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FOSTERING ENTREPRENEURIAL INVESTMENT DECISION IN MEDICAL TECHNOLOGY VENTURES IN A CHANGING BUSINESS ENVIRONMENT

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Abstract

This paper presents the results obtained from a survey among public and private venture capitalists from countries which attract a large amount of venture capital investment: Germany, Switzerland, Austria and Israel.

The objective is to investigate venture capitalists' investment criteria for medical technology ventures in the start-up or expansion phase. Since existing research evaluated venture capitalists' general investment criteria, the aim of this study is to provide specific results on entrepreneurial investment decisions for the medical technology sector, which constantly attracted a significant share of European venture capital. The research used semi-structured interviews with 39 venture capitalists and experts.

The results show that venture capitalists prefer to invest in companies which develop products for treating and diagnosing diseases showing a high prevalence and large market volumes, such as cardiovascular, metabolic and neurological diseases, and orthopaedic disorders. The study confirms that venture capitalists use a number of industry-specific criteria highly relevant in a changing business environment. These include a high medical need for the product, availability of clinical data, stage of European Conformity approval, high probability of receiving reimbursement from health insurances, medical key opinion leaders supporting technology, management's regulatory experience and their communication ability with doctors and key opinion leaders.

Keywords: entrepreneurial investment decisions, investment criteria, medical technology venture, venture capital

JEL Classification: D81, G24, L26, M13, O30

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Introduction

In a global and changing business environment characterised by fierce competition, innovative start-ups contribute significantly to technological progress and international competitiveness of a country. Therefore, the promotion of start-ups is one important means of fostering economic growth and employment. Public support for start-ups becomes even more important, if private investors, in particular venture capitalists (VCs), are less prepared to invest – e.g. during an economic crisis. From 2008 to 2013, venture capital investments in Europe have declined from EUR 6.3 billion to EUR 3.4 billion, which mainly resulted in smaller investment amounts per company, but also in a lower number of companies receiving venture capital. In 2008, 3.667 companies in Europe received venture capital – compared to 3.034 in 2013 (EVCA, 2014, pp. 31-32). Companies located in Germany, Switzerland or Austria attracted EUR 1 billion of venture capital (EVCA, 2014, p. 42), forming thus one of the regions in Europe receiving the largest amount of venture capital investment in 2013.

Due to the decline of private investment since 2008, public venture capital has gained importance. Funds might be provided directly, i.e. through state-owned venture capital firms operating with public funds, or indirectly through investments in financial intermediaries. The European Investment Fund (EIF) is the largest (indirect) venture capital investor in Europe and provides funds to specialized financial intermediaries, like venture capital firms, which again invest in auspicious companies. These are mostly young, privately held growth companies that have developed new and outstanding technologies or business models promising fast growth and high returns. Contrary to the state-owned venture capital firms, those funds also operate with money from private investors, like e.g. pension funds or family offices. In 2013, European venture capital firms raised EUR 4 billion from investors, thereof 38% from government agencies (including EIF) (EVCA, 2014, p. 9). In 2008, the share of public funds was only 15% - which shows that government agencies, including the EIF, have tried to compensate for the decline of private venture capital investment (EVCA, 2014, p. 17).

Despite the efforts of public investors, venture capital is scarce, and companies compete for capital; the competition is even more difficult as in a changing business environment our changing society, companies are required to create value added for each stakeholder in order to remain in the market (Olaru et al. 2010, p.11). But how should public and private VCs select a venture? What are important criteria to be applied in order to increase the probability of entrepreneurial success?

Previous research focused on general investment criteria (e.g. Muzyka, Birley and Leleux, 1996), but also identified few industry-specific criteria for biotech start-ups (Baum and Silverman, 2004). A number of studies have found that criteria of early stage VCs differ from criteria of late stage VCs (e.g. Gupta and Sapienza, 1992; Elango, et al. 1995) and that high-tech VCs differ from non-high tech VCs (Lockett, Murray and Wright, 2002). Therefore, the fact that research on investment decision making has only focused on the VC industry as a whole may be problematic (Clarysse, Knockaert and Lockett, 2005). In order to be more precise, research on investment criteria should clearly define parameters like geography, industry, and stage of the venture.

Since 2007, the life sciences sector has attracted the largest share of venture capital amongst all industries (EVCA, 2014, p. 53). One industry being part of the life sciences

sector is the medtech industry. Medtech companies constantly attracted about 7% of all venture capital investments in Europe from 2007 to June 2013 (with exception of a drop to 5% in 2012) (Ernst & Young, 2013). Many VCs preferred to invest in medtech companies, because the development risks are lower, development cycles are shorter, and the amounts of investment needed are smaller compared to investments in biotech and pharmaceutical companies (Ernst & Young, 2010). In 2013, the German-speaking part of Europe attracted 34% of all venture capital investments in the life sciences sector (authors' calculation based on data from EVCA, 2014). In total, this region attracted EUR 1 billion of venture capital in 2013 (EVCA, 2014, p. 41).

