratio of connections to followers as the medical device startup founders are typically not celebrities. I calculated the mean of the LinkedIn followers among founders who had LinkedIn profiles, given that the number of founders was already included as an independent variable.

Finding the information about the external success factors did not require the use of LinkedIn. I used the primary location of the company on Crunchbase to determine whether it was in the three major entrepreneurial ecosystems. I used the metropolitan area boundaries for these entrepreneurial ecosystems to determine whether a company was located within the ecosystem. I also subtracted the founding year supplied by Crunchbase's company profile from 2021 to determine the number of years that a continuing startup has been active. For startups that had succeeded or failed, I subtracted the year the startup had closed, been acquired, or had gone through an IPO from its founding year. Acquisition, IPO, and closure dates could be found through news articles or company press releases.

To find the FDA product classification, I first checked whether the product had gone through FDA review. A completed FDA review summary is public information and can be examined through the FDA's website. If the product had not gone through review, I looked for news articles that detailed whether the company was seeking or would seek Class 2 or Class 3 approval. If there was no such information or if the product was still in early development, I looked

at similar products that had been reviewed by the FDA and assigned a category accordingly. Note that Class 1 products are not individually reviewed by the FDA.

Dependent Variables

I estimated two empirical models, each with a different dependent variable. The primary model focused on entrepreneurial ventures still in startup mode. For these firms, I ran a model with the cumulative funding they were able to obtain as the dependent variable. To measure the amount of funding for companies that are startups as of Spring 2021, I used information from the company profile page on Crunchbase.

The secondary model uses the success or failure of the entrepreneurial startup as the dependent variable. To be considered under this category, the startup has to arrive at an end state – a launch as an active company, a buyout, some other positive outcome, or alternatively, an exit from the business. Alternatively, the company could still be in business in startup mode. To determine whether a company was still active or had succeeded or failed, I used Crunchbase information and corroborated that information with at least one news source. For example, some companies Crunchbase listed as active did not have a working website, were reported to be closed down, or had experienced a mass exodus of their upper management. Accordingly, these companies were considered to have exited or failed. To summarize, a set of companies were classified across the binary states of "success" or "failure."

Statistical Analysis

First, the variables were coded as follows. The dependent variables were coded funding obtained (FUNDING) and as Success or failure (SUCCESS) – this is a binary variable. The independent variables were coded as follows: Number of founders (NUM); whether a founder has an MD degree (MDYes); average number of prior jobs held by founders (PRIOR); founders' social

network strength (FOLLOWER); whether the device required Class 3 FDA approval (FDA3); whether the startup was located in one of the innovation ecosystems (ECOYes); and the number of years the startup was in existence (YEARS – this is a control variable).

The company information on my spreadsheet was imported to the R statistical software environment. Then, the columns containing information not directly relevant to the independent and dependent variables was filtered out. As I am measuring two dependent variables, the companies in my data set were split into two categories – one with startups that were currently active and the other with startups that had succeeded or failed.

For the continuing companies, I created a baseline linear regression with FUNDING as the dependent variable and the following independent variables (NUM, NUM^2, PRIOR, FOLLOWER, FDA3, ECOYes). Note that NUM^2 is included to capture any non-linear effects related to the number of founders. Specifically, it is unlikely that the benefits of having more founders is linear from an outside financier's perspective. A large number of founders will create numerous claims on the equity of the startup, reducing the attractiveness to outside financiers.

For the companies that had either succeeded of failed, I created a logistic regression using the glm function in R. I included the following independent variables: NUM, MDYes, PRIOR, FDA3, ECOYes, and YEARS. LinkedIn followers were excluded as a former entrepreneur's current LinkedIn followers do not reflect their social network when they were founding their startup. The MDYes variable is introduced here because the presence of related medical knowledge can impact the success of the startup. Likewise, the control variable YEARS is included here to accommodate the change in conditional likelihood of success as the startup remains active over time. I then conducted a Hosmer and Lemeshow goodness of fit test to determine whether the predicted successes and failures from the model match the observed ones.

Research Limitations

Industry Challenges

One large limitation in my study is that the medical device industry is not a clean source of information. Firstly, the medical device space is more amorphous than older industries such as the steel industry and the automobile industry. For example, classifying Nissan as a company in the automobile industry is more straightforward than classifying Apple as a medical device company even though the Apple Watch includes diagnostic sensors. Secondly, as the medical device space is ripe with entrepreneurs, it is relatively more innovative and dynamic than most other industries (Ramakrishna et al., 2015). Given the rapid growth of medical technologies in the last few decades, it may simply be too early to assess whether the success factors I have analyzed will hold up well in the future.

Data Limitations

Having to split my data into two sections weakens the statistical power that each will have. Unfortunately, finding cumulative funding data from companies just before they ceased being a startup either through succeeding or failing in the methods described earlier proved too elusive. Furthermore, combining the two dependent variables by assigning a threshold funding amount, for example $5 million, as another success criterion would be too arbitrary as companies have been acquired with $500,000 in prior funding and over $50 million in prior funding.

Model Completeness

Modeling data with a multivariable regression requires a complete set of data to be included in the model. Any company with missing information, such as having no founders with LinkedIn

followers means that the company cannot be included in the regression. If I had hundreds of complete cases, companies with missing information could be deleted without much worry. However, disregarding data in this study has more influence on the statistical power of the model. Methods exist to fill in missing data through prediction models, but those methods are difficult to implement for categorical variables and are outside the scope of the study.

RESULTS

The funding model

A dataset covering 32 current medical device startup companies was analyzed for the funding model. The correlation matrix in Table 1 lays out the correlations between the independent variables. The absolute value of the largest correlation between numerical variables was less than 0.25, indicating no concerning intervariable correlation. Note that binary/categorical variables are not included in the correlation matrix.

Table 1

Correlation Matrix of Non-Binary Variables in the Funding Model

	NUM	**PRIOR**	**FOLLOWER**	**YEARS**
NUM	1	0.0492	0.1688	-0.088
PRIOR	0.0492	1	-0.0621	-0.2361
FOLLOWER	0.1688	-0.0621	1	-0.0728
YEARS	-0.088	-0.2361	-0.0728	1

A linear regression was created using the variables NUM, NUM^2, PRIOR, FOLLOWER, FDA, and ECO. The findings are described in Table 2.

