



Franz Tödtling, Tanja Sinozic, Alexander Auer

Knowledge bases, multi-scale interaction and transformation of the Vienna medical cluster

SRE-Discussion 2016/03

2016

Institute for Multi-Level Governance and Development Department of Socioeconomics WU Vienna University of Economics and Business

# Knowledge bases, multi-scale interaction and transformation of the Vienna medical cluster

Research report

### Franz Tödtling<sup>1)</sup>, Tanja Sinozic<sup>2)</sup>, Alexander Auer<sup>1)</sup>

 Vienna University of Economics and Business; Institute for Multilevel Governance and Development
 2) ä sum to a s

<sup>2)</sup> ÖAW Austrian Academy of Sciences, Institute for Technology-Assessment (ITA)

June 2016

Research supported by the Jubilee Anniversary Fund of the City of Vienna for the WU Vienna University of Economics and Business and the Austrian Science Fund (FWF) Project No. I 582-G11

#### **Table of contents**

Summary	
1 Introduction	7
2 Literature review	
2.1 Medical devices innovation	8
2.2 Clustering	10
2.3 Knowledge bases and multi-level flows	12
3 Medical sector context, method and firm overview	
3.1 Medical devices sector and growth	15
3.2 Method and firm sample	27
3.3 Characteristics of sample firms	19
3.4 Local factors important for firm foundation in Vienna	20
4 Factors for growth and development of the firms and the clu	ster
4.1 Factors for firm development	22
4.2 Factors for cluster development	28
5 Knowledge bases and innovation	
5.1 Internal knowledge bases and competencies of firms	33
5.2 External knowledge sources: Innovation cooperation	35
6 Policies and regulations	
6.1 Policy frameworks and regulations at different territorial lev	els 39
6.2 Relevance of policies for firm development	43
7 Conclusions	46
References	48

## List of figures

Figure 1: Vienna medical devices firms by year of foundation	16
Figure 2: Importance of Vienna factors for founding firm there and for staying in the region	21
Figure 3: Regional, national and international factors important for firm development: Group A	24
Figure 4: Regional, national and international factors important for firm development: Group B	25
Figure 5: Regional, national and international factors important for firm development: Group C	26
Figure 6: Regional, national and international factors important for firm development: Group D	27
Figure 7: Regional, national and international factors important for cluster development: Group A	29
Figure 8: Regional, national and international factors important for cluster development: Group B	30
Figure 9: Regional, national and international factors important for cluster development: Group C	31
Figure 10: Regional, national and international factors important for cluster development: Group D	32

#### List of tables

Table 1: Selected indicators by group	19
Table 2: Firm competencies: Group A	33
Table 3: Firm competencies: Group B	34
Table 4: Firm competencies: Group C	34
Table 5: Firm competencies: Group D	35
Table 6: Cooperation partners for innovation by type and location: Group A	36
Table 7: Cooperation partners for innovation by type and location: Group B	36
Table 8: Cooperation partners for innovation by type and location: Group C	37
Table 9: The relevance of policies in general by firm group	44
Table 10: The relevance of specific policy areas by firm group	44
Table 11: Change of policy relevance in general by firm group	45
Table 12: The relevance of policies on different spatial scales by firm group	45

#### Summary

The health sector and medical technologies are of an increasing importance in society and for regional and national economies. Much like other life sciences industries, the medical devices sector relies upon specific factors and knowledge processes that shape and support its innovation capabilities and competitiveness. Previous studies have shown that growth and innovation in this sector depend on specific local factors and conditions as well as on markets and knowledge-interdependencies at higher spatial scales. There is still a research gap on the detailed nature of these driving factors and relationships, however. In this research, we have investigated these issues for the Vienna medical devices cluster that is part of the wider life sciences sector in this region. The main aims of the study were to generate insights into how different economic, knowledge- and policy conditions, and their spatial scales, interact to support and hinder development of the medical devices industry in Vienna, and to draw policy conclusions based on these findings.

The first stage of the study involved a literature review to factors and processes supporting medical cluster growth, and to medical devices innovation and related knowledge flows. The literature review also included a survey of contextual materials (such as reports and secondary data sources) on the medical devices industry in Vienna and in Austria, focusing on aspects of its history, size, structure and growth. The primary data collection on driving factors, knowledge bases, and policies of the Vienna medical devices cluster was carried out based on interviews with eight industry experts and with an interview survey of 30 firms. This analysis provided novel insights into, first, the importance of local, national and international factors for innovation and competitiveness of this sector in Vienna, second, knowledge processes and –interactions inside and outside the firm, and the policy- and governance environment.

The Vienna medical devices cluster is based on a long tradition in Medical science, engineering and precision mechanics in the region. Companies located there have some older roots, but most of them have been set up since the 1970s. One third of all Austrian medical devices firms are nowadays located in this region. R&D performing firms are specialised e.g. in software for medicine, telemedicine and e-health, electromechanical medical devices, dental technology, diagnostic and therapeutic devices, and surgical instruments, but there is a high heterogeneity of firms. In order to take this into account we distinguished between four groups. Group A firms are engaged in non-invasive high-tech medical devices, Group B in invasive high-tech products, Group C in low-tech devices, and Group D only sell and distribute medical devices products to the Austrian and nearby market. Both the high-tech and low-tech firms are highly specialised, and employ highly qualified people. The technology intensive Group A and B firms engage more in R&D and innovation, and they show a more steady growth. They also sell more internationally than the rest, and they are better networked at an international scale. Group C firms are in low-tech medical devices, they tend to be older, and they rely more on regional and national networks for knowledge flows and innovation. These firms face price-based competition from international markets and they show slower growth. Group D firms are sales- and distribution firms, often subsidiaries of global firms, specialised in selling to the Austrian and nearby CEE market. Overall, the main strengths of the sector are incremental innovation, local and national networks, and an understanding of the domestic market. Firms invest many resources also in meeting international regulatory environments for their products, which differ greatly across countries. The sector benefits from a growing domestic and foreign demand, and research collaborations mainly with local and Austrian universities.

The medical device sector in Vienna also has some weaknesses and challenges to overcome for maintaining its competitiveness. The R&D that the firms engage in does not yield the growth rates of other technology-based sectors in Austria. International networks are scarce and recent, and often lack a strategic orientation. International competition in the domestic market is rising. A further important challenge is increasing international regulation and marketing, which is becoming more complex to oversee and manage. Policy actors both on local and national levels should address these challenges facing the medical devices sector in Vienna and the country.

We arrive at the following policy conclusions for improving the competitiveness and performance of the medical devices cluster in Vienna. The knowledge bases and innovation capabilities of local firms need to be further strengthened. In this context, not just radical but also incremental innovation should be supported and enhanced in the sector and related technology areas. For this purpose, the domestic knowledge- and skills base should be strengthened through investment into schools, colleges and universities, and through recruitment of expertise from abroad. Local connections to hospitals, doctors and the broader healthcare sector in product development and testing, as well as international networks need to be deepened and broadened. Furthermore, a good understanding of and experience in meeting international regulatory settings for medical devices products is crucial.

#### 1. Introduction

Globalisation processes such as enhanced international trade and -competition, transnational firms and production relocation, and the associated challenges to employment, have transformed regional growth environments. Metropolitan regions such as Vienna are forced to adjust their development strategies in order to maintain the competitiveness and dynamics of their industries, and to foster new trajectories for job creation. In order to respond to such challenges, governments have placed particular importance on potentially highly profitable industries that might create high-paying jobs (Porter, 2000; OECD, 2014). Knowledge and technology intensive industries, such as information communication technologies (ICTs), new media, and life sciences including medical devices were explicitly targeted e.g. through cluster- and innovation policies. These sectors are engaging in processes of knowledge creation that differ by their respective knowledge bases (for example, analytic, symbolic or synthetic knowledge) and the processes of knowledge sourcing and its integration into firm, product- and service functions (Pouder and St John, 1996; Cooke, 2002; Asheim and Gertler, 2005).

Several studies have identified Vienna as a centre for medical activities, possessing high levels of competencies in areas such as pharma-biotech, prosthetics and imaging (LISA Vienna, 2014; Hochgatterer et al., 2014). Vienna's medical cluster benefits from worldleading research hospitals, a developing life sciences sector (Trippl and Tödtling 2007), and a small but growing medical devices and digital imaging sector. Overall, the sector is of considerable importance for innovation, growth and healthcare provision for the population in the region and beyond (Tödtling and Trippl, 2013). Moreover, since the early 2000s the life sciences- and medical devices sectors have been central pillars of Vienna's science, (Stadt 2004; technology and innovation (STI) policy Wien, ZIT. 2013; www.wiendenktzukunft.at, www.wienwin.at) and a major focus of large-scale funding programmes for enhancing the quality of life of citizens such as the Ambient Assisted Living Programme (BMWF et al., 2013). In addition to direct economic benefits for employment, sales, firm formation and economic growth, the Vienna medical cluster has substantial direct importance for the local population in meeting changing healthcare requirements of the elderly and increasing complexity of diseases that such demographic changes bring about.

While the biotechnology sector in Vienna has been well researched in the past (Trippl and Tödtling, 2007; 2008), there is less understanding of innovation dynamics in the broader medical devices cluster, that employs the same amount of people as the pharma-biotech cluster (see LISA Vienna, 2015). This has justified the enquiry of this study. It aims at a better understanding of the importance of and diversity in knowledge bases and knowledge flows that characterise the innovation processes in the Vienna medical devices cluster, and to inform and improve regional-policy making. In order to fulfil this aim and address the empirical gap, the research has been guided by the following questions:

- Which factors and processes were important for the development of the medical devices sector in Vienna?
- What are the knowledge bases and -sources of the Vienna medical cluster? How are firms using and combining different kinds of knowledge in order to innovate?
- What are the barriers and supports to innovation, upgrading and cluster growth?

In order to answer these questions, we undertook a review of theoretical and empirical literature, and collected and analysed secondary and primary data. The following section 2 presents a literature review of some of the main approaches to medical devices innovation and clustering, also highlighting the knowledge types and spatial dimensions of relevant factors and interactions. Section 3 gives a background to the medical devices industry in Vienna. We describe the beginnings of the local industry as well as the changes in its size, composition and structure, and some of the significant events that have influenced cluster formation and growth. This section relies on secondary data sources, such as the AURELIA database and the LISA Vienna Region database. In section 4 the results of the empirical survey addressing factors for the development of firms and the cluster, are presented. Using both quantitative and qualitative data collected in the interview survey of 30 medical devices firms in Vienna and eight industry experts, this chapter presents regional, national and international factors for the development of various types of medical devices firms in Vienna. Section 5 highlights empirical results for the knowledge- and innovation processes of the Vienna medical devices cluster dealing with internal competencies as well as external sources of knowledge such as collaborations at different spatial scales. Section 6 describes the governance- and policy context of the medical device sector in Vienna. The central institutions that formulate and implement policies for the sector are described, with a special focus on those that influence innovation and growth prospects of the firms. The chapter relies upon a review of grey literature and documents, as well as the expert and company interviews mentioned above. Finally, section 7 concludes with policy suggestions for strengthening the medical devices sector in the region.

#### 2. Literature review

The following section presents some of the main features of innovation in medical devices, to highlight the characteristics of knowledge processes and innovation in this sector. Second, we review the main empirical studies examining the spatial dimension of the medical devices sector development and its clustering are. The third body of literature links medical innovation to types of knowledge bases and -flows, and provides the theoretical rationale for the study.

#### 2.1 Medical devices innovation

Invention- and innovation processes in medical devices have been the subject of much scholarly work from the disciplines of medicine, history, economics and sociology. Here we

briefly review some of the main aspects highlighted by historians, economists and sociologists of technological change, focusing on the role of knowledge in medical devices innovation. The medical devices sector has been associated with a large quantity of innovations with the potential for the advancement of human health, wellbeing, and increase in life expectancy (Jennett, 1986; Pickstone, 1992; OECD 2008). Products are highly diverse, ranging from "high-technology" devices such as sophisticated surgical and medical instruments to "lowtechnology" devices such as hospital beds, wheelchairs, bandages, syringes and glasses (De Vet and Scott, 1992:146). Within these product categories we find a large technological diversity. High-technology medical devices include products such as computed tomography (CT) scanners that combine technologies such as X-rays with data processing power of computers, and magnetic resonance imaging (MRI) machines relying upon signals created by magnetic waves and their interpretation by computers (Gelijns and Rosenberg, 1999), as well as rapidly improving high-end visualisation software. Following Pickstone (1992), Metcalfe et al. (2005), Metcalfe and Pickstone (2006), the knowledge developed and used in medical innovation is inseparable from scientific developments, progress in other technological areas and the techniques with which it is applied (von Hippel, 1988). Contrary to innovations in the pharma-biotech fields, medical devices and their improvements have often been outcomes of discoveries in physics and engineering (Rosenberg, 2009).

Many scholars have shown that medical innovation is influenced by accumulation of knowledge through interactions of diverse actors and organisations such as firms, hospitals and healthcare providers (including research-minded doctors, user technicians, and patients), and medical research universities (Hippel, 1988; Metcalfe and Pickstone, 2006; Webster, 2006). Detailed histories of innovation in medical devices reveal its slow and incremental nature (Metcalfe et al., 2005) with slight modifications that do not normally reflect new knowledge (Rosenberg, 2009). In some areas such as prosthetics and orthotics, products such as artificial hips have emerged as relatively simple devices that gradually became more complex as they were combined with different technologies over time (Metcalfe and Pickstone, 2006).