For medtech companies, which are in the fundraising process, it might be interesting to know how venture capital firms proceed when they evaluate the business plan (BP) of a medtech venture and which selection criteria they use - it might thus be easier to draft a BP that raises attention. For VCs who plan to invest in medtech for the first time, it might be interesting to learn more about the proceeding of more experienced colleagues. Public organisations fostering start-up development might also find it useful to know VCs' industry-specific criteria when coaching start-ups from the medtech sector. The probability of successful fundraising could thus be increased, leading to the promotion of new technologies. Ultimately, new technology may result in benefits for patients and the healthcare system – e.g. through better diagnosis and cost reductions.

The objective of the study is to investigate VCs' investment criteria and entrepreneurial decision-making activities for investments in medtech ventures in the start-up or expansion phase. The region in focus is the German-speaking part of Europe, i.e. Germany, Switzerland and Austria. The intention of this study is to provide results specific for the medical technology sector in this region and specific for the VCs' first evaluation of a venture.

Therefore the next chapters will focus on presenting the current entrepreneurial challenges in the medical technology sector, identifying the existent investment criteria in this sector, proposing criteria that VCs can apply to medical technology ventures when evaluating the ventures' BP for the first time, based on the results of a survey driven by the authors.

Authors' results demonstrate that VCs use indeed a number of criteria specific to the medtech sector, which are highly relevant to their investment decision: the medical product must address a high medical need and show a high probability of receiving reimbursement from health insurances. Its efficiency should be supported by clinical data. Additionally, medical key opinion leaders should support the technology. Further relevant decision criteria are the product's stage of European Conformity approval as well as the management's regulatory experience and their ability to communicate with doctors and key opinion leaders. VCs strongly prefer therapeutic fields relating to cardiovascular diseases, orthopaedics/spine, neurology and metabolic diseases, which promise large market volumes due to high prevalence.

So far, venture capital investments in the medtech industry have not yet been in focus of empirical research. Existing research mainly identified general investment criteria independent of the ventures industry, location and stage. Therefore this research presents new contributions to the literature.

1. Literature review

The medical technology (“medtech”) sector is one industry, which shows a high degree of innovation, stable growth rates and a low correlation with macroeconomic development. A rising number of people striving for health and well-being, amongst others from emerging countries like China, India and Brazil (Crofts, 2012), and the demographic development in industrialized countries cause a growing demand for medical services. Innovative technologies allow for treating diseases that have been incurable to date (BVMed, 2012) and are thus able to satisfy hitherto unmet medical needs.

However, despite a growing demand for medical services and products, medtech companies have to cope with a number of challenges and a changing business environment: Budgetary pressures and escalating costs in healthcare cause governments in many major economies to look for possible savings – which also affect the medical device industry. Medtech companies face growing regulatory pressures, making it more difficult to gain marketing approval for a new product and to market the product to doctors and patients. Hurdles for getting reimbursement from health insurances have also increased. As a result, entrepreneurial investors reset their expectations and also reduce their investment in emerging companies. Entrepreneurial investors also fear that European legislation, i.e. the medical device directive, will make the European medtech approval system as complicated as that of the US Food and Drug Administration (FDA) (Ernst & Young, 2013).

Young, innovative companies, often spin-offs from universities, clinics, or large medical device companies, contribute considerably to innovation in medical technology. One important resource these companies need is capital, and in early stages, venture capital firms present one important source of capital. This study might help them to better understand VC’s expectations.

Previous research on VC investment criteria identified ten main categories of criteria that are crucial to the VCs’ investment decision in a changing business environment (e.g. Boocock and Woods, 1997; Brettel, 2002; Fried and Hisrich, 1994; Hall and Hofer, 1993; Khanin, 2006; Muzyka, Birley and Leleux, 1996; Tyebjee and Bruno, 1984): 1. Entrepreneur, 2. Top Management Team, 3. Product/Service Attractiveness, 4. Market, 5. Competition, 6. Business Model/Strategy, 7. Exit, 8. Deal, 9. Risk, and 10. Returns.

Moreover, researchers identified a set of venture capital firm-specific investment criteria relating to the venture’s stage (Camp, 2002), geography, industry, and to the size of the investment (Tyebjee and Bruno, 1984). VCs check these criteria at the very beginning of the evaluation process.

While there is some agreement on the investment criteria applied by VCs, there is little agreement on the importance of investment criteria during screening and/or evaluation phase. Differences may be due to methodological differences in research design (Hudson and Evans, 2005). Criteria showing the highest importance in the majority of the studies relate to the quality of the management team, followed by product and market-related criteria, like e.g. the product’s unique selling proposition (USP) and market growth (Khanin, et al., 2008). However, the relevance of certain criteria may depend on the venture’s industry: For VCs investing in life sciences start-ups, the start-up’s patents (Baum and Silverman, 2004) and research alliances with prominent affiliates seem to play an important role (Baeyens, Vanacker and Manigart, 2006; Baum and Silverman, 2004).

One reason is that patents may increase the attractiveness of a company as an acquisition target (Jell, Block and Henkel, 2011), which facilitates the VCs' exit. Criteria and evaluation activities also depend on the VC's stage focus and the venture's stage of development (Elango, et al., 1995). In addition, the VCs' location or nationality (Vinig and de Haan, 2001), and the stage of the investment process, i.e. whether a VC evaluates criteria during the screening phase or during the due diligence (DD) phase, seem to be relevant (Fried and Hisrich, 1994).