Table 2

Linear regression for the Funding Model

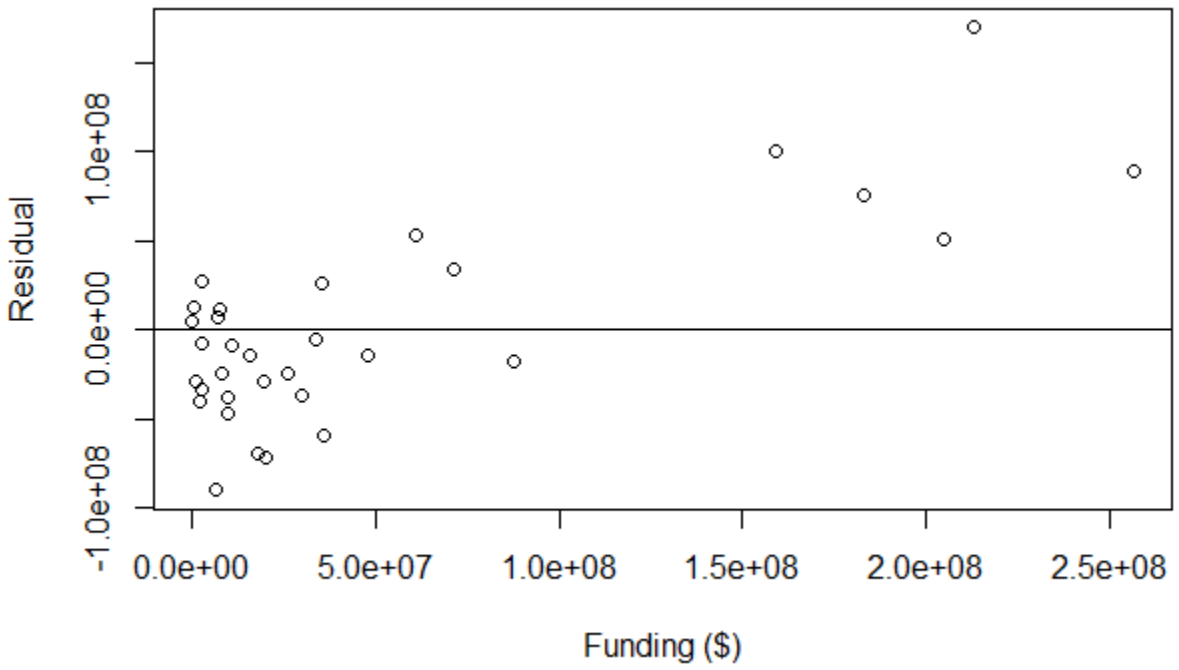
	Estimate	**Std. error**	**t-value**	**p-value**
Intercept	32617143	64641891	0.505	0.6183
NUM	-71487283	57973249	-1.233	0.2290
NUM^2	18730597	12151217	1.541	0.1358
PRIOR	5852793	6430262	0.910	0.3714
FOLLOWER	7167	3021	2.372	0.0257*
FDA	54442553	26422856	2.060	0.0499*
ECO	47558847	22986528	2.069	0.0490*
Notes: * implies significant at 0.05 level; Residual standard error: 61380000 on 25 degrees of freedom; Multiple R^2: 0.4048; Adjusted R^2: 0.262; F-statistic: 2.834 on 6 and 25 DF; p-value: 0.03031				

The variables for number of LinkedIn followers, FDA class, and entrepreneurial ecosystem presence were significant at $p < 0.05$. Furthermore, the model itself is significant at $p = 0.0301$ which is less than 0.05. The R^2 for the model is 0.4048 while the adjusted R^2 is 0.262.

Using the model to predict outcomes across the data set, a residual plot of the regression was created. This is displayed in Figure 1.

Figure 1

Residual plot for the Funding Model



The plot shows a random cluster of residuals below $50 million. The model tends to underpredict highly funded companies with over $100 million in funding.

The success model

A dataset covering 31 companies that reached a clear end-state of success or failure was analyzed for the success model. The correlation matrix in Table 3 lays out the correlations between the independent variables. The absolute value of the largest correlation between numerical variables was less than 0.25, indicating no concerning intervariable correlation. Note that binary/categorical variables are not included in the correlation matrix.

Table 3

Correlation Matrix of Non-Binary Variables in the Success Model

	NUM	**PRIOR**	**YEARS**
NUM	1	-0.1619	-0.1707
PRIOR	-0.1619	1	-0.1187
YEARS	-0.1707	-0.1187	1

A logistic regression was estimated using the variables NUM, MD, PRIOR, FDA, ECO and YEARS. The findings are described in Table 4.

Table 4

Logistic regression for the Success Model

	Estimate	**Std. error**	**z-value**	**p-value**
Intercept	-2.663	1.8212	-1.462	0.1437
NUM	1.0269	0.5704	1.800	0.0718*
MD	2.0741	1.1984	1.731	0.0835*
PRIOR	0.2513	0.2500	1.005	0.3150
FDA	-0.7054	1.1157	-0.632	0.5272
ECO	-0.5383	0.8660	-0.622	0.5432
YEARS	0.0480	0.0987	0.486	0.6270
Notes: * implies significant at 0.10 level; Null deviance: 42.165 on 30 degrees of freedom; Residual deviance: 34.575 on 24 degrees of freedom; AIC: 48.575				

The variables NUM ($p = 0.0718$) and MD ($p = 0.0835$) were significant with p-values less than 0.1. A Hosmer-Lemeshow goodness of fit test was also applied to the logistic regression model. This yielded the following fit statistics: $\chi^2 = 4.52$; $df = 8$; p-value = 0.8074. As the p-value is greater than 0.05, there is insufficient evidence to indicate that the model is a poor fit.

DISCUSSION

Funding model

The number of LinkedIn followers had a significant effect ($p = 0.0257$) on the funding that the medical device company received. Entrepreneurs who have bigger social networks likely have more direct and indirect access to funders through primary and secondary contacts. As LinkedIn and other online business networking platforms have grown in popularity, establishing more connections in these spaces will become even more valuable in the future.

