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XX cycle

**THE ROLE OF PUBLIC ADMINISTRATION
IN SUPPORTING THE BIOTECH CLUSTERS'
DEVELOPMENT**

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INTRODUCTION

The development of the biotech industry is perceived as an important competitive variable for territories, thanks to the qualified employment and the extensive use of modern technologies. In addition, red biotechnology serves the public interest of health. For these reasons, public administrations have differently tried to enhance the biotech industry, promoting different actions aimed at developing it and exploiting advantages from co-localisation. This public action has been particularly strong in those countries where the biotech sector has been historically less developed. In this respect, Germany is a very significant case-study, due to the systematic policies, that have been carrying out since 1995, when the first public funding programme of biotech regions was launched.

Evaluation of the effects produced by this kind of policies (if any) has usually been conducted only quantitatively, i.e. on the basis of the number of start-up companies, filed patent, products in development, attraction of private funds, effects on qualified occupation rates. Apart from the quantitative effects of this kind of policies, this research aims at investigating also in terms of (i) the relationships between the public administration, the industry and other actors and (ii) the perceived utility of these policies by all actors directly or indirectly involved.

The analysis will be focused on three German biotech clusters: Rhineland Bioregion and Munich Biotech Region, that obtained public funds in the second half of the '90s connected to BioRegio, the first publicly-funded program, and the Berlin-Brandenburg Bioregion, which received funds from the public administration later on, thanks to a another investment program called BioProfile.

The first chapter of this research presents the main theories concerning clustering in general and the role of public administrations in this respect and describes the main features of the environment of biotech firms.

The second chapter describes the methodology and outlines: i) the differences between spontaneous and policy driven clusters, necessary for justifying the choice of the clusters under analysis, ii) the research model and framework of analysis used to

collect and interpret information and data, iii) cluster policies and social interaction as further issues to be taken into account while comparing different clusters.

The third chapter focuses on the German public policy aimed at enhancing the biotech industry and illustrates the results of the analysis on each of the three investigated German clusters.

The fourth chapter discusses the results concerning the German clusters.

The fifth chapter draws the conclusions.

CHAPTER 1 - BACKGROUND

1.1 Public dimension of biotechnology

The present research focuses on biotechnologies applied to health care (Box 1).

Box 1 Definition of biotechnology and its fields of application

Although a unique and shared definition of biotechnology doesn't exist (McKelvey, Rickne e Laage-Hellman, 2004), according to OECD, it can be defined as «*the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services*». Since early 80s, the development and application of biotechnology have widely been enhanced. In this sense, the application fields increased and involved the health care, the food farming, the environment care, defense and aerospace industry. Up to now, the main fields of application are, however, the health care one (e.g. diagnostics, therapeutic, regenerative medicine, vaccines; the so-called 'red' biotechnologies) and the food farming one (the so-called 'green' biotechnologies).

Life-sciences, and among them, biotechnology, are performing an important revolution in many research-based industries. It is worldwide recognized that the related new research approach and new technologies imply a major change in the R&D process (Chiesa and Chiaroni, 2005).

Biotechnology originated from a series of scientific discoveries. The first, in 1953, is the discovery of the double helical structure of DNA by Watson and Crick. In 1957 the discovery of interferon followed (Chiesa, Chiaroni, 2005; Prevezer, 1997). Only in 1976 the first biotech company (Genentech, located in San Francisco Bay Area) was established, and in 1980 the first product (the genetically engineered human insulin)

entered the market. In the meanwhile, the United States, followed by other countries, started to develop and adapt their legal framework to the biotechnology 'revolution'. In the following years, biotech companies were created mainly in the US and then in UK and Germany, the other European countries followed.

The rise of biotechnology represents a real revolution in different fields. Among them, the division of labour within and between firms. The main manifestation has been the development of *dedicated biotechnology firms* (DBFs) that develop new products and processes derived from biotechnology (Nesta, Dibiaggio, 2003), becoming more specialized in particular niches (Orsenigo *et al.*, 2001). Thanks to the strength of their DBFs and, more generally, to the development of a deep market for technology, the US have accumulated and, if compared to Europe, maintain a dominant advantage in innovative activities in biotechnology. The European countries, in fact, lag behind the US in all facets of the commercial development of biotechnology (Allansdottir *et al.*, 2002). The advantage of US with respect to Europe is based on the ability in exploiting knowledge, and, hence, in generating innovations, i.e. putting biotechnology products on the market. This advantage has been significantly enhanced in the US with a more aggressive selection by a powerful venture capital system. In Europe, UK is, in this sense, the most advantaged country, because of the possession of the largest venture capital industry all over Europe. Also in Germany venture capital has grown, but it is considered to be embedded into a public – private partnership model (Cooke, 2001)(Chapter 3).

As to the public dimension of biotechnology, it is evident that most of biotech outputs have a remarkable public dimension. In fact they either are aimed at satisfying public needs (such as environmental or preventive health care) or they are generally perceived as merit goods (pharmaceuticals and medical devices) or they imply important ethical issues (expected results from staminall cells, genetically modified organisms, etc.) (Gambardella *et al.*, 2000; Chiesa and Chiaroni, 2005).

The world wide experience of biotech industry is characterized by the cluster dimension. Chiesa and Chiaroni (2005) show how Europe and US are the leading countries in the development of the biotech sector, while Asia still plays a marginal role.