The VC evaluation process starts with the screening phase, which "involves a perusal of a proposal's executive summary and/or BP to determine whether a closer evaluation is worthwhile" (Hudson and Evans, 2005, p. 3). VCs' activities in the subsequent evaluation phase involve a deeper analysis of the BP and a detailed evaluation of the venture's industry, products/services, strategy and competitive positioning, historical financials and financial projections. The DD is a separate phase following the approval of the VC's investment committee, during which VCs carefully check all relevant legal and financial documents (Klonowski, 2007). After the DD is successfully completed, VCs negotiate and sign the final legal documents. This is referred to as "Closing" (Fried and Hisrich, 1994).

2. Research methodology

This paper focuses on criteria VCs apply to medical technology ventures when they evaluate the ventures' BP for the first time ("screening"). Previous research mainly identified general criteria and used samples, which included ventures from different industries, countries and at different stages of development. This study, however, shall be a first attempt to work with carefully defined parameters for the venture's industry (medical technology), geography (Germany, Switzerland or Austria), and stage (start-up or expansion). Companies in the start-up phase have a working prototype, a small team, and a concept for market entry. They start preparing a ready-to-market product, production facilities, and market entry. In the subsequent expansion phase, the company generates already sales and seeks financing to expand its business, e.g. for geographical expansion (Schefczyk, 2006; Weitnauer, 2007).

The German medtech industry has a share in world trade with medtech products of 14.6%. It ranks second after the United States with 30.9% (BVMed, 2012, p. 4) and contributes 0.8% to the German GDP (Medtech Switzerland, 2012, p. 31). In terms of market size, Germany is the largest medtech market in Europe. Switzerland is an important production site for medical technology devices with around 1,600 companies active in this sector (mainly SME). Furthermore, Switzerland is the world's second largest per capita consumer of healthcare with the medtech industry contributing 2.1% to the Swiss GDP (Medtech Switzerland, 2012, p. 30-31). Therefore, these two countries are a good starting point for industry-specific research. The Austrian medtech sector contributes 0.3% to the Austrian GDP and is an industry in focus of the Austrian government's promotion activities (Ding et al., 2011; Statistik Austria, 2014). Austria has been included in order to complete the German-speaking region of Europe – which is a region in focus of VC firms as a whole.

"Medtech ventures" as defined in this study, are young companies developing, manufacturing and selling *medical devices* - as defined in the EU directive 2007/47/EC, Article 1, of the European Parliament and of the Council of 5 September 2007 -, *in vitro diagnostic medical devices* (e.g. reagent products, calibrators, and equipment intended to be used in vitro for the examination of specimens) - as defined in the Council Directive

93/42/EEC of 14 June 1993 -, as well as *active implantable devices* (e.g. cardiac pacemakers) - as defined by the Council Directive 90/385/EEC of 20 June 1990.

Since criteria specific for medtech ventures are a new field of research with exploratory character, the collection of qualitative data with certain standardization in data collection for subsequent statistical analysis seemed to be the most adequate research method. The semi-structured interview, also called “focused interview”, “is an attempt to combine some of the depth and ‘naturalness’ of nondirective interviews with the standardization of a structured interview” (Abrahamson, 1983, p. 339).

The authors identified all venture capital firms located in Germany, Switzerland and Austria investing in “medtech” from their personal network, industry directories (Anderer, 2012), and the member lists of the national venture capital and private equity associations (Austrian Private Equity and Venture Capital Organisation, 2011; Bundesverband deutscher Kapitalbeteiligungsgesellschaften e.V., 2011; European Private Equity & Venture Capital Association, 2011; Swiss Private Equity & Corporate Finance Association, 2011). These VC firms either had a general technology focus or a life science/healthcare or medtech focus. One VC firm from Israel, representing a pure medtech fund also investing in the German-speaking part of Europe, was included as well. This VC firm was a personal contact of one of the authors and was included due to its great expertise in this field, although it was not located in the focus region. Including the VC firm from Israel, 70 VC firms were identified and asked to participate in the survey. Only 39 of the invited companies took part in our survey.

We applied the following formula in order to determine the accuracy of the sample proportions (the normal approximation to the hypergeometric distribution, as the population is very small):

$$n = Nz^2pq / (E^2(N-1) + z^2pq) \quad (1)$$

where:

n – sample size;

N – population size;

z – confidence level;

E – accuracy of the sample proportions;

p and q – population proportions. As they are not known, they are set to 0.5 each.

For N = 70, z = 1.96 (95%) and n = 39, an E of 10.52% resulted.