Making a device that fit Class 3 FDA regulatory standards was significant ($p = 0.0499$) in predicting funding. There are two related explanations for this finding. One is that Class 3 devices require more regulatory clinical testing and formal trials before receiving FDA approval. Overcoming these increased regulatory obstacles requires more money than what would be needed for Class 2 devices. Indeed, Class 3 devices going through the pre-market approval (PMA) pathway require around ten times as much money for research and development than Class 2 devices going through the 510(k) process (Yang et al., 2017). The other explanation is that startups focused on Class 3 devices tend to be less common than those focused on Class 2 devices. This explanation is reflected in my data which showed more than twice the number of firms pursuing Class 2 devices than Class 3 devices. Together, these explanations may point towards a larger idea that investors do not want Class 3 focused medical device startups with significant R&D in progress to fail.

Being in a major entrepreneurial ecosystem was a significant ($p = 0.049$) and positive influence on medical device startup funding. This finding shows that the strong venture capital

presence in Boston, Austin, and especially Silicon Valley persists even with increased government regulation of businesses in states like California. Investors may be more willing to supply money to startups if they are embedded in a network, which can provide talent, knowledge, and cooperative opportunities.

In addition to examining the parameters described in the methodology, I also examined the relationship between the organ system affected by the device and funding with a Kruskal-Willis test. This test checks whether the means of the different groups are significantly different. A summary of the number of devices in the sample that pertain to each organ system is shown in Appendix C. The test shows the average funding amounts for devices addressing different organ systems are not significantly different ($p = 0.1835$). However, given that ten organ systems were involved, the sample subset is too small to make any definitive conclusions.

Success model

The number of founders in the startup was near significant at $p = 0.0718$. A larger initial leadership team may be able to handle organizational growth more efficiently, increasing productivity. A more productive organization will be able to make more breakthroughs and increase the appeal of the company in the acquisition context. More efficient company growth may also increase the likelihood of reaching the point where turning to public equity though an IPO becomes feasible.

Having an MD on the founding team also had a near significant effect ($p = 0.0835$) on startup success. Professionals with medical degrees can understand patient struggles and medical treatment shortcomings in a way few others can because of repeated patient interactions. Understanding patient needs is crucial for developing effective medical devices. Creating products using breakthrough research and state-of-the-art technology is meaningless in the medical device

industry if patients do not need or want them. Physicians can inform the founding team on important human factors to consider during the device development lifecycle. Physician-founders may also be useful in the context of organizing clinical studies and providing contacts for marketing outreach.

In addition to examining the parameters described in the methodology, I also examined the relationship between the organ system affected by the device and success with a categorical Chi-square test. This test checks whether the two parameters, success and organ system in this case, are dependent. A summary of the number of devices in the success data subset that pertain to each organ system is shown in Appendix C. The test shows that there is not enough evidence to conclude that the two parameters are dependent ($p = 0.8908$). However, given that there were eight different organ systems that the devices in this subset pertained to, the sample size of thirty-one companies is too small to make any definitive conclusions.

Research limitations

The most significant limitation to this study was the small sample size. The funding model was estimated using a sample size of 32 companies and the success model was estimated using a sample size of 31 companies. Data collection was a challenge, and given the small sample sizes, the finding of multiple significant results was striking. Going forward, building a larger and richer dataset can provide the basis for more detailed models and will likely yield additional significant findings.

Another limitation of the study is the lack of public information about failed medical device startups. From my research, acquisition and IPO information from successful companies was readily available. However, companies that failed typically had broken company website links and very little

published information. Thus, even the failed companies considered in this thesis had generated enough publicity to make a name for themselves and attract some funding.

Future research possibilities

The findings in this thesis are intriguing and warrant further investigation. First, the relationship between startup funding and success can be investigated in greater detail. The effects of the timing, source, and pattern of funding on the likelihood of success are worthy of investigation.

As I could only find current funding amounts for companies that had either succeeded or failed as of Spring 2021, I had to consider two dependent variables. If I were able to find pre-IPO or pre-acquisition funding amounts for medical device companies that had moved past the startup stage, I could directly investigate a relationship between funding and success. This would allow me to investigate the implications of funding across different FDA class devices.

Medical devices and medical research often experience trends – periods when a type of device or research method becomes very popular. For example, wearable health devices rose quickly in popularity in the mid-2010s (de Zambotti et al., 2016). Examining how these trends affect the funding flows and the success rates of startups in the "hot" area can provide valuable lessons for future entrepreneurs looking to ride on these trends.

As mentioned in the research limitations section, I could only measure success factors for which public information existed. If I had access to any data on the companies in this study, I would look at a few more factors. The first is whether the startups had access to a prototyping or lab space early in their development. These spaces could be a part of a university if a founder was affiliated with one, or they could be privately owned. From my experience, having consistent access to a prototyping space allowed my team to develop and reiterate our initial prototypes while learning new skills required to implement new functions. While forming a good idea is sometimes enough to

receive initial funding, neglecting the prototyping process will hurt a startup's chances for long-term investment. The second factor I would look for is whether the founders of the startup had a benevolent mentor with entrepreneurial experience who could teach the founding team the ins and outs of creating and growing a business. First-time entrepreneurs may feel overwhelmed at how much they need to manage and communicate to productively grow the business. The third factor, which especially applies to medical devices, is whether the founding team had access to a clinical facility to observe patients or ask targeted questions to physicians. I discussed that having an MD on the founding team could improve a startup's chances for success because of the physician's experience interacting with patients in a clinical setting. Clinical facilities and other physicians can provide invaluable information for a startup that does not have a physician on the team, allowing the team to understand patient needs from multiple lenses.

CONCLUSION

This thesis aligns closely with my interests in medical entrepreneurship and innovation. My hope is that the thesis provides some useful insights to entrepreneurs in the medical device startup space. The specific findings can guide entrepreneurial decisions both internal and external to the company.

