



Search regimes in the medical devices sector

A characterisation of the knowledge development process

Abstract

This thesis is inspired by the notion that over the last two decades the knowledge development process has been changing. The dichotomy between basic and applied research is disappearing and knowledge is increasingly recognised as a driver of economic growth and as a resource to solve societal challenges. As a result the science system is transforming and the attention of policymakers on the role of knowledge within society increases. Policymakers, however, tend to overlook the complexity of research policy, copying best practices in research policy from one field to another. These measures can be expected to fail since scientific fields exhibit distinct and localised dynamics that respond differently to government intervention.

This thesis aims to empirically validate the changes in the knowledge development process and draw implications for science policy. The medical devices sector is used as a case study. Due to aging of the population, the pressure on healthcare is increasing. The development of new medical devices is seen as an important way to increase the productivity of the healthcare professionals and thereby relieving the pressure on the system. In the Netherlands the Innovative Medical Devices Initiative (IMDI) was launched to stimulate this development. However, the nature of the research process this initiative attempts to stimulate is unexplored.

To analyse the changes in the knowledge development process this thesis builds on the search regime concept of Bonaccorsi (2004), which is “a summary description of the growth pattern of scientific knowledge and the actual carrying out of scientific research” in a field (p.2). Analysing the medical devices’ search regime will point out which of the changes in the knowledge development process described in innovation literature have an empirically recognisable counterpart and which factors should be considered when developing science policy.

This thesis uses bibliometric analysis to analyse the medical devices’ search regime and uses interviews to validate the results. This analysis points out that the knowledge development process is indeed changing. Knowledge development is becoming an ever-more collaborative process at an increasingly international scale. However, academic institutions remain a central position within these networks as institutional environments are only marginally overlapping.

In addition this thesis draws policy implications from the search regime and evaluates the IMDI. This thesis concludes that the IMDI attempts to increase multidisciplinary in the sector to overcome the European Paradox, but fails to take the fundamental role of the institutional features in the knowledge development process into account.

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January 4th, 2011

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1. Problem description

Over the last 20 years the science system has been transforming (Gibbons et al., 1994; Nowotny et al., 2001; Martin, 2003). Science does not function in isolation, but is constantly interacting with other parts of society (Rip, 1990). Knowledge is increasingly seen as a driver of economic growth and as a resource to address societal challenges (Heimeriks & Leydesdorff, 2010), which has changed the attitude of society towards science.

Since the strategic value of knowledge has increased, governments ask for more explicit science policy, thereby decreasing the autonomy of universities. At the same time the public has increased its demand for public accountability of government spending, which has increased the emphasis on the socio-economic contribution of science and has shifted the focus of knowledge development from basic research to applied research (Martin, 2010).

Several frameworks have been developed to analyse changes in the knowledge development process. The most famous account of the changing knowledge development process is the concept of 'Mode 2 knowledge production' (Hessels & van Lente, 2009). The Mode 2 concept refers to the emergence of a new knowledge development process that is socially distributed and is performed in the context of application (Gibbons et al., 1994). The Mode 2 concept is not unique; several other concepts have been developed, such as post-normal science (Functowicz & Ravetz, 1993), academic capitalism (Slaughter & Leslie, 1997), post-academic science (Ziman, 2000) and the triple helix concept (Etzkowitz & Leydesdorff, 1998). These concepts make fairly similar claims but add emphasis to different aspects of the knowledge development process (Hessels & van Lente, 2008).

While these concepts highlight interesting points, they are rather descriptive and lacking empirical evidence. Also, these concepts often neglect the diversity of science, as they treat the entire science system as a homologous unit. Heimeriks et al. (2008) and Heimeriks and Vasileiadou (2008) have shown that effects of the changing knowledge development process are visible to a different extent in different scientific fields.

Policy makers often neglect these differences between scientific fields. Copying best practices in research policy as identified by benchmarking studies is popular, but can be expected to fail due to the knowledge asymmetries between fields (Heimeriks, 2009). In order to successfully govern scientific fields has to be done through disaggregated measures that target different fields in a distinct way.

This thesis aims to determine what aspects of the changing knowledge development process can be empirically validated. In this analysis the medical devices sector is used as a case study. This sector is interesting to analyse since it aims to address societal challenges and also has a large potential for economic development (NWO, 2010a; 2010b). In addition, the provision of healthcare to an ageing population is seen as an important societal challenge of the 21st century (EC, 2008a; 2008b). The pressure on the healthcare system will increase in the near future and the development of medical devices is seen as motor to change the healthcare system (NWO, 2010b). The development of new medical devices has been characterised as R&D intensive, but despite the importance of the development of new knowledge, the nature of the knowledge development process has never been described in innovation literature.

This thesis therefore serves two goals: (1) it contributes to the development of innovation theory and (2) it develops a better understanding of the knowledge development process in the medical devices sector, which contributes to the improvement of the health of the public.

Since this thesis aims to explore a field-specific knowledge development process, it needs a conceptual framework that is able to take the heterogeneity of scientific fields into account. Therefore this thesis will follow Bonaccorsi (204; 2007; 2008) who described the changing knowledge development process in term of search regimes. Bonaccorsi (2004) describes a search regime as “a summary description of the growth pattern of scientific knowledge and the actual carrying out of scientific research” in a field (p.2). Since these search regimes are field specific this concept can be used to analyse a single scientific field.

This thesis will be guided by the following research question;

What are the characteristics of the medical devices' search regime between 1990 and 2009?

This question has a descriptive character. The object that will be described is the medical devices' search regime. In this research the term medical device refers to “any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings” (EP, 2007, p.23-24). The term medical devices sector is used in this thesis to refer to the set of organizations, both public and private, that are involved in the development of knowledge related to medical devices and/or to the development and production of medical devices.

The scope of the research has been set from 1990 to 2009. The medical devices field has a long history and it could therefore be possible to analyse the knowledge dynamics over a longer period. However, this would have prolonged the data-collection and data-analysis beyond the timeframe set for this thesis and was therefore not possible. The 20-year timeframe is believed to be a proper balance between the quality of the analysis and the quantity of the data that needs to be processed.

This thesis is structured as follows. Chapter two elaborates on the medical devices sector, while chapter three describes the added value of this thesis. Chapter four builds the theoretical framework that is used to analyse the medical devices sector, which is operationalised in chapter five. The results of the analysis are presented in chapter six, followed by a discussion of the results and implications in chapter seven. Chapter eight concludes.

2. Medical devices sector

The pressure on the Dutch healthcare system is expected to rise significantly over the next decades (ZIP, 2009; NWO, 2010a; 2010b). As a result of the baby boom after the Second World War the Dutch population composition is changing. Aging of the population has already started and will hit a maximum between 2025 and 2035 (NWO, 2010a). The effects of the aging population are enforced by an increasing life expectancy. As a result of the growing number of elderly people, the demand for healthcare will increase by 40% (NWO, 2010a). In addition, due to a decreasing birth rate the Dutch labour force will decrease by 5%, which will increase the shortage of labour in a sector that is already lacking sufficient manpower (NWO, 2010a). Finally, the costs of healthcare are increasing over time and are expected to continue to increase in the future (Statline, 2009; ZIP, 2009; NWO, 2010b).

In order to maintain the future quality, accessibility and affordability of the Dutch healthcare system, the system has to change. This transition should focus at (1) increasing the level of self-care, (2) shifting from intramural healthcare setting to extramural care and (3) increasing the efficiency of healthcare practices (NWO, 2010a). These three developments can relieve the pressure on the healthcare system by decreasing the duration of hospitalisation and reducing the number of people that require hospitalisation or healthcare. Less hospitalisation will relieve the workload of the labour force and will lower costs of the healthcare provision (NWO, 2010a). The application of new medical instruments is seen as a motor to drive the needed transition (Technopolis, 2009; ZIP, 2009; NWO, 2010b).

However, development of technology does not take place overnight, but usually take about 15 years from the start of the research to the introduction of the product in the market. Given the limited time available in which the necessary changes have to be realised, the Netherlands Organisation for Scientific Research (NWO) launched an initiative that is designed to ensure the availability of a new generation of instruments that will allow the Dutch healthcare system to meet the qualitative and quantitative demand of an aging population while at the same time controlling the costs of healthcare. This initiative is called the Innovative Medical Devices Initiative (IMDI) (NWO, 2010b).

The IMDI distinguishes three thematic subgroups in which the development of new medical devices will be stimulated: (1) home and rehabilitation care, (2) minimally invasive techniques and (3) biomedical imaging. The first is related to the need to increase patient autonomy and substitute hospitals care to primary care, while the latter two relate to the need to increase the efficiency of healthcare. The Netherlands traditionally has a strong scientific position related to these subgroups and has published many articles in the leading journals in the world. However, while European countries tend to have high quality research, as a result of excessive fragmentation in the European research and development infrastructure, the translation from research to actual products is poor (NWO, 2010b). The Netherlands is no exception in this regard (NWO, 2010b).

To overcome the fragmentation of research infrastructure the IMDI attempts to enhance the scale and focus on the research and development infrastructure in the Netherlands. IMDI aims to increase multidisciplinary and align stakeholders through the creation of Centres of Research Excellence (CoREs). In these CoREs researcher will work closely together with actors in the industry, healthcare professionals and patients. By grouping the leading institutions in the medical devices sector and providing them with a financial impulse, the acquisition power of these institutions will increase which in ten years will have doubled the available budgets for medical devices related R&D.

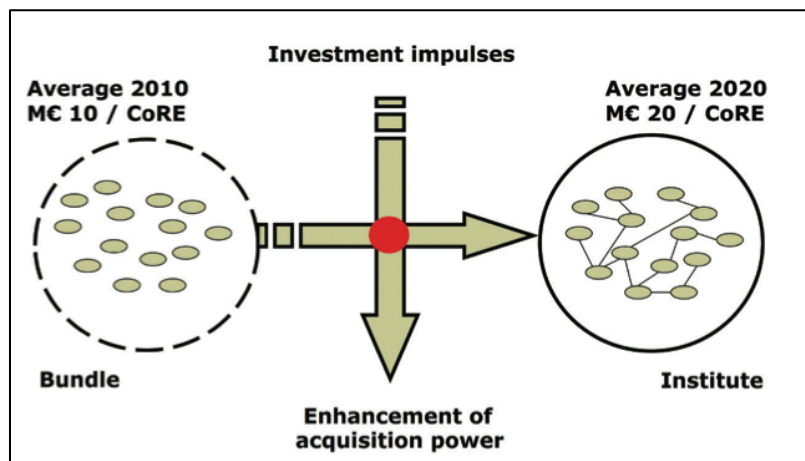


Figure 1: Funding plan of the Innovative Medical Devices Initiative (NWO, 2010b, p.24)

The medical devices sector is an interesting case to analyse. The medical devices sector is characterised by high R&D investments (OECD, 2009), which indicates that the development of new medical devices strongly relies on the development of new knowledge. New medical devices not only serve as a way to relieve the pressure on the healthcare system, they also form innovations that positively influence a country's competitiveness in the medical devices industry (NWO, 2010b). As such, the medical devices sector exemplifies the importance of knowledge development for economic growth as well as a resource to address societal challenges and is therefore an interesting case to study the changing knowledge development process.

However, the medical devices sector is a complex sector to analyse (NWO, 2010b). The number of different categories of available medical devices is estimated around 10.000 and if different models of medical devices are taken into account, the estimate of the number of different devices is about 90.000, while some even go as high as 1,5 million (WHO, 2010). These devices range from relatively simple, such as medical squeezers, to highly sophisticated, such as MRI equipment (NWO, 2010b). Delineating this sector for analysis is therefore not a straightforward task.

At the time this research project was started the name IMDI did not exist. Originally the program was launched under the name 'New Instruments for Healthcare' (NIG). As of August 2010, the name was changed into IMDI to improve its international recognition.

In the NIG program distinguished five innovation-clusters in order to delineate the sector;

1. Minimally invasive technology
2. Medical optics and acoustics
3. Medical image processing
4. High precision instrumentation
5. Safe extramural care

Initially this thesis followed these innovation-clusters to delineate the sector. The interviews with the chairmen of the innovation-clusters pointed out that the broad scope and low-tech character of the safe extramural care cluster required a radically different research design than the other innovation-clusters. It was therefore decided to exclude this cluster from this thesis and to use the other four innovation-clusters to delineate the sector.

At a later stage, during the interviews with the clinicians, it became clear that the distinction between the remaining four innovation-clusters also proved problematic due to significant overlap between the clusters. As an alternative, it was suggested to distinguish between diagnostic and therapeutic subsectors. This distinction is also not clear-cut, since endoscopic procedures can upfront not be classified as being

diagnostic or therapeutic, because discovered lesions are often treated immediately. The subsector of endoscopy was therefore characterized as a 'grey area' between diagnosis and therapy. The following delineation of the medical devices sector is used in this thesis.

Sector	Medical Devices				
Focus	<i>Diagnosis</i>	<i>Diagnosis/Therapy</i>		<i>Therapy</i>	
Subsector	Medical Imaging	Endoscopy (Gastroscopy, Laparoscopy and Arthroscopy)		Vascular and Interventional Radiology	Radiotherapy

Figure 2: Delineation on the medical devices sector

The following definitions are used to delineate the subsectors;

Medical Imaging: The production of visual representations of internal structures of parts of the human body, using x-ray methods, magnetic resonance imaging, single-photon-emission, positron-emission tomography and/or ultrasound, designed for use in clinical diagnosis.

Endoscopy: Examination of the body's interior through by means of an optic instrument inserted into a natural opening or an incision.

Vascular and Interventional Radiology: The performance of minimally invasive surgery the aid of simultaneous radiological imaging of the field of operation within the body.

Radiotherapy: The use of alpha or beta particles emitted from an implanted or ingested radioisotope or beams of high-energy radiation for the treatment of diseases.

Long after the delineation presented above was made, the NIG program was re-launched as IMDI. The notion that the overlap between the innovation-clusters was problematic was recognised by the developers of IMDI and the innovation-clusters were abandoned. Instead the three thematic subgroups, described above, were formed (NWO, 2010b). This new delineation is in line with the one developed in this thesis. The minimally invasive techniques subgroup is covered by the endoscopy, vascular and interventional radiology and radiotherapy subsectors and the biomedical imaging subgroup is covered by the medical imaging subsector. The home and rehabilitation subgroup is still excluded due to its low-tech and diverse nature.

3. Justification

The changing mode of knowledge production has received much attention of scholars within the field science, technology and innovation. However, these scholars have focused mainly on the theoretical development of various frameworks and concepts, while the empirical application and validation of these frameworks and concepts is still rather limited (Hessels & van Lente, 2008; Martin, 2010).

This is also true for the search regime concept. The search regime has emerged recently and it is still under development. As a result the empirical application of the concept is still focused on proving the validity of the concept, rather than using it to characterise the search regime in a particular field. This thesis does attempt to characterise a particular field and thereby tests to empirical validity of the search regimes concept to this end. In addition this thesis will test whether this characterisation can be used to draw policy implications and to evaluate the alignment of existing policy measures to the search regime.

In doing so this thesis will extend the search regime concept. Besides the dimensions described by Bonaccorsi (2004; 2007; 2008) the thesis will draw upon other innovation literature and incorporate other aspects of knowledge development that are suspect to change and will analyse the interaction of science with other parts of society.

Finally, this thesis aims to get a better understanding of the knowledge development process in the medical devices sector. Even though the medical industry is a labelled as high-tech and knowledge-intensive (OECD, 2009), the nature of knowledge development and the link between knowledge development and innovation in the medical devices sector have not been studied. Some studies have focused on innovation within the medical devices sector, but these approached the sector from an organisational perspective. These studies looked at the relation between new product development processes and organisational integration and innovation in the medical devices sector (Milson et al., 1998) and at the impact of industry experience on entrepreneurial performance and innovation in the sector (Chatterji, 2009).

Additionally, several scholars addressed the role of research governance in the medical devices sector. Steg and Thumm (2001) have looked at the influence of the European regulatory framework on innovation in a single European market, Howarth and Kneafsy (2005) have investigated the recognition of research governance programs, Howarth et al. (2008) focused on the effectiveness of the implementation of research governance and Shaw et al. (2009) focused on the effect of research governance on the type of research that is carried out.

Although these articles highlight various interesting aspects of the medical devices sector, the core of the knowledge development process is not addressed. This research will address this gap with the current literature by making a holistic characterization of the medical devices' search regime. This characterization is a first step into getting a better understanding of the innovation process in the medical devices sector and will serve as a building block for future studies of the medical devices sector.

Besides contributing to the understanding of knowledge development processes, this thesis also contributes to the realisation of the goals of IMDI. This thesis develops a holistic characterisation of the knowledge development process in the medical devices sector and might point out certain aspects of this process that the developers of IMDI have misconceived or overlooked. These new insights could be used to improve the initiative and thereby contribute to the realisation of the goals of the IMDI: increasing the return on R&D investments in the medical devices sector.

4. Theoretical framework

The science system does not function in a social vacuum, but its development is determined by a complex interplay of internal and external factors (Rip, 1990; Heimeriks, 2009). The interplay of science with other parts of society is often described in terms of a social contract (Rip, 1990; Martin, 2003; Hessels et al., 2009), which contains the expectations that society has of the return on the resources that are invested in scientific research. The notion that over the last 20 years this social contract has been changing is widely supported in innovation literature (Gibbons et al., 1994; Nowotny et al., 2001; Martin, 2003). To understand the changes the social contract between science and society has been undergoing, one must first consider the history of the social contract.

In the post World War II era, the social contract between science and society was based on the 'Vannevar Bush model' (Martin, 2003), also referred to as the 'endless frontier' (Etzkowitz & Leydesdorff, 1998). In this setting there was a clear distinction between basic research and applied research. Basic research was performed in discipline-based universities and research institutes and was aimed to produce scientific knowledge along with trained graduates. The universities were seen as the best place to conduct basic research and thereby united the task of research with the task of education. Applied research was performed in government and industrial laboratories and was as a follow-up on the basic research, aimed to produce and apply technological knowledge and develop inventions (Martin, 2010). The decision as to which areas of research should be funded was based on the opinion of peer reviewers. The expectation that basic research would ultimately lead to benefits for society in terms of wealth, health and national security, provided universities with a high level of autonomy (Bush, 1945 in Martin, 2010).

During the 1980's the social contract between science and society began to change (Martin, 2003). This change results from the perception that science is an increasingly important driver of economic growth and an increasingly important resource in addressing societal challenges (Heimeriks & Leydesdorff, 2010). This perception has given rise to the notion of the knowledge economy (EC, 2000; Hemert et al., 2009; Hoekman et al., 2009).

The process of innovation is increasingly dependent on science and technology (Etzkowitz & Leydesdorff, 1998; Martin, 2010). Since innovation is an important driver of economic growth, science and technology have become important resources to foster the competitiveness of a country (Hessels et al., 2009). The value of knowledge as a strategic resource is even higher in the light of globalisation. Due to enormous advancements in information and communication technologies, the science system has internationalised (Heimeriks & Vasileiadou, 2008), which in turn has increased the level of competition within the system. In order to increase or maintain a competitive position in this system, continuous development and application of new knowledge is necessary. As a result of these processes the desire of governments for explicit science policy has increased, which presents a conflicts with open-ended 'endless frontier' model.