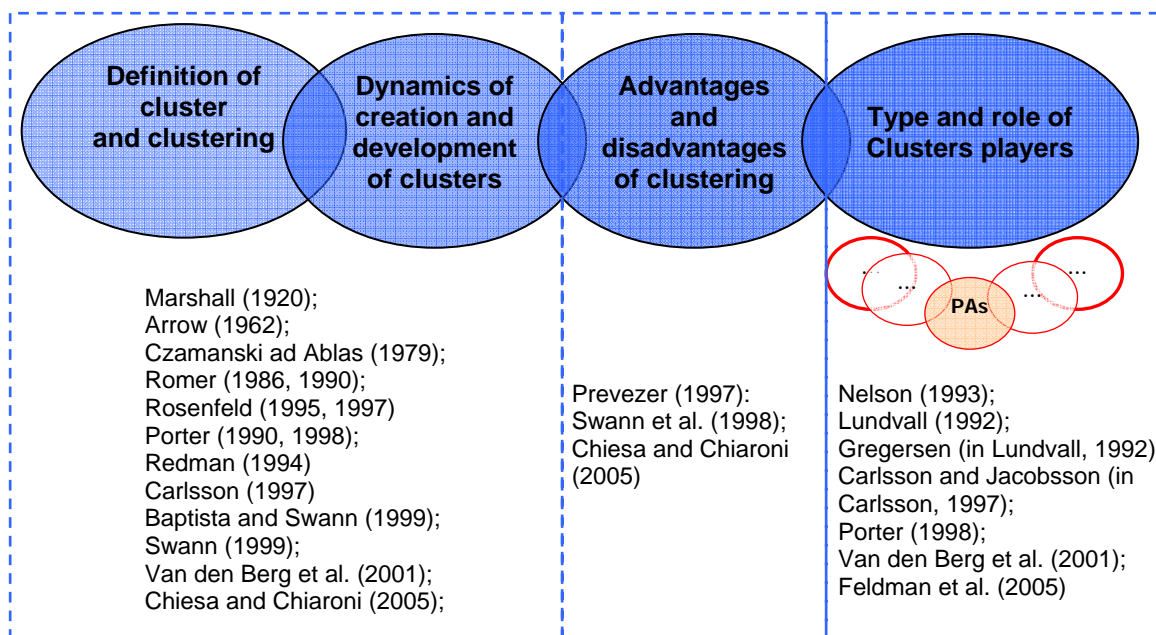
Both Europe and US biotech sectors have developed through a phenomenon of clustering. Hence, as it is widely recognised that advantages derived from clustering (Prevezer, 1997) fit with the biotechnology sector (Chiesa and Chiaroni, 2005), the investigation of public administrations role into the biotech R&D localization process can be performed at cluster levels.

1.2 Theories on cluster and clustering

Literature has contributed to define the concept of cluster and the dynamics of clustering by (Figure 1):

- a. Providing a definition of 'cluster' and of its formation ('clustering') and by analyzing the dynamics of cluster growth;
- b. Highlighting advantages and disadvantages from either creating a cluster and entering an already existing one;
- c. Identifying the type and role of the main clusters' players.

FIGURE 1 – THEORIES ON CLUSTERS AND CLUSTERING



The phenomenon of clustering is not a recent one and, during time, many theories have been developed. Different contributions on the cluster creation process, its definition and the derived advantages and disadvantages have been outlined.

First of all, Marshall (1920) observed the creation of industrial districts by analyzing the externalities of specialized industrial locations. Although he had described the phenomenon and acknowledged industrial districts as an integral feature to industrial organisation, he did not provide any explanation on how and why it started in certain

places and not others (Kuah, 2002). Then, Romer (1986, 1990), building on the earlier works by Marshall (1920) and Arrow (1962), concludes that MAR externalities (Marshall-Arrow-Romer) have positive influences on firms' growth, as the knowledge accumulated by one firm can help the technology to evolve in other firms. They pointed out that the main advantage for industries, that are regionally specialized, rise from the within-cluster diffusion of knowledge.

Czamanski and Ablas (1979) define clusters as *«a group of industries connected by important flows of goods and services»*, without mentioning the geographical concentration process. Apart from Czamanski and Ablas, only Krugman (1998) believes that knowledge flows are not measurable and do not have spatial boundaries, and, hence, geographical concentration and proximity is not perceived as a key feature for clusters development.

Porter (1990) introduces the concept of clusters as *«groups of interconnected firms, suppliers, related industries and specialised institutions in particular fields that are present in particular locations»*. Moreover he has acknowledged that the agglomeration of firms has long been recognized in a wide range of theories, such as agglomeration economies, economic geography, urban and regional economics, national innovation systems, regional science, industrial districts, and social networks (Porter, 1998). According to Porter (1998), clusters affect competition by increasing the productivity of constituent firms or industries, by improving their capacity for innovation and thus for productivity growth, and by stimulating new business formation that support innovation and expands the cluster. According to these advantages, each cluster can improve the national productivity. In particular, according to Porter, the advantages of clustering can be:

- in terms of productivity, due to lower transaction costs, as for the low distance and for the establishment of trust relations among companies, and due to reduced fixed costs as for joint purchasing services or shared infrastructures.
- In terms of innovation, due to the proximity between customers and suppliers that facilitate the transfer of tacit knowledge.
- In terms of new business, due to the circulation of information about market opportunities and potential, barriers and risks.

Also Redman (1994), as Porter did, includes in his definition of 'cluster' the geographic concentration as a key issue: *«A cluster is a pronounced geographic concentration of*

production chains for one product or a range of similar products, as well as linked institutions that influence the competitiveness of these concentrations».

A further outstanding contribution has been provided by researchers that developed the notion of *localized knowledge spillovers* (Breschi and Malerba, 2005). Jaffe et al. (1993) conclude that knowledge spills over locally and takes time to diffuse broadly across distance.

Rosenfeld (1995, 1997) identifies as key features of clusters: i) the geographical concentration, ii) the size, iii) the economic and strategic importance of the cluster, iv) the range of products and services, v) the sharing of inputs and services. Moreover he emphasizes the importance of interconnections and interdependences among intra- and inter- clusters, by defining clusters as: «*A geographically bounded concentration of similar, related or complementary businesses, with active channels for business transactions, communications and dialogue, that share specialized infrastructure, labour markets and services, and that are faced with common opportunities and threats*».