37 VCs (17 from Germany, 17 from Switzerland, 2 from Austria and 1 from Israel) participated in the survey, which is a total response rate of 52.9% related to the 70 VCs firms which had been contacted. In addition, the authors interviewed two experts with experience in financing medtech start-ups. The two experts answered the same questions as the VCs and have been also included in the sample (n = 39). All interviews have been conducted between 31st of March 2011 and 10th of August 2011, using a previously tested interview guide (in English and German). The questions were based on previous research, on expert interviews and on the authors’ own experience in venture capital and medtech investments. The interview guide included questions on the following categories: 1. Personal Data / Company Data of the interviewee, 2. Investment Process, 3. Activities and criteria for each stage of the investment process (Deal Sourcing, Screening, Evaluation,

Due Diligence, Structuring, Post-Monitoring, Exit), 4. Key success factors for medtech ventures. For the screening and evaluation stage (part of the 3. category), the following categories of criteria were discussed during the interviews:

- Product, Technology, Medical Need.
- Regulatory Criteria [Conformité Européenne (CE) Approval and Reimbursement].
- Intellectual Property (IP).
- Business Model and Strategy.
- Market and Competition.
- Management.
- Financials.

The interviews were conducted with investment managers or partners of the VC firms either face-to-face or by telephone, recorded and transcribed verbatim. The total length of all interviews was 2176 minutes, meaning an average of 56 minutes for each interview.

The data analysis procedure applied in this research combines elements of two different concepts of qualitative data analysis: “Grounded Theory” (Glaser and Strauss, 1967; Strauss and Corbin, 1996) and “Structuring Qualitative Content Analysis” (Mayring, 1994). Both concepts include the creation of categories and the subsequent assignment of text passages to these categories, allowing for the calculation of frequencies (Mayring, 2001). For qualitative data analysis, the software MAXQDA was used. Where applicable, the authors used quantitative methods and statistical tests, like e.g. the Chi-Square test.

3. Sample description

VCs and experts participating in the survey were mainly based in Germany (43.6%; n=39) or Switzerland (48.7%). In Austria, only two venture capital firms with a medtech focus were active in early stage financing (5.1%) and both were prepared to give an interview. In addition, one VC from Israel (2.6%), representing a pure medtech fund, participated in the survey. The sample received shows a high share of early stage investors (seed and start-up): 43.6% of the VCs interviewed are already active in the seed stage, for 48.7% the earliest point in time for an investment is the start-up stage and 7.7% only invest in the expansion stage or in later financing stages. All VCs investing in the seed stage are also active in the subsequent start-up stage and 66.7% of the VCs interviewed (also) offer expansion financing (see Figure no. 1).

38.5% of the VCs had an exclusive focus on life sciences, healthcare or medtech, whereas the remaining 61.5% stated a more general technology focus, or invested in selected industries only (amongst others in medtech). About three quarters of the VC firms were operating with funds invested by private investors, and about one quarter used public funds provided by the national governments and/or the European Union (hereafter referred to as “public VC firms”).

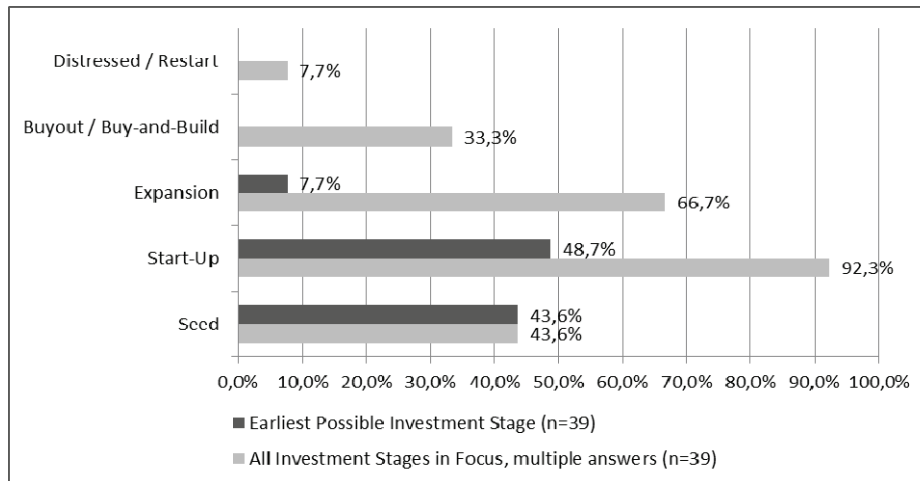


Figure no. 1: VCs' Investment Stages

4. Results of the Research

4.1 Results on Product-Related Criteria

The screening phase typically starts with a reading of the BP. VCs have preferences within the medtech sector and therefore pay attention to the market segment addressed by the venture, like e.g. diagnostics or medical devices. Within these market segments, therapeutic areas preferred and most frequently mentioned are cardiovascular diseases, orthopaedics / spine, neurology and metabolic diseases (see Figure no.2). These segments show a high prevalence and thus large market volumes. From a medical point of view, cardiovascular and metabolic diseases may overlap. However, VCs shy away from expensive capital goods (like e.g. X-ray apparatuses), marketing-intensive over-the-counter (OTC) products, and products using biotech or pharmaceutical components.