Since knowledge is an increasingly importance resource, more emphasis has been given to education. Ever more people are educated to obtain the skills necessary to function in the modern knowledge economy. Moreover, the strategic role of scientific knowledge has induced a model of 'life-long learning', as old skills tend to become obsolete due to continuous technological development. This has caused the higher education system to expand significantly. While governments are usually willing to invest to increase the scale of their education system, they are often not willing to invest to increase the scale of academic research (Martin, 2003). The consequence is that the tasks of education and research are no longer, or to a lesser extent, unified. This also conflicts with the 'endless frontier' model.

Finally, the energy crisis of the 1970's has faced governments with an increased demand for public accountability for all areas of government spending, including scientific research. Governments therefore have to be more selective in funding of scientific research, which has led to the use more systematic procedures to set priorities related to science and technology (Martin, 2003). Again, this presents a conflict with the highly autonomous 'endless frontier' model.

Besides the growing importance of knowledge as a driver of economic growth, knowledge is increasingly important to address societal problems. This notion is reflected in the objectives of the European Research Era (ERA) whose objective is to maximise to value contributed by research to not only economic goals, but also to so-called 'Grand Societal Challenges' (EC, 2008a). This term refers to societal problems that face the majority of Europeans and cannot be addressed by a single state (EC, 2008a). There is no concrete list of challenges, but several thematic areas have been identified, such as Europe's prosperity in the light of global competition, sustainable development and climate change, the ageing population and preservation of human health (EC, 2008b). In order to overcome these challenges, research needs to be targeted to specific areas, which again poses a conflict with the open-ended, autonomous 'endless frontier' model.

In short, the central position knowledge has obtained within the modern day society is not aligned with the traditional, open-ended knowledge development model. Since the knowledge development process co-evolves with its institutional environment, the changing position of knowledge in our society should have affected the nature of the knowledge development process.

Several frameworks have been developed to analyse the changing nature of the knowledge development process. The most famous concept is that of 'Mode 2' knowledge development, which main argument is that a new knowledge development process is emerging that is socially distributed. This process is no longer performed in disciplinary-based universities, but is instead carried out in a large variety of organisations and has little regard for disciplinary boundaries (Gibbons et al., 1994). Also knowledge development is socially reflexive, as it incorporates multiple views, and takes place within the context of application (Gibbons et al., 1994; Nowotny, 2001).

Other frameworks that describe changes in the knowledge development process make fairly similar claims in terms of the focus on the application of knowledge and the increasing level of interaction between organisations and overlap between institutional environments (Irvine & Martin, 1984 in Hessels & van Lente, 2008; Functowicz & Raventz, 1993; Slaughter & Leslie, 1997; Strokes, 1997; Etzkowitz & Leydesdorff, 1998; 2000; Ziman, 2000; Smits & Kuhlman, 2004; EC, 2005). Each framework applies a different scope in its analysis of the knowledge development process and as a consequence each framework has its own strengths and weaknesses (Hessels & van Lente, 2008; Martin, 2010).

Although these concepts highlight interesting features of the knowledge development process, these frameworks are of a rather descriptive nature and often missing empirical evidence to support their claims (Hessels & van Lente, 2008). Moreover, the frameworks often disregard the diversity of science (Weingart, 1997; Godin, 1998). Albert (2003) provides evidence that that academic research should not be seen as a homologous unit and that the heterogeneity of scientific disciplines should be taken into account. This notion is supported by Heimeriks et al. (2008) and Heimeriks and Vasileiadou (2008) who argue that the effects of Mode 2 are visible in various scientific fields, but to rather different extents. They therefore conclude that one should not speak in terms of a dichotomy between Mode 1 and Mode 2 science, but rather of "Mode 1 and Mode 2 aspects of knowledge production, with each scientific field characterized by a mix of both characteristics (p.1614).

This research will explore the field-specific characteristics of the knowledge development. It is therefore important to use a framework that is able to take the

heterogeneity of scientific fields into account. This research therefore builds on the search regimes concept proposed by Bonaccorsi (2004, 2007, 2008). This concept takes a somewhat different approach in its investigation of the changing mode of knowledge production by analysing the changes in knowledge production in terms of shifts in 'search regimes' (Bonaccorsi, 2004; Martin, 2010). Since these search regimes are field-specific, this framework corrects for the heterogeneity of scientific fields and is therefore suitable to use to answer the research question posed in this thesis.

Search Regimes

The search regimes framework is built on the notion that one can see scientists as situated in a particular field in which they search for solutions to scientific problems (Bonaccorsi, 2004). Each scientific field has an abstract space in which scientists explore different directions in order to find solutions to the posed problems. If one wants to explain the movement of scientists within this abstract space, one has two strategies available; concentrate on the cognitive abilities of the scientists or study the structural properties of the space the scientists are moving in (Simon, 1996). Since scientists possess the best knowledge available in their field, it is impossible for an external agent to explain the movement of the scientists better than the scientists can themselves (Simon, 1996). Therefore the second strategy, which focuses on the structural properties of the search space, is more useful.

Bonaccorsi (2004) argues that the space in which scientists search for solutions to scientific problems can be characterized along three dimensions: the rate of growth, the diversity of growth and the level of complementarity. Bonaccorsi (2008) distinguishes three types of complementarity; (1) cognitive complementarity, which refers to the dependence of researchers on other researchers, (2) institutional complementarity, which refers to the dependence of researchers on researchers or organisations from different institutional environments and (3) technical complementarity, which refers to the dependence of researchers on specific equipment or infrastructure to perform their research. Together these three dimensions form what Bonaccorsi (2004) refers to as a search regime: "a summary description of the growth pattern of scientific knowledge and the actual carrying out of scientific research" in a field (p.2).

The institutional and policy implications of search regimes are far reaching. Copying best practices in research policy from one scientific field to another is popular among policy makers, but can be expected to fail because of knowledge asymmetries (Heimeriks, 2009). While generic policy measures can have a positive effect, the different search regimes indicate the need for disaggregated measures (Bonaccorsi, 2007).

Bonaccorsi uses the search regimes concept to shine a different light on the European Paradox (Bonaccorsi, 2007). European science and technology policy has been strongly influenced by the notion of the 'European Paradox'. This notion refers to the fact that while the output of European science in terms of publications is comparable to American science, Europe's technological position in high technology is much weaker than America's (EC, 1995). The paradox is therefore that Europe's science is good, but the translation into commercially applicable solutions is poor.

Bonaccorsi (2004) argues this 'paradox' results from the fact European science is qualitatively weaker, compared to American science, in so-called 'new science fields', such as information science, materials science and life science (Bonaccorsi, 2007; 2008). Unfortunately for Europe, these new science fields are the fields that dominate the high technology scientific landscape of the 21st century.

The fact that European science is qualitatively weaker in these fields does result from poor science policy, but results from the deep-seated institutional features of Europe, which have not been able to adapt to the changes in search regimes over the last 25 years (Bonaccorsi, 2007). This does not say that policy does not matter, but one should

consider to what extent the impact of policy is neutralised by the existing institutional features.

The scientific fields that drive the current high-technology industry, called new sciences, were born in the twentieth century and follow a different development pattern characterised by a high, diverging growth rate and high levels of cognitive and institutional complementarities (Bonaccorsi, 2008). This pattern strongly differs from the more established, traditional scientific disciplines, which are characterised by low, convergent growth and a low level of complementarity or high complementarity, but based mainly on experimental infrastructure (Bonaccorsi, 2004). European countries are insufficiently equipped to address the tensions induced by the new search regimes (Bonaccorsi, 2007).

Although Bonaccorsi's concept of search regimes provides a useful starting point to conceptualize the inter-science differences and dynamics, it has its limitations. The search regimes concept provides a static snapshot of the state of a field, while using dynamic elements like growth and divergence of research directions (Heimeriks & Leydesdorff, 2010). Also, Bonaccorsi does not describe how search regimes emerge and how fields can switch from one search regime to another (Martin, 2010).

In order to make the search regime framework more dynamic, an evolutionary component needs to be added. The first evolutionary conceptualisation of knowledge development distinguished two processes; 'researching' and 'scientizing' (Rip, 1990). Researching referred to the concrete practises of researchers. The results of this process are presented to the scientific community through journals, conferences of informal communication. This forms the variation component of the system. The scientizing process includes the processes through which scientists acquire funding for research, such as recognition of scientific contributions and attractiveness to students. This forms the selection component of the evolutionary system, since the resources that are provided for the researching level determine which directions of research can be explored.

Rip (1990) argues however, that the model needs a third 'level', labelled 'politicking', that analyses the interaction of the science system with the wider world. This level also focuses on the mobilization of resources for science, but takes into account actors outside the science system and works as a second selection mechanism. Heimeriks and Vasileiadou (2008) and Heimeriks and Leydesdorff (2010) have further developed this conceptualisation, labelling it as a 'complex adaptive system'. This system is operating at three interrelated but analytically distinct levels of analysis: research, science and society. These levels are constantly interacting and shape on another through a process of co-evolution. The alignment of the three levels determines the stability of the system. If the levels are not compatible, the trajectories that researchers can explore will be set in such a way that the researchers will work towards alignment between the different levels. For example, when the societal needs are not satisfyingly addressed by research (society level), the public can pressure the government to direct funding to research activities (research level) towards the problems that society want to have addressed, which will result in new knowledge (science level) that can help solve the problems pointed out by the society and thereby providing stability to the system.

These levels can thus be used to analyse changing dynamics within a scientific discipline (Heimeriks & Vasileiadou, 2008). Combining the analytical levels from the complex adaptive system with the search regime concept creates a framework that can be used to analyse the horizontal (differences between scientific fields) as well as the vertical (different levels within a scientific field) dynamics of a search regime. As such this enhanced search regime concept provides more detailed and dynamic information about the knowledge development process and therefore provides a better basis to design policy measures. Therefore the research-, science- and society-level will be used to guide the medical devices' search regime analysis. The next section describes the processes that are relevant for analysis at each level and forms hypotheses.

Research

The research level refers to the daily activities of scientists. Research can be understood as a set of geographically situated practices in which scientists both collaborate and compete with one another. In this process the researchers use site-specific skills and equipment, localised at a particular site of investigation (Heimeriks & Leydesdorff, 2010).

As a result of rapid development of communication technologies and globalisation, the science system is likely to have become more internationalised (Heimeriks & Vasileiadou, 2008). New countries are able to engage in the research process and “learn to play the game” (Martin, 2010, p.33). This has important consequences for the level of competition within the science system, which rises as new players enter. Moreover, since the link between science and innovation is getting stronger, the entrance of new players in the science system also threatens the economic competitiveness in the incumbent countries. To determine whether the science system is becoming increasingly international, the following hypothesis is tested:

H1: The medical devices’ search regime is becoming increasingly international

The increased level of internationalisation is likely to boost the competition within the research community. The researchers compete more fiercely for recognition and, more importantly, resources. To acquire sufficient funding, universities engage in market-like competition (Slaughter & Leslie, 1997). The competition works as a selection mechanism and resources tend to concentrate in the best universities while the rest falls behind (Martin, 2010). As a result, the hierarchy between universities will become more pronounced (Florida, 2002 in Heimeriks, 2009). To determine whether this selection also takes place within the medical devices sector, the following hypothesis is tested:

H2: The hierarchy between research organisations in the medical devices’ search regime is becoming more pronounced

Since the relation between science and innovation has become stronger and the competition for funding amongst universities has increased, the science has become more industrialised and the interaction between academia and industry has increased (Slaughter & Leslie, 1997). New types of organisations have been formed at the intersection of academic and industry, such as research centres, high-tech spin-offs and consultancies (Gibbons et al., 1994; Hessels & van Lente, 2008). These new organisations provide new options for companies to outsource their knowledge development. To test whether these new types of research organisations are also forming in the medical devices’ search regime, the following hypothesis is tested:

H3: The variety of organisations in the medical devices’ search regime is increasing

Not only are new types of knowledge developing organisations emerging, the interaction between these organisations is increasing. This interaction is stimulated by the increasing complexity and the interdisciplinary nature of research activities (Functowics & Ravetz, 1993; Gibbons et al., 1994). This has made it impossible for researchers to solve problems alone and increased the dependence of researchers on additional researchers, theoretical perspectives and methodologies in their daily activities. Given the multidisciplinary nature of the research, these researchers are often from other institutions. As a result of this increased dependence between researchers knowledge development is no longer located in individual organisations, but instead takes place in the form of a network (Gibbons et al., 1994; Ziman, 2000; Smits & Kuhlmann, 2004).

Bonaccorsi (2004; 2008) refers to the dependence of researchers on other researchers in terms of complementarity. The dependence on other human resources is referred to as cognitive complementarity, while the dependence of researchers on (human) resources from different institutional environments is referred to as institutional complementarity (Bonaccorsi, 2008). As the cognitive and institutional complementarity rise, more resources have to be invested in the project-organization

(Whitley, 1984). These investments can often not be retrieved when the project ends and provide incentive to deploy new research activities using the same project-organisation. As such the increased interdependency between researchers in their daily activities decreases the flexibility of the involved researchers to explore new directions in the future and can therefore act as a source of path dependency (David, 1994). To test whether the medical devices sector is also characterized by increasing collaboration and as a result might suffer from path dependency, the following hypothesis is tested:

H4: The cognitive and institutional complementarity in the medical devices' search regime are increasing

Science

The science level refers to the emergent 'body of knowledge', formed by articles in scientific journals. Within this body of knowledge existing claims are continuously utilized to form new claims. Bonaccorsi (2004; Bonaccorsi & Vargas, 2010) distinguishes two patterns with respect to the use of previous claims: convergent and divergent regimes. With a convergent regime Bonaccorsi (2004, p.24) refers to "a dynamic pattern in which given one or more common premises (e.g. an accepted theory and an agreed research question or general hypothesis) each conclusion (i.e. experimental evidence or theoretical advancement) is a premise for further conclusions. In addition, all intermediate conclusions add support to a general conclusion" (Bonaccorsi, 2004, p.24). A divergent regime, on the other hand, refers to "a dynamic pattern in which given one or more common premises each conclusion gives origin to many other sub-hypotheses and then research programmes" (Bonaccorsi, 2004, p.24).

The direction of growth has strong impact on the knowledge development process, as it defines the nature of competition and strongly influences the degree of uncertainty in a field. The knowledge development in the medical devices sector mainly draws upon developments in health and life sciences and has strong link with computer science. These fields are characterised by Bonaccorsi (2007) as new science fields that display a divergent growth pattern. The medical devices field is therefore also expected to exhibit divergent growth, which has led to the fifth hypothesis that will be tested in this thesis.

H5: The medical devices' search regime is characterised by a divergent growth pattern

As Bonaccorsi (2004, 2007) has described one should also analyze the rate at which the emergent body of knowledge grows. As the body of knowledge grows it becomes more dominant and will attract more resources to stimulate further growth. Bonaccorsi (2004) argues that the rate of growth in a scientific field can be compared to the growth in an industry, in which entry, exit and productivity are the main determinants. If the output related to a certain area of interest, expressed in the number of publications, suddenly rises, this indicates that new scientists have entered the field or that the productivity in the field has increased (Bonaccorsi, 2004).

Like the direction of growth, the rate of growth has a strong impact on the competition in a field. When the rate of growth is very high, the scientists face more pressure to keep up to date with the latest development and have more urgency to publish their results. Bonaccorsi (2007) argues that new science fields are characterised by exponential growth rates. Since the medical devices sector draws upon new science regimes, the growth rate of the medical devices' search regime is expected to be high. This forms the sixth hypothesis of this thesis.

H6: The medical devices' search regime is characterised by an exponential growth pattern

Society

Due to the increased demand for public accountability of government spending the expectations of resources that are invested in scientific research have become more explicit (Martin, 2003). To fulfil expectations research has to be guided to a certain end-goal. Innovation literature devotes much attention to knowledge development as an end-goal in itself (basic research) and the application knowledge as an end-goal (applied research).

Many scholars treat this topic as a dichotomy between basic and applied research, in which modern research activities are increasingly focused on the application of research (Gibbons et al., 1994; Slaughter & Leslie, 1997; Etzkowitz & Leydesdorff, 1998; Ziman, 2010). An alternative notion is that of Pasteur's Quadrant. The idea behind this term is that modern research aims to generate new understanding as well as to develop a new application (Strokes, 1997). This notion is repeated in the concept 'frontier research' concept, which has been influential at the European Commission (EC, 2005).

Due to increased importance of knowledge as a driver of economic growth and as a resource to address societal challenges, the term 'applied research' usually refers to apply new knowledge to contribute to (one of) these ends. The socio-economic contribution of research is often used in research programmes to refer to this notion and forms the most important criterion of the legitimacy of modern scientific research (Heimeriks, 2009; Hessels et al., 2009). Since basic research, as an end in itself, is not aligned to this objective, funding for the 'endless frontier' is rapidly reduced (Etzkowitz & Leydesdorff, 2000).

To ensure that the output of scientific research will contribute to socio-economic development, the funding mechanisms have changed. The funding has shifted from general university funding to project-based funding in selected priority areas (Martin, 2010). Over time the number of targeted research programs is expected to increase and research programmes are expected to add more explicit emphasis to the description of the social and economic benefits of research. This forms the seventh hypothesis of this thesis.

H7: The socio-economic contribution of research has become more explicit in health research programs

To ensure the applicability of the knowledge being developed, there is increasing interaction of the academia with other 'institutional spheres' (Functowicz & Raventz, 1993; Gibbons et al., 1994; Etzkowitz & Leydesdorff, 1998; Smits & Kuhlman, 2004). This notion has led to the concept of the triple helix (Etzkowitz & Leydesdorff, 1998; 2000). This concept distinguishes three spheres that are increasingly overlapping and interacting in the knowledge development process; academia, industry and the state (Etzkowitz & Leydesdorff, 2000).

The interaction between academia and industry results from various processes. As a result of globalisation the industry is forced to innovate and companies turn to universities for assistance in this process (Slaughter & Leslie, 1997). At the same time, the flow of public money to universities is diminishing, which stimulates capitalistic behaviour of universities (Slaughter & Leslie, 1997; Wtzkowitz & Leydesdorff, 1998; Ziman, 2000). Finally, the government is stimulating university-industry interaction through science policy, for example by mandating collaboration with companies as a criterion for public research funding.

Kleinman and Valluas (2001) describe this development as a "process of asymmetrical convergence, in which previously distinct institutional domains grow intertwined, and come to adopt shared structures and modes of operation" (p.465). The academic practises are increasingly industrialized while the practises of the industry are increasingly 'collegialised'. As a result one can expect the role of the industry in the knowledge development to increase.