Jacobs and DeMan (1996) take into consideration a wide range of definitions, including features like the geographic concentration, the horizontal and vertical relationships, the shared technologies, the inter- intra- cluster interconnections. According, to their definition, the key feature of a cluster is the presence of a central actor.

According to Baptista and Swann (1999) geographical concentration, indeed, is important for organizational improvement and technological innovation. Concentration and accumulation of knowledge in the cluster attracts increased human capital to the cluster and the information exchange tends to be more informal. Moreover, the result of agglomeration in terms of demand and supply conditions, is better than in case of isolation and it contributes to promote the growth of incumbent firms and the entry of new firms (Kuah, 2002).

Then, Swann et al. (1998) and Prevezer (1997) take into consideration the entry of new firms and the growth of incumbent firms in clusters. They conclude that clustering can lead to a positive feedback loop that induces further growth within the cluster. Their main conclusions are that:

- firms in clusters grow faster than average;
- clusters attract new entries;
- firms in clusters are more innovative (in terms of number of patent and number of innovations);

- the strength of the science base in a biotech cluster has a strong positive effect on new firm formation and growth of firms in that cluster.

However they identify also some potential disadvantages in clustering due to the increased number of competitors in a geographical area that can lead to congestion, by reducing per firm sales, prices, profits and growth.

Carlsson (1997), instead of directly speaking about clusters, uses the concept of 'technological systems', defined as knowledge and competence networks (of firms, R&D infrastructures, educational institutions, and policy-making bodies) supporting the development, diffusion and utilization of technology in established or emerging fields of economic activity.

Chiesa and Chiaroni (2005) define a cluster as *«a geographical concentration of actors in vertical and horizontal relationships, showing a clear tendency of co-operating and sharing their competences, all involved in a localized infrastructure of support»*. According to these authors, *«the definition of cluster itself suggests that clustering can lead to significant advantages for firms»*. In fact, they can gain advantage by: i) the strong local demand, ii) the large supply of manpower; iii) the network of complementary strengths (e.g other firms); iv) the facilitated use and transfer of tacit knowledge.

Summing up, according to the literature contributions, the key features able to define a cluster and that have represented the starting point of the present research are: i) the inter- intra- cluster interconnections; ii) the geographic concentration of firms; iii) the sharing of knowledge, infrastructures and services.

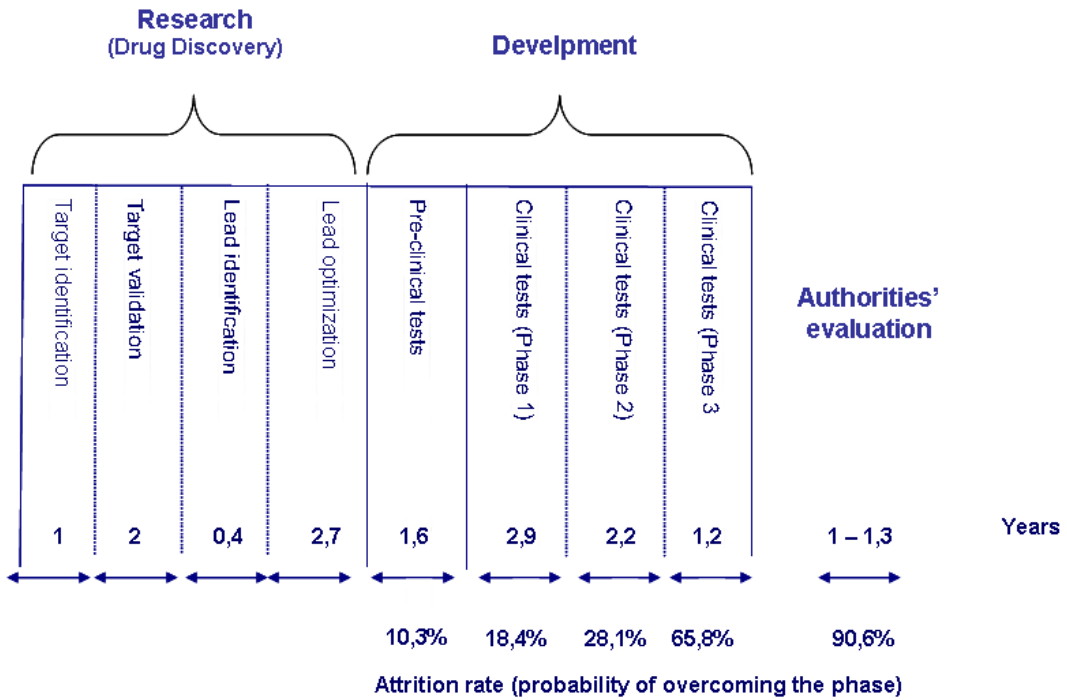
1.3 The environment of biotech firms

Biotech firms were traditionally born by research institutes' spin offs and, afterwards, also by other firms (such as the pharmaceutical ones). Research in biotechnology was born in the academic field as, compared to the pharmaceutical research, it doesn't require wide sizes (Gambardella, 1995). In the traditional pharmaceutical sector, instead, there is a correlation between research productivity and size, due to the presence of scope economies, (knowledge) externalities, and scale economies (Henderson e Cockburn, 1996). The creation of spin offs has been fostered by the opportunity and will to get scientific discoveries, through patents, economic advantages and by the presence of relationships between research institutes and firms.

As the industrial spin offs are concerned, their creation can be mainly motivated by the following issues (Chiesa, 2003): i) single research teams can either want or be fostered by a firm (the originator) to create new enterprises, as their activity was considered either not strategic or when the originated considered economically convenient to sell the discovery rights. The new firm can be either totally autonomous or controlled by the originator; ii) research labs are closed by firms due to mergers, acquisitions or changes of the organizational structure. Also in this case there can be a (financial) support by the originator.