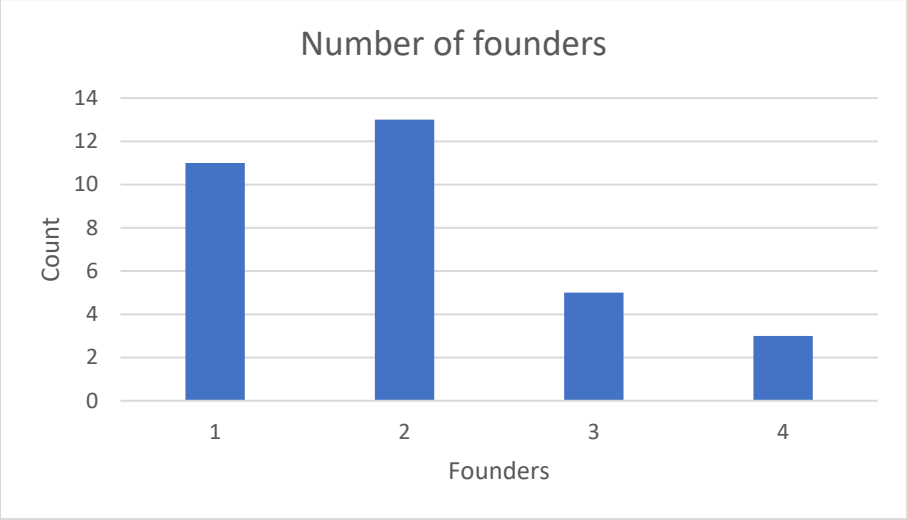
The literature on innovation and entrepreneurship is vast. However, as this study has highlighted, innovation and entrepreneurship in the medical device space has some special characteristics on account of the nature of the ultimate use of these innovations in the human health and well-being context, the inherently multidisciplinary nature of innovation, the extraordinarily high degree of outcome uncertainty, and the regulated environment within which innovation must take place. Some failure in inevitable in all of innovation, but this is particularly so in the medical device space. Much more research is needed for a systematic body of knowledge to be developed – one that medical device entrepreneurs and startups can leverage to increase their likelihood of success.