H8: The role of the industry is becoming increasingly important in the medical devices' search regime

Not only has the overlap between the academic sector and industry increased, the knowledge development process is increasingly interacting with the public (Functowicz & Ravetz, 1993; Gibbons et al., 1994; Ziman, 2000). The knowledge development process has become a dialogic process and has increased its capacity to incorporate multiple views (Gibbons et al., 1994; Hessels & van Lente, 2008). Increased interaction with the public makes research more socially reflexive and aligns research to societal challenges (Martin, 2010). The next section elaborates on the role of user-involvement in the medical devices sector.

Within innovation studies the assumption that product manufacturers are the prime innovator existed for a long time (Von Hippel, 1988). In this traditional view on innovation, the only role of the users is to have needs, which manufacturers fill by designing and producing new products. However, studies have shown that the sources of innovation are of an increasing variety (Von Hippel, 2005). Especially the users of innovation have become more able to express their needs or even innovate themselves. This has great advantages, since users are able to develop exactly what they want, rather than relying on manufacturers to act as their imperfect agents (Von Hippel, 2005).

Shah and Robinson (2006; 2007) have showed that this notion also applies to the medical devices sector, as there are numerous benefits of involving users in the development of medical device technology. Within the medical devices sector there is a range of actors influencing the technology development process, such as regulators, manufacturers and users (Shah et al., 2009). While the perspective of all these actors should be taken into account, the involvement of users' perspective in the development process is particularly important, especially in at an early stage in the development process (Shah & Robinson, 2006; Shah et al., 2009). However, despite the importance of the involvement of users in the development process, user involvement in medical devices development is still either limited or underreported in literature (Shah and Robinson, 2007).

The users of medical devices are not homogenous, but range from clinicians to physicists to patients and elderly people (Shah & Robinson, 2006). This heterogeneous group of users can be separated into two groups: healthcare professionals and end-users (Shah et al., 2009). Scholars have emphasised the importance of both groups. Lettl et al. (2006) have emphasized the role of healthcare professionals in the development of radical medical device innovations, while Grocott et al. (2007) have emphasised the importance of involving end-users to ensure optimal use of medical devices.

As a reaction to the absence of consensus on the involvement of users in medical device technology development, Shah et al. (2009) proposed a generic framework. This framework is based on the idea that the most effective way of developing medical devices technology is by taking both the healthcare professionals' and the end-users' perspective into account (Shah et al., 2009). However, the emphasis should lie on the group that will operate the device being developed. Since medical devices included in this thesis are solely used by healthcare professionals, the focus in this thesis is on this group.

As mentioned above, as a result of the increased focus on knowledge development to address societal challenges, the involvement of users in the knowledge development process is expected to have increased over recent years. Since the focus is on the healthcare professionals, the importance of hospitals in the knowledge development process is expected to have increased. This forms the last hypothesis of this thesis.

H9: The role of hospitals is becoming increasingly important in the medical devices' search regime

Testing the hypotheses will indicate which aspects of the knowledge development process are changing and, more importantly, to what extent. By combining the various dimensions of the knowledge development process that are analysed, a description of the medical devices' search regime can be given. This description will describe the dynamics at each of the three levels as well as how these levels are interacting and co-developing.

The additional step that is taken in this thesis is to draw policy implications from the search regime. The next section presents a literature overview of the policy measures that ought to be used to handle certain dynamics in the knowledge development process.

Policy Implications

The changing dynamics of knowledge development have strong implications for science policy (Gibbons, 1995). Not only is the importance of the governance of science increasing as a result of the increased dependence of economic growth on science and technology, but the 'new' mode of knowledge production that is emerging also calls for the use of a different kind of policy intervention tools (Heimeriks & Leydesdorff, 2010; Martin, 2010).

The most important policy implication is that it is impossible to determine a general scale or scope for public intervention that is most effective (Heimeriks, 2009). The tendency to apply the same policy ideas in an unimaginative way should be resisted since the changing knowledge dynamics are making the 'one size fits all' answer is becoming increasingly obsolete (Bonaccorsi; 2004; 2008; Heimeriks & Vasileidou, 2008). Policymakers should instead try to find original areas of expertise (Heimeriks & Leydesdorff, 2010) and develop disaggregated measures "targeting in a distinct way not only specific fields, but also, and more importantly, the interactions between local research practices, emergent scientific landscapes, and the field's relationship to its societal context" (Heimeriks, 2009, p. 13).

Even though the notion that disaggregated measures are needed is supported in various papers, this notion has not yet been extended by a conceptualisation of the measures that should be taken in a particular situation. As a result there is no theoretical framework that can be used to identify the measures that are suited for a particular field at a particular time. However, Bonaccorsi (2007) has elaborated to some extent on the policy implications of certain characteristics of search regimes. Bonaccorsi (2007) distinguishes the implications of growth patterns and the implications of the type and level of complementarity.

The growth pattern of a scientific field relates to the science-level of the complex adaptive system. Bonaccorsi (2007) states that search regimes characterized by convergent patterns coupled with rapid growth cannot be managed within the traditional university model. First, divergent patterns are better managed in systems subject to severe competitive pressure based on international publication standards. Universities should therefore base their recruitment policy on consistent international track record, which will increase their credibility and facilitate the flow of private funding. Second, divergent regimes benefit from high mobility of researchers. Divergent regimes require continuously reconfiguration of research teams to target the continuous formation of new hypotheses. In this light, scientists should be stimulated to move around in search of frontier laboratories, rather than spending their entire life in the same institution. Finally, divergent patterns are better managed under a multi-layered funding system. In such a system researchers will be able to find funding from different sources depending on the level of uncertainty and the time horizon and stage of discovery of the project. Such a system avoids scientists from having to spend a large part of their time lobbying the government for mission-oriented budgets.

The level of complementarity relates to the research level of the complex adaptive system, since it describes the extent to which a scientist needs additional resources in order to carry out its research activities. Bonaccorsi describes (2008) three types of

complementarity. The first type is cognitive complementarity, which refers to the minimum size of project teams needed to execute research and the disciplinary background of the scientists in these teams. Bonaccorsi (2004; 2007; 2008) does not describe the policy implications of this type of complementarity. One can argue that regimes characterised by high levels of cognitive complementarity also benefit from high mobility among scientists, since this facilitates the formation of research teams.

The second type of complementarity is technical complementarity, which refers to the importance of infrastructure in order to execute research (Bonaccorsi, 2008). If the needed equipment is not available to the research, the output of that researcher will fall to zero (Bonaccorsi, 2004). Strong technical complementarities are managed best by institutions with separately allocated budgets. This provides stable funding of the needed equipment, since scientists do not have to compete for funding with other disciplines (Bonaccorsi, 2007).

The final type of complementarity is institutional complementarity, which refers to the extent that researchers use knowledge produced in a different institutional environment (Bonaccorsi, 2008). A single artefact is often explored by multiple groups of scientists in various institutional environments, working on different hierarchical levels of the artefact. In order to transfer the knowledge on each level of the artefact between the research groups, the different institutional environments need to be connected and coordinated. This process is more difficult to handle than technical complementarities. It is important that the institutional complementarities are built-in from the start. This avoids the political problems that result from political deliberation when the complementarities need to be designed and managed ad hoc (Bonaccorsi, 2007).

An important note to the creation of new institutions is that one should carefully consider the lifetime of these institutions. One should avoid creating permanent laboratories, but should instead plan to wind down the institution after a fixed number of years and devoted the resources to new growth areas (Martin, 2010). If, however, more permanent research organisations are created, these are likely to benefit from organisational modes that foster the influx of new research themes and provide creativity-supporting funding.

In addition to these field specific policy implications, the implications of the changing social contract between science and society have also been described within innovation literature. The current funding and evaluation of university research is not suited to assess third mission activities. These third mission activities are often highly multidisciplinary, while funding agencies are structured around traditional disciplines and are held back by peer review systems that favour these traditional disciplines (Martin, 2010). Therefore suitable incentive and reward structures should be set up for these new activities, while carefully controlling for that fact that these are not interfering with the traditional university missions (Martin, 2003).

The changing social contract also creates the need to integrate policies for science, technology and industry into one comprehensive innovation policy (Gibbons, 1995, Martin, 2010). As a result government ministerial responsibilities also need to be restructured, which is not an easy task since this requires cross-ministry negotiation and might give rise to inter-ministerial jealousy.

As a result of the increasing overlap and interaction between various types of institutional actors, the system has become more complex, making it more difficult to intervene through policy measures. Since intervention from the supply side is therefore becoming increasingly difficult, greater emphasis should be given to demand-oriented innovation policy (Martin, 2010).

Finally, while government involvement used to be on the national level, policy is increasing shifting towards a multi-layered system, comprised of regional, national, European and global policy. There is therefore a growing need to develop policy intervention that are aligned at each level in order to avoid contradictory effect at multiple levels (Gibbons, 1995; Martin, 2010).

Level	Knowledge dynamics	Policy Implications
Research	Cognitive complementarity Technical complementarity Institutional complementarity	High mobility of scientists Allocate separate funding Build-in institutional flexibility
Science	Divergent growth patterns	Maximise competitive pressure Increase mobility of scientists Create multi-layered funding system
Society	Multidisciplinarity Overlapping institutional environments Shift towards multi-layered policy	Create mission-oriented funding Use non-traditional evaluation tools Integrate science, technology and industry policy Shift to demand-oriented innovation policy Devote attention to alignment of different layers

Figure 3: Overview of policy implications

Changing the institutional features is, however, a difficult process. According to Swan et al. (2010) institutional change can be thought to result from competing institutional logics of different constituent communities within an organizational field. These logics consists are underpinned by the community's socio-political legitimacy and taken-for-granted practises. Swan et al (2010) state that when aspiring institutional change, it is important to not only alter the socio-political legitimacy but also change the taken-for-granted practises, since the latter can counter the effects of the former. Contradiction between the socio-political legitimacy and the taken-for-granted practices can rise between different communities as well as within the same community. For example, a funding agency trying to stimulate multidisciplinary research might set up a mission-oriented funding program (alternative socio-political legitimacy). However, if the agency does not alter its evaluation method and evaluated proposals on the basis on discipline based peer-review, the mission-oriented program will fail to achieve its goal (more multidisciplinary research).

Hessels et al. (2009) make a similar point using the credibility cycle. They argue that interventions in the credibility cycle can be made to steer the research in a particular direction, for example by providing earmarked funding for projects. However, similar to the contradictions described above, Hessels et al. (2009) argue that the effect of public policy is limited when it only intervenes at one position in the credibility cycle. In order to successfully alter the direction of research, a combination of instruments are needed directed at various stages of the credibility cycle. This is also coherent with the notion of Martin (2010), who advocates a more holistic approach to science policy, which is targeted at the interactions between actors in the system, to ensure that the system as a whole works as effectively as possible.

5. Methodology

In order to test the hypotheses presented above, variables and corresponding indicators need to be developed. Due to the intangible nature of the concept, knowledge development is difficult to measure. This thesis will use bibliometric analysis as the basis for its analysis.

Bibliometric analysis can be defined as “the application of those quantitative methods which are dealing with the analysis of science viewed as an information process” (Nalimov & Mulchenko, 1969 in Lundberg, 2006, p.9). A key assumption within the field of bibliometrics is that scientific literature represents scientific activity, an assumption that is met when researchers settle conflict through the publication of papers and when all important researcher findings are sooner or later reported. According to Lundberg (2006) the medical sciences fulfils these requirements.

The delineation of the medical devices sector presented in figure 2 guides the analysis of the search regime. The medical devices sector is an area of application rather than a scientific field. Moreover, the sector cuts across various scientific disciplines. In this thesis the subsectors of the medical devices sector are aligned to medical fields in order to link the application of knowledge to the development of knowledge.

Besides the four subsectors this thesis also includes one traditional scientific field and one new science field. These fields serve as a frame of reference to interpret the result of the medical devices analysis. For the traditional and new scientific field respectively astronomy and nanotechnology have been selected. These fields are accepted examples of old and new science field within innovation literature (Bonaccorsi, 2007, Heimeriks & Leydesdorff, 2010).

For each of the subsectors of the medical devices sector and reference fields, a publication set was created through the selection of journals (see Appendix A). The journals that had the best trade-off between several criteria were selected for the analysis. The following criteria were used;

- ISI journal category, as an indicator of the scope of the journal
- impact factor, as an indicator of the quality of the journal
- number of articles, as a trade-off between quality and quantity of the dataset
- base country, to correct for geographical differences
- expert opinions indentified through interviews, as an indicator of the scope and quality of the journal

The data for the bibliometric analysis was collected using the ISI Web of Knowledge database. This database is chosen since this database provides the option to download the records, which significantly increases the options for and time-efficiency of the data-analysis.

The publication-set ranges from 1990 to 2009. This thesis does not aim to define relations between variables, but instead tries to highlight trends within the knowledge dynamics. Therefore data is presented for three separate timeframes; 1992-1995, 1999-2002 and 2006-2009. These timeframes are considered broad enough to provide representative results, yet separated enough to spot changes over time.

Unfortunately not enough data was available for each timeframe for the vascular and interventional radiology subsector and the nanotechnology field. These fields, and corresponding journals, were emerging at the beginning of the '90's and as a result the number of publications was at that time insufficient for analysis (see appendix B). For the vascular and interventional radiology field the first timeframe, 1992-1995, is therefore not included in the research and the analysis will be based on the changes between the second and third timeframe.

In the case of nanotechnology the number of publication also proved insufficient for the second timeframe. It was therefore decided to use different timeframes for this field; 2001-2003 and 2007-2009 (see appendix B). By limiting the years within each timeframe and the years between the two timeframes, the robustness of the analysis is decreased. However, the data is still perceived as representative, also because the field of nanotechnology also serves as reference field and is as a result not the main focus of this research.

Like all indicators, bibliometric indicators only highlight one aspect of a complex and therefore do not represent an absolute truth (Lundberg, 2006). In order to improve the validity of the results of the bibliometric analysis two rounds of interviews were held. The first round served to find a proper way to delineate the medical devices sector and to find a starting point for the bibliometric analysis. The second round served to verify the journals selected for the bibliometric analysis and to find explanations for the observed trends. The list of interviewees can be found in Appendix C).

The test the hypotheses formed in the previous chapter, indicators have to be developed for all relevant processes. The next section describes the indicators that have been developed.

Research

The first hypothesis at the research level is that the medical devices' search regime is becoming increasingly international. The geographical concentration of research activities is analysed using three indicators. The first indicator of the geographical concentration is the number of countries involved in research activities. If the number of involved countries increases over time, this is a sign of internationalisation.

The second indicator that is used to analyse the geographical concentration is the share over time that the countries have in the publication-output in the field. In this analysis European and American journals are distinguished. This distinction is made since the publications cultures of Europe and the United States are different. American researchers usually only publish in American Journals, while European researchers publish in European as well as American journals. If this was not corrected the American share in the publications would always be lower since the American researchers have less possibilities to publish their articles. To reduce the amount of data to present, only the aggregates of the data per continent will be presented. Finally the share of each continent in the top-250 most cited publications per subsector is analysed and compared to the share in the total publication-set to determine whether the Bonaccorsi's (2007) notion regarding the European Paradox is also of influence in the medical devices sector.

The third indicator used to determine the internationalisation of the medical devices' search regime is the share of the international co-authored publications. If the share of international publications rises, this indicates that the search regime is becoming more international.

The second hypothesis is that the hierarchy between research organisations in the medical devices' search regime has become more pronounced. The hierarchy between these organisations is analysed using the share of the top ten institutions in a country account for as an indicator. Since it would be too time consuming to perform this analysis for all countries, only the top three countries in terms of their share in the publication set are used for this analysis. If the cumulative share of the top 10 institutions is increasing over time, this indicates that the hierarchy between the institutions is becoming more pronounced.

The third hypothesis is that the variety of organisations in the medical devices' search regime is increasing. To test this hypothesis the share of various types of institutions in the publication set is analysed. In each of the medical devices subsectors the affiliated organisations are labelled into five categories; academic hospitals, academic organisations (non hospital), hospitals (non academic), research institutes and

companies. Since manually labelling the affiliated organisations is too time consuming, this will be done using formulas based on the appearance of specific strings in the name of the affiliated organisation (see appendix D). The formulas are not perfect and as a result up to 10 percent of the cases will not be labelled. This is regarded as an acceptable trade-off between the time needed to label all of the record and the quality of the analysis.

For each type of affiliated institution the percentage of the publications that list this particular type of institutions will be determined and analysed over time. This will show whether the composition of affiliated institutions is changing over time and which type of institutions are becoming more active in the knowledge development process.

The final hypothesis at the research level is that the level of cognitive and institutional complementarity in the medical devices' search regime is increasing. Two indicators are used to test this hypothesis. The first indicator is the average number of researchers that are affiliated to a publication. If this number is increasing over time this indicates that the cognitive complementarity is increasing, since researcher need an increasing number of additional researchers to perform their research. The second indicator is the average number of institutions that is affiliated per publication. An increase in the number of institutions per publication indicates that the institutional complementarity is increasing.

Science

Two hypotheses are tested at the science level. The first is that the medical devices' search regime is characterised by a divergent growth pattern. To analyse the convergence in research topics, the use of keywords in publications is analysed over time. In the case that the literature is convergent, the same keywords will be used over a long period of time. If the literature is divergent, the used keywords change over time as the research activities are geared from one direction to another.

The second hypothesis is that the medical devices' search regime is characterised by exponential growth. This hypothesis is tested using the number of publications as an indicator. To determine whether increases in the growth rate are caused by increased productivity or by the entrance of new researchers in the field, the number of authors that are active in the field is included as a second indicator.

For the analysis of the rate of growth a different publication set is used. Since this level refers to the whole emergent body of knowledge, the journal-based selection could not be used. The top 100 of the most frequently affiliated keywords used to analyse the concentration of keywords was used as the built this second publication set for each subsector. Out of the top 100 keywords the field-specific keywords were selected manually. The publications that contained one or more of these keywords in the publications title were selected (see appendix E for an overview of the keywords).

Society

The society level lists three hypotheses. The first is that the importance of the socio-economic contribution of research has increased. As a result of increased public accountability of government spending, research is increasingly funded through targeted research programme. It was, however, impossible to find data that could be used to verify this statement. Data on direct university funding and project based funding on an international scale is very limited and only available for a short timeframe. The socio-economic contribution of science will therefore be analysed qualitatively, by examining the extent to which the socio-economic contribution is explicitly described in research programmes. The analysis focuses on the research programmes of the European Union and the United States, since Europe and the United States account for the largest share of the academic knowledge development in the medical devices sector.

The final two hypotheses describe the increased importance of the industry and hospitals in the medical devices' search regime. These hypotheses will be tested using the same indicators. The first indicator is fairly similar to the indicator used to determine the variety of involved institutions. This time, however, instead of analysing the percentage of publications that list each type of institution, the share of each institution in the total number of affiliated institutions will be analysed. Thereby shifting the focus from involvement of the institutions, to the importance of the institutions in the knowledge development process.