The main strength of biotechnological firms has always been the scientific and research heritage and the capacity to lead the innovative processes. As production and commercialization are concerned, at the beginning of their activity, the biotech firms are characterized by poor performances. During the past, the activities of biotechnological firms consisted in carrying out R&D activity and selling the rights of their discoveries to other firms (typically to traditional pharmaceutical enterprises). Hence, the traditional biotechnological firms placed their activity at an intermediate phase of the product development cycle. The risks of leading to an end the experimentation, of scale production and commercialization (after having registered the product) were suffered by other firms (Figure 2).

Figure 2 - R&D phases in pharmaceutical and biotech firms



Source: Data processing on Chiesa, 2003

1.3.1 The biotech market structure

During time, the specialization and the growth of market have led to vertical integration of biotech firms. In this way, these firms, able to cover the whole product development cycle (e.g., Amgen and Genentech), have become real competitors of pharmaceutical enterprises. Moreover, the growth of biotechnologies has fostered the creation of service firms that do not have in biotechnology their core business. These enterprises provide the biotech firms (whose core business is indeed biotechnology) with products, services and technologies (e.g data base management) necessary to handle the R&D process (Allansdottir et al, 2002; Chiesa, 2003). The main features characterizing the biotechnological firms are hereafter examined.

First, nevertheless some biotech firms are able to cover the whole value chain, their average size is small, as a low rate of enterprises experience a vertical integration and the research in biotechnology doesn't imply significant sizes. According to Ernst&Young report (Ernst&Young, 2006), in 2004 in the European Union the number of biotech firms was 1.664, with 39 employees per firm, against 1.346 firms with 139 employees per firm in United States (Table 1). The difference between the number of the American and European firms is due to the structure of the two: vertically integrated the former, and focused on the R&D activity the latter. Also the historical trend of data concerning the number of firms and employees (Table 1) shows how the biotechnological firms are relatively younger in European Union than in United States. In fact, in the EU during the period 1998-2004 the number of firms increased of the 23% (with a growth of employees of 13%), while in the US the number of firms had a lower increase (3%) with a significant growth of the employees (21%).

TABLE 1 - NUMBER OF BIOTECH FIRMS AND EMPLOYEES

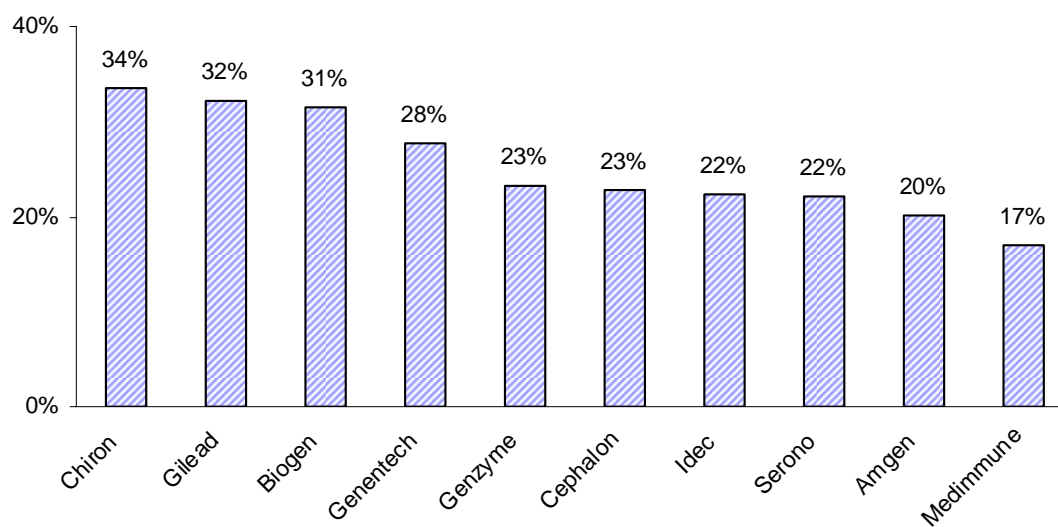
Biotech firms	1998		1999		2000		2001		2002		2003		2004	
	EU	US	EU	US	EU	US	EU	US	EU	US	EU	US	EU	US
Number of firms	1.352	1.311	1.570	1.273	1.734	1.374	1.879	1.457	1.878	1.466	1.861	1.473	1.664	1.346
Number of employees (thousands)	58	155	61	162	67	176	n.a.	191	78	195	82	198	65	188
Average number of employees per firm	43	118	39	127	39	128	n.a.	131	41	133	44	134	39	139

Source: Data processing on Ernst&Young, 2006

A second feature of biotechnological firms is the high rate of R&D investment on turnover. On average, it is between the 20% and the 30% (McKelvey, Rickne and Laage-Hellman, 2004; 2001 data) (Figure 3). In the pharmaceutical sector, on average the investment in R&D on turnover represents the 15% in 2003, 18% in 2002 and 20% in 1998 (Chiesa, 2003).

The reason of this trend can be explained by the low vertical integration of biotech firms with respect to the pharmaceutical ones. In fact their cost structure is focused on research activity. Moreover, while a number of biotech products are still at the clinical stage, the most consolidated pharmaceutical drugs have been already on the market since years.

FIGURE 3 – R&D INVESTMENT ON TURNOVER IN THE MAIN BIOTECH ENTERPRISES



Source: Data processing on McKelvey, Rickne e Laage-Hellman, 2004

The economic structure of the biotech enterprises (i.e. the recent start up of activity and the focus on R&D) has contributed to either a negative profitability or a lower profitability if compared to the pharmaceutical firms.

In 2002 the biggest biotech vertically integrated firm (Amgen) had a loss of 25% on its turnover. Genentech (the second biotech firm in size and the first for year of foundation)

had a profit of only 3% of its turnover. On the other hand, the multinational pharmaceutical enterprises count profits between the 14% and the 38% of their turnover (Chiesa, 2003).