APPENDICES

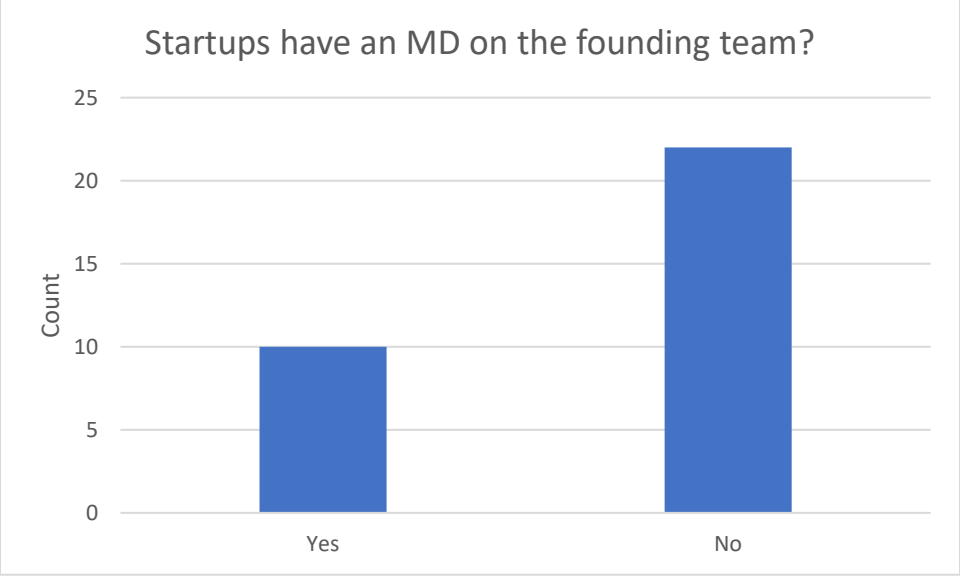
Appendix A

Summary statistics for funding data subset

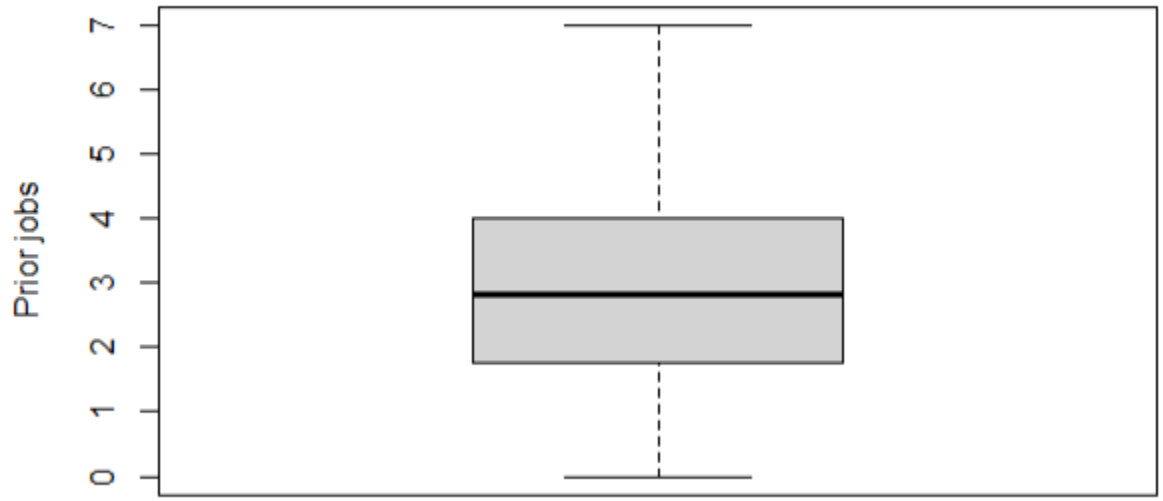
Number of Founders



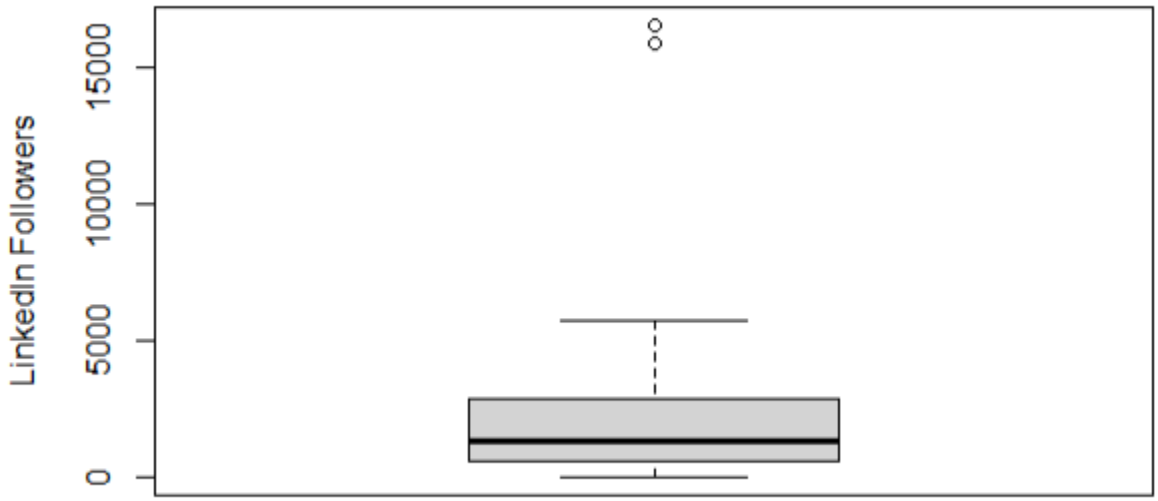
Number of startups with an MD on the founding team