Secondly, the interactions between academic institutions and companies and hospitals are analysed, to determine whether the supposedly increasing overlap between different institutional environments actually takes. This will be indicated by the share of publications that are developed through these interactions.

Testing all hypotheses will provide information on the development of the different levels of the search regime over time (see figure 4). By combining various trends, a dynamic description of the medical devices' search regime can be formed. This description will then be compared with the policy implications described in the previous chapter to determine which implications should be taken into account in the medical devices sector and whether these implications are taken into account in the IMDI.

Level	Hypotheses	Indicators	Data Source
Research	H1: The medical devices' search regime is becoming increasingly international	- Number of countries in the publication-set - Share of continents in total publication-set - Share of continents in the top-250 most cited publications	Journal-set Journal-set Journal-set
	H2: The hierarchy between research organisations in the medical devices' search regime is becoming more pronounced	- Share of top 10 institutions in national publications	Journal-set
	H3: The variety of organisations in the medical devices' search regime is increasing	- Share of publications listing each type of affiliated institution	Journal-set
	H4: The cognitive and institutional complementarity in the medical devices' search regime are increasing	- Number of authors per publication - Number of organizations per publication - % of publications with international co-authors	Journal-set Journal-set Journal-set
Science	H5: The medical devices' search regime is characterised by a divergent growth pattern	- Concentration of keywords	Journal-set
	H6: The medical devices' search regime is characterised by an exponential growth pattern	- Number of publications - Number of affiliated authors	Keyword-set Keyword-set
Society	H7: The socio-economic contribution of research has become more explicit in health research programs	- Explicitness of socio-economic objectives in research programmes	Research-programmes
	H8: The role of the industry is becoming increasingly important in the medical devices' search regime	- Share of each type of institution in the publication-set	Journal-set
	H9: The role of hospitals is becoming increasingly important in the medical devices' search regime	- Publications share of academic-industry interactions	Journal-set

Figure 4: Variables and corresponding indicators

6. Results

The next chapter display the analysis of the variables of the research, science and society level, following the indicators in figure 4. The results of the analysis will be used to confirm or reject the stated hypothesis and to develop the characterisation of the knowledge dynamics in the medical devices sector.

Research level

H1: The medical devices' search regime is becoming increasingly international

This section determines whether the internationalisation of medical devices search regime has increased over time. The most straightforward indicator to determine the level of internationalisation is to determine the number of different countries that are involved in research activities.

Active Countries	'92-'95	'99-'02	'06-'09	Change
<i>Astronomy</i>	63	61	66	104,76%
<i>Nanotechnology*</i>		51	74	145,10%
<i>Medical Imaging</i>	48	58	65	135,42%
<i>Endoscopy</i>	52	61	70	134,62%
<i>Vasc. and Int. Radiology</i>		53	62	116,98%
<i>Radiotherapy</i>	42	56	64	152,38%

* data from '01-'03 and '07-'09

Figure 5: Countries active in research activities

The data shows that research is indeed becoming more international, as the number of active countries has increased in each of the fields. The traditional nature of astronomy is reflected in the relatively high number of active countries by the early '90's. Since astronomy is a discipline that has been around for thousands of years, countries have had plenty of time to become familiarized to and active in this field.

The medical devices subsectors are relatively new and therefore the number of active countries by the early '90's is less than in astronomy. In the years after the number has increased to similar levels as in the field of astronomy and as a results the growth rates are moderate.

Nanotechnology is a very new field. In the beginning of the new millennium, the number of active countries was the lowest of all fields. However, nanotechnology is also a very fast growing field. The number of active countries has increased very rapidly in a relatively short period of time. Currently nanotechnology has the highest number of active countries of all fields included in this thesis. This might result from the high expectations surrounding the future importance of nanotechnology that makes that all countries want to 'get onboard'.

However, the fact that the number of active countries has increased does not mean that the concentration of research has decreased, since the new countries might only account for a very small percentage of the research. Therefore the share of each active country in the total number of publications was determined. Since this data was very fluctuant and too extensive to present, the shares have been accumulated per continent. Asia, Europe and North America account for more than 90% of shares in astronomy and more than 95% in the other fields only the data on these continents is presented.

Field / Continent	European Journals				American Journals				All Journals			
Astronomy	'92-'95	'99-'02	'06-'09	Change	'92-'95	'99-'02	'06-'09	Change	'92-'95	'99-'02	'06-'09	Change
Asia	31,46%	28,38%	30,72%	-0,73%	3,52%	7,90%	9,74%	6,21%	11,04%	13,59%	15,54%	4,50%
Europe	33,23%	34,35%	33,05%	-0,18%	11,92%	14,76%	17,32%	5,40%	17,66%	20,21%	21,67%	4,02%
North America	31,68%	30,81%	30,56%	-1,12%	76,33%	69,51%	65,03%	-11,30%	64,31%	58,75%	55,49%	-8,82%
Nanotechnology	-	'01-'03	'07-'09	Change	-	'01-'03	'07-'09	Change	-	'01-'03	'07-'09	Change
Asia	-	35,20%	46,25%	11,05%	-	16,12%	15,54%	-0,58%	-	21,34%	34,70%	13,36%
Europe	-	39,30%	26,10%	-13,19%	-	22,26%	27,59%	5,33%	-	26,92%	26,66%	-0,25%
North America	-	22,81%	24,09%	1,29%	-	59,98%	55,18%	-4,80%	-	49,82%	35,78%	-14,03%
Medical Imaging	'92-'95	'99-'02	'06-'09	Change	'92-'95	'99-'02	'06-'09	Change	'92-'95	'99-'02	'06-'09	Change
Asia	12,68%	19,00%	17,83%	5,15%	10,10%	12,21%	14,86%	4,76%	10,79%	15,89%	16,86%	6,07%
Europe	51,99%	64,19%	61,27%	9,28%	18,23%	29,00%	37,51%	19,27%	27,29%	48,09%	53,53%	26,23%
North America	34,12%	16,06%	19,40%	-14,72%	71,28%	57,83%	46,80%	-24,48%	61,30%	35,17%	28,33%	-32,98%
Endoscopy	'92-'95	'99-'02	'06-'09	Change	'92-'95	'99-'02	'06-'09	Change	'92-'95	'99-'02	'06-'09	Change
Asia	14,62%	30,45%	27,17%	12,56%	13,07%	24,06%	23,90%	10,82%	13,51%	25,64%	24,49%	10,98%
Europe	64,69%	54,48%	54,69%	-9,99%	25,12%	32,23%	31,20%	6,09%	36,31%	37,74%	35,43%	-0,88%
North America	18,69%	12,16%	16,68%	-2,00%	59,21%	40,66%	41,07%	-18,14%	47,75%	33,61%	36,68%	-11,07%
Vasc. And Int. Radiology	'92-'95	'99-'02	'06-'09	Change	'92-'95	'99-'02	'06-'09	Change	'92-'95	'99-'02	'06-'09	Change
Asia	-	-	-	-	-	-	-	-	-	17,28%	19,84%	2,56%
Europe	-	-	-	-	-	-	-	-	-	28,44%	35,32%	6,88%
North America	-	-	-	-	-	-	-	-	-	52,51%	42,58%	-9,93%
Radiotherapy	'92-'95	'99-'02	'06-'09	Change	'92-'95	'99-'02	'06-'09	Change	'92-'95	'99-'02	'06-'09	Change
Asia	3,71%	8,72%	11,79%	8,08%	5,80%	12,78%	14,78%	8,97%	5,20%	11,67%	13,92%	8,72%
Europe	69,00%	73,36%	66,55%	-2,45%	20,75%	28,53%	31,86%	11,10%	34,69%	40,73%	41,86%	7,17%
North America	23,57%	15,30%	17,70%	-5,87%	69,45%	56,03%	51,13%	-18,31%	56,20%	44,94%	41,50%	-14,70%

Figure 6: Geographical concentration of research activities

The data confirms the notion of increasing internationalisation. In general, the concentration of research activities has decreased over time, as the differences between the shares of the top 3 continents are decreasing in all fields and have thus become more equally dispersed. Also, the boundaries between North American and European publication communities seem to be vanishing, since the share of publications of European countries in European journals is decreasing, while the North American share is increasing, and vice versa.

The radiotherapy and medical imaging fields are exceptions to this trend. In these fields Europe's position is clearly getting stronger, while the North American position is getting weaker. In the medical imaging field Europe has, when taking into account both European as American journals, taken over North America in terms of publications shares. One can question whether this process can still be characterized as dispersion, as Europe's share has moved past the point where it was equal to North America's share and research activities seem to concentrate in Europe.

The notion that America's position in the medical imaging sector is weakening while Europe is improving is confirmed by the interviews. The interviewees give various explanations for this trend. One is that the imaging companies in the United States has been too focused on commerce and as a result have devoted relatively little resources to the development of their technology, which is why they fail to keep up with Europe at the moment. Likewise, hospitals are, due to heavy pressure from health-insurers, forced to focus solely on efficiency and therefore unable to devote large amounts of resources to research.

An alternate explanation that is given is that the United States has never had a leading technological position to begin with. The reason that United States has become the leader in publication output has to do with the large amount of venture capital that was available in the '80's and '90's and resulted in rapid installation of CT- and MRI-scanners in hospitals, which in turn provided much 'room' for research. In Europe the implementation of the scanners was much slower and the scientific output therefore

grew less rapid and caused Europe to fall behind. In the technological development, however, Europe, and the Netherlands especially, always maintained a leading position. Much of the essential components of the scanners are patented by Dutch or other European companies.

The interviewees were also questioned as to whether they think that the scientific quality of publications of the United States and Europe are comparable. The majority stated that this is the case, while some favoured either the United States or Europe. This is an interesting point, with respect to Bonaccorsi's notion of the European Paradox and therefore deserves to be analysed in more detail.

Bonaccorsi (2007) argues that the scientific quality of Europe in fields that drive the high-tech industry is lacking because the institutions in the European science system have found it difficult to adapt to the characteristics of the new science regimes. To determine whether Europe's scientific performance is equal to American science in the medical devices industry, the share of the top-three continents in the total publication-set is compared with their respective share in the top-250 most cited publications.

Field / Continent	1992-1995			1999-2002			2006-2009			Change
	Top 250	Total	Factor	Top 250	Total	Factor	Top 250	Total	Factor	
Astronomy										
Asia	2,41%	11,96%	0,20	5,48%	13,09%	0,42	7,22%	12,73%	0,57	0,37
Europe	40,11%	43,50%	0,92	47,26%	47,17%	1,00	55,38%	49,29%	1,12	0,20
North America	50,53%	36,61%	1,38	38,94%	31,50%	1,24	31,44%	28,97%	1,09	-0,29
Nanotechnology*										
Asia	-	-	-	18,28%	43,49%	0,42	19,18%	49,74%	0,39	-0,03
Europe	-	-	-	16,13%	29,03%	0,56	24,21%	25,46%	0,95	0,40
North America	-	-	-	64,16%	24,92%	2,57	54,09%	20,95%	2,58	0,01
Medical Imaging										
Asia	1,97%	14,02%	0,14	3,04%	18,87%	0,16	8,38%	22,33%	0,38	0,23
Europe	34,87%	42,12%	0,83	47,11%	45,90%	1,03	47,84%	42,36%	1,13	0,30
North America	61,51%	41,66%	1,48	47,72%	32,10%	1,49	41,35%	30,77%	1,34	-0,13
Endoscopy										
Asia	7,04%	12,03%	0,58	9,68%	20,93%	0,46	12,66%	27,91%	0,45	-0,13
Europe	41,11%	43,47%	0,95	45,48%	43,74%	1,04	41,23%	38,53%	1,07	0,12
North America	48,89%	39,70%	1,23	39,03%	30,04%	1,30	41,88%	27,96%	1,50	0,27
Vasc. And Int. Radiology										
Asia	4,91%	19,93%	0,25	6,19%	24,20%	0,26	5,56%	22,42%	0,25	0,00
Europe	51,17%	43,46%	1,18	59,40%	43,23%	1,37	55,32%	43,32%	1,28	0,10
North America	38,79%	32,95%	1,18	30,28%	28,43%	1,06	34,49%	30,32%	1,14	-0,04
Radiotherapy										
Asia	2,51%	12,21%	0,21	6,22%	16,77%	0,37	7,42%	21,00%	0,35	0,15
Europe	47,35%	46,12%	1,03	50,24%	47,44%	1,06	55,47%	43,40%	1,28	0,25
North America	47,35%	37,75%	1,25	40,91%	31,99%	1,28	32,42%	30,75%	1,05	-0,20

* data from '01-'03 and '07-'09

Figure 7: Continents' share in total set of publications and top-250 most cited publications

Before discussing the result for the medical devices sector, let's first analyse the reference fields. As can be seen in the table, the difference between the European and North American the share in the total publication-set and the top-250 most cited publications is much larger in the field of nanotechnology than in astronomy. The data thus clearly supports the notion of Bonaccorsi (2007) that Europe's qualitative performance is lacking in new science fields. It is also interesting that even in astronomy, which is characterised as a traditional field of science, European science's qualitative performance used to be lower and has only recently caught up to the

American level. This might, however, partly result from the differences in the European and American citation-behaviour, which tends to favour citations of American authors.

In the medical devices subsectors American science used to dominate in terms of qualitative performance as well. In the medical imaging subsector and the endoscopy subsector, this trend is still observable, even though in the medical imaging sector the gap is closing. In the case of the endoscopy subsector, the gap between European and American qualitative performance seems to be increasing. The data therefore suggest that European institutions are not as well equipped to handle the endoscopy and medical imaging search regimes as North American institutions.

In the vascular and interventional radiology subsector and radiotherapy subsector the European science system seems to have been able to adapt the corresponding search regime. European science is improving its qualitative performance, while the America's qualitative performance is decreasing. As such, the data does not indicate that the European institutions are unable to address the tensions induced by the search regimes in these subsectors.

Bonaccorsi (2007) has not included the Asian continent in his analysis of search regimes. The position of Asia is of course different, since the continent's large-scale activities in all science fields have been developed only recently. It is therefore not surprising that Asia is severely under-represented in the upper-tail of scientific quality. However, the fact that its performance is increasing more rapidly in the field of astronomy than in nanotechnology, can indicate that Asia, like Europe, has its difficulties in dealing with new science regimes.

The last indicator that was used to analyse the internationalisation of the search regime is that number of international publications. Because of the developments in communication technologies, international collaboration is facilitated. The table below shows the percentage of international co-authored publications over time.

International publications	'92-'95	'99-'02	'06-'09	Change
<i>Astronomy</i>	30,27%	41,07%	46,26%	15,98%
<i>Nanotechnology</i>	-	17,98%	24,61%	6,62%
<i>Medical Imaging</i>	5,70%	11,54%	18,83%	13,13%
<i>Endoscopy</i>	3,04%	4,88%	11,01%	7,97%
<i>Vasc. and Int. Radiology</i>	-	7,65%	12,17%	4,51%
<i>Radiotherapy</i>	10,92%	14,59%	17,26%	6,34%

* data from '01-'03 and '07-'09

Figure 8: Share of international publications

The data again indicates that the medical devices' search regime is internationalising. Both the reference fields as the medical devices subsectors exhibit growth in the percentage of internationally co-authored publications. Again, there does not seem to be a relation between the dynamics of knowledge development in a field and the growing internationalisation.

The level of internationalisation in the medical devices subsectors is relatively low compared to the astronomy and nanotechnology fields. This might be explained by the long existence of the astronomy field. Institutions have been active for a long time and have had plenty of time to become familiarised with another. The nanotechnology and medical devices subsectors have emerged more recent and institutions might therefore still be in the process of finding partners to work with and understanding each other's culture.

An interesting point is that multiple interviewees pointed to the fact that international collaboration is not necessary for Dutch institutions since the Dutch knowledge base is of a very high quality. Since collaboration gets more difficult as geographical and cultural distances increase, collaboration on a national scale is preferred over

international collaboration. Nevertheless the internationalisation is recognized and is expected to increase, as more funding will be issued through the European Commission. This source of funding is at this point inferior to national funding, but all interviewees expect to devoted more attention to the European level in the future, even though the paperwork associated to these funds is very complicated and time-consuming.

H2: The hierarchy between research organisations in the medical devices’ search regime is becoming more pronounced

The increased level of internationalisation in the medical devices sector should theoretically lead to a more pronounced hierarchy or research organisations. To analyze whether this effect has also taken place in the medical devices search regime, the combined share of the top ten most publishing institutions in the top three most publishing countries is analysed over time for each subsector.

Subfield	Country	'92-'95	'99-'02	'06-'09	Change
Medical Imaging	USA	25,80%	27,40%	33,30%	7,50%
	Germany	47,10%	39,20%	39,40%	-7,70%
	Japan	34,60%	29,90%	34,10%	-0,50%
Endoscopy	USA	18,20%	18,80%	18,80%	0,60%
	Japan	38,50%	27,10%	31,60%	-6,90%
	Germany	44,80%	38,90%	30,90%	-13,90%
Vasc. and Int. Radiology	USA	-	18,20%	21,80%	3,60%
	Germany	-	30,90%	37,00%	6,10%
	Japan	-	29,10%	28,40%	-0,70%
Radiotherapy	USA	36,30%	31,80%	33,10%	-3,20%
	Netherlands	64,50%	58,80%	51,20%	-13,30%
	Germany	54,30%	47,20%	48,60%	-5,70%

Figure 9: Combined share of the top ten most predominant research organisations

The results of the analysis do not provide evidence to support the stated hypothesis that the hierarchy of research organisations has become more pronounced. This hypothesis would suggest that the combined share of the top universities would have increased over time. The data shows that in most countries the combined share of the top ten organisations has decreased or increased only slightly. Only in the American medical imaging field, the Germany interventional radiology field and, to a lesser extent, the American interventional radiology field the data suggests a stricter hierarchy. However, the organisations in the top ten in these fields differ in each timeframe and it can therefore not be concluded that the hierarchy has become more pronounced.

H3: The variety of organisations in the medical devices’ search regime is increasing

To analyse whether the variety of research organisations has increased over time, the affiliated organisations were labelled and the share of publications that cite each type of affiliated institution were analysed. According to the hypothesis the publication-share of companies in the knowledge development process should have decreased, since these companies can more easily outsource their R&D activities.

The data does not clearly reflect this notion. In the vascular and interventional radiology there is a minor decrease and in the other medical devices subsectors, the involvement of companies is increasing. This is contradictory to the hypothesis, which suggests that company involvement should be decreasing.

However, if hospitals are also characterized as companies, the data does provide some support for the hypothesis. Especially in the medical imaging field, and to a lesser extent in the endoscopy field, the involvement of hospitals is decreasing. This could indicate that hospitals are outsourcing their research activities to other institutions.