Further important aspects of medical innovation are the industry- and market structure. The medical device industry is composed of several smaller industries that contribute to a variety of technology areas and a broad range of products. The diagnostic imaging devices industry is dominated by few very large firms, such as Siemens, Philips, Toshiba and General Electric (Gelijns and Rosenberg, 1999). The rapidly growing small instruments industry (such as for example cardiovascular devices, glucose monitors, and insulin delivery devices) is dominated by the US players Johnson & Johnson, Boston Scientific, Abbott, Medtronic and others (Chatterji, 2009). The larger firms in these industries tend to behave much like manufacturing firms, focusing on incrementally improving their existing products (such as Siemens, Toshiba and GE in developing the next generation CT scanner). The smaller firms rather invest in developing radically different products, to be patented and licensed to other firms or to healthcare providers.

In their study of the national competitiveness of the medical diagnostic devices industry, Gelijns and Rosenberg (1999) find three main dimensions of the national innovation system that strongly influence competitiveness: the science base, intellectual property rights, and features of the national healthcare system. Universities, especially physicists and engineers in European and US universities played an important role in some of the major developments in medical devices technology areas. However, unlike pharma-biotech, which is highly dependent upon scientific research conducted in universities, much research for medical devices occurred in firms. There is a higher dependency on medical universities and hospitals, which are important for delivering ideas and for testing devices. National healthcare systems have different regulations and these can significantly affect the processes by which medical innovation and industry growth can occur. The degree to which a medical specialisation is prevalent in a country co-determines the demand for the devices (Gelijns and Rosenberg, 1999). Healthcare systems also differ in how they are financed (publicly, as in Germany, UK and other European countries, or privately, as in the US) and how various products and product classes are regulated. In a privately financed and less regulated system such as in the US, the demand for many types of medical devices is higher and they are easier to sell. In publicly funded systems, procurement and reimbursement policies can determine whether a product is sold or not. In a sector where testing and reputation is very important, the home market can be crucial in the early stages of product development (Gelijns and Rosenberg, 1999).

#### 2.2 Clustering in the medical devices sector – A view from the literature

In addition to national advantages, some cities and regions have a specific science- and knowledge base, infrastructure, organisations, and social and institutional cultures (Boschma, 2005) that make them superior to other localities for particular sectors and firms (Saxenian 1994, Keeble and Wilkinson 2000). Medical devices firms sometimes exhibit clustering behaviour for reasons such as the existence of key organisations and institutions in a particular location. Large R&D intensive firms can be key organisations for exploiting knowledge from local universities and for anchoring an industry in a region (Feldman et al. 2005). Individual work experience in large firms may be essential for gaining knowledge and skills and professional networks for setting up new firms. The existence of organisations such as venture capital firms are further important location- and innovation factors, especially for sectors such as life sciences (Powell et al., 2002). Universities, university hospitals, and the broader institutional advantages of regions such as Cambridge UK and Boston, foster conditions and an entrepreneurial culture in which it is easier to set up new medical devices firms than in other regions (Feldman et al., 2005; Garnsey and Heffernan, 2005).

In their 1991 study on the US, Jan de Vet and Scott identify medical clusters in five states: California, Florida, Illinois, Massachusetts and New York, with the biggest concentration of medical devices firms in Southern California. Their study traces the development of the Southern Californian cluster and highlights important events that shaped its successful trajectory. The cluster partially emerged from the entry of several important actors in the region in the 1950s, such as a manufacturing firm specialised in aerospace electronics, a hospital supply firm, and the opening of an airport. These attracted other aerospace electronics firms to the region, some of which expanded into medical devices because of similarity in techniques (Jan de Vet and Scott, 1991:150). In the 1970s the cluster saw a series of spin-offs from a large research and biomedical firm, and has continued to grow ever since. The labour pool of experienced engineers and managers in the locality made it easier for spin-offs to grow, through hires and direct contacts. The diverse labour pool (and the related knowledge and skills) benefits the firms because of the partially unpredictable knowledge requirements of innovation in this sector. Formal contacts to universities were frequent, and over 90% of the firms have patented innovations. Venture capital has been very important, especially for the high-end segment of the industry.

In his more recent study of the US medical devices industry Chatterji (2009) finds that academic research and patenting are very important, indicating an increase in the importance of scientific knowledge for the industry over time (p. 189). Doctors acted as key innovators, and their ideas were relevant for new firm formation. Moreover, venture capital has been very important, taking over 700 million US dollars in 2004. Experience in large firms was very useful for spin-off founders, as well as multiple experiences in starting firms. Other people who founded firms were serial entrepreneurs, doctors, or outsiders to the industry. Those firms founded by people who used to work in the larger companies performed better than other ventures, but based on patent citation analyses, they did not rely upon the technical knowledge from the parent firm. Rather nontechnical knowledge has been more relevant, including regulatory knowledge, marketing knowledge (how to market to doctors) and how to identify new market opportunities in medical devices, all of which were said to be more important than technical knowledge for spin-off success.

According to the Warwick Institute for Employment Research (2004) report on medical devices clusters, some of the most advanced medical clusters in the world are located in the West Midlands and in Scotland (United Kingdom), in Baden-Wuerttemberg and Bavaria (Germany), in Medicon Valley (Denmark and Sweden), and in Massachusetts (USA). The study compares and contrasts the six clusters based on their institutional arrangements for skills training and provision for the medical devices clusters. It finds that all medical technology clusters are dependent upon a high skill input. The most important skill types were related to R&D, such as scientists and engineers. Other important competencies are those associated with production (management and production line) and in strategy (strategic vision and marketing). The specialisations of the clusters were found to be important, as well as close links between local research institutions and medical technology firms (especially in Germany and in the US). The study concludes that medical technologies industries possess an enormous growth potential with a high capacity to generate high skill and high wage employment, perhaps more so than most other manufacturing sectors.

In the study of Toronto's life sciences industries, Lowe and Gertler (2009) go beyond the listing of supporting factors such as research universities, commercialisation systems, venture capital, recruitment of 'star scientists', and experienced managers and entrepreneurs. They

argue that such a listing ignores important roles played by institutions for the development of clusters. Using the case study of Toronto, the authors find that the region receives the most funds for medical research for Canada, but also shapes the regulations for drug pricing by the government. Further important features are the ways in which local hospitals procure products, the demand for research support by the local generic drug makers, and the diversity of life sciences research that "encourages experimentation across disciplinary boundaries" (ibid. p. 596). They find evidence of frequent consumption of local products as well as of centralised procurement offices and inter-hospital buying 'clubs' who give contracts to highvolume multinationals such as GE, Baxter, Johnson & Johnson and Medtronic (ibid. p. 597). The interviews they carried out suggest that specialty- and customized products are purchased via front-line practitioners and division administrators, giving rise to a kind of 'bifurcated' purchasing system (ibid. p. 597). The medical practitioners, who set up their own companies in the region, said that they used their previous professional networks in the hospital system to distribute their products. There is also a high concentration of generic drug development firms, the highest in the country. Venture capital in the region has long favoured core biotechnology over medical devices firms.

#### 2.3 Knowledge bases and multi-level sources of knowledge

#### Industries differ according to the characteristics of their predominant knowledge bases

By providing a frame to differentiate between the modes and structures of knowledge accumulation the knowledge base approach is a complementary view to how knowledge is adopted, generated and applied in organisations, regions and sectors (Manniche, 2012). Asheim and Gertler (2005) characterise knowledge bases of individual industries as a key feature underlying innovation. The typology is composed of analytic, synthetic and symbolic (SAS) knowledge bases. The analytic knowledge base represents industries that predominantly rely upon scientific advancements for innovation processes, such as the biotechnology industry (Gertler and Wolfe, 2006). The processes by which knowledge in these industries is derived involve deductive reasoning and formal modelling, mainly carried out in R&D labs of firms or universities. Academic spin-offs therefore are a frequent phenomenon. Knowledge tends to be codified and, relative to tacit knowledge, more easily transferred. The individual skills that these firms rely upon are analytical skills, abilities to think abstractly, to build theories and test them, as well as the documentation of research in reports and scientific publications (Plum and Hassink, 2011). Industries characterised by a synthetic knowledge base tend to combine existing knowledge, such as is the case predominantly in many manufacturing industries. Knowledge combination in these industries occurs through interactions between firms, clients and suppliers. Innovation here relies upon inductive reasoning and problem solving, and activities focus on development (rather than research) such as "system design, prototyping, fine-tuning, testing and practical work" (Plum and Hassink, 2011:1144). Tacit knowledge plays an important role in knowledge creation through practice and problem solving typical for these industries. Skills are acquired on the job, or through apprenticeships and polytechnic colleges (Plum and Hassink, 2011:1144). The symbolic knowledge base supports the aesthetics, design and the "economic use of various forms of cultural artefacts" (Asheim, 2007:226). The importance of this knowledge base is reflected in the importance of design in successful products, and the increase in the role of creative industries in the economy. The activities associated with the symbolic knowledge base are about new ideas, images, appearance and symbols that rely upon interpretation rather than production (Asheim, 2007:226). Symbolic knowledge is strongly connected to the understanding of social norms and 'everyday culture' of social groups and is therefore highly tacit (Asheim, 2007:226; Martin and Moodysson, 2011). The skills for creativity in design are acquired through practice and learning-by-doing, rather than through formal training. Creative industries tend to work in projects that tend to be limited in time. It is more efficient to rely upon social and professional networks to carry out the individual tasks, rather than to have all people in-house. In practice all industries will rely upon several knowledge bases (Asheim, 2007:226), but the degree to which they do will differ, putting them at different points on the spectrum of the individual knowledge types. Some empirical studies have suggested that it is the combination between knowledge bases, rather than singular rooting within them that characterise innovation in clusters (Strambach and Klement, 2012; Tödtling and Grillitsch, 2015).

Complementing the SAS literature, Strambach and Klement (2012) offer two further dimensions that are helpful in highlighting how and why certain sectors innovate and grow more in some regions than in others. These authors emphasise the cumulativeness of knowledge in industries and draw on institutional theory in innovation studies to emphasise the co-evolutionary nature of learning and socio-cultural processes. They offer a distinction between sectors that rely predominantly on cumulative processes (such as tourism) and sectors that combine different types of knowledge at the micro level (such as new media; Strambach and Klement, 2012:1855). Cumulative knowledge bases are incrementally adjusting knowledge in a path-dependent way, whereas combinatorial knowledge is a mode of creating links and components of previously (regionally) disconnected knowledge types. Industries draw on combinations of knowledge types (SAS), and combine them to different intensities. For example, the biotechnology and the ICTs sectors tend to put a lot of effort in combining different knowledge types. Strambach and Klement (2012) and Manniche (2012) state that the SAS approach is perhaps more suited in studying micro-level knowledge dynamics which may more readily fit individual knowledge base types, but that at higher levels of aggregation such as regions and sectors it becomes more likely that we find combinations of knowledge bases.

#### Knowledge flows occur at different spatial levels

A second hypothesis extending the knowledge base approach is that knowledge flows in and out of clusters at different spatial levels, from local to global ones (Asheim et al., 2011; Tödtling et al., 2013). The argument is that the territorial dimension of knowledge relations and their multilevel character matters for learning and innovation in clusters. Whereas geographical and institutional proximities at the local and regional levels support the exchange of tacit knowledge and interactive learning, selective knowledge links with firms and research organisations at the international and global levels contribute complementary and specialised, often codified, knowledge assets (Bathelt et al., 2004). Innovative cluster firms tend to be both well embedded in the regional innovation system and well connected to partners and networks of production, distribution, R&D, and knowledge exchange at international and global levels (Archibugi and Lundvall, 2001; Powell and Grodal, 2005). Accordingly, recent studies have pointed to the multi-level and multi-scalar nature of knowledge relations in the innovation process (Asheim et al. 2011, Tödtling et al., 2013). Indeed, Strambach and Klement (2012) state ... "it is rare that innovation dynamics unfold on one spatial scale" (p. 1851).

Some aspects of knowledge- and learning processes are highly localised (i.e. embedded in local, regional and national institutional settings), such as social norms, legal frameworks, and the capabilities of firms and organisations that are located there. This idea and argument was inspired by the national innovation systems concept (Edquist (1997, Lundvall 2007), where innovation has been conceptualised as based on interactions between firms, universities, governmental and non-governmental agencies, governed by an institutional framework that is specific to a national context. Furthermore, a regional innovation system (RIS) was said to exist when institutions support and interact with the industries in a region (Cooke et al., 2000). In particular, in federal countries the regional level acts as a meso-level that supports economic coordination through decentralised governance structures (Cooke et al., 2004). Other studies have emphasised the role of global processes such as market- and technological changes, R&D collaboration, and FDI. More recent research has highlighted the importance of interactions between local and global processes (Bathelt et al. 2004), and shifts of scales over time as the local cluster evolves (Menzel and Fornahl, 2009).

Plum and Hassink (2011) in their study on the Aachen biotechnology cluster refer to the role of nationally and globally distributed knowledge networks. The advantages of physical proximity and closeness at regional and national levels are associated with lower cognitive distance, ease of communication provided by opportunities for face-to-face interaction and a common language, and potentially higher levels of trust. These aspects can make innovation processes between firms and other organisations closely located to one another easier, such as in regional innovation systems or in clusters. However, the competitiveness of clusters also often depends on the quality of their connections to global actors and networks.

Asheim and Coenen (2007) analyse how industries differ on the extent and degree to which they rely upon different knowledge bases and therefore types of knowledge. Also the mechanisms of knowledge transfer (such as face to face and buzz) vary by industries. The buzz concept highlights the importance of know-who in creative work, since it is important to know which individuals are good at what in order to be successful. Buzz refers to rumours, impressions, recommendations and strategic information that tend to be local and more important in symbolic industries. Furthermore, symbolic knowledge relates to an aesthetic quality of products, tied to an understanding of everyday culture of social groups because of the cultural embeddedness of interpretation, thus making the local context for knowledge exchange highly important.