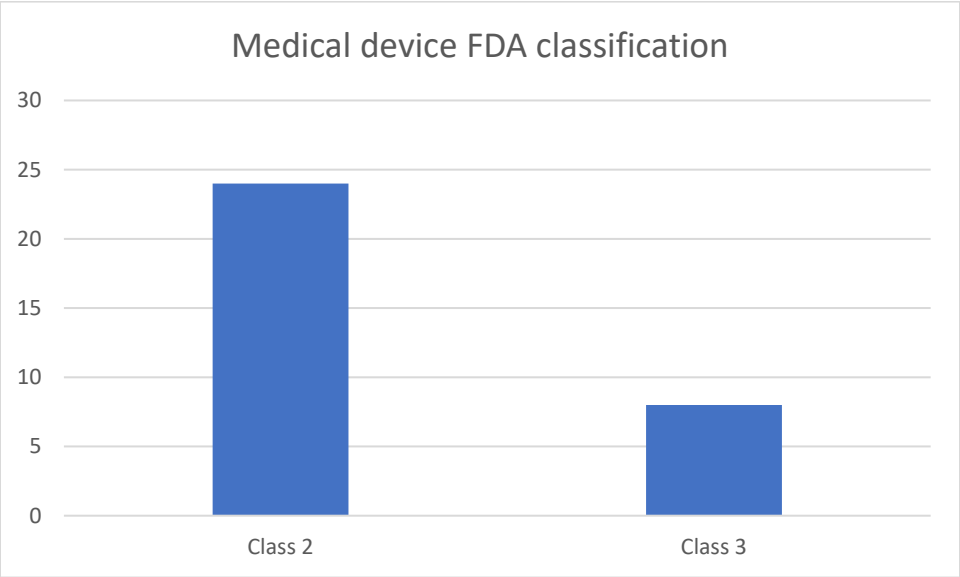
Average Prior Job Experience



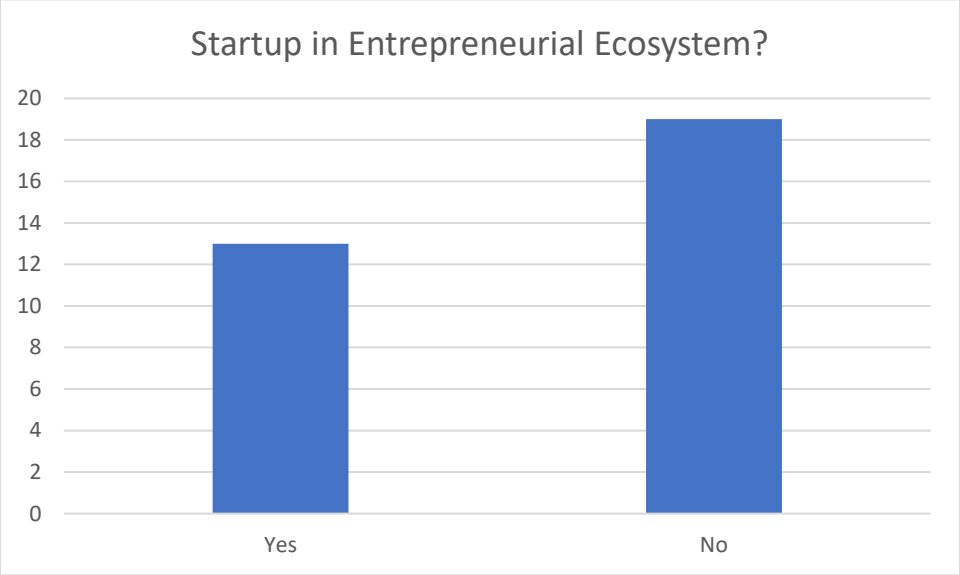
Average LinkedIn Followers



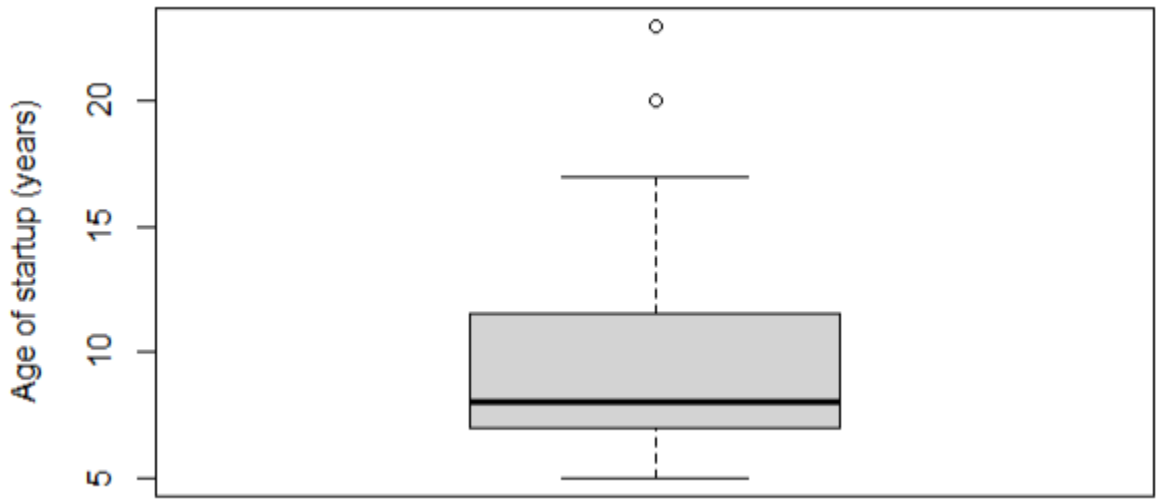
Medical Device FDA Classification



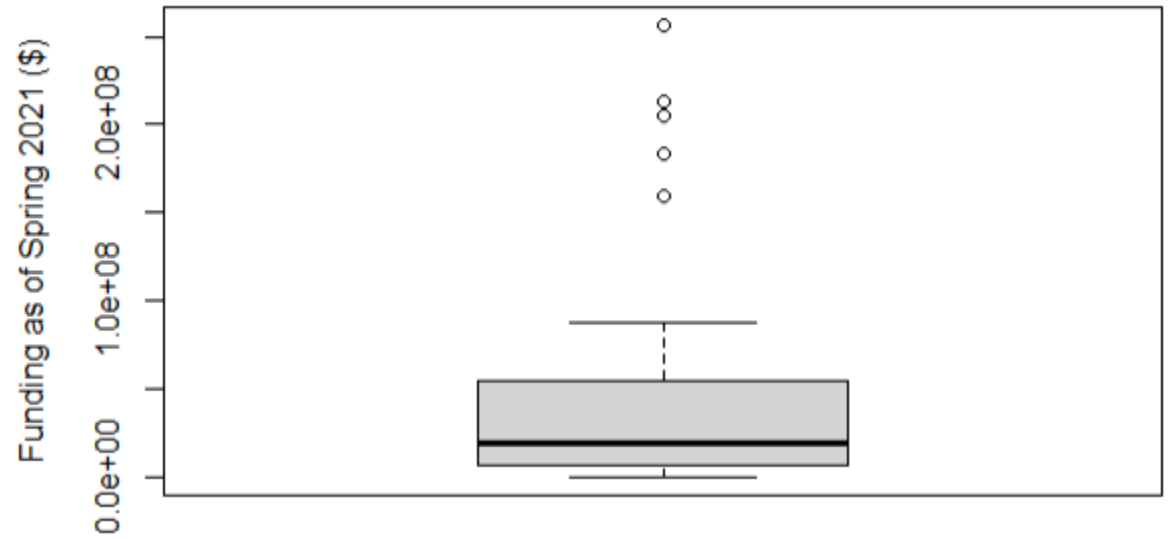
Major Entrepreneurial Ecosystem



Age of Startup