Subfield	Type of research institution	'92-'95	'99-'02	'06-'09	Change
Medical Imaging	Academic Hospital	60,47%	59,45%	69,64%	9,17%
	Academic organisation (non hospital)	27,28%	32,87%	38,98%	11,71%
	Hospital (non academic)	33,94%	29,03%	25,61%	-8,33%
	Research institutes	5,05%	5,12%	7,25%	2,19%
	Company	2,87%	4,22%	6,27%	3,40%
	Sum				18,14%
Endoscopy	Academic Hospital	49,57%	58,05%	62,57%	13,00%
	Academic organisation (non hospital)	15,71%	19,21%	25,35%	9,64%
	Hospital (non academic)	43,73%	38,15%	41,11%	-2,62%
	Research institutes	2,24%	3,33%	4,43%	2,19%
	Company	0,56%	1,14%	1,73%	1,17%
	Sum				23,39%
Vasc. and Int. Radiology	Academic Hospital	-	58,75%	62,66%	3,91%
	Academic organisation (non hospital)	-	17,11%	22,06%	4,95%
	Hospital (non academic)	-	39,30%	40,45%	1,15%
	Research institutes	-	6,44%	6,90%	0,46%
	Company	-	2,68%	2,20%	-0,48%
	Sum				9,99%
Radiotherapy	Academic Hospital	51,15%	57,11%	61,29%	10,14%
	Academic organisation (non hospital)	32,54%	34,48%	41,09%	8,55%
	Hospital (non academic)	33,12%	33,97%	32,32%	-0,80%
	Research institutes	14,51%	15,72%	15,43%	0,92%
	Company	1,29%	1,19%	2,49%	1,20%
	Sum				20,01%

Figure 10: The share of publications that affiliate the type of research organisation

The data shows that in the medical imaging and endoscopy fields, the involvement of academic institutions, both hospitals as non-hospital, has significantly increased. This is not in line with the hypothesis, which suggests that the variety of research sites should have increased as a result of the higher level of outsourcing. Instead of an increasing variety, the research activities seem to move away from hospitals and seem to concentrate in the academic institutions. This in line with the observations of Godin and Gingras (2000), that noted that ‘universities are still at the heart of the system and that all other actors rely heavily on their expertise’ (p. 274).

The hypothesis is not confirmed for the vascular and interventional radiology field and radiotherapy field, since there is no clear sign of decreasing involvement of companies or hospitals. The hypothesis is also not confirmed for the medical imaging and endoscopy fields. Even though there seems a trend that hospitals are getting less involved in research activities, this has not led to an increasing variety of research sites, as the research seems to be concentrating in academic institutions.

The data does not only provide information on the involvement of the various types of institutions, but also on the cooperation between the institutions. If the sum of the change of the share of publications that list each type of institution is greater than zero, this indicates that more institutions are collaborating in the research process. As is visible in figure 10, this is the case for every medical devices subsector and it can thus be concluded that the research activities are increasingly taking place in networks instead of in individual institutions. The level of collaboration between institutions (and researchers) is further analysed in the next section.

H4: The cognitive and institutional complementarity in the medical devices’ search regime are increasing

Knowledge development in modern times is thought to no longer be an individual process but to take place in networks of institutions. The previous section already indicated that the medical devices’ search regime is characterised by increasing interaction between various institutions. This section analyses the level of

collaboration by examining the number of affiliated authors and institutions per publication.

Authors per publication	'92-'95	'99-'02	'06-'09	Change
<i>Astronomy</i>	3,36	4,65	4,46	133%
<i>Nanotechnology</i>	-	4,41	5,20	118%
<i>Medical Imaging</i>	4,99	5,19	6,21	124%
<i>Endoscopy</i>	4,02	4,96	5,59	139%
<i>Vasc. and Int. Radiology</i>	-	5,53	5,71	103%
<i>Radiotherapy</i>	5,42	6,36	7,41	137%

* data from '01-'03 and '07-'09

Figure 11: Authors per publication

Institutions per publication	'92-'95	'99-'02	'06-'09	Change
<i>Astronomy</i>	2,30	2,98	3,40	148%
<i>Nanotechnology*</i>	-	2,04	2,43	119%
<i>Medical Imaging</i>	2,30	2,35	2,99	130%
<i>Endoscopy</i>	1,51	1,81	2,32	153%
<i>Vasc. and Int. Radiology</i>	-	1,98	2,51	127%
<i>Radiotherapy</i>	2,63	2,96	3,49	133%

* data from '01-'03 and '07-'09

Figure 12: Institutions per publication

The data shows that the level of collaboration between both researchers and institutions in research activities is increasing over time. Since the rate of growth, when corrected for the timeframe, only slightly differs between the astronomy and nanotechnology, there is no sign that the increased level of collaboration results from different characteristics of the search regimes.

The collaboration between authors is an indicator for the cognitive complementarity between in the search regime. The data shows that the medical devices subsector are all characterised by a relatively high number of authors per publication and thus by a high level of cognitive complementarities.

The interviewees confirm the notion of the increasing level of collaboration. Several driving forces of this trend were indentified. The most important are the multidisciplinary character of clinical research and the complexity of modern science. Specialists from several disciplines, such as technicians, clinicians and staticians, need to be brought together in order to perform good quality research. Often these specialists are not available within the same institution, especially when technical and clinical knowledge need to be combined, which explains the growing number of institutions per publication. Not only is the cognitive complementarity rising, the institutions complementarity in the search regime also seems to be increasing. It is important to take this into account when assessing the path dependency of researchers, as significant resources, mostly in the form of time, have to be invested in order to bridge the gaps between the different cultures of the disciplines.

A different driving force of the growing cognitive complementarity is that all of the medical subsectors are, to a different extent, depended on images. Since the quantity of images produced has rapidly increased, multiple researchers are needed in order to analyse the large quantity of images.

Collaboration is also stimulated by technical complementarities. Especially in the medical imaging field, but to a lesser extent also in the other subsectors, research depends on the access to research facilities. Most important factor is the access to MRI- and CT-scanners in medical imaging research. The pressure from clinical practice on these modalities is very high and as a result the room for researchers to use the scanners is limited. Some institutions have scanners that are dedicated to research.

Since the room for research at these sites is higher, other institutions will start strategic collaborations with these institutions. As such the technical complementarity in the search regime stimulates the cognitive and institutional complementarity

The interviewees also point out that collaboration is becoming a structural part of research, as the collaboration often last for a long period. Instead of searching a suitable partner for a specific project, research institutions tend to form strategic networks in which the necessary partners for their future activities are involved. In most cases these networks are virtual, as the collaboration is based on communication throughout the network instead of collocation of actors from different institutions.

The interviews also indicated that the increased collaboration might be a source of path dependency. One barrier for the development of the medical devices sector is that the cultural gap between the clinical and technical 'world' needs to be bridged. The process of getting to know and understand each other does not happen overnight but can take up to several years. As a result one tends to collaborate with the ones they already know. Research collaboration is as a result often long-term to get maximum return on the invested time in the relationship. This can, however, stimulate the researchers and institutions to continuously work in the same direction and thus become path dependent. This is an important point to take into account when designing policy for the medical devices field.

Science level

H5: The medical devices' search regime is characterised by a divergent growth pattern

The first hypothesis at the science level relates to the convergence of the growth of the emergent body of knowledge. The growth pattern is analysed by examining the keywords assigned to publications. To determine whether the growth pattern could be characterised as convergent or divergent the keywords that are used in the publications set were analysed for each field (see figure 13). The figures below show the rank of keywords in two periods of time. The more frequently a keyword is listed in a publication in a time period, the higher the rank of the keyword in that period. Since the use of keywords changes over time, the rankings become different between the two time-periods. The red line represents a perfectly convergent regime, where the keyword ranking in the first period is identical to the ranking in the second period. The more the dots (representing the keywords) deviate from the red line, the more divergent the growth in the field is. The graphs also show an R^2 -value, which quantifies the deviation of the keywords from the red line. The value can be understood as the percentage of variance in the later time period that can statistically be explained by the variance in the first time period.

The data for the astronomy and nanotechnology fields are not as expected. Astronomy is a traditional field and should therefore exhibit a convergent growth pattern, while nanotechnology, as a new science field, should exhibit a divergent growth pattern (Bonaccorsi 2007). The results, however, show the opposite, as the R^2 -value is larger for nanotechnology than of the astronomy field, which indicates that the nanotechnology search regime is more convergent than the astronomy search regime.

This can, however, be explained. Nanotechnology is a new field and as a result the publication set used to analyse nanotechnology consists of a smaller timeframe. The expected variance in the keywords becomes smaller, as the timeframe decreases since there is less time for the researchers to switch from one research direction into another. A timeframe of 9 years is very small considering that researchers often spend multiple years on a single research project.

In order to create a frame of the R^2 -value for nanotechnology for the time period from 1992 to 2009 has to be estimated. To do so, the R^2 -values of astronomy for the time period 1992-2009 and 2001-2009 are compared (see figure 14). This analysis shows that the R^2 -value of the short timeframe is approximately the square root of the R^2 -value of longer time frame. This is not surprising if one views the divergence of

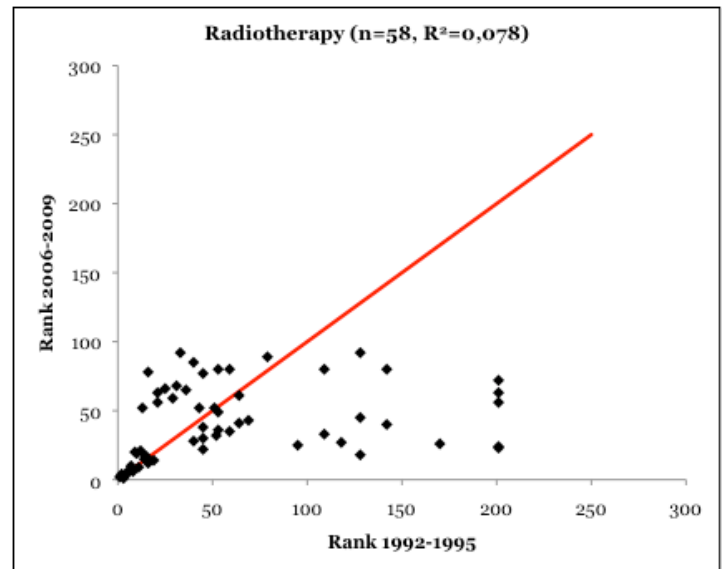
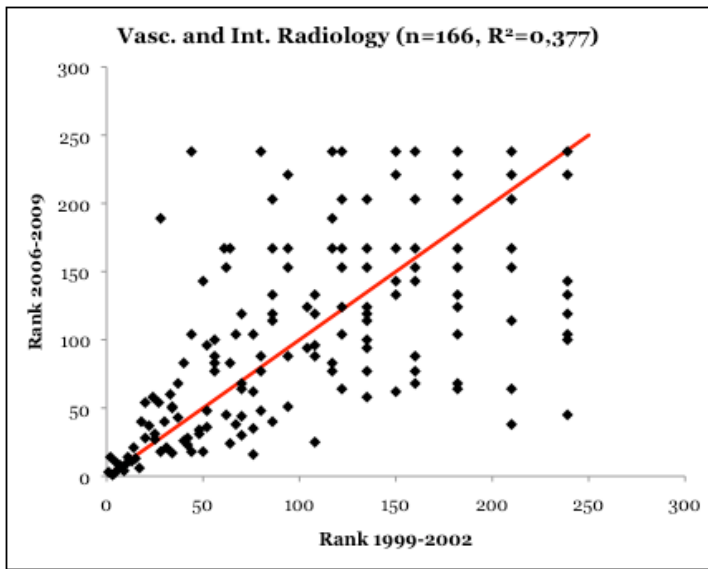
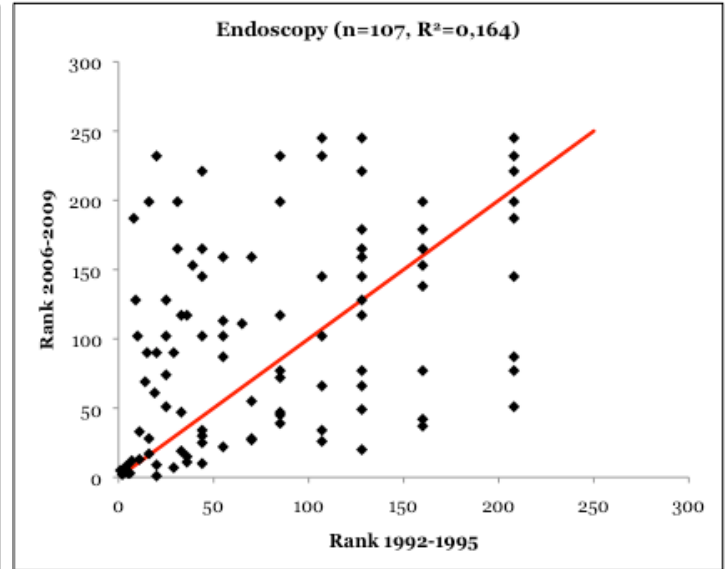
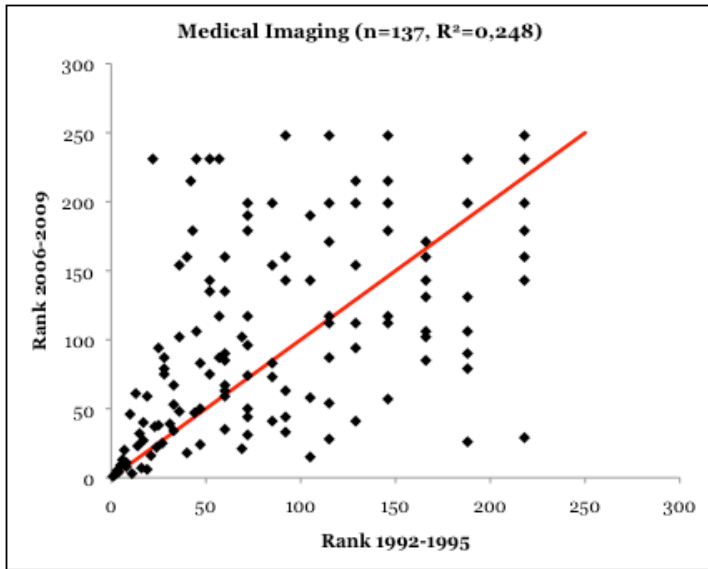
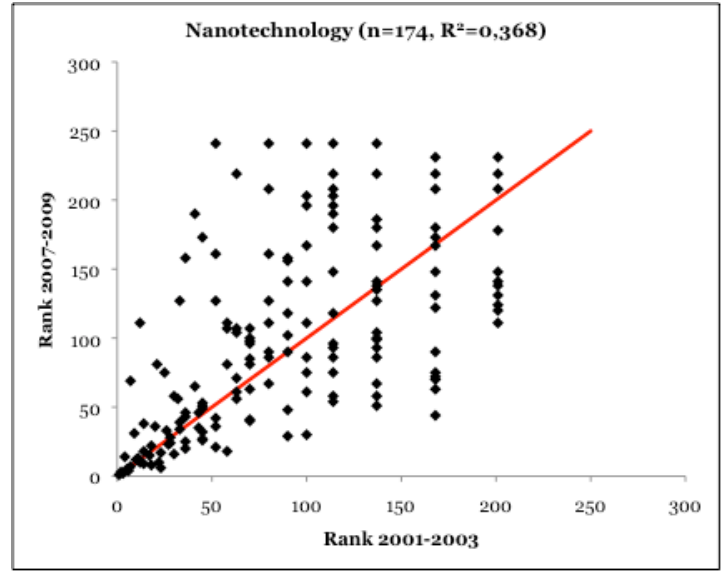
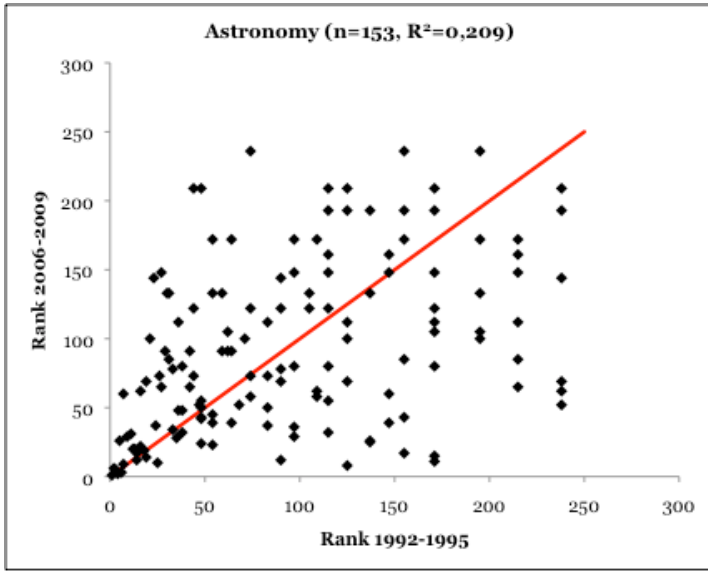


Figure 13: Concentration of keywords

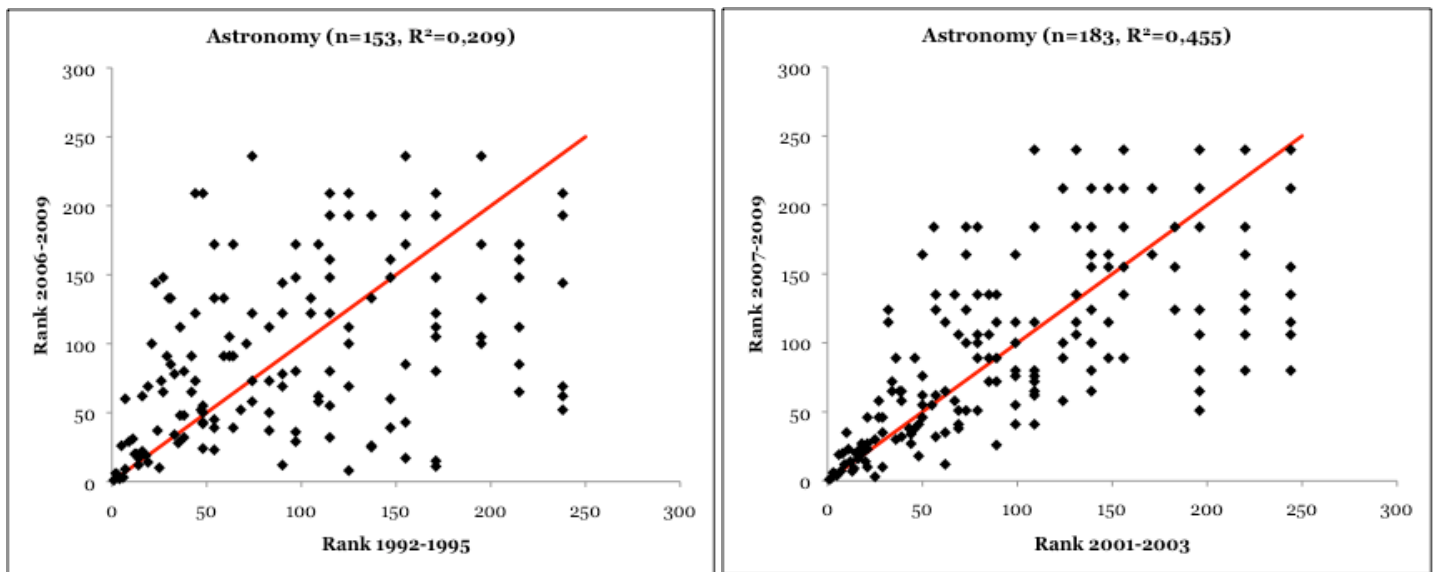


Figure 14: Comparison of R^2 -value of astronomy keyword ranking for two timeframes

keywords as an exponential process, given that the longer timeframe is twice the length of the shorter timeframe.