Face-to-face communication is also important for synthetic knowledge base industries because of the partly tacit nature of this knowledge. Inspiration for new products and

techniques comes from problems experiences of customers, which are revealed through personal contact. According to Martin and Moodysson (2011), however, the synthetic knowledge-based industries rely both on regional and global knowledge as well as on tacit and codified knowledge. Engineering- and applied knowledge is more important for them than science based knowledge, so spatially proximate firms and users are important network partners, as Plum and Hassink (2012) argue in their analysis of a German automotive cluster. Even though the authors underlie the contextual specificity as a hinderance to making analytic generalisation (Plum and Hassink, 2012:223), we assume that these processes will be similar to other synthetic knowledge based industries.

For the medical devices sector it can be summarised that the innovation process differs from the one in other medical fields (such as pharma-biotech), in that it relies relatively more on practical knowledge and know how (i.e. synthetic knowledge base) than on scientific knowledge (i.e. an analytical knowledge base). Competencies inside the firm as well as interactions between firms and users play a bigger role for innovation than knowledge produced in cooperation with universities. Furthermore, the need to combine knowledge from different fields makes combinatorial capabilities of firms important. Further relevant factors are the local skills base (quantity as well as diversity in qualifications, skills and experience), and proximity to hospitals, medical institutions and users.

#### 3. Medical sector context, method and firm overview

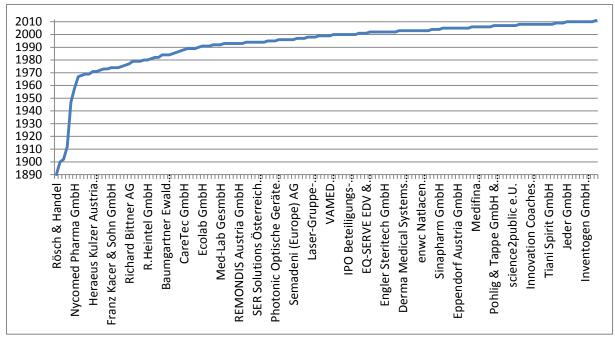
This section first characterises the medical devices sector in Vienna dealing with its size and structure, and relates to regional innovation system features. In the second part, we describe the method and firm sample characteristics, which sets the scene for analysing factors for growth and innovation in sections 4 and 5.

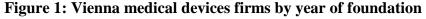
#### 3.1 Medical devices sector and growth

Vienna is the main centre for medical activities in Austria and possesses competencies in areas such as pharma-biotech, prosthetics and imaging (LISA Vienna, 2014; Hochgatterer et al., 2014). The Vienna medical devices industry is based on a long and centuries old tradition in Medical science, engineering and precision mechanics.1 One third of all Austrian medical devices firms are located in this region (33 out of 98 firms) (LISA Vienna, 2015). LISA Vienna classifies medical technology firms in 'dedicated' medical technology firms (domestic firms performing R&D) and 'active' medical technology firms (domestic producing firms). The main firms performing R&D are specialised in software for medicine, telemedicine and e-health, electromechanical medical devices, consumables, dental technology, diagnostic and therapeutic radiation technologies, reusable and surgical instruments, and technical aids for invalids. The average age of the companies is 18 years and the cluster can be considered, on

<sup>&</sup>lt;sup>1</sup> We characterise the life sciences cluster Vienna as having two main industry components: the medical technology industry specialised in medical devices, and the pharma-biotechnology industry specialised in drugs. In this research project, we focus on the first, building on previous work by Franz Tödtling and his colleagues on the biotechnology and ICTs clusters in Vienna and in Austria.

the one hand, as maturing and on the other as growing especially through the accumulation of IT capabilities. More than half of the firms in this industry have been set up in the last 10 to 15 years. In contrast to biotechnology, medical devices have shorter development times and a lower development risk, generating on average four times the revenue invested in R&D. The firms are mainly small, employing less than 10 people, and highly specialised. Table 1 below shows the 30 firms by year of foundation, demonstrating that the majority of the firms were founded after the 1970s, with a notable increase in foundations in the 1990s and 2000s, indicating an emerging industrial specialisation for Vienna.





Source: Authors' own elaboration based on AURELIA database

The Vienna city region and its innovation system have the highest concentration of specialised and teaching hospitals in Austria, and hosts one of the two main medical and technical university centres in the country (the second is in Innsbruck). The city is the location of the largest hospital in Europe (the General Hospital, or AKH), which is engaged also in teaching and research, in addition to a number of smaller and specialised hospitals. Vienna also has a medical university and a technical university, both of which are important for training medical practitioners, scientists and engineers in Austria. These health and other organisations act both as powerful clients and as providers of various kinds of knowledge for the medical devices sector. The large variety of organisations and institutions in large and capital cities such as Vienna imply that their clusters exhibit characteristics of both specialisation and diversity (Huallachain and Lee, 2011). Furthermore, the social, economic and cultural proximities of Austria to German and Swiss markets (also known as the "DACH" region) are significant for R&D and production channels for many sectors in Austria, and also for this sector. One of the largest R&D firms in medical devices in Vienna is a R&D subsidiary of the German Otto Bock Healthcare Products, specialised in prosthetics.

#### 3.2 Method and firm sample

We surveyed 30 firms<sup>2</sup> in total, 25 of which were innovation-active, and 5 of which were trading and resale firms<sup>3</sup>. We included both Austrian-owned and foreign-owned firms in the sample. We selected firms by using the AURELIA Database, a comprehensive firm database for Austria, as well as the LISA Vienna data, showing a detailed listing of medical devices firms in Vienna and their characteristics. We interviewed general managers of the firms from one to four hours. The interview schedule focused on the following topics: (1) general firm characteristics, (2) history and development of the firm, and (3) of the medical devices cluster in Vienna, (4) firm innovation activities, (5) firm cooperation and knowledge relations, (6) financing and business model, (7) role of policy, and (8) expectations, challenges and need for action. Before carrying out the firm survey, we got first-hand background information with six open-ended exploratory interviews with persons experienced in the medical devices sector in Vienna (business- and research consultants, policy-actor, university-technology-transfer office, and an intermediary between government and industry). The quantitative data was analysed with descriptive statistics using SPSS for Windows and Windows Excel. Qualitative data were analysed by coding them relying on concepts of the theoretical frame, and in a second step drawing analytic conclusions based on relations and interpretations from the analysis.

The following potential biases and problems may have affected our sample and results. The selection of "innovation active" firms (in 2015) is static, and ignores the possibility that some firms may have invested in innovation in the past or intend to do so in future. Most of our sample firms were founded after the 2nd World War (with the majority founded after 1970), which can be taken as a reasonable long period of time to investigate growth- and innovation conditions for this sector in Vienna. However, asking people questions about the past is always tricky, because they may not remember things accurately, or at all. We tried therefore to corroborate with grey literature on the medical devices industry in Austria and Vienna. Our interviews, thus, dealt with both objectively quantifiable data that we were able to check with other sources (such as year of foundation and changes in the number of employees over time) and subjective data (such as the importance of specific skills for company- and cluster development). It was, therefore, essential to pose questions in different ways and to allow respondents to talk freely. Still we need to interpret the results with great care.

Data for the whole sector, such as depicted in Figure 1, are important in understanding general patterns. Aggregations however hide possible difference across technology areas, such as ICTs and fine mechanics, and important insights might get lost. For the purpose of differentiation, we follow therefore scholars of the medical devices sector investigating the innovation process. Gelijns and Rosenberg (1999:313) suggested distinguishing between firms in the diagnostic devices industry according to the non-invasive (not inserted under the

<sup>&</sup>lt;sup>2</sup> We are grateful to Lorenz Stör for his help with the firm interviews.

 $<sup>^3</sup>$  Trade and sale firms usually do not innovate. They were, therefore excluded from the analysis in some subsections. The reason for including some of them in our survey is that sales and distribution firms make up the majority of medical firms in Vienna (over 90%) and we wanted to obtain insights also into this important part of the sector.

skin or inside the body) and invasive nature of products (inserted under the skin or attached to the body). De Vet and Scott (1992) in their analysis of medical devices industries in the United States, differentiate between high-tech and low-tech firms. Based on a first analysis of our data, we combine the distinctions used in these two studies, and categorise our sample in four main groups: high-tech non-invasive diagnostics and monitoring devices (Group A), high-tech invasive prosthetics, mechanical and robotic devices (Group B), low-tech products (Group C), and medical devices distribution and sales firms (Group D). We describe some of the basic features of the four groups below. The analyses carried out in the remainder of this section use the groups as a lens to compare and contrast the main factors underpinning firm and cluster development in the medical devices industry in Vienna.

#### Group A: High-tech non-invasive diagnostics and monitoring devices

Group A firms (11 out of 30) are active in the rapidly evolving technological areas of diagnostics and monitoring devices for healthcare that are non-invasive. The firms in this group produce and sell digital electrical imaging products and applications for monitoring and diagnosing skin surface and inner body changes (for example, skin injuries and changes in tumours) and IT systems for data and logistics for healthcare organisations. Most of these firms are originally IT firms or have re-specialised to software engineering and information requirements of the healthcare sector, or were originally electronics firms that have diversified into non-invasive diagnostic devices for healthcare applications.

#### Group B: High-tech invasive prosthetics, mechanical and robotic devices

Group B (nine out of 30) is composed of firms that produce invasive medical devices in the areas of dentistry, cardiology, prosthetics and ophthalmology devices. Strictly speaking, not all products in Group B are equally invasive. Prosthetic limbs, for example, are typically attached to rather than inserted into the body. The products include dentistry products for jaw operations and implants, and ophthalmology products and services for treatment of eye diseases and eye surgery, and cardiology devices for healing of the heart tissue after a heart attack among others. This group also contains Otto Bock Healthcare Products, a relatively large, innovative and internationally competitive subsidiary performing R&D in Vienna. In terms of innovation interactions, it is a potential regional anchor for the medical devices sector.

#### Group C: Low-tech products

Group C firms (five out of 30) innovate at the 'lower' end of the technological complexity spectrum. These firms sell products that can be invasive (for example surgical instruments such as knives and syringes, artificial eyes) or non-invasive (such as bandages and disposable materials and textiles for hospitals). This group has the oldest medical devices firms in Vienna, and includes firms specializing in bandages and surgical knives among others. Most of the production of such products has moved to countries where labour is cheaper (for example, Pakistan for the manufacturing of surgical knives), and many firms that had previously been active in these product areas have gone out of business because of price competition from abroad (for example, from China). Together, Groups A, B and C make up over 90% of all medical devices firms in Vienna that perform R&D.

#### Group D: Medical devices distribution and sales firms

Group D are trading firms (five out of 30) who at the time of interviewing and in the previous three to five years did not carry out any R&D or production in their location in Vienna or Austria. In the overall population of medical devices firms in Vienna, this group of firms is the largest, making up over 90% of all firms in this sector<sup>4</sup>. These firms are mostly subsidiaries of multinationals that have been placed in Vienna to cover the Austrian healthcare market (or, in some cases, the Eastern European market). The five distribution and sales firms in the sample have their headquarters in Switzerland, Germany, Denmark and France. The firms distribute products such as cardiac valves and devices for hemodynamic monitoring, products for cardiac surgery, supply and delivery of hearing aids, orthopaedic implants, and pharmaceuticals and chemicals. The know-how that is important for the successful distribution of medical devices is knowledge of the product, sales competencies such as ability to bridge medical, technical and economic knowledge of the healthcare system, and maintenance of customer relationships over time.

#### 3.3 Characteristics of sample firms

The findings in our interview survey suggest that there are important differences between the ways in which global technology and production changes affect firm performance and innovation in the four groups (see Table 1 below). This section briefly discusses general economic characteristics of the four groups of firms, before the analysing their knowledge bases and innovation activities in section 4. Group A firms are rather small (on average 14 employees), whereas Groups B and C also have some larger firms. Despite their small size, Group A firms have a higher percentage of international sales, and have the highest percentage of new-to-market innovations, i.e. they are more innovative and relatively more oriented to external markets, although they still sell almost 80% within Austria.

	Number	Number of	Change in	International	Innovation
	of firms	employees	employees	sales in 2015	new-to- market
		(2015)	since 2010		since 2010
			(% of firms)	(% of total sales)	(% of firms)
Group A	11	147	17.7	21.3	90.9
Group B	9	587	22.8	16.7	77.8
Group C	5	4037	12.6	14.0	60.0
Group D	5*	73	8.2	0**	N/A

\*This is not the total number of sales firms in the firm population. For all the other groups, the firms in our sample represent about 90% of all the firms in the respective population.

\*\*Group D firms located in Vienna in order to access the Austrian market and therefore typically do not sell internationally.

<sup>&</sup>lt;sup>4</sup> Statistics obtained from the AURELIA database of firms in Austria in 2014.

Furthermore, technology intensive Group A and B are engaged in areas at earlier stages of the industry life cycle and have experienced a higher employment growth in the last five years, whereas the more mature and less technology intensive Group C and Group D (the sales and trade firms) grew less in comparison. However, the growth rates of all groups show that production and demand for medical devices is growing overall, i.e. the medical devices sector is a dynamic one in general. The high number of employees in Group C, however, indicates a mature segment with large firms, a lower rate of new-to-market innovation, and more stability. Groups A and B, in contrast, represent younger and more dynamic segments of the sector that are combining technologies such as mechanical and electronic technologies with new technology areas such as ICTs and software. The high level of new-to-market innovations in Groups A and B further indicates a technologically dynamic segment in which capabilities to combine internal and external knowledge exist as well as conditions to exploit such new knowledge. In addition to firm characteristics and performance, a central focus of our research lay in the local factors that make Vienna attractive for firm foundation (see the following section).