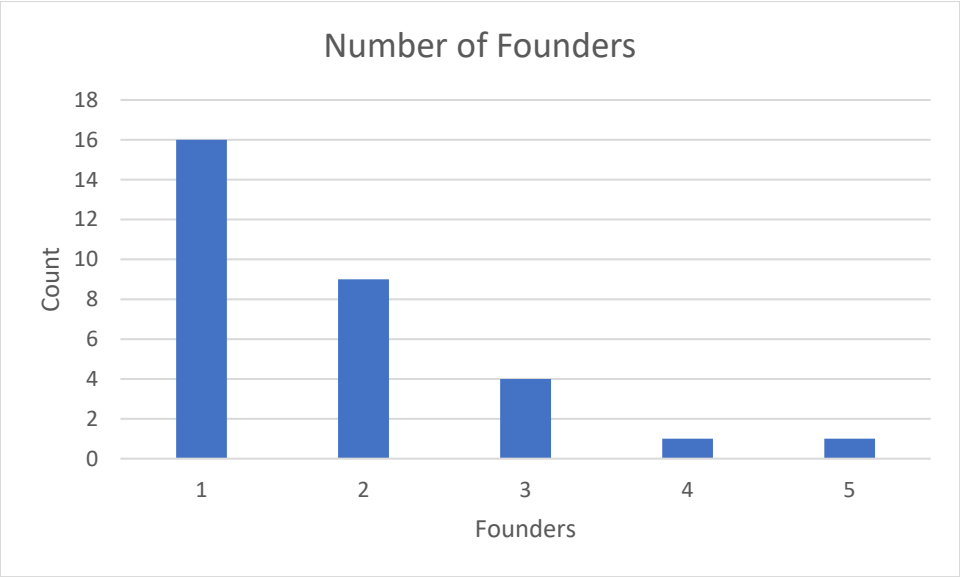
Funding



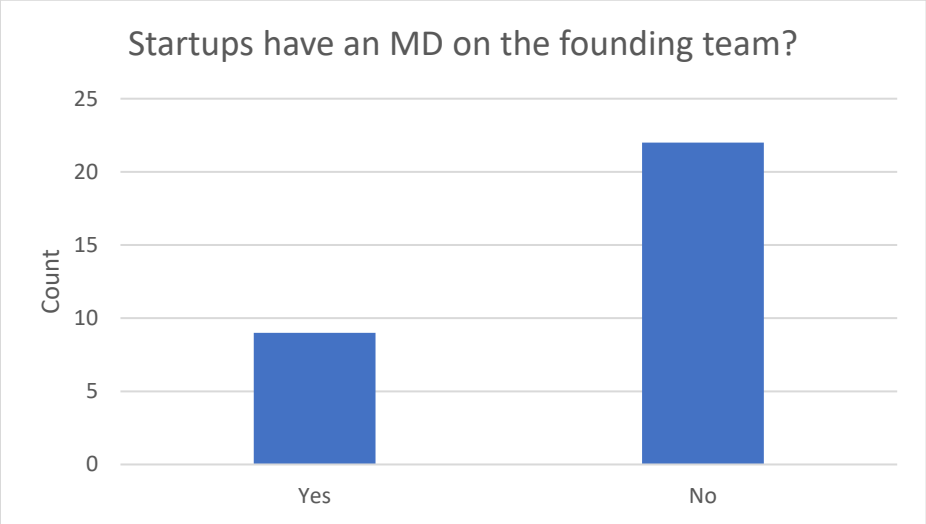
Appendix B

Summary statistics for success data subset

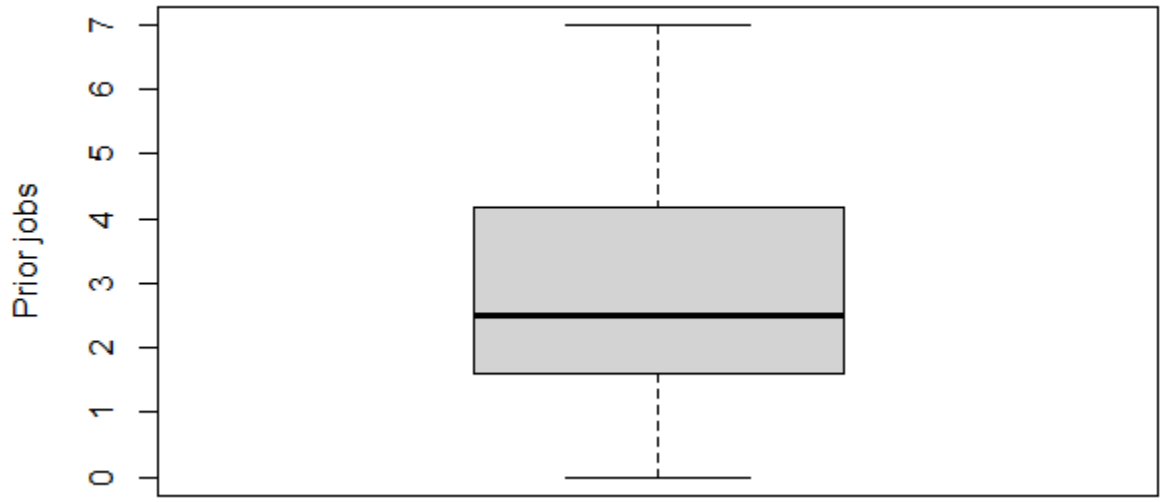
Number of Founders



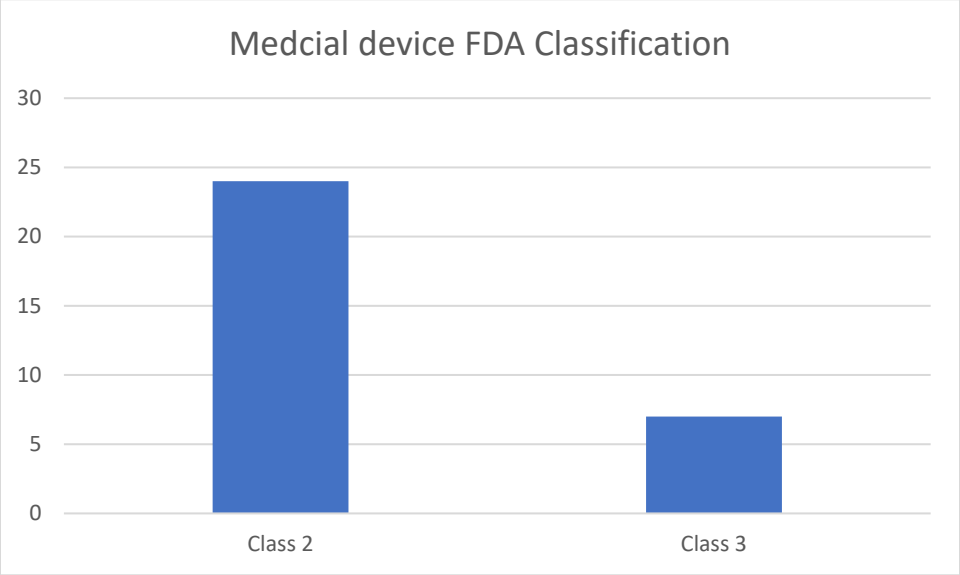
Number of startups with an MD on the founding team