However, it is important to underline how, during the last years, losses have been lowering: while in 1998 the global biotechnology loss represented the 13% of the overall revenues, in 2005 it represented only the 7% (Ernst&Young, 2006).

Then the biotech enterprises have a limited range of products that is highly oriented towards the specialized care. While the pharmaceutical firms produce drugs typically prescribed by both general practitioners and specialized physicians for primary and secondary care.

Table 2 outlines the main mentioned differences between pharmaceutical and biotechnological firms. Moreover the latter are distinguished between product biotech and drug agent biotech firms that are differently positioned along the value chain.

TABLE 2 – COMPARISON BETWEEN PHARMACEUTICAL AND BIOTECH FIRMS

ISSUE	MULTINATIONAL PHARMACEUTICAL FIRMS	PRODUCT BIOTECH*	DRUG AGENT BIOTECH**
Research	Chemical synthesis	Biotech process	Biotech process
Positioning along the value chain	Whole value chain (few products before Phase III)	Whole value chain	R&D up to Phase III
Type of products	Primary and secondary care, over the counter drugs	Secondary care	-
Profitability	Positive/High	Negative/low	Negative
Financial support	Middle risk taker	High risk taker (venture capital)	High risk taker (venture capital)

* Firms whose business consists of discovery, development, production, and commercialization of therapeutic products.

** Firms that develop active principles for new drugs and usually out license the exploitation rights of their products (Chiesa and Chiaroni, 2005).

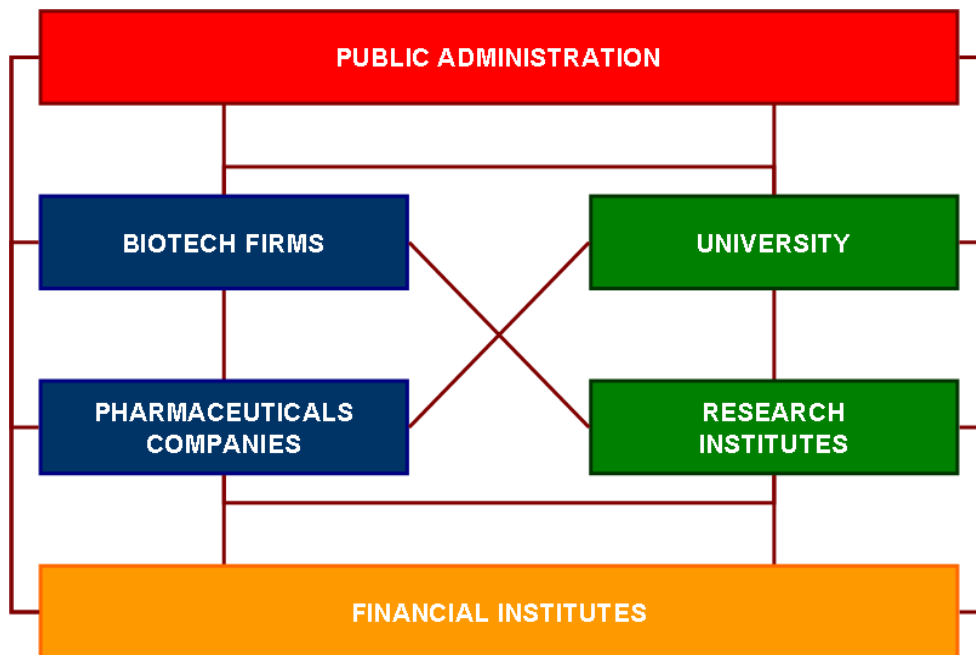
1.3.2 The relationships system

The biotech firms are embedded in a complex web of relationships due to:

- the complexity, cost and length of R&D;
- the public dimension of its products;
- the related ethical issues;
- the high technological-scientific value of the production activity.

According to these considerations a number of relationships need to be taken into account (Figure 4), i.e. those between biotech firms and other (biotech and pharmaceutical) enterprises, the public administration, centers for research, universities, financial institutes.

FIGURE 4 - RELATIONSHIPS SYSTEM AND BIOTECH FIRMS' ENVIRONMENT



a) Relationships between biotechnological firms and research institutes/ universities: the innovation system

The 'innovation system' is made of the whole actors (public administration, university, centers for research, and firms) that cooperate in order to enhance innovation and competitiveness of a territorial area.

The ability of firms to produce innovation is, first of all, influenced by the presence of external sources of knowledge. There is clear empirical evidence concerning the correlation between the creation of new biotech firms and specialization of universities and public centers for research. In other words, the presence of external sources of knowledge (universities and centers for research) and, hence, the growth and location of intellectual human capital, contributes to the growth and location of industry itself (Zucker, Darby e Brewer, 1998).

A second issue is the promotion of the scientific knowledge, through *ad hoc* training programs. In Anglo-Saxon countries there is a higher scientific content of medical university programs. While, in other countries, the clinical (and in particular the biomedical) research has been less integrated with teaching. In fact, within medical schools in Continental Europe, medical research has had a marginal role if compared to patient care (Gambardella, Orsenigo e Pammolli, 2001).

However the presence of external sources of knowledge and the promotion of the scientific knowledge are not enough to grant the firms' development. It is necessary to foster the interaction between research institutes and enterprises.

In European countries (with the exception of United Kingdom) basic research has historically been developed in universities and in highly specialized public institutes with very few interactions with the industrial sphere. This is partly due to the presence of closed employment system, structured and incremental career paths (not based on a merit system), and interactions based on hierarchical relationships. Most of the agreements on research, co-projects and technology/knowledge transfer are mainly widespread in United States.

The relationship between firms and universities some critiques has been criticized. Dasgupta and Davis (1994) have highlighted that this kind of relationship can raise conflicts of interest, undermine transparency, and reduce the innovation rate. In fact, the firms could not make public the results as unfavorable to their interests, and, hence, compromise the diffusion of knowledge through scientific publication. Hence, it is

important to identify policies and manage relationships in a way that could allow achieving both a higher collaboration and independency of the research institutes from enterprises.