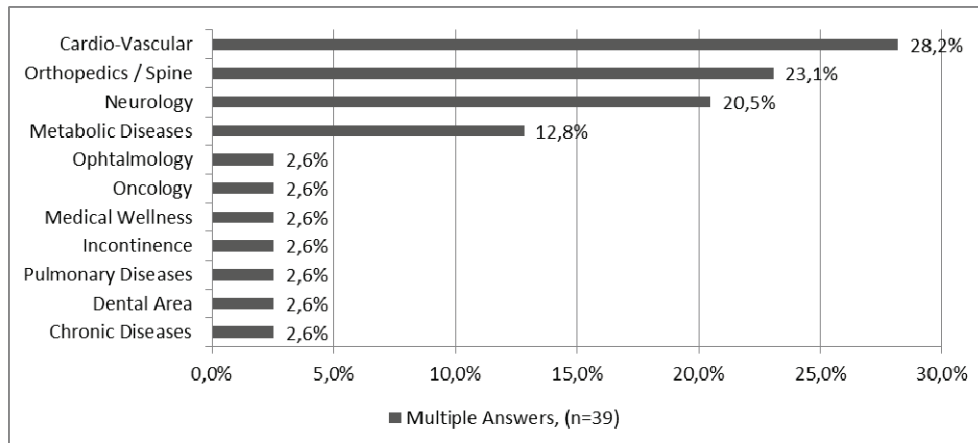


Figure no. 2: VCs' preferred market segments in the medical technology sector

Contrary to literature findings (Brettel, 2002; MacMillan, Siegel and Subbanarasimha, 1985), VCs strongly prefer to invest in fields they know. VCs therefore check if the fund-seeking venture is active in a field they know (and they have in focus) and whether their portfolio companies could benefit from synergies with the venture.

Similar to literature findings (e.g. Fried and Hisrich, 1994), *innovative products with a clear USP* that fulfil a *medical need* are crucial for all VCs (n = 39). The fulfilment of a medical need is a logic precondition for any patient, doctor, clinic, or health insurance to pay for a new technology. Although involving a higher risk, disruptive technologies (“game-changers”) are a must criterion for 43.6% of the VCs. Those VCs would like to see products fulfilling a high, unmet medical need, i.e. products or new technologies addressing severe diseases for which no therapy or detailed diagnostics leading to better therapy are available yet. The remaining 56.4% *also* invest in innovative improvements of existing technologies or innovations that fulfil a medical need in a better way than the current solutions offered, or they invest in innovative business concepts. Innovative business concepts or technologies leading to significant cost reductions for the healthcare stakeholders (patients, doctors, clinics, and health insurances) may also present interesting USPs. *Market acceptance* is relevant to success (MacMillan, Siegel and Subbanarasimha., 1987), and very important for all VCs (100%, n=39). However, it is difficult to evaluate as long as the product has not been launched: VCs have to take a decision on whether they believe that the newly developed product could demonstrate market acceptance in the future.

In order to evaluate crucial criteria like the product’s USP and the medical need, VCs may make first reference calls at medical key opinion leaders (KOLs) or doctors from the VCs’ network. KOLs in the present research are professors and leading clinical researchers with expert knowledge in the company’s field of activity. KOLs are able to influence physicians and surgeons in their decisions and in their clinical practice, in particular, if they are enthusiastic personalities with strong ability to listen and to give advice (Mathie, 1997). KOLs supporting the technology/product of the venture may provide evidence that there is a medical need for such a product and that the company has developed an adequate solution to the problem. Thus, to a certain extent, KOL support also contributes to proof of concept. Furthermore, KOLs often maintain relationships to leading industry players and can help drawing potential acquirers’ attention to the venture’s technology. *KOL support* is therefore an important criterion for 48.7% VCs (n = 39) in the screening phase and verified during the evaluation and DD. For 15.4%, missing KOL support could even be a deal killer. 25.6% of the VCs qualify it as a plus, and 10.3% do not consider it relevant.

4.2 Results on Intellectual Property

Strong intellectual property rights are a key feature of the innovation in the medical device industry (Smith, 2008). *Patents* protecting the company’s USP play an important role for VCs active in medtech: for 69.2% of the VCs the patentability of the technology, filed patent applications or even granted patents are a must criterion, to 20.5% patent applications are important. However, 10.3% state to prefer trade secrets in some cases as patents may disclose too much information to competitors. For VCs, patents are important assets and value drivers when it comes to the exit of the company.

4.3 Results on Regulatory Criteria: CE Approval and Reimbursement

Reimbursement of a new product by the health insurances is a critical success factor for most medtech companies. In case of disruptive technologies addressing an unmet medical need, where no “gold standard” exists, the health outcome alone (proven by clinical studies) has to justify the cost, which involves a higher risk of failure for the new venture, if health insurances refuse reimbursement and patients would have to pay themselves. If the costs of the new product or treatment are not affordable by the average patient or if the medical need of the patient is not high enough, the business model is doomed to failure.

A high probability of receiving reimbursement by health insurances is therefore a must for 35.9% of all participants ($n = 39$) and 51.3% consider it important, depending on the kind of product, i.e. they would also invest in classical self-pay products like e.g. dental implants. The remaining 12.8% of the VCs classify a high reimbursement probability as a “plus” as they are also open to invest in products offered directly to consumers, like e.g. cosmetic laser surgery.