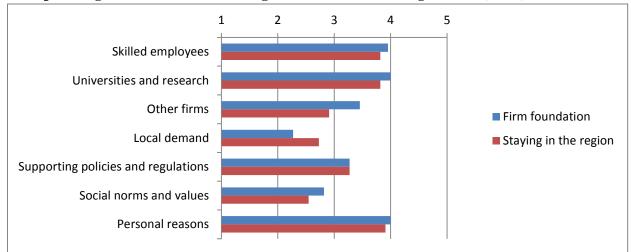
#### 3.4 Local factors important for firm foundation in Vienna

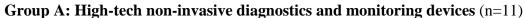
Firms rely upon a variety of local factors and conditions to set up a firm in a region and to stay there. An important question in our research was thus to understand why the medical devices firms had decided to choose Vienna for their location, and whether these factors remained important over time to keep the firms there. Figure 2 below shows, for Groups A to  $C^5$ , the importance of different factors for the foundation of the firm in Vienna (as opposed to elsewhere), and for remaining in Vienna later on. For all three groups of firms, personal reasons (for example, that the founders already lived there, that they had studied there, and that their family and friends were there) were the most important factors for founding the firm in Vienna. This finding is in line with other location studies that also often have shown a high importance of personal factors for the location of firms. These personal factors remained consistently of high importance also for staying in the region for all groups. In Group A in particular, the importance that the founder had studied in Vienna, and that his/her cooperation partners were former fellow students at the same university, was raised as a key reason for setting up the firm in Vienna.

There are differences across the groups in terms of the other factors to locate and remain. For Group A location factors, universities and research institutes were second most important, and third came local qualifications and skills. The universities were important especially for firms set up by persons who had graduated and still had links to other university staff. The top three reasons for staying in the region are the same as the factors for setting up the firm there. This indicates that personal factors remain highly important, but also that the firms continue to mirror the competencies of the universities and the local labour pool. In contrast, local demand was the second most important factor for locating the firm in the region for Group B firms.

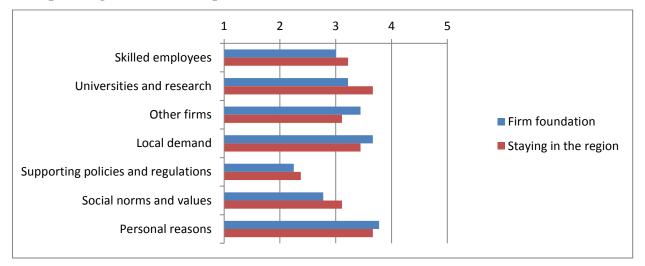
<sup>&</sup>lt;sup>5</sup> Group D firms (not depicted here) are all subsidiaries and were located in Vienna to directly access the Austrian market.

#### Figure 2: Importance of Vienna factors for founding the firm and for staying in the region

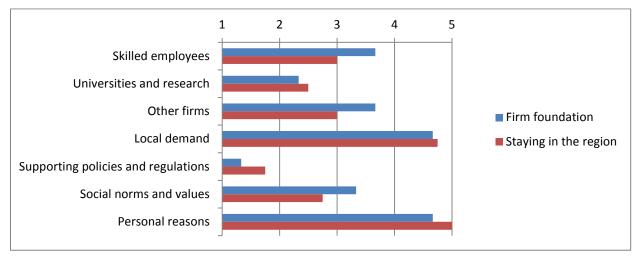




**Group B: High-tech invasive prosthetics, mechanical and robotic devices** (n=9)







Over time, universities and research institutes became more important than previously, for staying in the region. For Group C (low technology) firms, personal reasons and local demand were highly important, and more so than for all other firms (rated 4 or 5). Group C contains firms that are relatively older, and the high importance of personal reasons and local demand indicated that these sets of factors are indeed key in embedding these firms in Vienna. The next chapter presents the analysis of the factors and processes that underpin the developmental changes of the firms.

#### 4. Factors for growth and development of the firms and the cluster

Which factors did companies regard as most important for driving firm- and cluster development? And how did these factors change in the past 5 years? Section 4 investigates such factors and processes that underpin the development of the medical devices firms in Vienna from a multi-scale perspective and for two points in time. In 4.1 we investigate the perceived importance of economic and institutional factors (such as qualifications and skills, demand, and financial capital, regulation, and universities and research institutes) in the Vienna region, in Austria and at the international scale across the four groups of firms. In 4.2, we will focus on factors for development at the cluster level (4.2).

#### 4.1 Factors for firm development

There are some important differences between the investigated firm groups in this respect. For the technology intensive Groups A and B we find that a highly qualified labour force as well as universities and research organisations are of key importance (figures 3-4). For low-technology firms, rather the access to clients (demand) and the role of networks matter most strongly (Figure 5).

Looking more closely to the driving factors for Group A firms (high-tech non-invasive diagnostics and monitoring device: figure 3) we can see that the availability of qualified people and access to universities and research organisations matter strongly at the regional level. Also, Group A firms benefited most from local and national STI policies in form of subsidies for high-tech firms and products. As regards clients and suppliers it is the international level that is most important and of an increasing relevance. These firms, thus, rely strongly on the regional and the Austrian talent and knowledge assets for innovation and qualified production as well as on respective subsidies, but they also link up into large-scale value chains as regards suppliers and clients. Regulations at the regional levels were considered unimportant, because the regulatory framework for these companies is at the national and EU levels. The importance of international relations has been clearly increasing in the past years, and the same networks (which are more durable relations and collaborations).

Group B firms (high-tech invasive prosthetics, mechanical and robotic devices: figure 4) share the reliance on local skills and qualifications with Group A firms. Universities and research

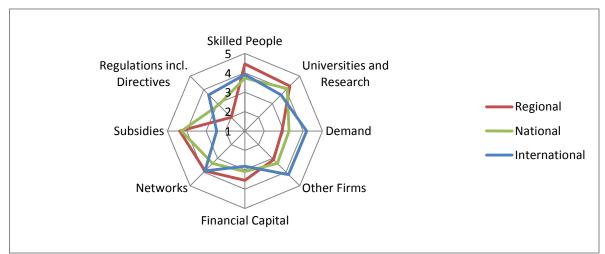
organisations from the region, however, were less relevant for them. Universities as well as regulations became relevant only recently, but on an international scale. Obviously, local universities and research organisations could not offer the kind of specialised knowledge that those companies needed for innovating. In terms of markets and clients, they are more oriented to the regional and Austrian market in comparison, and this applies also to suppliers and supporting services.

The pattern for the low-technology product firms contrasts sharply (Group C: figure 5). The two key factors for these firms are regional and Austrian clients (i.e. the health system, hospital and doctors) as well as regional and national networks for opening up these markets. Over time we see, however, an increase of the skill- and knowledge factors (universities and research), mostly on the Austrian scale. It seems that these companies are strongly oriented to the Austrian market for medical products and also relying on respective qualifications and competencies at the national level. All international factors were previously unimportant, and some increased in importance over time. In particular, international regulations and networks have become more relevant (in particular EU-level regulation). Indeed, the biggest shift for these firms over time occurred in the international institutional dimension.

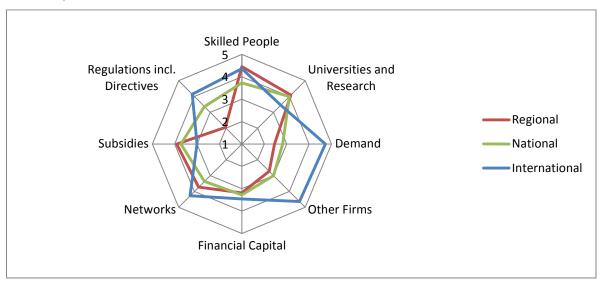
For medical devices distribution and sales firms (Group D firms: figure 6), unsurprisingly access to the Austrian health market and supporting firms matters strongly, as well as networks to open up these markets. Furthermore, the availability of qualified labour and skills on the regional and Austrian labour market is important. Previously, international factors were unimportant, but almost all factors gained in importance internationally over time. This might be due to an increasing relevance of European regulations and directives, as well as various kinds of European and global networks.

When comparing the results across groups, we find that Group A firms were previously intensively engaged at the regional level (four out of the nine factors were considered important), and internationally (where five out of nine factors were considered important). For all four groups the biggest shift occurred in the importance of international factors, and in particular regulations, over time. The Low-tech firms are strongly oriented to the Austrian market for medical products, relying also on respective competencies and skills. The importance of skills at the national level is most important for Group D firms, at least partially because of the importance of local and national knowledge for sales (intersection between technical knowledge and customer knowledge of doctor and hospital needs).

#### **Figure 3: Regional, national and international factors important for firm development Group A: High-tech non-invasive diagnostics and monitoring devices** (n=11)



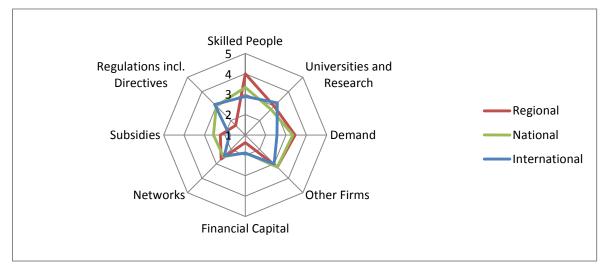
#### **Previously**<sup>6</sup>

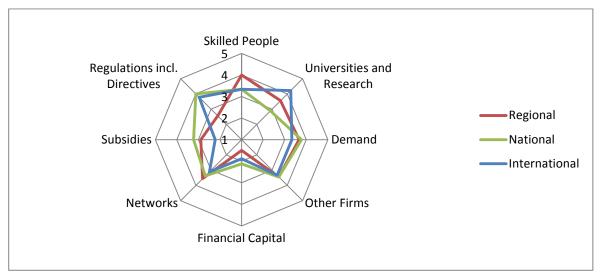


<sup>&</sup>lt;sup>6</sup> Previously denoted about three to five years ago, and presently represented the time of the interviews, which took place in 2015.

#### **Figure 4: Regional, national and international factors important for firm development: Group B: High-tech invasive prosthetics, mechanical and robotic devices** (n=9)

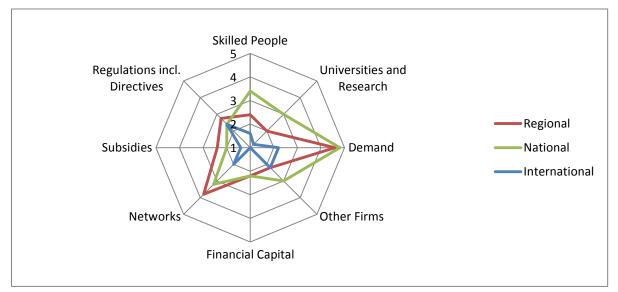
#### Previously

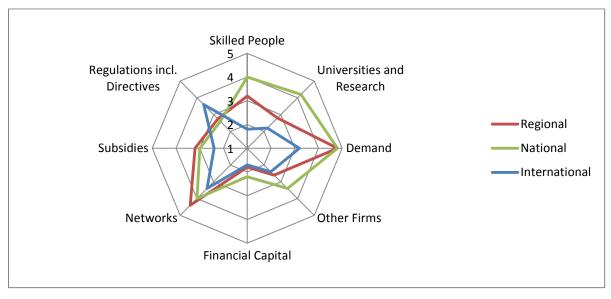




#### Figure 5: Regional, national and international factors important for firm development Group C: Low-tech products (n=5)

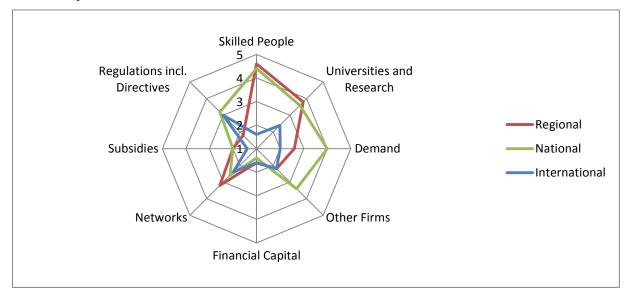
#### Previously

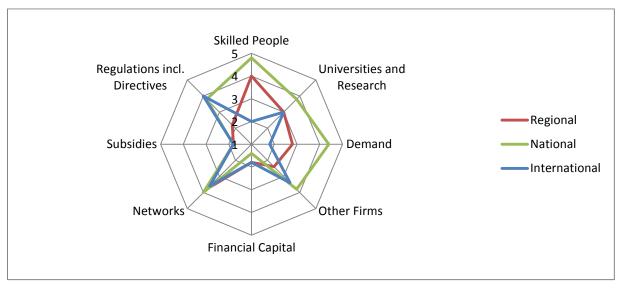




#### **Figure 6: Regional, national and international factors important for firm development Group D: Medical devices distribution and sales firms** (n=5)

#### Previously





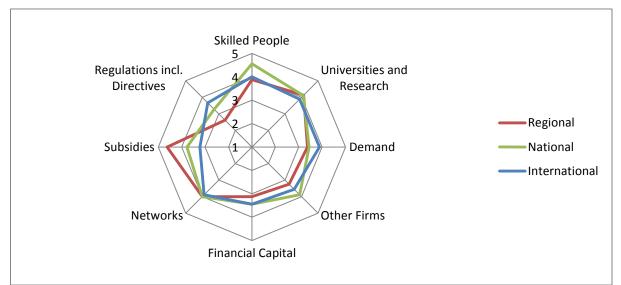
#### 4.2 Factors for cluster development

Firms also benefit from a suitable environment at the meso-level of the cluster or sector. These conditions may differ from those at the firm level, since they are more indirect to the firms and because they might show a higher stability than those of the firms. The cluster may benefit also other firms and make it easier to create new firms. However, each technology sub-area may have different perceptions of cluster factor conditions that are important for growth. The empirical findings show that the factors for cluster development differ from the company factors in several respects. The distinctive profiles of factors for the groups A-D seem to get lost, i.e. the companies see more or less all factors as relevant for cluster development, whereas there were clear distinctions at the firm level. What is similar to the firm level perspective is the increasing importance of the international scale for all firm groups. For the technology-intensive Group A and B firms this applies to all investigated factors, and for Group C and D firms in particular for regulations and networks. Group D firms emphasise the high importance of the national level (i.e. the Austrian health system) also at the cluster level.