The interaction between firms and research institutes/universities can be facilitated by career paths and technology transfer able to support the translation of innovation into marketable products/services and the cooperation among actors: e.g. incubators and scientific parks that make the firms able to exploit the co-localization with scientific institutes and universities.

b) Relationship between biotech firms and pharmaceutical enterprises

The growth of biotechnology and the changes that have characterized the pharmaceutical sector are creating a continuous evolution of the relationships between biotech firms and pharmaceutical enterprises. The former are undergoing a downstream integration process. The vertical integration rate of the latter is decreasing above all as the R&D activity is concerned. At the beginning, the multinational pharmaceutical enterprises were active in all the value chain, thanks to the distinctive competences on pharmaceutical chemistry, the presence of a lot of centers for production and a capillary commercial net. During time, the placement in the value chain has slowly changed. In particular, as the R&D activity is concerned, changes have been encouraged by an increase of costs, the development of new technologies and the application of new research methodologies connected to the advent of biotechnologies. The latter have, in this way, contributed to weaken the distinctive competences of the traditional enterprises. This evolution has generated a process of upstream de-integration, through the creation of industrial spin-offs (see above): the new firms focused then their activity on biotechnologies. In some cases the pharmaceutical originators have not had any further contact with the new firms; in other circumstances the former have supported the latter, even from the financial point of view; finally, in other cases the former have maintained links (for instance due to royalties) with the latter.

The main relationships between biotechnological firms and pharmaceutical enterprises consist of:

- collaboration through research agreements;

- Licensing-in, that is the pharmaceutical firms purchase the rights of biotech research results and translate them into marketable products. This kind of relationship is typical in case of *Drug Agent Biotechs*, i.e. companies whose core business is to develop active agents for new drugs and usually out license the exploitation of rights (Chiesa and Chiaroni, 2005);
- Acquisition of biotech enterprises. Those acquisitions reflect the necessity of internalizing new competences related to biotechnological processes and widening the range of products.

c) Relationship between biotechnological firms and financial institutes

The relationships between biotechnological firms and financial institutes are influenced by the importance and the degree of risk related to investments into these firms.

In fact, biotechnological firms, as the pharmaceutical ones do, require many years of R&D activity before being able to produce any economic value. Hence, these firms are compelled to gain external funding for a long time period (Chiesa, 2003).

The financial supporters of biotechnological activities can be defined as risk taker, as the profitability of biotech firms is normally negative in the short-middle term. The negative trend of profitability can be mainly explained by the fact that (Chiesa and Chiaroni, 2005):

- biotechnology is applied for treating complex diseases that, being less known than the traditional ones, can easily lead to high failure rates and long clinical trials;
- the main technologies are in the development phase, that means, far away from the maturity and marketable phase that take a long run (see above).

The financial institutes that interact with the biotechnological firms are the venture capital companies, the business angels¹ and the traditional lending institutes (banks and bank foundations).

A key role is played by the *venture capitalists*, i.e. fund managers who invest into private companies, above all in the American context (Allansdottir et al., 2002). The venture capital companies intervene immediately after the establishment of a new biotechnological firm. Their purpose is not to own and control the firm but to re-sell the

¹ Business angels are persons interested in investing into private enterprises. Normally they invest between 25.000 and 100.000 dollar in each firm and often finance more than one enterprise at the same time (Chiesa, 2003).

related shares at a higher price than the one they paid for, through either the quotation on financial markets or the transfer to other enterprises.

Business angels are persons interested in investing into private enterprises. Their interactions with biotechnological firms are quite limited.

In Europe and if compared to venture capital companies and business angels, the traditional lending institutes and the public institutes have had have played a major role (Allansdottir et al., 2002).

d) Public administrations and biotech clusters

According to the role played by public administrations in and for biotechnological clusters the literature provides a number of contributions.

Lundvall (1992) analyses 'national systems of innovation' located within or rooted inside the borders of a national state, which interact in the production, diffusion, and use of new, and economically useful, knowledge. According to Gregersen (in Lundvall, 1992), public administrations can play an important role as stabilizing and stimulating pacer, when the private sector is confronted with unstable environments. In practice, public administrations are required to maintain and renew learning processes (in terms of technology transfer, education, research etc.), and to provide financial support.

Afterwards, Nelson (1993), through the comparative analysis of national innovation systems defines 'national innovation systems' as national systems of institutions supporting technical innovation in one field. He performs a comparative analysis of different national innovation systems and concludes that, across these examples, public administrations can assume different roles, by providing funds for university research or industrial R&D, by increasing financial institutions, establishing their analogue to the 'venture capital' market, with the goal of fostering industrial innovation.

Carlsson and Jacobsson (in Carlsson, 1997) draw out the role public administrations in technological systems. According to their analysis, public administrations can intervene into the educational system and university R&D, they can increase the degree of connectivity of the system's actors, and they can be useful in broadening and diversifying the capital market.

Porter (1998) states that public administration is required to facilitate clusters' development and upgrading. Through its diamond² (Porter, 1998), the author highlights the role of public administrations in cluster upgrading, i.e.:

- to convene forums of firms, institutions, and appropriate government agencies;
- to collect and compile cluster-specific information;
- to set educational policies encouraging public universities and schools to respond to local cluster needs;
- to clarify and simplify regulations;
- to improve the sophistication of local demand for cluster products and services.

Van den Berg *et al.* (2001) analyze the development of clusters (or, as they are also defined, localized networks) in European cities under the perspective of urban economic development. Clusters are characterized by informal exchange of information, knowledge and creative ideas. Their study concludes that public-private co-operation is a prerequisite for the development of effective and efficient cluster policies. According to their results, this kind of co-operation (defined by the authors as 'interactive policy-making') is considered indispensable for facilitating the localization and the success of the cluster activity.