Previous research provides evidence that early-stage investors differ from later stage investors (Gupta and Sapienza, 1992; Elango, et al. 1995). Therefore the authors hypothesized that the investment stage might influence the VCs’ decision and might have a direct impact on stage-related criteria. Since the sample included VCs already active in the seed stage and VCs active in later stages, the authors evaluated whether the earliest possible investment stage in which a VC is prepared to invest influences the relevance of stage-related criteria such as the *development stage* of the product, the stage of the *CE approval* process and the *availability of clinical data*. For testing the hypothesis, the authors used the Chi-Square Test according to Pearson. The test has been implemented using MS Excel 2010.

Results are highly significant: The required stage of product development (p -value: 0.000018; χ^2 test; $\alpha = 0.05$) and CE approval (p - value: 0.000003; χ^2 test; $\alpha = 0.05$) depend on the earliest stage, in which the VC is prepared to invest. *Clinical data* (either animal models or preferably first in patient data) are required or considered important because of CE-marking, but also as a proof of concept of the technology. Investors only active in start-up and expansion phase rate the relevance of clinical data significantly higher than investors already active in the seed phase (p - value: 0.000072; χ^2 test; $\alpha = 0.05$). This means that the investment stage influences VCs’ decision. Therefore, stage-related criteria need to be analysed taking into account the earliest possible investment stage of each VC.

The sample included VCs with a broader technology focus and VCs with an explicit life science, healthcare or medtech focus. Previous research suggests that the VC’ industry focus has an impact on criteria applied (Baum & Silverman, 2004; Baeyens et al., 2006). Therefore the authors tested whether the groups differ with regard to the very industry-specific criterion “*availability of clinical data*”. The Chi-Square-Test applied for the two groups revealed that the requirements of VCs with a life science, healthcare or medtech focus and of VCs with a broader technology focus do not differ (p - value: 0.613819; χ^2 test; $\alpha = 0.05$). This might be due to the fact that one criterion for the sample selection was to include the medtech specialists of VC firms with a broader technology focus.

If VCs like the technology, but judge the development stage as too early, they may reject the deal and ask the founders to come back later. Usually, they keep in touch with the founders and monitor the development of the company.

4.4 Results on Business Model and Strategy

As already described by Kaplan and Stroemberg (2004), the *plausibility of the venture’s business model* is a crucial criterion all VCs (n = 39) check in the screening phase. Highly scalable models with *recurring revenues* seem to be very attractive to VCs: these models are regarded as more sustainable and less risky, which is also advantageous when the company shall be exited. In medtech, the company may offer a device, which is replaced after a couple of years, and disposables, which have to be bought regularly as long as the device is used. The compulsory use of disposables only sold by the venture can create an entry barrier for potential competitors in the form of customer switching costs. Such models are preferred by 65.7% (n = 35) of the VCs.

Strategy-related criteria explicitly mentioned in the interviews referred to the venture’s *regulatory strategy* (for obtaining reimbursement), *IP-strategy*, *commercialization strategy*, and *pricing strategy*. The regulatory strategy and the IP strategy are industry-specific and an IP strategy is necessary in knowhow-driven industries like the medtech industry.

4.5 Results on market and competition related criteria

The market and competition of the current changing business environment are important issues for all VCs, who participated in the survey and are usually evaluated together. Similar to literature findings (e.g. Muzyka, Birley and Leleux, 1996), *market growth* is a very important criterion. Sustainable growth is expected from products for the diagnosis or treatment of diseases with high prevalence and incidence rates, like e.g. metabolic diseases, but also for medtech in general: shrinking or declining markets are only expected for products that are replaced by new and more advanced technologies, but not because of a decrease in demand. The great majority of the VCs have a clear idea of the minimum *size of the market*, which shows a trend towards market volumes of more than 100 million EUR. Six VCs rather look at their exit potential than at the market potential, i.e. the exit value is calculated based on sales multiples and those sales must be achievable in the target market: either within the investment period by the company itself, or afterwards by the potential acquirer if the company is sold at a pre-revenue stage based on forward-looking sales (see Figure no. 3).

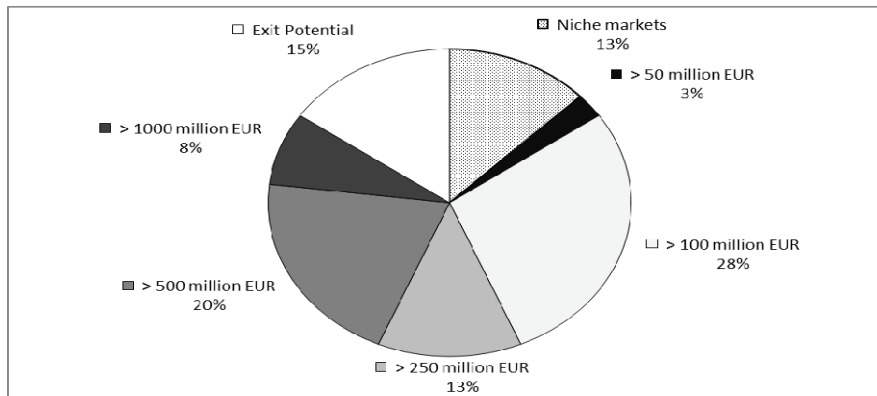


Figure no. 3: VCs’ idea of minimum market size for medtech ventures

For one third of the VCs, the *degree of competition* tolerated depends on the market size and growth (33.3%; n = 39), but also on the stage of the market respectively the development stage of the company. Investors active in later stages are more inclined to accept a higher degree of competition as markets are more mature and the company has achieved a certain competitive position on the market. However, this competitive position has to be based on a strong competitive advantage (USP). On young and growing (consumer) markets, competition could also be favourable to make a new technology known to the market and to benefit from competitors' marketing expenses for promoting this technology. This view is also shared by Porter (1980). From a resource-based view, small companies should rather tolerate other small competitors and "one small one should not try to kill the other small one". Furthermore, the existence of one or two competitors is regarded as a signal that a market exists, which lowers the risk of failure due to missing customer need.