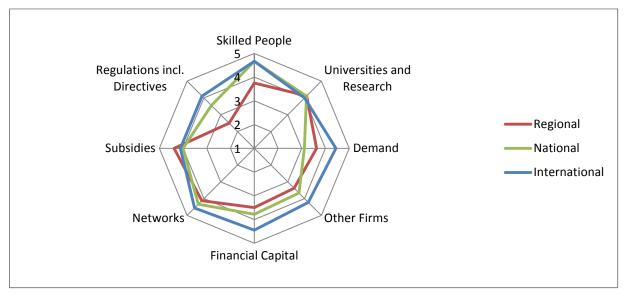
For Group A firms (high-tech non-invasive diagnostics and monitoring devices: Figure 7), subsidies, followed by networks, universities and research institutes and skilled people, were considered important regional factors for cluster development. Less important at the regional level were directives and regulations, which is due to the fact that the regulatory framework for this sector is mainly defined at the EU and national, not the regional levels). Regional factors either remained stable in their importance for the cluster, or declined somewhat (skills and subsidies). At the national scale, all factors were considered important for the cluster, especially qualifications and skills. Over time, we can observe a marked increase of importance of all factors including demand, networks, talent, and financial capital at the international scale.

The picture of cluster factors for Group B firms (high-tech invasive prosthetics, mechanical and robotic devices) differs from Group A since most of the regional and national factors were less important in comparison except the universities and research. The latter finding contrasts to the micro (firm-) results and indicates that companies see an important role for Vienna and Austrian based knowledge providers for the overall cluster but not directly for their firm. Similar to Group A firms we can observe that all international factors have gained in importance for the cluster also according to Group B firms, especially international regulations, skills, universities and research institutes, demand and supporting firms.

#### Figure 7: Regional, national and international factors important for cluster development Group A (high-tech non-invasive diagnostics and monitoring devices) (n=11)

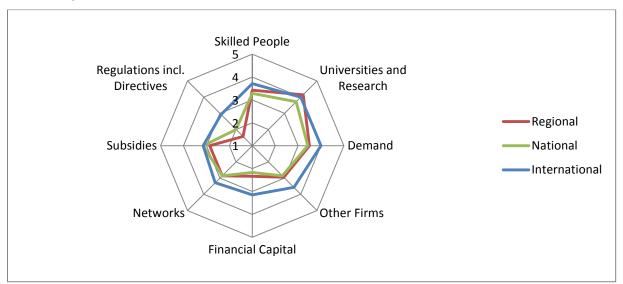


#### Previously

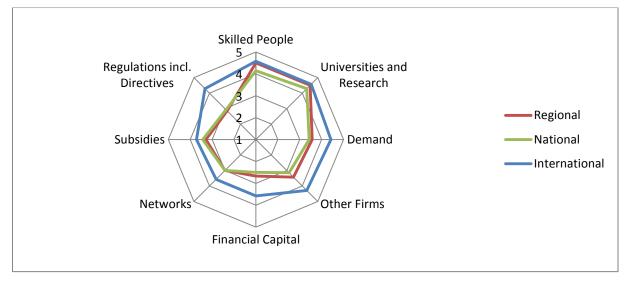


#### **Figure 8: Regional, national and international factors important for cluster development Group B (High-tech invasive prosthetics, mechanical and robotic devices)** (n=9)

#### Previously



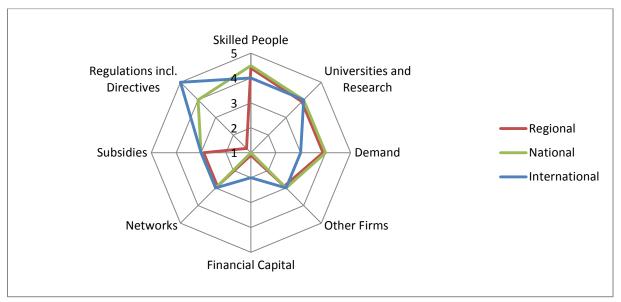
#### Presently



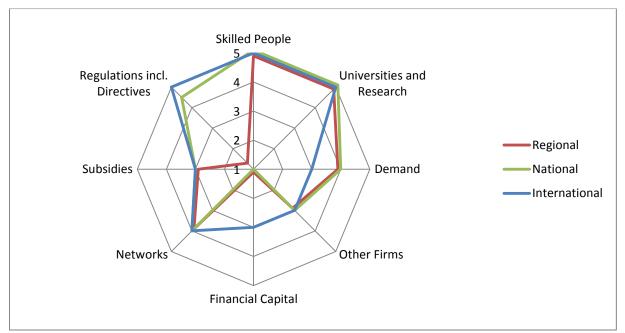
For Group C firms (low-tech products) regional and national cluster factors were important in particular for qualified labour, universities, networks and demand, while these two levels had no relevance for the sourcing of financial capital. As regards regulations, the cluster is seen to depend on national and international rules and directives. Over time, we observe an increase of cluster factors on all three scales in particular for the competence- and knowledge related factors (qualifications, universities and research). This is to some extent unexpected for the low-tech firms and contrasts to the micro (firm-based) results. It implies that companies see an important role for competencies and knowledge for the overall cluster even if these factors are regarded as less relevant for their firms.

#### Figure 9: Regional, national and international factors important for cluster development Group C (Low tech products) (n=5)

#### Previously



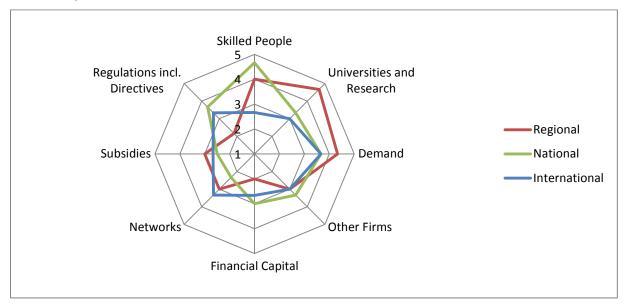
#### Presently

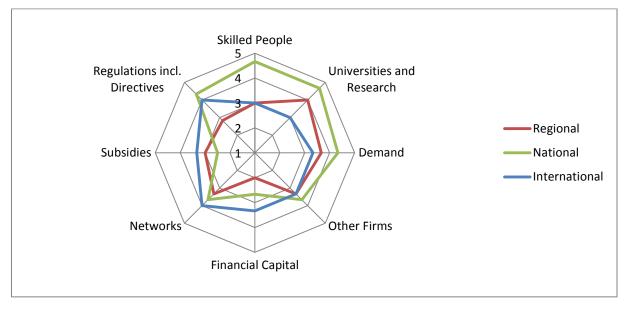


Group D (sales and distribution) firms considered regional level universities and research institutes, demand and local skills as most important for the cluster. At the national level, skills, regulations and directives were evaluated as most important for the cluster. Over time, we observe a shrinking importance of the region for most cluster factors, whereas the national level has gained importance for knowledge organisations (universities and research) and demand, in addition to the already important qualifications and regulations. The international level has gained in importance for the cluster over time for regulation, networks and financial capital.

# Figure 10: Regional, national and international factors important for cluster development: Group D (Sales and distribution firms) (n=5)

#### Previously





#### 5. Knowledge bases and innovation

This chapter focuses on knowledge bases and competencies for innovation in the firms. Guided by the literature on innovation and knowledge flows, the interview questions were directed towards knowledge processes "inside" the firm, and "outside" the firm. Although these two 'bodies of knowledge' are of course inseparable, the literature suggests that they rely upon somewhat different embodiments, mechanisms and patterns of knowledge creation, and inform different types of policies. The first part of this chapter discusses the knowledge bases internal to the firm, such as competencies embodied in people and in innovation-relevant activities. Second, the chapter presents the results on external knowledge sources, such as different types of interactions and collaborations, and their characteristics such as their duration and intensity.

#### **5.1 Internal firm competencies**

Firm competencies are made-up of skills, routines, practices and tasks that the firms engage in in order to bring forward innovations. In this research, we focused on competencies specific to the medical devices industry to gain insight into micro level dimensions of knowledge base creation. The tables below suggest that the predominant knowledge base in the medical devices cluster is represented by the synthetic category, and second by the analytic knowledge base. In comparison, the groups differ somewhat as to which knowledge types are important. For Group A and Group B firms, the combined synthetic-analytic knowledge base seems to be the most important. Synthetic knowledge is most important also for Group C firms, whereas these firms are less relying on analytic knowledge (scientific know how).

	Previously	Presently	Change
	(5 years ago)		
High-skilled employees	4.64	4.73	0.09
Scientific know-how	4.64	4.73	0.09
Technical know-how	4.64	4.82	0.18
Creativity and design	4.45	4.64	0.19
Marketing	1.64	4.55	2.91
Organising and logistics	3.91	4.27	0.36
Product and process development	4.36	4.55	0.19
Manufacturing know-how	3.45	3.73	0.28

 Table 2: Firm competencies (average importance on 1-5 Likert-scale)

 Group A: High-tech non-invasive diagnostics and monitoring devices (n=11)

Group A firms (high-tech non-invasive diagnostics and monitoring devices) place a very high importance on high-level skills, and scientific and technical knowledge, as well as creativity and design know how. Over time, the importance of all types of skills increased. In particular,

the importance of marketing know how increased by far to the largest degree than all other types of knowledge. This indicates an increased importance of knowledge how to penetrate the market, contact with medical practitioners, and how to market the product globally. A high-level of skills, scientific knowledge and technical Know-how remain the most valuable knowledge types for this group.

	Previously	Presently	Change
High-skilled employees	(5 years ago) 4.11	4.56	0.45
Scientific know-how	3.00	3.78	0.78
Technical know-how	4.22	4.78	0.56
Creativity and design	3.56	4.22	0.66
Marketing	2.44	4.11	1.67
Organising and logistics	3.56	4.33	0.77
Product and process development	4.11	4.44	0.33
Manufacturing know-how	3.00	3.56	0.56

 Table 3: Firm competencies (average importance on 1-5 Likert-scale)

 Group B: High-tech invasive prosthetics, mechanical and robotic devices (n=9)

Group B firms (high-tech invasive prosthetics, mechanical and robotic devices) also place a high level of importance on all types of skills, and the highest importance on technical knowhow and high-level skills. The highest importance is given to technical knowledge as well as product and process development. Creativity and design is third most important, followed by organising and logistics. This group also experienced by far the biggest increase in importance for symbolic (creativity, design and marketing) knowledge.

Table 4: Firm competencies: Group C (average importance on 1-5 Likert-scale) Low tech products (n=5)

	Previously (5 years ago)	Presently	Change
High-skilled employees	3.00	3.80	0.80
Scientific know-how	1.80	2.80	1.00
Technical know-how	3.60	3.80	0.20
Creativity and design	2.80	3.20	0.40
Marketing	3.00	4.00	1.00
Organising and logistics	3.20	3.20	0.00
Product and process development	2.80	3.20	0.40
Manufacturing know-how	2.60	2.80	0.20

Group C (low-tech firms) does not place as much importance on the different types of knowledge as Group A and B. This indicates a lower technological intensity, but also a lower combinatorial knowledge intensity overall in this group of firms in Vienna. However, in relative terms, Group C firms place the highest importance on synthetic and symbolic knowledge (technical Know-how and marketing knowledge). The biggest increase in importance occurred in marketing knowledge and scientific knowledge for this group, however scientific knowledge plays a relatively small role overall. This indicates that for these low-tech firms practical knowledge such as technical and organisational Know-how is overall most relevant. It is interesting to observe that scientific Know-how has also gained importance showing a certain trend towards combining practical and scientific knowledge. Similar trends were observed in the literature for other sectors and regions as shown in the literature review.

-			
	Previously Presently		Change
	(5 years ago)		
High-skilled employees	4.80	5.00	0.20
Scientific know-how	3.60	4.60	1.00
Technical know-how	4.20	4.40	0.20
Creativity and design	2.80	3.20	0.40
Marketing	2.40	4.60	2.20
Organising and logistics	3.80	4.00	0.20
Product and process development	3.20	3.40	0.20
Manufacturing know-how	3.00	3.00	0.00

Table 5: Firm competencies (average importance on 1-5 Likert-scale) Group D: Sales and distribution firms (n=5)

Group D (sales and distribution firms), composed of trading firms, place a high importance on high skills in general. Also scientific knowledge and marketing knowledge are important for this group. When asked to elaborate on what is meant by 'high-skills', these firms responded that the types of skills that are required are business skills and technical understanding of the product that is being sold. These two types of knowledge are essential when selling to a competitive market such as the healthcare sector. Similar to all the other groups, the firms in this group also experienced the largest increase in importance of marketing knowledge.

#### 5.2 External knowledge flows: Innovation cooperation

Knowledge accumulation and innovation is supported by relationships that firms have with other organisations. The tables below present information on Groups A, B and C (Group D is excluded because innovation is less relevant for these sales and distribution firms). The results are presented as the numbers of collaborations that the firms of each group have with different types of innovation partners (suppliers, clients, competitors, firms from the same sector, firms

from a different sector, universities, and public sector agencies) at different spatial scales. Some of the interviewed firms listed all of their innovation partners, others (particularly the larger firms) indicated only their most important ones. Another fact that should be taken into account is that some of the numbers result from only few responses.