Another contribution from the literature concerning the role of public administrations within clusters, comes from Feldman *et al.* (2005). The authors state that in a well-functioning entrepreneurial system, each component (i.e. entrepreneurs, government policy and local environment) reinforces the other to promote firms, industry and cluster development.

Allansdottir *et al.* (2002) mention, as active role of public administration,:

- i) the provision of public funding due to the costs of the biotech research and its public dimension (see above);
- ii) The regulation settings.

No mention is made to a direct involvement of public administration in the management and hence development of biotech clusters. Public administration, according to this

² The four corners of the diamond include factor conditions, demand conditions, industry strategy/rivalry, and related and supporting industries. Porter used this diamond to determine which firms and industries had competitive advantages

perspective, seems to assume a partial role: i.e. it sets the framework within which the universities, research institutes and firms play and manage the whole cluster.

Jommi and Paruzzolo (2007) analyse the variables able to influence localisation of R&D on medicines: the regulatory environment, the institutional framework, the national system of innovation, and the local development and specialisation. According to this study, the role of public administrations may concern a number of issues. First, public administrations make public policies that directly influence the biotech and pharmaceutical firms. They are patent protection policy, the scientific procedures in clinical trials, the price regulation and reimbursement criteria, and the structure of the off-patent market. Germany provides an example of the importance of the regulatory environment for innovation development. German university researchers have had no incentive to exploit patents because, under German law, universities³ had no right to intellectual property generated there, as it is assigned to the individual. If researchers wish to register patents, they act privately at their own cost and risk, acting as a private citizen. A further point is that, unlike their counterparts in the US or UK, German researchers and academics are civil servants and, as such, are not allowed to found their own enterprise or even take a second job as a member of a university. In countries where this is not the case, such as the US, UK, Netherlands and Sweden, academic entrepreneurship and one of its key supports, venture capital, are traditionally much higher (Cooke, 2001). In Germany some revisions of the regulations have been recently developed and others are in progress.

Second, R&D localisation and intensity are influenced by the institutional framework that includes the companies' ownership composition, corporate governance laws and the structure of the capital and labour markets.

Third, the national system of innovation, which can be described as a framework where different actors (public administrations, the education system, research centres, and the industry) cooperate to facilitate the production of innovation and competitiveness, is considered to be crucial. In particular, the relevant assets for a national system of innovation are: i) external sources of knowledge, ii) public investments and public – private partnerships in R&D, iii) fiscal and financial incentives. All initiatives in favour of this system should support a closer relationship between public administrations,

³ In Germany almost all Universities are public and publicly funded.

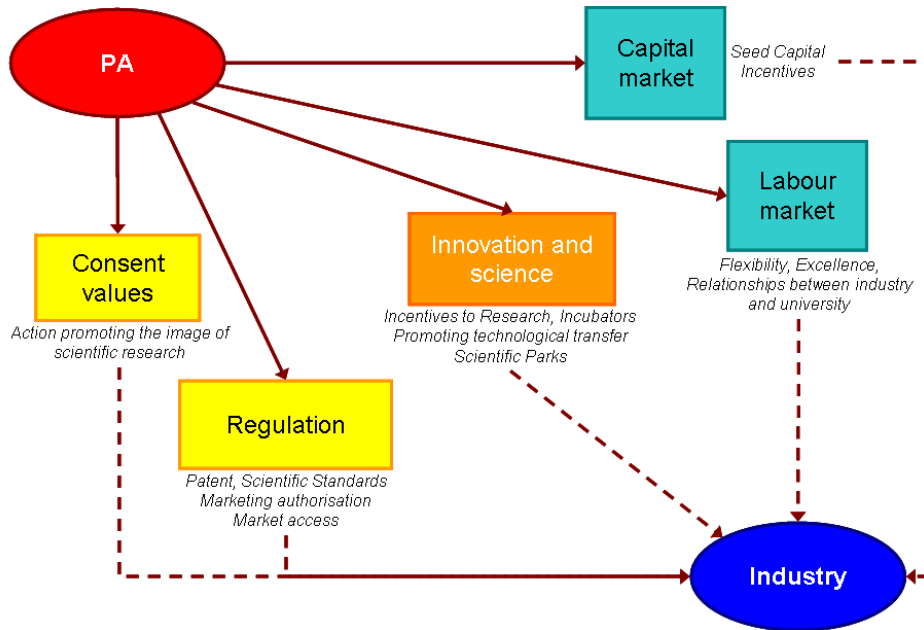
research, and industry. Finally, according to the literature, the last important variable influencing R&D localisation is the local development and the level of specialisation in innovative products (Jommi and Paruzzolo, 2007). In particular public administrations play a key role in the promotion of local development. In fact, 'promoting local development' means to make available to enterprises, which are located in the territory, a set of conditions/assets able to foster competitive advantages (Borroni *et al.*, 2006). The local development promotion has gradually become of local governments competence. In order to promote local development the presence of a mix of 'crucial resources' (e.g. infrastructures, presence of technologies, productive inputs etc.) and the setting of a territorial system, where all these resources can be properly coordinated, are required.

Whereas there is unanimous agreement on the crucial role played by regulatory issues (see above), some authors argue that the role of the institutional framework has been exaggerated and that a body of empirical evidence is still lacking (Gambardella *et al.*, 2001). According to this literature, public administration role is mainly regulatory and not significant in influencing the performance and development of biotechnological clusters.

According to other literature, the public administration's role is not poorly limited to the regulatory one. In fact, according to the numerous contributions abovementioned, it can be concluded that the public administration can mainly (figure 5):

- i) grant the respect of the ethical socially shared values;
- ii) regulate the system, i.e. both the biotech market and the capital and labor market;
- iii) Influence the innovation system.