4.6 Results on management - related criteria

Management-related criteria checked during the screening phase mainly refer to the *education, industry and management experience* and the *personal track record* of the founder(s), as this is the only information that could be found in a BP - if the VC has not yet met the founders before (e.g. at a conference). As also identified by previous research (e.g. Fried and Hisrich, 1994; Franke, et al., 2008; Chatterji, 2009), management-related criteria are very important for all VCs. Two industry-specific criteria, which form new contributions to research, are the *management's regulatory experience* (stated by 48.7% of the VCs) and their *ability to communicate to doctors and KOLs* (stated by 28.2% of the VCs).

Regulatory experience is necessary for managing the CE respectively FDA approval process, and for preparing reimbursement applications. However, for CE and in particular for FDA approval most companies need external support, also in later stages. This may be the reason why only 19 VCs (48.7%) stated that at least one team member should have already successfully gone through an approval process. For management-related criteria, the authors also hypothesized that VCs generally consider the development stage of the company, when looking at the team's skills. Using the Chi-Square-Test in MS Excel 2010, the authors tested the hypothesis that VCs' requirements regarding the management team's *industry experience* and *commercial skills* depend on the earliest investment stage in which VCs are prepared to invest. The hypothesis can be confirmed: VCs also active in the seed phase were not able to detach themselves from their seed approach, i.e. their requirements regarding the industry experience (p - value: 0.008699; χ^2 test; $\alpha = 0.05$) and commercial skills (p - value: 0.046995; χ^2 test; $\alpha = 0.05$) of the team are significantly lower than those of VCs only investing in start-up or expansion stages. Technical skills are indispensable at all development stages, because at least one team member has to develop the core technology. Financial skills are not mandatory for venture teams in the seed and start-up phase - but present a strong plus, if they are available (see Figure no. 4).

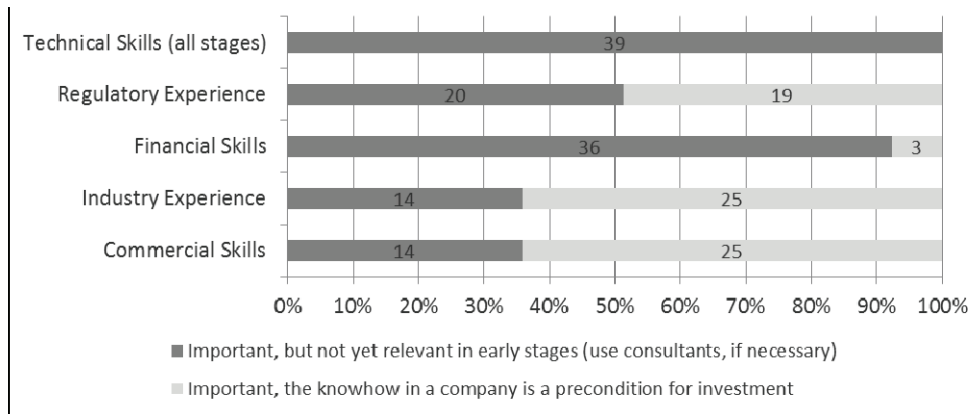


Figure no. 4: Management Skills required by VCs

4.7 Results on Financial Criteria and Exit Options

In screening, VCs only roughly evaluate financials presented in the BP - financial projections mainly serve as a basis for the VC's initial estimate of the company's cash need. Having the exit already in mind, VCs try to estimate time to break-even, financing needs to break-even, and time to exit which are known to be relevant criteria (Muzyka, Birley and Leleux, 1996; Silva, 2004). A high return is a crucial criterion for all VCs (e.g. Elango, et al., 1995; Muzyka, Birley and Leleux, 1996). A great majority (86.5%, n=37) of the VCs share this view, and would reject a deal in the screening or evaluation phase, if parameters influencing the return like e.g. the pre-money valuation, are not in line with the VC's expectations. The average expected IRR for medtech ventures in this survey is 42.15% (SD: 25.77%; n = 35), which is line with IRR ranges reported previously (e.g. by Fried and Hisrich, 1994). Only five VCs (13.5%, n=37) working with public funds consider return being relevant, but not one of the most relevant criteria. They see their main task in the promotion of economic development respectively of new technologies, and thus for them generating returns comes second. In medtech, VCs would like to see gross margins between 40% and 80%. A high gross margin is a criterion, which might be industry-specific. Since the medtech industry is innovation-driven, R&D spending is much higher than in other industries. In Germany, e.g., R&D spending of medtech companies amounts to 9% of sales on average, which is more than twice the average of industrial goods (BVMed, 2012).