# Table 6: Cooperation partners for innovation by partner type and location(Number of responding firms = 8, multiple responses possible)Group A: High-tech non-invasive diagnostics and monitoring devices

	Vienna	National	EU	Global	Total
Supplier	2	1	3	2	8
Client	2	3	5	1	11
Competitor	0	0	1	1	2
Firm from same sector	0	1	0	1	2
Firm from different sector	0	1	0	0	1
University	9	6	2	2	19
Public sector agency	2	0	0	1	3
Total	15	12	11	8	46

**Table 7: Cooperation partners for innovation by partner type and location**(Number of responding firms = 9, multiple responses possible)

Group D. Ingn-teen invasive prostitettes, incenanical and robotic devices							
	Vienna	National	EU	Global	Total		
Supplier	2	0	4	0	6		
Client	5	7	2	2	16		
Competitor	0	0	0	0	0		
Firm from same sector	0	1	1	0	2		
Firm from different sector	0	0	0	0	0		
University	6	3	4	1	14		
Public sector agency	0	0	0	0	0		
Total	13	11	11	3	38		

Group B: High-tech invasive prosthetics, mechanical and robotic devices

	Vienna	National	EU	Global	Total
Supplier	0	0	3	1	4
Client	2	7	0	0	9
Competitor	0	1	0	0	1
Firm from same sector	1	0	0	0	1
Firm from different sector	0	0	0	0	0
University	1	2	0	0	3
Public sector agency	0	0	0	0	0
Total	4	10	3	1	18

Table 8: Cooperation partners for innovation by partner type and location(Number of responding firms = 4, multiple responses possible)Group C: Low tech products

Comparing the results for these groups we can observe that the most active group in terms of innovation cooperation is Group A specialised in High-tech non-invasive diagnostics and monitoring devices. The 8 responding firms indicate overall 46 innovation cooperations, whereas the 9 Group B firms have 37 and the 4 Group C firms have 18. As regards the pattern of cooperation, Groups A and B share certain features: The main innovation partners are universities & research organisations as well as clients that are most often at the regional and national levels (i.e. from the RIS and NIS). Clients and suppliers as innovation partners are more often located at the national (e.g. Austrian hospitals) and European scale. Group A firms are most strongly relying on university partners (19 out of 46). Obviously, the research profile of Viennese and Austrian universities fits the needs of these Non-invasive diagnostics and monitoring devices firms quite well. Group B firms (High tech invasive prosthetics, mechanical and robotic devices) have clients from the region and Austria as predominant partner type for innovation. It seems that this type of firms relies more on knowledge from the users (hospitals and doctors) for improving the products and services or for developing new ones. As to be expected, for Group C firms (Low technology products) universities are less relevant in comparison (only 3 out of 18 cooperations). These firms rely even more on clients and users from the Austrian health system as innovation partners. Less relevant as innovation partners for the medical devices firms are other firms from the sector and beyond including competitors, as well as public sector agencies that are active in various kinds of support. Regarding the spatial orientation, it is obvious that the region and the country are the predominant levels of innovation interactions, whereas the global level is less relevant in general. The regional- and country focus in innovation relationships is stronger for this sector than e.g. for ICT, biotech or automotives (see Tödtling et al. 2006, Trippl et al. 2009). This finding can be explained by the important role of local research hospitals and medical universities as well users for knowledge generation and innovation in this sector (see the literature review in section 2).

## Duration of collaborations

Group A firms had the longest during cooperations with suppliers in Vienna and in the EU. This fact might be explained by the ways in which products in this group of firms are produced, and that inputs from suppliers often have to be changed and adjusted to fit the client requirements. Furthermore, it is not surprising that in this sector which is highly dependent upon knowledge produced in the process of application, clients are the second group in which cooperation last relatively long (between 2 and 6.25 years on average). Also for this type of cooperation partner, the region is more important than for any other, followed by the national level. The third longest cooperation is with universities, of which collaborations with Viennese universities last the longest, followed by other universities at the national level.

Group B firms have longer during cooperations with suppliers, clients and universities, than with other organisations. The longest cooperation in this group, different from Group A, is that with local and national universities. Second longest are collaborations with EU suppliers, followed by those with regional and national clients. The long duration of collaborations with universities such as medical universities and teaching hospitals, are necessary because it takes a long time to test the products. Group C firms have the longest cooperation with external partners overall, and especially with local and national clients, and with EU suppliers. This group has a higher proportion of older firms, which partially explains the long cooperation times. Cooperation with universities is third longest, with local universities and national clients, and with EU suppliers. This group has a higher proportion of older firms, which partially explains the long cooperation times. Cooperation with universities is third longest, with local universities and national universities and national universities and national universities and national universities being the main cooperation partners.

## Intensity of collaborations

Group A firms have the highest level of intensity of collaborations with suppliers, clients and universities at all levels. As such, the intensity of collaborations mirror quite closely their duration, which is to be expected. The highest numbers of responses are for clients and universities. For these types of partners, the most important functions involved are use and application. Universities are often consulted because they have access to hospitals where the products can be tested (not because of the scientific knowledge base, for pharma-biotech).

Group B has the highest intensity of collaboration with clients at regional, national and EU levels. The intensity of innovation interactions with suppliers at the EU level is slightly higher than for Group A firms, indicating a higher EU focus of Group B firms in this regard. Group B firms also have a high intensity of innovation cooperation with EU universities, and second with Austrian universities. The high degree of specialisation in this group is an important driver for building intensive collaborations with such knowledge organisations beyond the region. Group C firms also have relatively intense collaborations with suppliers, clients, and universities, although the number of such collaborations is lower than for Group A and B firms. As was already stated, Group C firms are older, and this is also true for their innovation collaborations. The combination of these features signals a certain danger for functional and cognitive "lock-in" (Grabher 1993, Hassink and Shin 2005), since these firms are engaged intensively with the same partners for a long time.

Our findings on knowledge bases and innovation show that firms in all four groups are all quite similar in their dependency on high-level skills and in particular technical skills. The main differences between the groups are the higher reliance of Group A firms on scientific knowledge internal to the firm, and the lower high-skilled and combinatorial knowledge intensity of Group C firms. For all firms, having in-house marketing knowledge has increased in importance over time, both for accessing the local, and increasingly the global market. Regarding external knowledge interactions of firms we observe that the most important actors for knowledge sourcing and innovation collaboration for all groups of firms are universities and research institutes, an important mechanism for the creation of the synthetic-analytic knowledge base. However, there are some differences between the groups of firms, in the type of network partner and the duration and intensity of these collaborations: Group A firms cooperate most with actors in Vienna, specifically universities and research institutes than with any other type of organisation. Second most important are clients, and then suppliers, located in Austria and internationally. Group B creates more specialised products, so national clients play a bigger role than local clients. Similarly, for Group C firms clients at the regional and national levels are most important, whereas they are less dependent on the science base than the two other groups.

# 6. Policies and regulations

This chapter deals with policies and regulations at regional, national and European scales relevant for the medical devices sector in Vienna. Some of these policies seem to have a more direct impact. Others take effect more indirectly depending on the spatial scale on which they are implemented. Furthermore, the role of policies varies between groups of firms within the cluster. These groups differ with regard to the technologies used as well as with regard to their knowledge bases and –flows. Typically, cluster firms rely upon knowledge networks and - flows on multiple spatial scales (Strambach and Klement, 2012). This makes them also dependent on policy settings on these different levels. In the following we examine med-tech relevant policies and regulations on regional, national and European levels. Then we investigate the role of policies for the development of the different firm groups in the medical device cluster in Vienna.

#### 6.1 Policy frameworks and regulations at different territorial levels

Policies and regulations relevant for the medical devices sector exist on several geographical levels that are often inter-related. Thus, a multitude of policy activities and institutions has developed that support but also limit sectoral and cluster development. At higher spatial scale, the more general regulatory framework is laid down. At lower levels, policy activities tend be more specific and targeted to promote sector growth, performance and innovation within regions and clusters. The complexity of policy settings becomes apparent in the formulation and implementation of such policy activities. There is an unclear division of responsibilities between member states and European legislation, and the various participants in the policy

formulation process often have conflicting interests (Kent et al., 2006). Which policy settings and regulations relevant for the medical device cluster in Vienna can we identify at different spatial scales?

# European level

Regulations and directives at the European level matter considerably for the medical devices sector. Medical device regulations share a number of characteristics with other knowledgebased sectors. They evolved over time, are multi-faceted, intersect with other sectors, and are not expressed in one single EU directive (Altenstetter, 2003). They provide a uniform definition for medical devices within the European Union, and aim at a higher transparency and a better coordination and communication of market surveillance activities (Schreyoegg et al., 2009). The EU regulation on medical devices is based on the general policy on the single market and three specific medical devices directives: The directive on medical devices (MDD, 93/42/42/EEC) aims at harmonizing laws that are related to medical devices on the European level. The directive on active implantable medical devices (AIMD, 90/385/EEC) regulates the market readiness and service parameters for AIMDs. The in vitro diagnostic devices directive (IVDD, 98/79/EC) regulates the performance, safety and quality of in vitro diagnostic devices in the European Union (Altenstetter, 2003).

The uniform regulation of medical devices at the European level brings forth both advantages and disadvantages. On the one hand, it is expected that transnational market opportunities grow in situations where such standards are not yet met (WHO, 2003). More importantly, the safety and performance of medical devices and the competitiveness of respective companies are expected to rise. On the other hand, the harmonization of standards across the European Union exposes the firms of some countries to stronger international competition. Moreover, different national interests have often slowed down the formulation and implementation of policy activities. For example, the delay of almost eight years in adopting the IVDD was largely due to diverging interests between the European Union, France, Germany and the United Kingdom (Altenstetter, 2003).

The medical devices sector is also affected by the European Union's objective to promote competitiveness and growth. In its strategy for Europe 2020 the European Union has formulated three interdependent priorities in this regard. "Intelligent growth" should promote growth within the EU based on knowledge and innovation, "sustainable growth" supports activities that use resources in a responsible way, and "integrative growth" aims at stimulating employment growth as well as social and territorial cohesion (EC, 2010). The strategy for Europe 2020 has also relevance for the medical device sector. It is suggested that knowledge and innovations should be increased by means of enhancing the quality of education, raising the research performance, stimulating knowledge transfers, adopting ICTs, and supporting marketability of innovative ideas (EC, 2010).

Some policy activities are more specific with regard to medical devices. The key initiative "Innovation Union", for example, has a strong focus on health- and demographic related

challenges. The initiative seeks to stimulate private R&D investments in this area by reforming patent regulation, facilitating access to venture capital and providing unrestricted access to demand-side policies such as public procurement (EC, 2010). Policy instruments that have been already established in the EU should be reformulated in order to support those aims and stakeholders (research organisations, SMEs, etc.) that were neglected before (EC, 2010).

## National level

National governments also have considerable power in directing the medical device sector. Whereas the EU regulations and directives directly or indirectly related to medical devices sector provide the general regulatory frame, it is the national institutions that translate these directives into national law and regulations. This may cause differing routes and interpretations of European directives. Three distinct kinds of organisations are responsible for implementation of regulations at the national level. First, state-based competent authorities are responsible for their oversight, enforcement and compliance. Second, there are notified bodies that overlook certification processes and conduct formal audits of medical devices. Third, manufacturers are obliged to inform the competent authorities of any incidents that arise from malfunctioning of any medical device (Altenstetter, 2003).

In Austria, the three European directives on medical devices are implemented in the Medical Products Law (MPG) and the Medical Devices Marketing Regulation (MPBV) in which the use of medical devices in Austrian health-care organisations is settled. Moreover, medical device companies that are located in Austria have to register new products at the Austrian Federal Institute for Health before the market launch. An example put forward by the Austrian Life Sciences study 2012 conducted by AWS (2011) is the e-health initiative of the European Union that resulted in the conception of the Austrian Electronic Healthcare Record project (ELGA). On basis of this project, each patient in Austria will have the opportunity to review personal medical data and provide it to the attending doctors. Policy actors not only expect an increase of transparency and more efficient therapy concepts but also a more cost-efficient healthcare system (AWS, 2011).

National policies have the advantage to take account of country-specific conditions that might be hard to grasp on international or European levels. National policies apart from regulations and standards tend to be more systemically organised in order to take account of different interests and needs of stakeholders directly or indirectly affected by policy decisions (WHO, 2003). These policy instruments often support networking, provide a learning platform or help firms to get returns on their investments (Smits and Kuhlmann, 2004). In contrast to regulations and standards, they often do not require a lengthy legal process of policy formulation, implementation or amendment (WHO, 2003).

The use of policy instruments in Austria is influenced by estimations of future growth potentials. Areas of medical devices that are expected to grow are mainly linked to demographic changes and the aging of society. Consequently, AWS (2011) expects an

increase in demand for orthopaedic devices, dental implants or cardiological products, ophthalmology, diagnostic systems as well as rehab equipment. The development of the medical devices sector also depends on funding and financial support. Public funding has an important role in financing medical activities in Austria and is decisive for their growth and innovation performance. With about 13% of total funding, public authorities are the second most important capital provider. Nevertheless, they range far behind traditional banking credits that amount to almost 70% of risk capital. Public financial support relevant for the medical device sector is organised by the Austrian federal promotional bank, or the Austria Wirtschaftsservice GmbH (AWS). It assists companies to implement innovative projects by granting loans, awarding subsidies or issuing guarantees at favourable interest rates. In addition, it provides support in the form of specific information, advisory- and other services to prospective, established and expanding companies (AWS, 2015). Other important funding organisations are the Austrian Research Promotion Agency (FFG) that offers a range of services to Austrian companies in the field of applied research and development and the Austrian Science Fund (FWF) which funds basic academic research in Austria (LISA Vienna, 2015).