Since the R^2 -value of the divergence in the nanotechnology field was 0,368 for the short timeframe, the expected divergence for the long timeframe is $(0,368)^2$, which is 0,135. Now that the frame of reference is in place, the convergence in the medical devices subsectors can be analysed.

The keyword-analysis indicates that the medical imaging subsector and the vascular and interventional radiology subsector can be characterised as convergent. Both fields have an R^2 -value that exceeds that of the astronomy field. The interviews confirm the convergent growth in these fields. These fields are based around the three main imaging modalities; CT, MRI and PET. Since these technologies all have their own strengths and weaknesses, no dominant technology has been established and they develop in co-existence. These three main technologies form the backbone of the majority of research that is carried out in these subsectors.

The endoscopy subsector has a R^2 -value that is comparable to that of the nanotechnology field and can therefore be characterised as divergent. This notion is confirmed by the interviews as well. In the field of endoscopy researchers strive to develop procedures that are as minimally invasive as possible. As a result there is a desire to make everything as small as possible. However, when minimizing equipment technological difficulties are bound to arise. Researchers are continuously faced with these problems and come up with new ways to solve them. As a result new problems are arising almost continuously, causing the growth to be divergent.

The radiotherapy field can be characterised as highly divergent, as this field has an R^2 -value that is far below that of the nanotechnology field. The high convergence results from the fact that numerous types of radiotherapy are listed as keywords. Within the top 500 keywords in each timeframe, more than 60 different types of radiotherapy could be indentified. These therapies can be thought of as competing amongst each other and therefore selection between the therapies takes place, which causes the divergent growth pattern.

The interviews pointed out a more fundamental explanation for the difference in growth pattern. The medical imaging field and vascular and interventional radiology fields can be characterised as technology-driven fields, while endoscopy and radiotherapy are more demand-driven fields. Medical imaging technology was initially not developed as a reaction to a particular problem, but emerged due to technological

development, partly by development in other scientific fields. In the endoscopy and radiotherapy fields, technological development has been problem-based. Since problems arise at a more frequent rate than technological trajectories, demand-driven fields are characterised by a more divergent growth pattern than technological-driven fields.

H6: The medical devices' search regime is characterised by an exponential growth pattern

The second hypothesis at the science level relates to the rate of growth. Scientific fields grow at different rates, which require the government to use different measures in different fields to intervene. The rate of growth is indicated by the number of scientific articles that are published in a field. To control for changes in the publication behaviour the interviewees were asked whether the duration of research activities leading to a publications has changed. Also, the interviewees were asked whether the perceived that the competition for publications has increased.

According to the interviewees the time frame leading to a publication has not changed over the last decades. Due to the internationalisation and massification of higher education, the number of active researchers has increased. As a result, the competition for publication in high impact journals has increased. However, over time new journals have been founded, which have lowered the overall level of competition for publications. Therefore, for the sector as a whole, the publication behaviour of researchers has not changed.

Figure 15 shows the publications per year for the astronomy, nanotechnology fields and the medical devices subsectors since 1950. The graph clearly shows the expected difference between the growth rate of the astronomy and nanotechnology fields. The number of articles related to the astronomy field grows almost linearly from the 1960's onwards. Nanotechnology on the other hand shows no growth until the 1990's, but shows an exponential growth pattern afterwards, which is characteristic for a new science field (Bonaccorsi, 2007).

The growth patterns of the medical devices subsectors all fall in between astronomy and nanotechnology. The endoscopy field and vascular and interventional field display a growth pattern that is fairly similar to that of the astronomy field and can be characterized as linear. The field of radiotherapy displays a pattern that is linear, but as of the start of the new millennium has started to growth more than linearly. It is, however, difficult to judge whether the growth rate will continue to become more exponential in the future.

The growth rate of the medical imaging field is the most interesting. This pattern clearly shows periods in which the rate suddenly increases, but also periods where the growth rate falls. The interviewees point out that this is most likely the result of the 'battle' between CT and MRI, which displays the 'sailing ship effect'. The sailing ship effect refers to the situation where the efforts to increase one technology are suddenly increased as this technology is challenged by a large improvements of a competitive technology (Geels, 2005). Both CT as MRI technology emerged in the mid '70's. In this decade both technologies developed rapidly. In the '80's the development of the CT consolidated, while MRI development was boosted by the invention of functional MRI, which could capture organisms in action (National Academies, 2002). The development of MRI compared to CT was that much more rapid, that CT technology was deemed dead (Kalender, 2005). In the '90's however, the CT made a comeback due to rapid developments as spiral CT technology and later on by the development of multislice CT scanners (Kalender, 2005). This is the most probable explanation for the sudden increase in the number of articles in the mid '90's. In the new millennium both technologies are perceived as equally mature, but are both still rapidly developing and competing with each other. Combined with the rapid increase of the application of CT and MRI-technology, this might be the cause of the emergence of the exponential growth pattern, whereas the growth used to be relatively linear up to the new millennium.

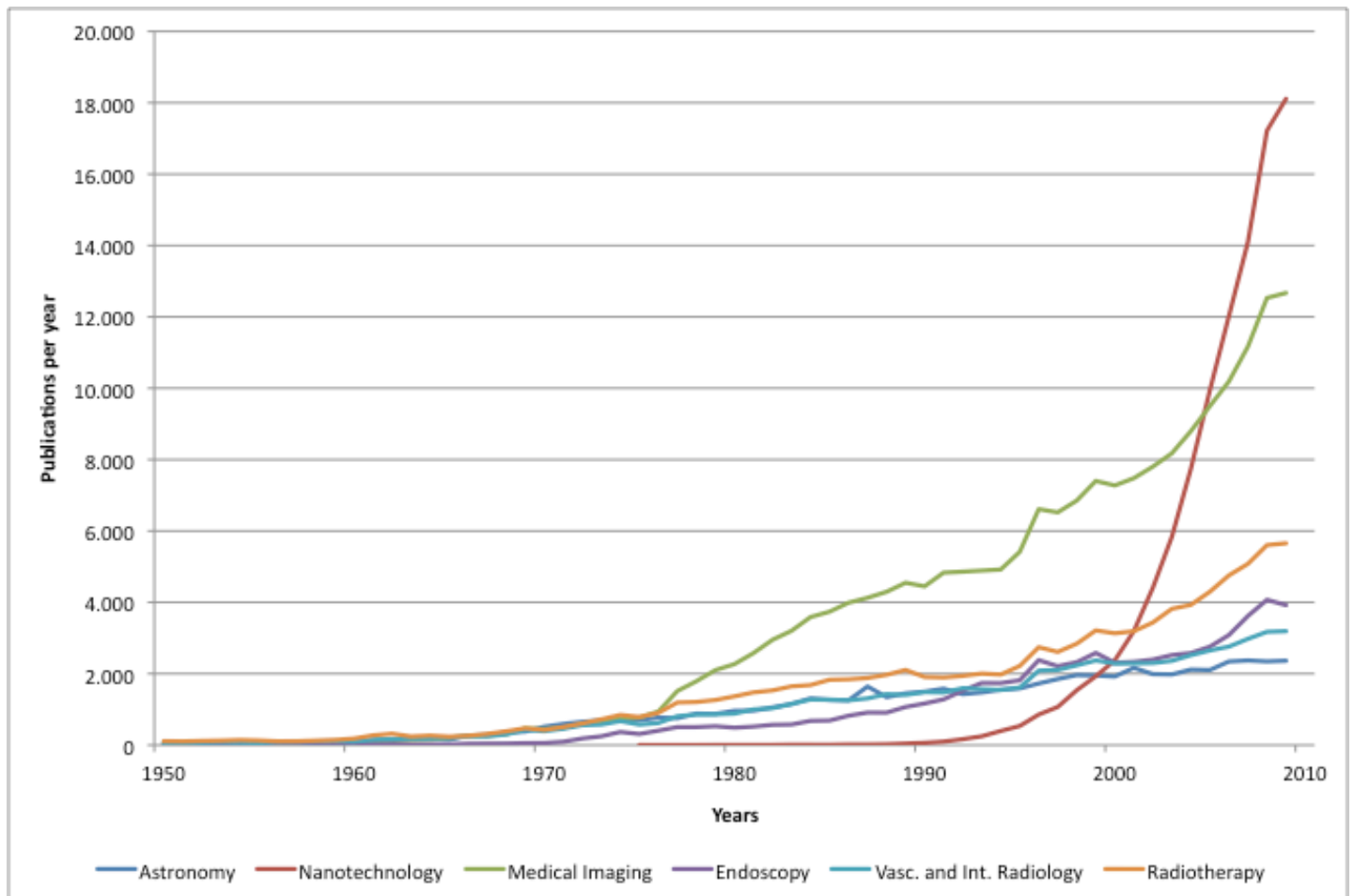


Figure 15: number of articles per year

To determine whether the growth in a sector originates from increased productivity of incumbent authors or from the entrance of new authors in the field, the number of unique authors and the affiliations per authors are analysed (see figure 16).

In general the growth of the number of publications in each subsector is caused by an increased productivity of the authors as well as by the entrance of new authors in the field. The increase of the number of unique authors is striking, and supports the notion of the massification of the science system as noted by Martin (2003; 2010). Especially in the case of nanotechnology, the increase in the number of authors is massive. The number of authors between 2007 and 2009 is sextuple of the number between 2001 and 2003.

The growth in the medical devices subsectors can also largely be assigned to the increasing number of active authors. The medical imaging sector has the relatively largest increase in the productivity compared to the increase in the number of authors, but even here the increase in the number of authors is 7 times the increase of the productivity.

Field	Authors	92-'95	99-'02	06-'09	Change
<i>Astronomy</i>	Affiliated authors	7558	12553	12033	159,21%
	Unique authors	3918	5452	6209	158,47%
	Affiliations per author	1,93	2,30	1,94	100,46%
<i>Nanotechnology*</i>	Affiliated authors	-	4804	31947	665,01%
	Unique authors	-	3700	19193	518,73%
	Affiliations per author	-	1,30	1,66	128,20%
<i>Medical Imaging</i>	Affiliated authors	13972	20722	25532	182,74%
	Unique authors	9321	13251	15621	167,59%
	Affiliations per author	1,50	1,56	1,63	109,04%
<i>Endoscopy</i>	Affiliated authors	6693	17194	21355	319,06%
	Unique authors	4791	10666	13202	275,56%
	Affiliations per author	1,40	1,61	1,62	115,79%
<i>Vasc. and Int. Rad.</i>	Affiliated authors	-	11437	15186	132,78%
	Unique authors	-	7295	9453	129,58%
	Affiliations per author	-	1,57	1,61	102,47%
<i>Radiotherapy</i>	Affiliated authors	7574	12349	20015	264,26%
	Unique authors	4657	7469	11462	246,12%
	Affiliations per author	1,63	1,65	1,75	107,37%

* data from '01-'03 and '07-'09

Figure 16: Affiliations per author

Society Level

H7: The socio-economic contribution of research has become more explicit in health research programs

To analyse whether the socio-economic contribution of science has become increasingly important, funding programs of the European Union and the United States are analysed. The analysis is focused on the explicitness of the socio-economic contribution in the programs as an objective of the funding of research.

European Union

The most influential research programme at the European Union level is the “*Framework Programme*”, currently running its seventh programme. This first framework within the timeframe of this thesis was the third framework programme, which ran from 1990 to 1994. In this framework the thematic approach was already established since the program distinguishes five different thematic areas in which research funding is provided (CEC, 1993).

One of the themes is ‘life sciences and technologies’ under which the subtheme ‘biomedical and health research’ is listed, which receives 2,3% of the total budget of the third framework programme (CEC, 1993). The objective of this subtheme is formulated as (CEC, 1993);

“To contribute to improving the efficacy of medical and health research and development in the Member States, in particular by better coordination of their research and development activities and application of the results through Community cooperation and a pooling of resources”.

In the latest version of the framework programme ten thematic areas are distinguished, ‘health’ is one on these thematic areas (EC, 2006). In this program 12% of the program budget is reserved for the health theme. The objective for the health theme is formulated as (EC, 2006);

“The objective of the health research programme is to improve the health of European citizens, and increase and strengthen the competitiveness and innovative capacity of European health-related industries and businesses. Global health issues, like emerging epidemics, will also be addressed. European collaboration with developing countries will allow those countries to develop research capacities.”

When comparing the third and the seventh framework programme, several differences can be identified. The first is that the budget for health research has increased almost sixfold, which indicates that the importance of this theme has increased significantly. More interesting for the analysis of the socio-economic contribution are the objectives that are formulated for health research. While the application of results was already included in the third framework programme, it is given much more emphasis in the latest program. While the former objectives are mainly focused at research coordination and cooperation, the latter is mainly focused at improving the health of citizens and strengthening the competitiveness of the economy. Moreover, the seventh framework explicitly states the benefits that the research will have for each of the spheres of the triple helix: citizens (state), researchers (academia) and industry and SMEs (industry). This supports the hypothesis that the socio-economic contribution of research has increased.

United States

Analysis of the socio-economic contribution of science in the United States is much more complicated due to the decentralised character of innovation programmes in the United States (EC, 2009). Instead of examining policy documents that are comparable to the framework programme, the analysis is based on the R&D budgets for 2010 and the motivation for these budgets documented in the “*Renewed Commitment to Science and Technology*”. This document states that in 2010 30.8 billion dollar will be invested in health-related R&D. This is a huge amount, given that the total budget of the seventh framework programme for 7 years is 50.5 million euro.

The National Institute for Health (NIH) is the government body responsible for the appropriation of the health R&D budget. The objective of the NIH is formulated as (OSTP, 2009):

“The discovery of knowledge and therapies that will lead to better health outcomes for all Americans”

This is only a very brief statement that does not provide much information. Nevertheless it has a strong social emphasis, focusing on the contribution that the research projects have to make in terms of the health of the American citizens. However, the research budget also states that the United States is striving to double the budget for three areas of basic research over the next decade (OSTP, 2009). Also, the NIH still seems to hold a fairly traditional, linear view of innovation as it states that “Many concepts and tools central to understanding and improving health have come from basic, untargeted research. NIH not only supports these basic advances but also conducts the clinical and translational research that transforms discoveries into medical practice” (NIH, 2010). This is in line with the concept of ‘strategic research’ (Irvine & Marvin, 1984) in which basic research is carried out with the expectation that it will produce knowledge that will serve as a basis to solve societal challenges in the future.

The socio-economic contribution is thus also important in the United States. However, the means by which this socio-economic contribution is realised is different from the European case. Where in European research programs the direction of research projects is explicitly steered towards areas with direct socio-economic contribution, in the United States the research is not steered and the socio-economic contribution is seen as a follow-up to basic research. As a result, the United States research is much less explicitly influenced by the increasing socio-economic emphasis. Therefore the stated hypothesis cannot be confirmed for the United States.

H8: The role of the industry is becoming increasingly important in the medical devices’ search regime

H9: The role of hospitals is becoming increasingly important in the medical devices' search regime

To analyse the final two hypotheses the types of institutions that are involved in the research process are analysed again. This time the focus is not on the involvement of each type of institution per research project, as was the case at the research level. Instead the focus is on the importance of each type of institution in the knowledge development process. Therefore the share of each type of institution in the total number of institutions is analysed over time.

Subfield	Type of research institution	'92-'95	'99-'02	'06-'09	Change
Medical Imaging	Academic Hospital	52,53%	51,01%	55,87%	3,33%
	Academic organisation (non hospital)	20,57%	24,80%	24,57%	4,00%
	Hospital (non academic)	20,14%	18,30%	12,63%	-7,51%
	Research institutes	5,10%	3,66%	4,27%	-0,83%
	Company	1,66%	2,22%	2,67%	1,00%
Endoscopy	Academic Hospital	45,19%	49,30%	48,96%	3,77%
	Academic organisation (non hospital)	13,08%	14,38%	17,21%	4,13%
	Hospital (non academic)	39,37%	33,00%	30,33%	-9,04%
	Research institutes	1,97%	2,62%	2,51%	0,55%
	Company	0,39%	0,70%	0,98%	0,59%
Vasc. and Int. Radiology	Academic Hospital	-	47,39%	49,98%	2,59%
	Academic organisation (non hospital)	-	12,91%	14,93%	2,02%
	Hospital (non academic)	-	33,78%	30,15%	-3,63%
	Research institutes	-	4,28%	3,85%	-0,43%
	Company	-	1,65%	1,08%	-0,57%
Radiotherapy	Academic Hospital	38,64%	41,84%	43,88%	5,24%
	Academic organisation (non hospital)	24,15%	23,84%	25,85%	1,69%
	Hospital (non academic)	26,89%	24,35%	21,01%	-5,88%
	Research institutes	9,73%	9,50%	8,38%	-1,35%
	Company	0,59%	0,47%	0,88%	0,30%

Figure 17: Importance of the type of institutions.

Even though the exact percentages vary, all sectors show similar trends. The academic institutions are becoming increasingly important, the importance of research institutes and companies is relatively stable and the hospitals are becoming less important.

On the basis of this data the hypothesis that the importance of industry in the medical devices' search regime is increasing has to be rejected, since importance of companies is not significantly increasing. Additionally, rather than decreasing, the importance of academic institutions seems to be increasing. The data suggests that the increased focus on the socio-economic contribution has not (yet) affected the importance of companies in the knowledge development process.

The data also indicates that hospitals seem to increasingly rely on research activities of the academic institutions, as the importance of regular hospitals decreases. This is an interesting result given the fact that modern research is thought to have an increasing level of user-involvement. The decrease of non-academic hospitals is accompanied with an increase of the importance of academic hospitals. However, this increase is smaller than the decrease of non-academic hospitals and the number of people being treated in non-academic hospitals is six-fold that of the number treated in academic hospitals (Statline, 2010). Overall the research process seems to be moving away from the regular healthcare practises and as such the level of user-involvement seems to decrease. The hypothesis that hospitals are becoming more important in the medical devices' search regime is therefore rejected.

However, the importance of the industry and hospitals can also be analysed by looking at the interactions between academia and companies/hospitals. This analysis shows a different picture.