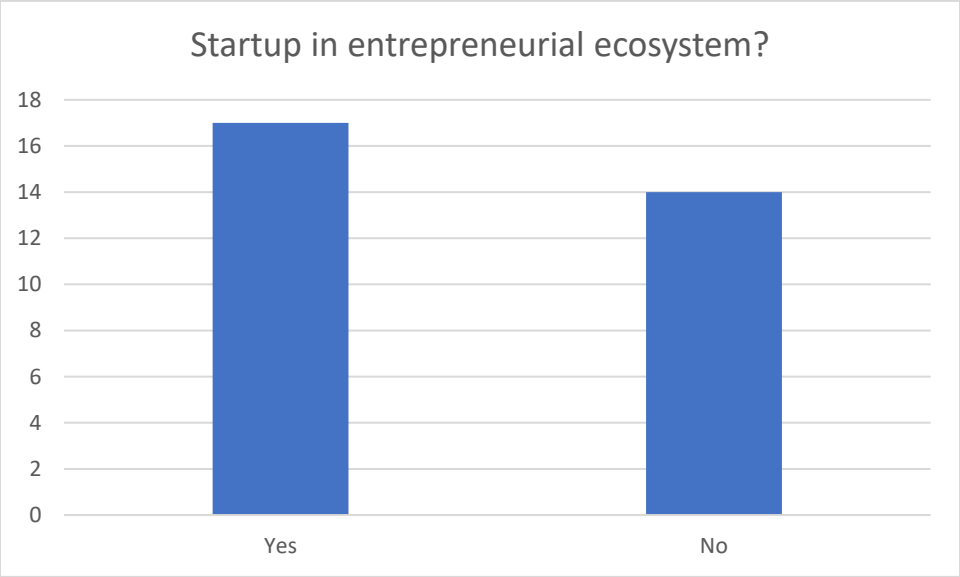
Average number of prior jobs



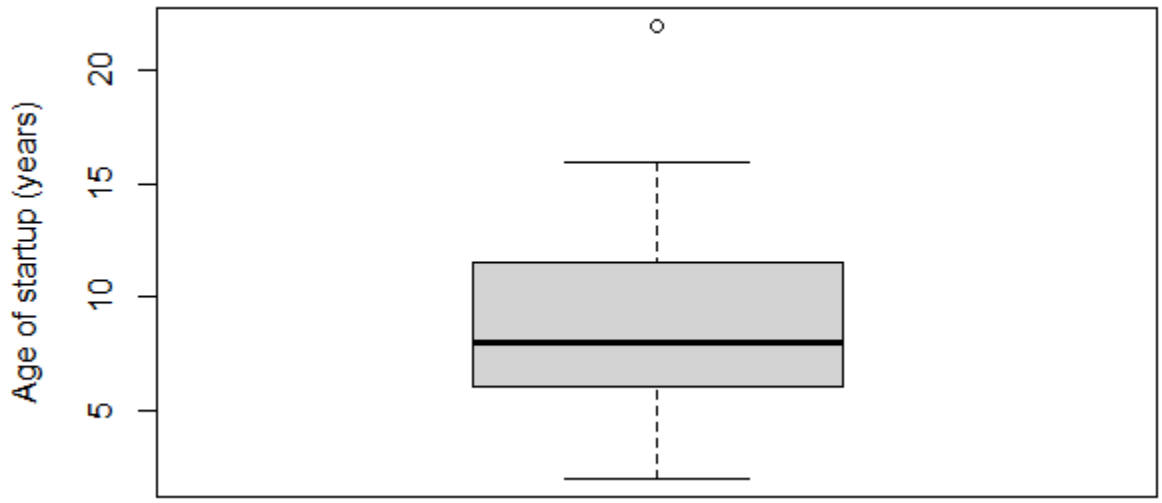
Medical Device FDA Classification



Major Entrepreneurial Ecosystem



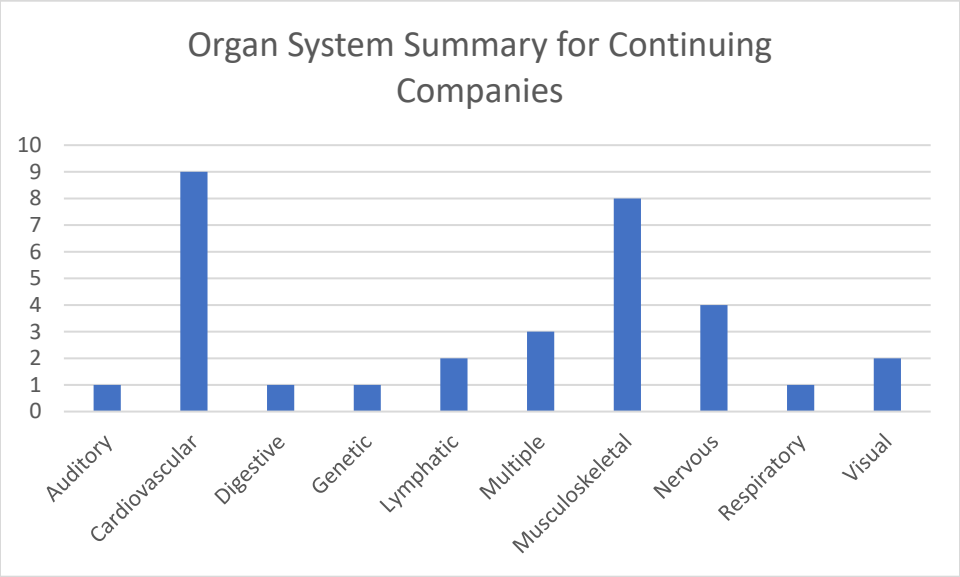
Age of Startup



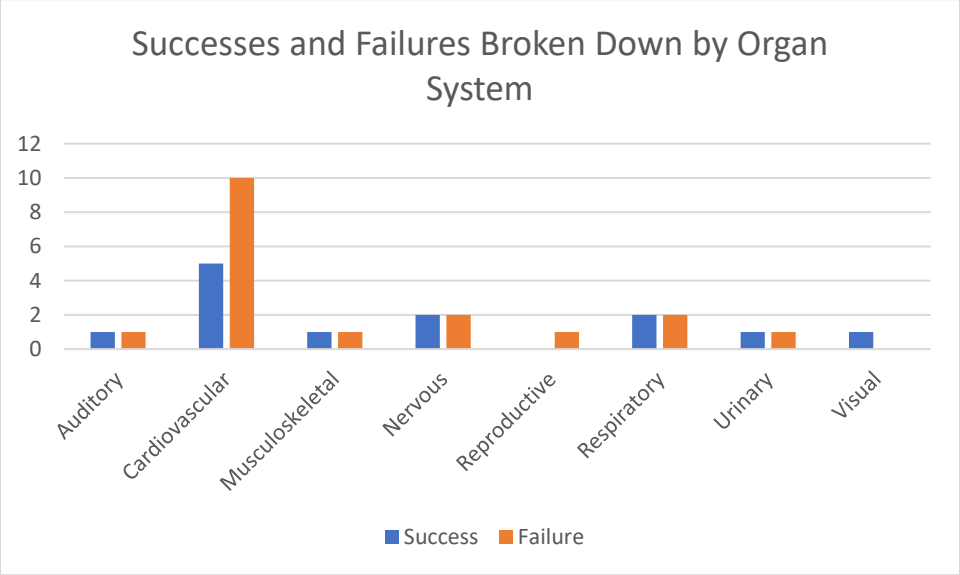
Appendix C

Summary statistics for organ system factor

Funding



Success



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