The "Austria Wirtschaftsservice GmbH" has established a support program for start-ups in the life science sector. Life Science Austria (LISA) serves the whole spectrum from the business plan to financial and managerial support (LISA Vienna, 2015). Moreover, it represents the medical device sector internationally and assists respective companies to move abroad. It closely collaborates with regional cluster initiatives such as ECOPLUS (Lower Austria), the Health cluster (Upper Austria), LISA Vienna Region (Vienna), Human Technology Styria (Styria) and the Standortagentur Tyrol (Tyrol) which aim at enhancing regional network structures.

## Regional level

Life sciences and medical devices are central pillars of Vienna's science, technology and innovation (STI) policy (Stadt Wien, 2004; ZIT, 2013; www.wiendenktzukunft.at, www.wienwin.at). More than a third of R&D funding is provided by the public sector of which only ten per cent come from the City of Vienna. A major share is financed by the national government because most of the public research organisations and universities in Vienna remain under national responsibility (wiendenktzukunft.at). In 2014 the life science sector in Vienna was able to attract 97 million euros from national and regional funding agencies (LISA Vienna, 2015).

Despite their limited access to financial resources policy actors at the regional level have become more actively involved in supporting firm- and industry development. Since the early 1990s several policy initiatives have led to the foundation of new public institutions such as the ZIT – Technology Agency of the City of Vienna, the Vienna Science and Technolgy Fund (WWTF) or DEPARTURE – the Creative Agency of the City of Vienna. One of the main objectives was to enhance Vienna's economic infrastructure in order to attract external knowledge and capital to the region. Therefore, these institutions have a strong focus on flexible funding programmes and projects.

A particularly strong focus is on the support of SMEs that tends to be less considered by policies on the national and European level. This includes measures for a better access to applied research funding and other R&D activities. Also, there have been attempts to promote specific technologies in the Vienna region. Cluster initiatives such as LISA Vienna or the Automotive Cluster Vienna Region (ACVR) have been established in order to attract foreign direct investments to the region. The Vienna Business Agency, the Vienna Science and Technology Fund (WWTF) and the INiTS business incubator are among the most important policy institutions at the regional level. The first is particularly important for national and international companies to get a variety of business and development support including funding, consulting and innovation support (viennabusinessagency.at). The Vienna Science and Technology Fund (WWTF) also has an important role for medical devices because it attracts promising young researchers from abroad and, thereby, enhances the locational attraction for foreign direct investments in Vienna. The INiTS business incubator adds to the support programs of the Vienna Business Agency and the WWTF. It helps entrepreneurs to turn their ideas into a successful business. INiTS provides managerial advice, access to venture capital and to international business network.

# 6.2 Relevance of policies for firm development

As we have demonstrated, medical device firms are affected by policies at these different levels. While the ones at the European level are usually of a more general nature, policies at lower spatial scales become more concrete and policy actors more actively involved in the market and the industry. The findings from our company interviews show that policies in general matter, but they matter differently for the types of firms in the cluster. In our interviews firms were asked about the role of policy for their foundation as well as their further development. Overall, they gave the impression that policies are relevant and that the importance of policies rises as firms develop. While only 40% of the firms interviewed consider policies to be directly or indirectly relevant for their foundation, there is a tendency for policies to become more important over time (table 9). However, this is not true for non-invasive firms (Group A) that consider policies to be more relevant in the founding stage, whereas invasive and low-tech firms see a stronger role of public activities in later stages.

	Non-invasive (n=11)	Invasive (n=9)	Low-tech (n=5)	Trading (n=5)	Overall (n=30)
Policy relevant for firm foundation	72.8%	22.2%	20%	20%	40%
Policy relevant for firm development	54.5%	55.6%	60%	20%	50%

Table 9: The relevance of policies in general by firm group

Table 10 below features policy activities that medical device firms consider important for their development in greater detail. Regulations and standards as well as subsidies and public funding are regarded as most important overall.

	Non-invasive (n=11)	Invasive (n=9)	Low-tech	Trading (n=5)	Overall (n=30)
Awards, enhancing visibility	9.1%	0%	0%	0%	3.3%
Subsidies and Funding	72.7%	33.3%	20%	0%	40%
Cluster organisation & networks	9.1%	0%	40%	0%	10%
Regulations and standards	36.4%	55.6%	40%	40%	43.3%
Public procurement, public clients, business partner	9.1%	22.2%	20%	0%	13.3%
Internationalisation, business facilitator	18.2%	0%	0%	0%	6.7%

 Table 10: The relevance of specific policy areas by firm group

However, the results for the firm groups differ substantially. Non-invasive firms, for example, rely heavily on subsidies and public funding and indicate a greater variety of policy activities to have a role for their development. Particular reasons might be the strong R&D and capital intensity for creating non-invasive devices, and a highly competitive market. By contrast, invasive and low-tech firms consider a particular strong role for regulations and standards and a relatively high relevance of public procurement and public firms as business partners. This might be due to the fact, that invasive firms depend strongly on the regulatory setting and the demand of the public sector (hospitals). Low-tech companies, moreover, regard cluster organisations to be highly important for their development, whereas other firm groups rely less on cluster organisations, since they see a risk in revealing business secrets to their country-specific and need to be taken into account for selling their products in Austria. Companies were also asked to what extent policies were changing over time in their nature or in their importance.

Table 11: Change of policy relevance by firm group

	Non-invasive (n=10)	Invasive (n=9)	Low-tech (n=4)	Trading (n=4)	Overall (n=27)
Getting more important	20%	33.3%	25%	25%	25.9%
Getting less important	10%	0%	0%	0%	3.7%
No changes	30%	33.3%	50%	75%	40.7%
Getting stricter, tighter	20%	33.3%	25%	0%	22.2%
Shifting to higher levels	20%	0%	0%	0%	7.4%

Overall, there seems to be certain stability in the policy setting since 41% of the interviewed firms reported no changes. There was more stability in the policy landscape in particular for the trading firms (75%) and the low-tech firms (50%). For the technology intensive Groups A and B there is more change in the policy setting. This is particularly true for the invasive Group B where 33% saw an increasing importance of policies and further 33% reported that regulations have become stricter. Obviously, the high complexity of some of their products makes technological and medical requirements and regulations more important for them.

The medical devices firms were also asked on which spatial scales policies had an influence on firm- and cluster development. Multiple selections were possible:

	Non-invasive (n=11)	Invasive (n=7)	Low-tech (n=2)	Trading (n=4)	Overall (n=24)
No level	0%	0%	0%	25%	4.2%
Regional	45.5%	57.1%	0%	0%	37.5%
National	72.7%	85.7%	50%	50%	70.8%
International	72.7%	42.9%	50%	50%	58.3%

Table 12: The relevance of policies on different spatial scales by firm group

Generally, policies and regulations at the national and international levels were considered to be most important. And this is more so the case for the technology intensive Group A (noninvasive) and B firms (invasive). At the national level we find important regulations for the health sector as well as support structures for the firms such as support for R&D. The international scale refers mainly to the European were also important regulations and directives exist (see above). Interestingly the regional level was only relevant for these two groups of technology intensive firms, and had no relevance for the low-tech and the trading firms. Their reliance on regional policies might also be due to the focus of regional support structures on high-tech products and services. But obviously, policies and regulations have a higher relevance for the technology intensive Group A and B firms at all levels including the regional one.

# 7 Conclusions

Based on the research presented here, which conclusions can we draw for the field and for policies to support the Vienna medical devices sector? We first present a summary of main findings and indicate strengths, weaknesses and challenges faced by the firms in this cluster. The second part draws policy conclusions based on the research findings.

## Main findings

The medical devices cluster in Vienna has a heterogeneous firm population by age, size and technology. We identified firms focusing on high-technology medical devices (Group A: noninvasive and Group B: invasive), firms active in low-tech medical devices (Group C), and sales and distribution firms (Group D). Groups A, B and C together represent over 90% of all R&D intensive medical devices firms in Vienna. The firms are highly specialised, innovate regularly and employ highly skilled people. Group A firms are most innovative, sell more of their products or services abroad than the other firms, and are also more internationally networked. Group B have one of the most important global players in prosthetics innovation, and other highly specialised firms with steady market growth, and connections to national, European and global actors. Together these two groups, because of their combinatorial capabilities, carry the highest potential of world-class innovations in the cluster and require specific supporting infrastructures in order to prosper and grow. Group C firms are active in low-tech medical devices, tend to be older, and rely upon established local and national sales networks. These firms tend to face price-based competition from international firms. Group D firms are sales- and distribution firms that are mainly subsidiaries of global firms, and are specialised in selling to the Austrian and nearby Eastern European markets. Success in Group D is most reliant upon deep understanding the local and national markets and requirements.

The main strengths of the sector are incremental innovation, the reliance on local and national networks, and understanding of the domestic market. Although some Groups A and B also have radical innovations, most of them and in particular Group C firms mainly perform incremental innovation and improvements of existing products. In this process they interact with their main clients (hospitals) and with local universities and research organisations. We understand this incremental and user-led innovation not as a weakness, but rather as a strength and it is globally the norm for this sector (see literature review in section 2). The firms spend also many efforts in understanding and meeting national and international regulatory environments for their products, which differ greatly across countries. A further strength of the sector is the growing local and national demand driven by an aging society and public efforts to meet this demand. The high value that Austria places on excellent healthcare is an incentive for firms to create innovations that meet high standards similarly as in other highly countries. This increases also their international cost-efficiency developed competitiveness. For this purpose, the firms also engage in long-standing collaborations with local and national health care organisations and universities, benefitting both types of organisations.

Although the Vienna medical devices sector has such strengths, there are also weaknesses and challenges that need to be addressed. The firms engage in R&D, but their international performance is weaker compared to the growth that is enjoyed by other technology-based industries in Austria. International networks do exist, but these are sporadic and relatively recent, and the firms do not seem to have strategies to improve this situation. Furthermore, the proximity of the Austrian market to the German and Swiss markets seems to be both a blessing and a curse: a blessing when the firms are doing well, and a disadvantage because of the increase in competition from especially German firms on the domestic market which is likely to increase in future. A final and related challenge is international regulation and marketing (in medical devices these tend to go hand in hand) which is changing rapidly and because of the growth of different players (for example, the EU level in addition to the national levels) is also becoming more complex to oversee. In light of these findings and observations, the City of Vienna needs to focus on supporting the strengths, minimising the weaknesses and address the challenges facing the local medical devices sector.

#### Policy conclusions

We can draw the following policy conclusions based on our results. First, innovation policies for the sector, such as those being currently endorsed in Vienna and in Austria, need to acknowledge the importance of both radical and incremental innovation (and not, as currently, radical innovation only). For example, currently Group A firms (which tend to produce such radical product innovations) have been the focus of Vienna's innovation policy, and this could be maintained or increased, but just as importantly, the range of government funded R&D should be broadened to include technology areas important for Groups B and C respectively.

Second, the knowledge of the domestic health sector is clearly an advantage and a strength of these firms, however, this knowledge should not just include which customers to sell to (as it tends to do) but which actors in the hospital and medical landscape could be useful partners in the innovation process (such as in product testing). The testing stage is highly reliant upon doctors' usage of individual items in their practice, and feedback to the firms that arises from this usage benefits from face-to-face interactions with the firm. Policies that are specifically designed to support firms in the development and testing phases of their product innovation could greatly shorten this phase and increase the success of the product in the market. Furthermore, a good reputation of a product in a market with high standards such as Austria is an advantage in international marketing of such products.

Third, although some firms manage to navigate international regulatory requirements well, this type of knowledge needs to be improved and acquired by all firms in this sector. Regulation can be a major barrier to market entry and it is therefore essential that this type of knowledge is acknowledged as important for the sector. For example, policy measures could be designed for local inter-firm knowledge transfer, and for the inflow of international expertise. Furthermore, this knowledge needs to be acquired as early on as possible in the

product development stage to avoid additional future costs. The Austrian government could support the increase of firm Know-how on the large medical devices markets such as USA and Germany, as well as growing markets such as China and India.

Fourth, the Vienna medical sector is locally and nationally much better networked than internationally. This situation needs to be improved by specific measures that build firm competencies for internationalisation (such as easier recruitment of international high-skilled labour, and alliances with international firms such as joint ventures and R&D collaborations). Fifth and finally, the highly skilled labour pool needs to be invested in nationally, targeting specific technology areas that are required for medical devices innovation such as ICTs, mechatronics, and electrical engineering of micro products.

## References

- Altenstetter, C. (2003) 'EU and member state medical devices regulation', *International Journal of Technology Assessment in Health Care*, 19, 1, pp. 228-248.
- Archibugi, D. and Lundvall, B.-A. (2001) *The Globalizing Learning Economy*, Oxford: Oxford University Press.
- Asheim, B., Moodysson, J. and Tödtling, F. (2011) 'Constructing Regional Advantage: Towards State-of-the-Art Regional Innovation System Policies in Europe?' *European Planning Studies*, 19/7, pp. 1133-1139.
- Asheim, B. and Gertler, M. S. (2005) The Geography of Innovation: Regional Innovation Systems, in Fagerberg, J., Mowery, D. C., and Nelson, R. R. (Eds.) *The Oxford Handbook of Innovation*, Oxford University Press.
- Asheim, B., Boschma, R., Cooke, P. (2011) 'Constructing Regional Advantage: Platform Policies Based on Related Variety and Differentiated Knowledge Bases', *Regional Studies*, 45/7, pp. 893-904.
- Asheim, B. (2007) 'Differentiated knowledge bases and varieties of regional innovation systems', *Innovation*, 20/3, pp. 223-241.
- Asheim, B., Coenen, L. and Vang, J. (2007) 'Face-to-face, buzz and knowledge bases: sociospatial implications for learning, innovation and innovation policy', *Environment and Planning C: Government and Policy*, 25, pp. 655-670.
- AWS (2011) 'Austrian Life Sciences study 2012', Austria Wirtschaftsservice GmbH (aws), Wien.
- Bathelt, H., Malmberg, A. and Maskell, P. (2004) Clusters and knowledge: local buzz, global pipelines and the process of knowledge creation, *Progress in Human Geography*, 28, pp. 31-56.