Subfield	Academic Institution	1992-1995		1999-2002		2006-2009		Change	
		Hospital	Company	Hospital	Company	Hospital	Company	Hospital	Company
Medical Imaging	University	6,99%	1,36%	5,58%	1,94%	7,64%	2,79%	0,65%	1,43%
	Academic Hospital	12,87%	1,00%	10,55%	1,87%	14,01%	4,02%	1,14%	3,01%
Endoscopy	University	5,19%	0,00%	3,90%	0,25%	5,54%	0,93%	0,34%	0,93%
	Academic Hospital	16,11%	0,53%	15,28%	0,63%	17,76%	1,58%	1,65%	1,05%
Vasc. and Int. Radiology	University	-	-	4,68%	0,63%	7,05%	0,83%	2,37%	0,20%
	Academic Hospital	-	-	13,02%	1,71%	16,98%	1,44%	3,96%	-0,27%
Radiotherapy	University	8,41%	0,29%	9,43%	0,41%	12,50%	1,30%	4,09%	1,01%
	Academic Hospital	10,20%	0,86%	14,85%	0,67%	17,11%	1,56%	6,91%	0,70%

Figure 18: Share of publications resulting from academic-industry and academic-hospital interactions.

Strictly taken, the data shows that the share of publications resulting from academic-industry interactions as well as from academic-hospital interactions is increasing, which confirms the hypothesis. However, in most cases the increases in the publication share is very small. Especially the academic-industry interactions have increased only marginally. The same holds for the academic-hospital interactions in the medical imaging and endoscopy field. Only the academic-hospital interactions in the vascular and interventional radiology sector and in the radiotherapy sector show a more robust increase, especially between academic hospitals and regular hospitals.

As stated above, the two indicators seem to draw two different pictures. While in the former the importance of hospitals seems to decline, it seems to increase (in some of the subsectors) in the latter picture. As shown above, knowledge development is characterised by increasing collaboration between institutions, while the university seems to maintain its central position in this process. The fact that the importance of hospitals declines, while the interactions between academic institutions and hospitals increases means that the level of collaboration of universities is increasing at a faster rate, than the level of collaboration of hospitals. This might result from the fact that university-university collaboration is more common than hospital-hospital collaboration. Further research into this topic, preferably using network-analysis, is needed to provide the data to support these claims.

Since the share of companies in the knowledge development process and the academic-industry interactions in the sector have only increased marginally the hypothesis that the industry is becoming more important in the knowledge development process is not supported. This notion was also expressed during interviews, in which it was stated that the valorisation process usually takes place within the academic hospitals without involvement of the industry.

The hypothesis that the level of user-involvement has increased is also not supported. The interaction between academic institutions and regular hospitals seem to be increasing, but at the same time hospitals seem to become of less importance in the process since their share in the total number of affiliated institutions decreases. During the interviews, the role of users in the innovation process was also discussed, the results of which are described below.

User-involvement

As explained in the theoretical framework the healthcare professionals are the most relevant users to involve in the development process. Interviews pointed out that the healthcare professional are involved in the majority of research projects. They often

have a position in which they are active as a researcher as well as a clinician. The role of the clinicians in the research process differs. Two roles can be distinguished. First, the clinician can be the inspirer of research projects. Since the clinicians are directly in contact with various medical devices on a day-to-day basis, they are most likely to experience problems with the conventional technology. This in turn can motivate research to find solutions to these problems. The second role that clinicians can have in research projects is to act as a monitor of the applicability of the knowledge and/or technology being developed. Because of the multidisciplinary character of the medical devices sector, part of the research in this field is executed by researchers with a non-medical background (such as physicists, computer scientists or mechanical engineers). To ensure that these non-medical researchers are not working on non-viable projects, a clinician is included in the project.

The role that the clinicians have also seems to depend on the nature of the development of the technology and way the devices are used. The nature of the developments in the medical imaging field differs from that of the endoscopy field. The medical imaging technology was never explicitly developed to solve a particular problem, but was largely driven by autonomous technological development, often stimulated by developments in other fields (such as high energy physics). The development in the endoscopy field on the other hand, originated due to a mechanical engineer that started to observe the daily routines of surgeons and noticed that much of the used equipment could be improved. In the latter case the development is inspired by particular problems and the involvement of users therefore seems more important. In the case of medical imaging the involvement of users seemed less important since the technology was not being developed to solve a particular problem, but rather to satisfy the never-ending desire to obtain a more detailed image of the inside of the human body. Since there is no problem to solve and/or solution to choose, involving the clinicians seems of less use.

Also the interaction of the clinicians with the medical devices differs between the medical imaging and endoscopy field. In the field of endoscopy the clinician is heavily interacting with the devices as he's operating it inside the patient's body. In the medical imaging field, there is much less interaction, as the medical device provides information to the clinician, which is then used to make a diagnosis. In this case there is no feedback from the clinician to the device (assuming that the clinician has enough information to make a proper diagnosis). Since the level of interaction is less, there are less aspects of the research project in which the clinicians need to be involved. For example, when comparing the development of an improved endoscope versus the development of an improved CT-scanner, clinicians should be involved in both cases to determine whether the visual information that is provided by the device meets all criteria. However, in the case of the endoscope, the importance to involve the clinician, to ensure the usability of the new device, seems higher since the use of an endoscope is more complex than the use of a CT-scanner.

The number of interviews held is too low to deduct significant conclusions about the role the healthcare professionals play in the research process. The framework of Shah et al. (2009) distinguishes between the type of user as well as the newness of the technology to the market, but does not take the technological nature of the device and the interaction between the device and its user into account. Additional research is needed to determine whether these factors also influence the user-involvement process.

Even though the analysis of the process of user-involvement described above should be treated with caution, it does indicate that while the involvement of clinicians in the research process seems beneficial, although to a different extent for different subsectors, for each of the medical devices subsectors, the research is moving away from the regular healthcare practices. Again, further research is needed to investigate these claims.

Characterising the medical devices search regime

Since all hypotheses have been tested it is now possible to develop a characterisation of the medical devices' search regime. The three dimensions described by Bonaccorsi (2004; 2007; 2008) form the basis of the search regime. The three dimensions already show that it is impossible to characterise a single search regime across the different subsectors. The subsectors differ with respect to their rate of growth, direction of growth and their level of complementarity.

Dimension	Medical Imaging	Endoscopy	Vasc. and Int. Radiology	Radiotherapy
<i>Rate of growth</i>	Moderate	Low	Low	Low
<i>Direction of growth</i>	Convergent	Divergent	Convergent	Divergent
<i>Cognitive comp.</i>	High	High	High	High
<i>Technical comp.</i>	High	Low	High	High
<i>Institutional comp.</i>	High	High	High	High

Figure 19: Medical devices sector's search regimes

The dynamics that the subsectors have in common are the growing cognitive and institutional complementarity. The increasing complexity and multidisciplinary nature of research calls for an increasing number of researchers to be involved in a project, often from different institutions. The subsectors that are dependent upon imaging technology are also characterised by a high level of technical complementarity, due to the limited time that is available for researcher to use the imaging equipment.

The high level of complementarity in the medical devices' search regime has important policy implications. Since knowledge development is highly dependent on collaboration between multiple researchers, the regime is likely to benefit from highly mobile researchers. If researchers are not free to move within the scientific community, the group of researchers that is needed to perform a research-project can possibly not be brought together. Moreover, if researchers remain within a permanent research-organisation for a long period of time, they are at risk of becoming path dependent.

Multidisciplinary research not only requires the collaboration between researchers, but also between multiple institutions. Institutional complementarity is far more complex to handle than cognitive complementarity (Bonaccorsi, 2007). The best way to manage institutional complementarity is if it is built-in into institutions. The missions and operational goals of an institutions should be flexible and allow research-groups to deviated from them if this is necessary to collaborate with other institutions. Existing institutions already have established mission, routines and missions, which do not provide sufficient space for collaboration and as a result makes them very rigid. It is very difficult to increase institutional flexibility ad-hoc.

The technical complementarity also has implications for policy. The tensions related to the access to imaging equipment arise as a result of the competition between daily clinical practise and research. The provision of imaging equipment that is dedicated to research is a way to reduce this tension. The funds to establish and maintain this imaging infrastructure should be allocated separately, to prevent medical devices researcher to spend a large part of their time lobbying for funding for their equipment.

Even though the subsectors are characterised by different growth patterns, none of the subsectors qualifies as a new science regime, since none of the field is characterised by a high, divergent growth rate. The analysis of the search regimes in the medical devices sector has shown that three different growth patterns can be identified; (1) moderate, convergent growth, (2) slow, convergent growth and (3) slow, divergent growth. According to Bonaccorsi (2007) these growth patterns do not induce tensions that cannot be managed by conventional policy tools.

The search regimes dimensions form, however, only a part of the analysis. If all hypotheses are taken together a more dynamic description of the search regimes can be given.

Level	Hypotheses	Medical Imaging	Endoscopy	Vasc. and Int. Radiology	Radiotherapy
Research	H1: Internationalisation	Confirmed	Confirmed	Confirmed	Confirmed
	H2 Hierarchy	Not confirmed	Not confirmed	Not confirmed	Not confirmed
	H3 Variety Organisations	Not confirmed	Not confirmed	Not confirmed	Not confirmed
	H4 Cog. and Inst. Complementarity	Confirmed	Confirmed	Confirmed	Confirmed
Science	H5 Growth direction	Not confirmed	Confirmed	Not confirmed	Confirmed
	H6 Growth rate	Confirmed	Not confirmed	Not confirmed	Not confirmed
Society	H7 Socio eco. contribution	Europe: Confirmed - United States: Not Confirmed			
	H8 Role of industry	Not confirmed	Not confirmed	Not confirmed	Not confirmed
	H9 Role of users	Not confirmed	Not confirmed	Not confirmed	Not confirmed

Figure 20: Overview of hypotheses

The analysis showed that in Europe the socio-economic contribution of scientific research has gained additional emphasis. This holds to a lesser extent for the United States, where application of knowledge to increase public health is also the objective, but the application of knowledge is seen as a follow-up of basic research and is therefore of less influence on the knowledge development process.

As a result of the increased focus on the application of new knowledge to contributes to society, one would expect that the industry and hospitals would become more important in the knowledge development process as a representative of the, respectively, economic and social contribution of research. This is, however, not confirmed in the analysis.

The search regimes can be characterised by increasing interaction in networks of a growing number of researchers and institutions. Moreover, the search regime is becoming increasingly international as more countries are deploying research activities, publications shares are dispersing over North America, Europe and Asia and an increasing number of publications have international co-authors. However, although networks are forming, the academic institutions still form the core of these networks. Research seems to be concentrating in the academic sphere while other interaction with other institutional spheres is still limited and grows at a very marginal rate.

While the driving forces of institutional changes are recognised, the effect on the actual carrying out of research could not empirically be confirmed. Only the future can tell whether this is because the transition has just started and it will take some time before the new knowledge development process will establish itself or whether the current 'way of doing research' is still aligned to the features of the institutional environment.

Since policy makers are attempting to increase the socio-economic contribution of research, the fact that academia are not increasingly interacting with the industry and the end-users is undesirable. To increase the overlap between academia and the industry policy makers should integrate science, technology and industry policy. The addition of socio-economic criteria in research programmes is a start of this process, but this could be extended by making stronger demands in terms of its economic and social contribution and by increasing the importance of these criteria in the selection process.

Alternatively policy makers could use demand-side policy. Instead of actively trying to bring the different institutional environments together, policy makers could try to find ways to steer the demand for medical devices in such a way that industry and academia are forced to collaborate and involve users in this process. This is however

difficult to do. First, this requires a high level of institutional flexibility, which is not yet present in the sector. Second, the relation between demand and supply is special in the medical industry due to the fact that patients do not directly pay for the health care that they use. Since the insurers are faced with the costs of healthcare, the patients' demand for better healthcare is very high. One could therefore try to influence the demand of healthcare professionals, but these are constrained in their use of medical devices by insurers, since they can only use devices that are covered by the insurers. The insurers therefore hold a crucial position in the innovation process, but these are difficult to influence by means of policy. Demand oriented policy is therefore difficult to use in the medical devices sector.

7. Discussion

Alignment of IMDI

Now that the medical devices' search regime and corresponding policy implication have been defined, it is possible to evaluate the alignment of the IMDI to the search regime.

The IMDI has a very strong socio-economic focus as it states that “by consolidating strengths and funding for research and development in the area of medical devices, the efforts of IMDI.nl are expected to make a substantial contribution to resolving the urgent problems facing the future of healthcare in the Netherlands [...] [and] will also reinforce the Dutch economy, particularly within the medical technology sector” (NWO, 2010b, p.10). To realise this socio-economic contribution, researchers from various fields need to be brought together. Often these researchers come from different institutions from different institutional environments, such as (academic) hospitals, (technical) universities and companies. The field is therefore characterised by a high level of cognitive and institutional complementarity.

The realisation of multidisciplinary research is one of the objectives of the IMDI. The initiative aims to effect a fundamental transition from a linear development chain towards a trilateral development circle, in which researchers, companies and users collaborate in order to develop innovative medical devices. Moreover, the IMDI attempts to realise such collaboration on a larger scale than is customary for academic research and development in the area of medical devices.

As such, the IMDI recognises the importance of institutional complementarity and aims to increase the synergy between various institutional environments, but it does not explicitly specify the measures that will be taken to this end. These specific measures are also not specified within innovation literature, but Bonaccorsi (2007) has pointed out that institutional complementarity can be best built-in as institutions are created. Since IMDI attempts to increase the complementarity between institutions that have been in existence for many years, aligning the goals and culture of these institutions can be expected to be problematic.

Nevertheless, the aim of the IMDI to provide a funding to stimulate multidisciplinary medical devices research is a very important contribution. As Martin (2010) noted, funding for research is still often structured around traditional disciplines and as a result multidisciplinary research projects have difficulties acquiring funding. This was also expressed in the interviews, in which the healthcare professionals expressed that they were very content with the fact that the need for funds for multidisciplinary medical research are finally recognised.

There are, however, two downsides to the funding plans of the IMDI. The first is that the investment by IMDI were designed to be funded from the FES funds, but the new Dutch cabinet decided nullify these funds, leaving IMDI with a gap in its budget (VNSU, 2010).

The second downside is that the investment of IMDI itself is less than half of the total budget that initiative aims to acquire. The majority of the investments have to be attracted from conventional funding agencies. As such, the success of the initiative is dependent of the amount of funding that is available for multidisciplinary research projects. Creating excellent multidisciplinary research centres will not increase the attracted funding when the funding agencies are still discipline-based.

The IMDI also recognises, although less explicitly, the cognitive complementarity in the sector. The initiative states that “many fundamental and applied researchers from a variety of disciplines are working with physicians and technologists as well as with the producers and users of medical devices” (NWO, 2010b, p.8). However, the

remainder of the document does not relate to the cooperation between researchers, but only discusses the interaction between institutions. Naturally, increasing the interaction and synergy on the institutional level is likely to increase the synergy at the interaction at the level of the researcher, but increased interaction could also have negative effects.

Although it is difficult to determine how rigid the CoREs are, the formation of these centres appears to stimulate path dependency as the cooperation is designed to take place between a fixed set of institutions for a longer period of time. Especially when the researchers maintain their positions throughout this period path dependency might be encouraged. For the developers of IMDI it is therefore important to monitor whether researchers are constrained in their activities by past projects.

Interestingly, while the IMDI explicitly describes issues related to the institutional and cognitive complementarity, it does not discuss the technical complementarity. The interviews confirmed the notion that, with the exception of the endoscopy sector, the access to research infrastructure is a crucial point in the knowledge development process. Even though the institutes involved in the CoREs are leading in the Netherlands and often have dedicated equipment or other arrangements that provide them access to the required equipment, it is surprising that no attention is given to this topic. Especially since the one of the projects of the European Strategy Forum on Research Infrastructures' (ESFRI) projects is focused on infrastructure for biomedical imaging research (EuroBioImaging) (EC, 2008c).

A second interesting finding is that the subsectors of the medical devices sector are characterised by different growth patterns. Despite these differences NWO tries to stimulate all subsectors through the IMDI. Because of the different search regimes that exist within the medical devices sector, more disaggregated policy interventions could be advocated.

However, this can also be considered as a limitation of the search regimes concept. Since scientific disciplines can be seen as hierarchical layers, the dynamics of a search regime can be characterised at various layers. While a certain search regime might be dominant in a particular field, the search regime that are at a lower hierarchical layer, the subfields, do not necessarily exhibit the same characteristics. The medical devices case is this thesis illustrates this. Even if the subsector in this case would be distinguished into sub-subsectors various search regimes could be expected to be found. For example, if medical imaging would be split up as to the different modalities that are used, differences are expected to be found between regimes guiding CT, MRI and PET research. The modalities have distinct features which are likely to influence the research regime. For one, the need for radioactive material for PET imaging will influence the research in a way that CT and MRI related research is not.

Bonaccorsi (2004) explicitly states that it was never his goal to develop a taxonomy of scientific disciplines and that the concept should be used at an appropriate abstract level, but one can then question what the use of the concept is for policymakers. While advocating disaggregated measures for different scientific fields, the concept can only be used at a high level of aggregation. As a result of this contradiction the use of the concept to develop science policy is limited.

Implementing change

As Hessels et al. (2009) and Swan et al. (2010) have noted, changing the dynamics of the knowledge production process is a complex process, as competing practises and routines within a field can counter the effects imposed by policy measures. Since the IMDI attempts to increase the interaction between different institutional environments, the initiative has to integrate research policy with technology and industry policy. The initiative aims to do so by focusing the research on solutions to problems in healthcare, thereby stimulating technological development, and tries to stimulate economic development by selecting areas within the medical devices sector

in which the Netherlands has a leading industrial position, which should expand through this initiative.

While the initiative aims to deploy third mission activities, the criteria that were used to select the CoREs seem to be fairly traditional. The introduction of the IMDI states that “the formation of the eight IMDI-CoREs is the result of interaction between top-down and bottom-up processes that are guided by [...] proven research excellence; proven ability to create productive relations with healthcare institutions and enterprises; a clear vision regarding how future healthcare demands can be supported by new generations of medical devices; and the guarantee that the development of such devices is feasible within each CoRE” (NWO, 2010b, p.12). However, the final selection of the CoREs was based on “the quality and focus of research and development, as well as the potential to achieve international recognition as a leading centre of research and development in the area of medical devices” (NWO, 2010b, p.29). While in the former the criteria are aligned with the third mission activities, the incentive for these activities is much less present in the latter. Especially the international reputation in research and development seems to have prevailed over the link with the industry.

The lack of socio-economic incentive was also expressed during an interview with a chairman of one of the innovation clusters, which expressed that the selection of the CoREs was dominated by the scientific quality of the proposal and the magnitude of contribution to the problems in healthcare was underrepresented.

This is even more interesting in the light that the IMDI states that users will play an active role in the research and development process. According to the theory on user-involvement this is a very desirable move, but in what way the users-involvement process is coordinated in the IMDI is not described. As a result the extent to which the contribution to healthcare problems was represented in the selection of the CoREs could not be determined.