Findings from this research suggest that nearly all VCs (94.9%; n = 39) evaluate potential exit options during the screening phase, i.e. they try to get an understanding of who could be potential acquirers of the company and how the venture could fit into their strategy.

The initial screening process, in which the VC quickly tries to find out, if the proposal meets his/her general investment criteria like e.g. the market segment and therapeutic area addressed, nature of the product, and stage of the venture, lasts between five minutes and one hour. If the VC likes the proposal, he/she invests between 4 hours and 4 weeks to read the BP thoroughly and to make further investigations, like internet research and reference calls with experts. The deal is then presented to the VC firm's investment team respectively to the partners, who decide on the further proceeding. Either the venture's management will get the chance to present the business case in a personal meeting, or the VCs will reject the deal. Table no. 1 provides a summary of the medtech-specific criteria identified in this research.

Table no.1: Venture Capitalist's Industry-Specific Criteria for Medtech Ventures

Criterion Category	Specific Criterion	Criterion	Specific Criterion
Therapeutic Area	Cardiovascular Diseases	Regulatory Criteria	Probability of Reimbursement Stage of CE Approval Clinical Data
	Orthopedics / Spine Neurology Metabolic Diseases		
Product	High Medical Need	Business Model / Strategy	Recurring Revenues Regulatory Strategy
	KOL Support	Market	Min. Market Size of 100 Million EUR
Intellectual Property	Patents	Management	Regulatory Experience Ability to communicate to Doctors and KOLs
Financials	High Gross Margin		

The research reveals a problem in medical technology which is already known from the pharmaceutical industry: the cost of developing a drug for rare diseases, so called “orphan diseases”, are higher than the expected sales. VCs’ preferences for high market volumes and therapeutic fields addressing diseases with a high prevalence mean that ventures developing medical products addressing rare diseases with small market volumes will most probably not receive financing. For drugs, this “market failure” has already been addressed by the European Union in “Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products”, which allows for incentives to pharmaceutical companies developing medicinal products for orphan diseases.

As seen in the literature, several factors make it difficult to attract the necessary investment in the field of rare diseases, in particular the perceived and actual low market returns for these investments. Therefore, important actors in the public and philanthropic sectors now argue that the costs and risks of investment in medical products for rare diseases must be shared with industry to ensure a public health dividend (Buse and Walt, 2000).

In the authors’ opinion, future researches can be developed taking into account a new economic model, called the “social venture capital”. Such an alternative solution to a more “classic” capital venture could be the public – private partnerships. These kinds of partnerships are able to focus on funding high-risk and high-cost projects to convert basic scientific ideas into usable medical products. (Wheeler and Berkley, 2001)

Rather than linking with a single company, they interact competitively with many companies. Their business model lies at the core of today’s technology revolution and exploits in the same time the venture-capital approach to investing. Operating as social venture capitalists, these new public-private partnerships seek to pool the skills and efforts of partner organizations around specific projects, including corporations, industry groups, academic institutions, non-profit community efforts, and government agencies. Together they can offer an effective response to the medical needs associated with low commercial returns, such as in the case of “orphan diseases”.

Conclusions

Whereas previous research mainly focused on VCs' general investment criteria for new ventures independent of their industry, location and stage, this research contributes to literature by identifying new criteria specific for the screening of medtech ventures, like a medical need for the product, availability of clinical data, stage of CE approval, a high probability of receiving reimbursement from health insurances, medical key opinion leaders supporting the technology, business models with recurring revenues, the management's regulatory experience and their communication ability with doctors and key opinion leaders. Furthermore, a venture should address markets with a volume of more than EUR 100 million. Therapeutic fields in focus are cardiovascular diseases, orthopaedics / spine, neurology and metabolic diseases, which promise large market volumes due to high prevalence. Since regulation plays an important role in the medtech industry, it is not surprising that several criteria refer to regulatory hurdles a venture has to overcome in order to survive in a changing business environment.

The required development stage of the venture's product and the stage of CE approval depend on the VC's earliest stage of investment. The same applies to the availability of clinical data, which have to be presented during the CE approval process. VCs' requirements for management skills like industry experience and commercial experience also depend on their stage focus. This confirms that venture capital research should differentiate between early stage and later stage entrepreneurs.

In addition, this qualitative research also contributes to literature by identifying the reasons why VCs use certain criteria and how they evaluate them, e.g. with the help of medical KOLs. Criteria identified in previous research are relevant for medtech ventures as well and already occur at the screening stage, e.g. quality of the management team, market size, and growth, level of competition, USP, business model, strategy, and return.

Taking into account the results of the performed research, one can conclude that venture capitalists prefer to invest in companies that develop products for treating and diagnosing diseases showing a high prevalence and large market volumes.

The results of this study may represent a starting point for future research, on the so called "social venture capital", such as the public-private partnerships, today still nascent and experimental, that apply social venture capital approaches to bridge the investment gap, which may be an alternative solution to a more "classic" capital.

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