- BMWF, BMVIT, JR, AIT, ZEW and Statistics Austria (2013) Austrian Research and Technology Report 2013, Report under Section 8(1) of the Research Organisation Act, on federally subsidised research, technology and innovation in Austria, Federal Ministry of Science and Research (BMWF), Federal Ministry for Transport, Innovation and Technology (BMVIT), Federal Ministry of Economy, Family and Youth (BMWF), Vienna.
- Boschma, R. (2005) Proximity and innovation A critical assessment, *Regional Studies*, 39, pp. 61-74.
- Chatterji, A. K. (2009) Spawned with a silver spoon? Entrepreneurial performance and innovation in the medical device industry, *Strategic Management Journal*, 30/2, pp. 185–206, John Wiley & Sons, Ltd.
- Coenen, L., Moodysson, J., Ryan, C. D., Asheim, B., and Phillips, P. (2006) 'Comparing a Pharmaceutical and an Agro-food Bioregion: On the Importance of Knowledge Bases for Socio-spatial Patterns of Innovation', *Industry and Innovation*, 13/4, pp. 393-414.
- Cooke, P., Boekholt, P., Tödtling, F. (2000) *The Governance of Innovation in Europe*, Pinter, London.
- Cooke, P. (2002) Regional Innovations Systems: General Findings and Some New Evidence from Biotechnology Clusters, *The Journal of Technology Transfer*, 27/1, pp. 133-145.
- Cooke, P. (2003) Biotechnology clusters, 'Big Pharma' and the knowledge-driven economy, International Journal of Technology Management, 25/1-2, pp. 65-80.
- Cooke, P., Heidenreich, M., Braczyk, H.-J. (Eds.) (2004) *Regional innovation systems*, 2nd Edition. Routledge, London and New York.
- De Vet, J.M. and A. Scott (1991) The Southern Californian Medical Device Industry: Innovation, New Firm Formation, and Location, *Research Policy* 21(2), pp.145-161.
- EC (2010) 'Eine Strategie für intelligentes, nachhaltiges und integratives Wachstum', Mitteilung der Kommission, Europa 2020, Brussels.
- Edquist, C. (1997) Systems of Innovation Approaches Their Emergence and Characteristics, in: Edquist, C. (Ed.), *Systems of Innovation*, Pinter, London, pp. 1-35.
- Feldman, M.P., J. Francis, and J. Bercovitz (2005) Creating a Cluster While Building a Firm: Entrepreneurs and the Formation of Industrial Clusters, *Regional Studies*, 39, pp. 129-141.
- Garnsey, E and Heffernan, P. (2005) High Technology Clustering through spin-out and attraction: the Cambridge case, *Regional Studies* 39, pp. 1127-1144.
- Gelijns, A. C., and Rosenberg, N. (1999) Diagnostic Devices: An Analysis of Comparative Advantages, in: Mowery D. C. and Nelson R. R., (Eds) Sources of Industrial Leadership: Studies of Seven Industries. Cambridge: Cambridge University Press, pp. 312-358.

- Gerlter, M. and Wolfe, D. (2006) 'Spaces of knowledge flows: Clusters in a global context, in Asheim, B., Cooke, P. and Martin, R., (Eds.) *Clusters and Regional Development: Critical Reflections and Explorations*, pp. 218-235, New York: Routledge.
- Grabher, G. (1993) The weakness of strong ties: the lock-in of regional development in the Ruhr-area, in: Grabher, G. (Ed.), *The embedded firm: on the socioeconomics of industrial networks*, T.J. Press, London, pp. 255-278.
- Hassink, R., Shin, D.-O. (2005) The restructuring of old industrial areas in Europe and Asia: An introduction, *Environment and Planning A*, 37/4, pp. 571-580.
- Hochgatterer, A., Drobics, M., Kropf, J., Bammer, M., Kastner, P., and Fritz, M. (2014) 'Ambient Assisted Living – Intelligente Assistenz durch M2M-Technologies', *Elektrotechnik und Informationstechnik*, 131/1, pp. 26-32.
- hUallachain, B.O. and Lee, D.S. (2011)Technological Specialization and Variety in Urban Invention. *Regional Studies*, 45/1, pp. 67-88.
- Jennett, B. (1986) High Technology Medicine: Benefits and Burdens, Oxford University Press.
- Keeble, D. and Wilkinson, F. (Eds.) (2000) *High-Technology Clusters, Networking and Collective Learning in Europe*, Ashgate, Aldershot.
- LISA Vienna (2014) Vienna Life Science Report 2013/14, Lisa Vienna Life Sciences Austria.
- LISA Vienna (2015) Vienna Life Science Report 2014/15, Lisa Vienna Life Sciences Austria.
- Lowe, N. and M. Gertler (2009) Building on Diversity: Institutional Foundations of Hybrid Strategies in Toronto's Life Sciences, *Regional Studies*, 43/4.
- Lundvall, B.-Å. (2007) National Innovation Systems—Analytical Concept and Development Tool, *Industry and Innovation*, 14:95-119.
- Manniche, J. (2012) 'Combinatorial Knowledge Dynamics: On the Usefulness of the Differentiated Knowledge Bases Model', *European Planning Studies*, 20/11, pp. 1823-1841
- Martin, R. and Moodysson, J. (2011) Innovation in Symbolic Industries: The Geography and Organization of Knowledge Sourcing, *European Planning Studies*, 19/7, pp. 1183-1203.
- Martin, R. and Moodysson, J. (2013) Comparing knowledge bases: on the geography and organization of knowledge sourcing in the regional innovation system of Scania, Sweden, *European Urban and Regional Studies* 20, pp. 170-87.
- Martin, R. and Moodyson, J. (2011) 'Innovation in Symbolic Industries: The Geography and Organization of Knowledge Sourcing', *European Planning Studies*, 19/7, pp. 1183-1203.
- Martin, R., and Sunley, P. (2007) 'Complexity thinking and evolutionary economic geography', *Journal of Economic Geography*, 7, pp. 573-601.

- Menzel, M-P., Fornahl, D. (2009) Cluster life cycles dimensions and rationales of cluster evolution, *Industrial and Corporate Change*, 19/1, pp. 205-238.
- Metcalfe, J. S. and Pickstone, J. (2006) Replacing Hips and Lenses: Surgery, Industry and Innovation in Post War Britain, in A. Webster (Ed.) *New Technologies in Health Care: Challenge, Change and Innovation*, Health, Technology and Society Series. Basingstoke, Palgrave Macmillan.
- Metcalfe, J. S., James, A. and Mina, A. (2005) Emergent innovation systems and the delivery of clinical services: The case of intra-ocular lenses, *Research Policy*, 34, pp. 1283-1304.
- OECD (2008) OECD Health Data, OECD Paris.
- OECD (2014) OECD Work on Science, Technology and Industry, OECD Paris.
- Pickstone, J. (Ed.) (1992) *Medical Innovations in Historical Perspective*, Basingstoke, Palgrave Macmillan.
- Plum, O. and Hassink, R. (2011) 'On the Nature and Geography of Innovation and Interactive Learning: A Case Study of the Biotechnology Industry in the Aachen Technology Region, Germany', *European Planning Studies*, 19/7, pp. 1141-1163.
- Plum, O. and Hassink, R. (2012) 'Analysing the knowledge base configuration that drives southwest Saxony's automotive firms', *European Urban and Regional Studies*, 20/2, pp. 206-226.
- Porter, M. E. (2000) Location, Competition and Economic Development: Local Clusters in a Global Economy, *Economic Development Quarterly*, 14, 1, pp. 15-34.
- Pouder, R. and St. John, C. H. (1996) Hot Spots and Blind Spots: Geographical Clusters of Firms and Innovation, *Academy of Management Review*, 21/4, pp. 1192-1225.
- Powell, W., K. W. Kogut, J. I. Bowie and L. Smith-Doerr (2002) "The Spatial Clustering of Science and Capital: Accounting for Biotech Firm-Venture Capital Relationships." *Regional Studies* 36 (3), pp. 291–306.
- Powell, W.W. and Grodal, S. (2005) Networks of Innovators. In Fagerberg, J., Mowery, D. C. and Nelson, R. R. (Eds.) *The Oxford Handbook of Innovation*, Oxford, Oxford University Press, pp. 56-85.
- Rosenberg, N. (2009) Studies on Science and the Innovation Process: Selected Works of Nathan Rosenberg, World Scientific Pub. Co. Inc.
- Saxenian, A. (1994) 'Regional Advantage: Culture and Competition in Silicon Valley and Route 128`, Cambridge (Mass.), Harvard University Press.
- Schreyögg, J., Bäumler, M. and Busse, R. (2009) 'Balancing adoption and affordability of medical devices in Europe', *Health Policy*, 92, pp. 218-224.
- Smits, R. and Kuhlmann, S. (2004) 'The rise of systemic instruments in innovation policy', *International Journal of Foresight and Innovation Policy*, 1/1-2, pp. 4-32.

- Sotarauta, M. and Kosonen, K-J. (2011) 'Customized innovation policies and the regions: digital content services and intelligent machinery in Finland', *European Urban and Regional Studies*, 20/2, pp. 258-274.
- Stadt Wien (2004) Strategieplan Wien, Magistrat der Stadt Wien, Stadtplanung Wien.
- Strambach, S. and Dietrich, I. (2011) 'The territorial shaping of knowledge dynamics in Baden-Württemberg; Inter-organizational relations in the sectoral knowledge domain of the automotive industry', Working Papers on Innovation and Space, 1.11, University of Marburg, Marburg.
- Strambach, S., and Klement, B. (2012) 'Cumulative and Combinatorial Micro-dynamics of Knowledge: The Role of Space and Place in Knowledge Integration', *European Planning Studies*, 20/11, pp. 1843-1866
- Tödtling, F., Asheim, B. and Boschma, R. (2013) 'Knowledge sourcing, innovation and constructing advantage in regions of Europe', *European Urban and Regional Studies*, 20/2, pp. 161-169
- Tödtling, F. and M. Grillitsch (2015) Does Combinatorial Knowledge Lead to a Better Innovation Performance of Firms? *European Planning Studies*, 23/9, pp. 1741-1758.
- Tödtling, F., Lehner, P. and Kaufmann, A. (2009) Do different types of innovation rely on specific kinds of knowledge interactions? *Technovation*, 29, pp. 59-71.
- Tödtling, F., P. Lehner, and M. Trippl (2006) Innovation in knowledge intensive industries: The nature and geography of knowledge links, *European Planning Studies* 14:1035-1035.
- Tödtling, F. Lengauer, L. and Höglinger, C. (2011) 'Knowledge Sourcing and Innovation in "Thick" and "Thin" Regional Innovation Systems – Comparing ICT Firms in Two Austrian Regions', *European Planning Studies*, 19/7, pp. 1245-1276.
- Tödtling, F., Skokan, K., Höglinger, C., Rumpel, P. and Grillitsch, M. (2011) 'Innovation and knowledge sourcing of modern sectors in old industrial regions: Comparing software firms in Moravia-Silesia and Upper Austria', *European Urban and Regional Studies*, 20/2, pp. 188-205.
- Tödtling, F. and Trippl, M. (2007) 'Knowledge links in high-technology industries: Markets, networks, or milieu? The case of the Vienna biotechnology cluster', *International Journal of Entrepreneurship and Innovation Management*, 2/3/4/5, pp. 345-365.
- Tödtling, F. and Trippl, M. (2013) Innovation and Knowledge Links in Metropolitan Regions: The Case of Vienna, in Klaesson, J., Johansson, B. and Karlsson, C., (Eds.) *Metropolitan Regions: Knowledge Infrastructures and the Global Economy*, pp. 451-472.
- Trippl, M. and Tödtling, F. (2007) Developing Biotechnology Clusters in Non-high Technology Regions- The Case of Austria, *Industry and Innovation*, 14/1, pp. 47-67.
- Trippl, M., F. Tödtling, and L. Lengauer (2009) Knowledge Sourcing Beyond Buzz and Pipelines: Evidence from the Vienna Software Sector, *Economic Geography* 85:443-462.

- Trippl, M. and Tödtling, F. (2008) From the Ivory Tower to the Marketplace: Knowledge Organisations in the Development of Biotechnology Clusters, *The Journal of Regional Analysis and Policy*, 38/2, pp. 159-175.
- von Hippel, E. (1988) *The Sources of Innovation*. New York and Oxford, Oxford University Press.
- Warwick Institute for Employment Research, Economix Research and Consulting, PLS Ramboll (2004) Developing Excellence in Medical Technologies, Synthesis Report. Warwick, UK.
- Webster, A. (Ed.) (2006) New Technologies in Health Care: Challenge, Change and Innovation. Health, Technology and Society Series. Basingstoke, Palgrave Macmillan.
- WHO (World Health Organisation) (2003) 'Medical Device Regulations: Global Overview and Guiding Principles', Geneva.

www.wiendenktzukunft.at last accessed 22.04.14

www.wienwin.at last accessed 22.04.14

ZIT (2013) Innovationsaktivitäten der Stadt Wien: Ergebnisse einer Erhebung, ZIT Die Technologieagentur der Stadt Wien.

Multilevel Governance and Development Wirtschaftsuniversität Wien Institutsvorstand : ao.Univ.Prof. Dr. Andreas Novy Welthandelsplatz 1 A-1020 Wien, Austria Tel.: +43-1-31336/4777 Fax: +43-1-31336/705 E-Mail: mlgd@wu.ac.at http://www.wu.ac.at/mlgd