The IMDI is not the only Dutch initiative related to medical devices. The developers of IMDI recognise the need for alignment of policy measures since they have checked that their initiative does not conflict with the other initiatives that are developed, such as the priority medical devices report of the World Health Organisation (WHO, 2010) and the research agenda on medical devices currently being developed by the Advisory Council on Health Research (NWO, 2010b). The IMDI CoREs are expected to be able to adopt the recommendation that result from these additional initiatives.

Role of institutions

Even though the measures in IMDI are in some cases not very specific, it seems to take most of the aspects that are important when attempting to change the research infrastructure into account. However, the initiative fails to take the role of scientific institutions into account. The IMDI states that while “the quality of research and development activities in Europe is high” the development process from basic research to demand driven-products fails because the research infrastructure is excessively fragmented (NWO, 2010b, p.15). Bonaccorsi (2007) has raised the question whether the outcome of science-policy depends on the policies themselves, or rather on “deeper factors linked to institutional long-term settings” (p.311). The aim of IMDI to overcome the knowledge paradox and improve the rate of socio-economic return on investments in research by enhancing the scale and focus of the research infrastructure seems to ignore the role of institutions features. This is an important flaw of the initiative as Bonaccorsi (2007) argues that the impact of policy measures may be neutralised by institutional features.

Bonaccorsi (2007) gives several examples of mission-oriented programmes that addressed the need to establish new complementarities between different institutional environments. “These has great value in creating the human capital infrastructure, but in general failed to change the depth microstructure of research, that is, professional roles, incentive schedules, current scientific practices, patterns of interaction among

actors and disciplines” (p.311). To achieve greater success new types of world-class research institutions should be created or redesigned, in which the complementarities are institutionally embedded.

Validity of results

Although the results of this thesis are produced using a framework that is strongly embedded within innovation literature, it is subject to some limitations. The first limitation is that the main focus of this thesis has been on academic knowledge development. R&D activities of companies are of a different nature and often not visible in scientific publications, since companies do not publish their new knowledge in scientific journals but instead try to protect it through IPR or by relying on secrecy. As a result the role of the industry might be underrepresented in this thesis.

The second limitation of this thesis is that scientific journals are only one of many carriers of new knowledge. Even though scientific journals are the most important carrier (Lundberg, 2006), other media, such as books, letters and conferences, are not included, but might also be used to present new knowledge to the scientific community.

This limitation becomes even more important in the light of the Mode 2 concept of knowledge production, which is increasingly focused on applied knowledge. Applied knowledge is more likely to be presented in technological artefacts or at conferences than in scientific publications. As a result the application of knowledge might be underrepresented in this thesis as well.

Finally the analysis of the direction of growth is subject to limitation. The analysis of the direction of growth is based on only one indicator, the convergence of keywords, while according to Hacking (1992 in Bonaccorsi, 2008) research can be characterised with respect to as many as 15 dimensions, among which are background knowledge, theory, specific sub-hypotheses, equipment and data source. In this light the keyword analysis that was performed seems rather simplistic and can be expected not to capture all these dimensions. Within the timeframe of this research it was not possible to examine all dimensions, but additional, more detailed research to verify the claims of this thesis seems useful.

8. Conclusions

The aim of this thesis was to characterise the knowledge development process for the medical devices sector using the search regime concept. This analysis was performed against the background of the changes in the knowledge development process described by various scholars in the field of innovation. The analysis pointed out that the developments that have been described in innovation have an empirically recognizable counterpart. Following the search regime concept of Bonaccorsi (2004; 2007; 2008) and extending it with three analytical levels as described by Heimeriks and Leydersdorff (2010) a framework was developed to analyse a field-specific knowledge development process. Through bibliometric analysis of this framework several of changes in the knowledge development process as described in innovation literature could be confirmed.

In Europe, there is a clear increase in the importance of the socio-economic contribution of research as a selection criterion. While research projects often still expand the basic knowledge in the field, an idea of the future applicability is required to acquire funding. The IMDI is a clear example of this trend.

Even though the focus of research has shifted towards applied knowledge, the analysis did not confirm increased involvement of industry in the process. However, the organisation of research is changing. Institutions do not operate in isolation, but knowledge development is taking a network-like shape. Moreover, these networks are increasingly international. Still, the academic institutions are in the centre of these networks and the increasing collaboration mainly takes place between these organisations. Companies and hospitals seem to be located more at the outside of these networks. Again the IMDI confirms this notion as universities and academic hospitals form the core of the CoREs while the position of hospitals and companies is less pronounced.

The growth pattern of the medical devices sector was also analysed. The growth patterns are relatively stable as the growth is either convergent, or divergent at a low growth rate. These growth patterns can be governed using traditional measures. The fact that the medical devices sectors are characterised by a high level of complementarity does have implications for policy. Especially the institutional complementarity is important to take into account to facilitate the necessary interaction between different institutional environments.

In addition this thesis confirmed the need for disaggregated measures as it confirmed the notion that different fields are characterised by different dynamics. Also, it confirmed the notion of Bonaccorsi (2007) that the role of the impact of the underlying institutional layer is often overlooked in policy design. The IMDI served as an example, as it aims to overcome the European paradox by improving the interaction between different institutional environments, but does not change the institutional features. Policy-makers tend to overlook the fact that the institutional features need to be matched to the knowledge dynamics in a scientific field.

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Appendix

Appendix A: Selected journals

<i>(Sub)Field</i>	<i>Journal</i>	<i>Journal Country</i>	<i>Impact Factor</i>	<i>Number of articles ('90-'09)</i>
Medical Imaging	IEEE Transactions on Medical Imaging	United States	3,540	2.152
	Radiology	United States	6,341	8.612
	European Radiology	Germany	3,589	4.332
	European Journal of Radiology	Ireland	2,645	2.635
	<u>Total</u>			<u>17.731</u>
Endoscopy	Endoscopy	Germany	5,545	2.575
	Gastrointestinal Endoscopy	United States	6,713	3.866
	Surgical Endoscopy and Other Interventional Techniques	United States	3,304	4.423
	Minimally Invasive Therapy & Allied Technologies	Norway	1,330	896
	Arthroscopy-The Journal of Arthroscopic and Related Surgery	United States	2,608	2.841
<u>Total</u>			<u>14.601</u>	
Vascular and Interventional Radiology	Catheterization and Cardiovascular Interventions	United States	2,363	2.696
	Cardiovascular and Interventional Radiology	United States	1,949	2.077
	Journal of Vascular and Interventional Radiology	United States	1,805	2.620
<u>Total</u>			<u>7.393</u>	
Radiotherapy	International Journal of Radiation Oncology Biology Physics	United States	4,592	6.859
	Radiotherapy and Oncology	Netherlands	4,343	2.788
<u>Total</u>			<u>9.647</u>	
Nanotechnology	Nano Letters	United States	11,520	4.606
	Nanotechnology	England	3,137	6.272
<u>Total</u>			<u>10.878</u>	
Astronomy	Astronomical Journal	United States	4,481	8.729
	Solar Physics	Netherlands	3,628	3.283
<u>Total</u>			<u>12.012</u>	

Appendix B: Number of articles in the publication-set

	Total	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Medical Imaging																					
EUROPEAN JOURNAL OF RADIOLOGY	2635	100	94	128	74	71	99	85	79	115	106	111	121	124	115	124	214	216	201	195	263
EUROPEAN RADIOLOGY	4332	0	0	0	0	0	81	137	231	230	252	297	343	351	369	333	334	326	348	354	346
IEEE TRANSACTIONS ON MEDICAL IMAGING	2152	48	64	65	91	70	70	80	84	99	97	112	122	132	128	132	142	137	141	156	182
RADIOLOGY	8612	506	596	566	519	527	437	428	385	396	435	437	391	426	392	384	457	346	292	342	350
Total	17731	654	754	759	684	668	687	730	779	840	890	957	977	1033	1004	973	1147	1025	982	1047	1141
Endoscopy																					
ARTHROSCOPY	2841			62	94	84	86	121	115	167	140	127	148	136	198	194	287	270	258	200	154
ENDOSCOPY	2555	75	69	93	69	65	79	172	197	193	136	193	189	114	103	111	134	166	154	126	117
GASTROINTESTINAL ENDOSCOPY	3866	123	128	133	112	94	126	236	161	197	285	297	231	248	238	206	171	183	219	217	261
MINIMALLY INVASIVE THERAPY & ALLIED TECHNOLOGIES	896		10	48	65	45	51	111	87	89	67	67	30	42	38	34	37	28	24	35	38
SURGICAL ENDOSCOPY AND OTHER INTERVENTIONAL TECHNIQUES	4423	58	62	60	92	129	127	188	194	189	282	211	236	269	419	305	235	310	343	321	393
Total	14581	256	269	396	432	417	469	828	754	835	910	895	834	809	996	850	864	957	998	899	963
Vascular and Interventional Radiology																					
CARDIOVASCULAR AND INTERVENTIONAL RADIOLOGY	2057	62	59	53	58	33	40	87	88	97	103	98	77	89	105	108	139	196	209	175	181
CATHETERIZATION AND CARDIOVASCULAR INTERVENTIONS	2696	0	0	0	0	0	0	0	0	0	223	244	231	233	241	238	224	262	272	265	263
JOURNAL OF VASCULAR AND INTERVENTIONAL RADIOLOGY	2620	0	0	0	0	103	112	133	135	131	172	172	164	162	164	152	183	208	185	244	200
Total	7373	62	59	53	58	136	152	220	223	228	498	514	472	484	510	498	546	666	666	684	644
Radiotherapy																					
INTERNATIONAL JOURNAL OF RADIATION ONCOLOGY BIOLOGY PHYSICS	6843	229	191	268	254	227	245	377	321	311	327	371	335	381	331	354	403	440	435	522	521
RADIOTHERAPY AND ONCOLOGY	2779	88	111	92	97	109	105	130	136	149	138	129	146	115	150	143	159	164	164	184	270
Total	9622	317	302	360	351	336	350	507	457	460	465	500	481	496	481	497	562	604	599	706	791
Nanotechnology																					
NANO LETTERS	4606	0	0	0	0	0	0	0	0	0	0	0	151	294	347	459	489	555	689	818	804
NANOTECHNOLOGY	6200	0	0	0	0	14	24	41	29	17	55	16	14	102	182	338	531	1003	1170	1392	1276
Total	10806	0	0	0	0	14	24	41	29	17	55	16	165	396	529	797	1020	1558	1859	2210	2076
Astronomy																					
ASTRONOMICAL JOURNAL	8729	350	367	353	408	402	479	448	435	482	465	488	516	482	461	499	429	456	434	391	364
SOLAR PHYSICS	3272	166	138	146	157	144	158	171	166	223	195	187	192	177	167	125	132	176	137	140	175
Total	13498	516	505	499	565	546	637	619	601	705	660	675	708	659	718	755	708	835	833	850	884

Appendix C: List of interviewees

Round 1

Name: Sytze Brandenburg
Organisation: KVI
Date: 21-04-2010

Name: Luc de Witte
Organisation: Hogeschool Zuyd
Date: 27-04-2010

Name: Els Koffeman
Organisation: NIKHEF
Date: 28-04-2010

Round 2

Name: Marcel van Herk
Organisation: NKI-AVL
Date: 15-07-2010

Name: Matthijs Oudkerk
Organisation: UMC Groningen
Date: 11-08-2010

Name: Jenny Dankelman
Organisation: TU Delft
Date: 13-08-2010

Name: Vinod Subramaniam
Organisation: Universiteit Twente
Date: 19-08-2010

Name: Alfred Schouten
Organisation: TU Delft
Date: 20-08-2010

Name: Willem Mali
Organisation: UMC Utrecht
Date: 30-08-2010

Name: Frederique Barkhof
Organisation: VUMC
Date: 02-09-2010

Name: Mark van Buchem
Organisation: LUMC
Date: 06-09-2010

Name: Max Viergever
Organisation: Universiteit Utrecht
Date: 14-09-2010

Appendix D: Search strings used to code the affiliated institutions

Academic Hospitals

```
ACAD_HOSP = 1 IF (CHAR.INDEX(cs,"UNIV") > 0 AND CHAR.INDEX(cs,"HOSP") > 0) OR (CHAR.INDEX(cs,"ACAD") > 0 AND CHAR.INDEX(cs,"HOSP") > 0) OR (CHAR.INDEX(cs,"MED") > 0 AND CHAR.INDEX(cs,"SCH") > 0) OR (CHAR.INDEX(cs,"MED") > 0 AND CHAR.INDEX(cs,"UNIV") > 0) OR (CHAR.INDEX(cs,"MED") > 0 AND CHAR.INDEX(cs,"COLL") > 0) OR (CHAR.INDEX(cs,"OSPED") > 0 AND CHAR.INDEX(cs,"UNIV") > 0) OR CHAR.INDEX(cs,"CHU") > 0 OR CHAR.INDEX(cs,"CHRU") > 0
```

Universities

```
(CHAR.INDEX(cs,"UNIV") > 0 OR CHAR.INDEX(cs,"ACAD") > 0 OR CHAR.INDEX(cs,"COLL") > 0 OR CHAR.INDEX(cs,"ECOLE") > 0) AND ACAD_HOSP = 0
```

Academic Institutions

```
ACAD_INST = 1 IF (CHAR.INDEX(cs,"UNIV") > 0 OR CHAR.INDEX(cs,"ACAD") > 0 OR CHAR.INDEX(cs,"COLL") > 0 OR CHAR.INDEX(cs,"ECOLE") > 0) AND ACAD_HOSP = 0
```

Hospitals

```
HOSP = 1 IF (CHAR.INDEX(cs,"HOSP") > 0 OR CHAR.INDEX(cs,"MED CTR") > 0 OR CHAR.INDEX(cs,"AZIENDA") > 0 OR CHAR.INDEX(cs,"ZIEKENHUIS") > 0 OR CHAR.INDEX(cs,"KRANKENHAUS") > 0 OR CHAR.INDEX(cs,"OSPED") > 0 OR CHAR.INDEX(cs,"CLIN") > 0 OR CHAR.INDEX(cs,"INFIRM") > 0 OR CHAR.INDEX(cs,"HOP") > 0) AND ACAD_HOSP = 0 AND UNIV = 0
```

Research Institutes

```
RES_INT = 1 IF CHAR.INDEX(cs,"INST") > 0 AND ACAD_HOSP = 0 AND UNIV = 0 AND HOSP = 0
```

Companies

```
COMP = 1 IF (CHAR.INDEX(cs,"CORP") > 0 OR CHAR.INDEX(cs,"INC") > 0 OR CHAR.INDEX(cs,"GMBH") > 0) AND ACAD_HOSP = 0 AND UNIV = 0 AND HOSP = 0 AND INST = 0
```

Appendix E: search strings used to construct second data-set

Medical Imaging

TI=("angiography" OR "arterial portography" OR "arthrography" OR "balloon angioplasty" OR "cholangiography" OR "colonography" OR "computed " OR "tomography" OR "ct" OR "echocardiography" OR "elastography" OR "emission tomography" OR "endosonography" OR "flash mri" OR "fluoroscopy" OR "fmri" OR "intravascular ultrasound" OR "magnetic resonance imag*" OR "magnetic resonance spectroscopy" OR "magnetic-resonance angiography" OR "mammography" OR "medical imag*" OR "mr angiography" OR "mr arthrography" OR "mr imag*" OR "mri" OR "pet" OR "positron emission tomography" OR "radiography" OR "sonography" OR "tomography" OR "ultrasonography" OR "ultrasound" OR "virtual colonoscopy")

Endoscopy

TI=("ercp" OR "colonoscop*" OR "cholecystectomy" OR "endoscopic retrograde cholangiopanc" OR "endoscop*" OR "laparoscop*" OR "arthroscop*" OR "coloscop*" OR "cystoscop*" OR "thoracoscop*" OR "mediastinoscop*" OR "gastrointestinal endoscopy" OR "endosonography" OR "endoscopic ultrasonography" OR "upper gastrointestinal endoscopy" OR "endoscopic sphincterotomy" OR "polypectomy" OR "retrograde cholangiopancreatography" OR "laparoscopic cholecystectomy" OR "injection sclerotherapy" OR "lithotripsy" OR "electrohydraulic lithotripsy" OR "endoscopic ultrasound" OR "open colectomy" OR "laparoscopic surgery" OR "chromoendoscopy")

Vascular and Interventional Radiology

TI=("angioplasty" OR "balloon angioplasty" OR "embolization" OR "angiography" OR "intravascular ultrasound" OR "cardiac-catheterization" OR "acute myocardial-infarction" OR "percutaneous transluminal angioplas" OR "revascularization" OR "transcatheter closure" OR "stent placement" OR "endarterectomy" OR "coronary angioplasty" OR "trans-luminal angioplasty" OR "intrahepatic portosystemic shunt" OR "arteriography" OR "thrombectomy" OR "catheterization" OR "stent implantation" OR "thrombolytic therapy" OR "endovascular repair" OR "embolotherapy" OR "percutaneous coronary intervention" OR "endovascular treatment" OR "transluminal coronary angioplasty" OR "atherectomy" OR "rotational atherectomy" OR "thermal ablation" OR "chemoembolization" OR "primary angioplasty" OR "radiofrequency ablation")

Radiotherapy

TI=("radiotherapy" OR "radiation-therapy" OR "chemotherapy" OR "brachytherapy" OR "chemoradiotherapy" OR "radiosurgery" OR "tomotherapy" OR "combined modality therapy" OR "radioimmunotherapy" OR "radiochemotherapy")

Nanotechnology

TI=("nanobelts" OR "nanoclusters" OR "nanocomposites" OR "nanocrystal*" OR "nanodevices" OR "nanofabrication" OR "nanofibers" OR "nanoimprint lithography" OR "nanoindentation" OR "nanolithography" OR "nanomaterials" OR "nanoparticle*" OR "nanopores" OR "nanoribbons" OR "nanorods" OR "nanosensors" OR "nanosheets" OR "nanoshells" OR "nanosphere lithography" OR "nanospheres" OR "nanostructures" OR "nanotechnology" OR "nanotubes" OR "nanowire*")

Astronomy

TI=("stars" OR "galaxies" OR "galaxy" OR "globular-clusters" OR "spiral galaxies" OR "standard stars" OR "solar-flares" OR "h-ii regions" OR "nearby galaxies" OR "disk galaxies" OR "quasars" OR "t-tauri stars" OR "main-sequence stars" OR "solar corona" OR "horizontal-branch stars" OR "star-formation" OR "planetary-nebulae" OR "elliptic galaxies" OR "stellar populations" OR "low-mass stars" OR "interstellar-medium" OR "dwarf galaxies" OR "milky-way" OR "metal-poor stars" OR "brown dwarfs" OR "solar neighborhood" OR "young stellar objects" OR "star-clusters" OR "elliptical galaxies" OR "star formation" OR "red giants" OR "wolf-rayet stars" OR "stellar content" OR "seiyfert-galaxies" OR "large-magellanic-cloud" OR "star-formation history" OR "star-forming galaxies")