FIGURE 5 - RELATIONSHIPS BETWEEN PUBLIC ADMINISTRATION AND BIOTECHNOLOGICAL FIRMS



i) Public administration and social shared values

Biotechnologies have an ethical dimension, above all in the field of environment and health care. On the one hand the social value of biotechnologies is tied to the possibility of increasing the quantity and quality of agricultural goods and of preventing and treating health incurable diseases and/or treating them in a less invasive and/or decreasing side effects. On the other hand biodiversity and the ethical involvements of the scientific research, above all in the genomic field, need to be kept under consideration.

From the industrial point of view, the decrease of investment for ethical reasons in highly innovative fields has generated a loss of competitiveness and consequences in terms of unemployment.

These values have differently influences the public administrations' behavior, leading them in some realities (and historical period) to foster the biotech development.

ii) Public administration and system regulation

The patent, clinical trial, reimbursement and pricing regulations represent a key factor able to influence the dynamics of biotech market.

The patent policies concerning the biotechnological products show many differences between the American and European realities. The Supreme Court of United States, in the “*Diamond vs Chakrabarty*” (447 US 303 - 1980) widened the concept of patent protection for innovation by including “*anything under the sun that is made by men*”. In 1980 the Bayh-Dole Act passed and introduced the opportunity to patent inventions discovered in universities and centers for research (also the results of public or publicly funded research programmes). This decision strengthened the relationships between the university and enterprises and the technology transfer processes (i.e. the translation of innovation into economic profits).

In Europe, after years characterized by debates on economic and ethical issues, the patent protection of biotech products was approved by the European Union in 1998 (Directive 98/44/EC). The European Directive introduced the patentability of biotechnological products that exist in nature and limited it to the processes (not to the products). Afterwards, a number of European inventions have been marketed in the US. For instance, in the early 1980s, the technology of monoclonal antibodies, developed in the Cambridge University (UK), was purchased by firms of the San Diego area.

Also price regulation and reimbursement criteria can influence investments in R&D. Free pricing or indirect regulation of prices through caps on profits are preferred by pharmaceutical companies. A strict regulation, in fact, could undermine investments in R&D (Jommi and Paruzzolo, 2007).

According to the regulation of the R&D process, the literature converges on the idea that (Gambardella, Orsenigo e Pammolli, 2001):

- the adoption of tight scientific procedures in clinical trials i) has contributed to the increase of innovative capacities of enterprises, ii) has induced an improvement in their scientific capability, iii) has speeded up the birth and development of research institutes;
- The selective criteria for registration and the competitive systems tend to facilitate innovation.

The Public Administration can also regulate the capital and labor market structure. On the one hand, the public administration can represent a source of funding for the biotechnological firms: e.g. fiscal incentives, participation in incubators/scientific parks. On the other hand, the public administration can: (i) foster the excellence, by investing

in research centers or supporting the private ones; (ii) encourage exchanges between research institutes and enterprises by fostering the short term contracts and remuneration systems based on results.

A comparison between German and English pharmaceutical firms (Casper and Matraves, 2003) highlighted that the English ones are characterized by a higher ability of adaptation to environmental changes and a higher performance in terms of innovative capacity due to: i) a high flexibility of the labor market, ii) informal corporate governance systems; iii) widespread ownership (including banks and venture capitalists).

iii) Public Administration and innovation system.

The Public Administration can directly intervene into the research activity. The amount and investment strategy into basic research are different throughout countries. In 2000, the American public funding in health research was eight times greater than the European one (Ministère de l'Economie, des finances et de l'industrie, 2003) and the American pharmaceutical market was three times the European one (IMS Health, 2004).

Moreover in US there exist a strategy of concentration of public fund for research (into the *NIH, National Institute for Health*) and of integration among different research areas. In most European countries the funding system is more fragmented.

This literature review demonstrates how widely the phenomenon of clustering has been analyzed. Even if the contributions on the public administrations role are a number, none of them empirically analyzes in detail the specific activities that public administrations can put into action for sustaining the cluster and, in a broader sense, the local territories development. Even when the literature describes the actual or potential role of the government, it is done in a marginal way. There is not a focused empirical study that tackles the issue.

1.4 Research questions

An important goal of most industrialized countries is to promote their high-technology sectors, such as aerospace, pharmaceuticals, biotech, and telecommunication. An important issue that these countries are compelled to face is the appropriate role of the government on these efforts (Di Tommaso, Schweitzer, 2005). The heterogeneous abovementioned literature has been largely used to “describe” international clusters (Chiesa and Chiaroni, 2005) and what influences their performance. However, no-one has explicitly evidenced the role of public administrations in the development of firms in an innovative market as the biotechnological one, qualified the relationships between public administration and firms and examined these relationships from the a management theory point of view.

This theoretical background shows that public administrations play and must play a role in clusters development. But the practical activities public administrations can put into action in order to facilitate the localization of R&D in their territories and, then, enhance the biotech cluster development are not specified.

After these considerations, with the support of literature, it is necessary to identify those variables that influence R&D localisation by biotech companies. By identifying them, it could be possible to determine the way in which public administrations can adopt to influence and facilitate R&D localization, and, hence, the clusters' growth.

According to the previous literature review and the identification of some gaps in it, this research aims at defining what kind of role public administration can play for supporting the biotech clusters' development, by answering the following research questions:

RQ 1: *have the birth and development of biotech clusters been influenced by the actual implementation of public policy?*

RQ 2: *if so, and where this has occurred, is there any structured path of managing the relationships between public administration, biotech companies and possibly other organisations?*

The approach for studying clusters can be twofold. On the one hand, clusters are commonly studied from a quantitative point of view. For instance, through the input - output analyses mentioned by Rosenfel (1997). The quantitative approach allows to identify the size of the cluster and the basic buyer-seller interactions. However, the quantitative analysis does not define whether relationships really exist among firms, and between the latter and other institutions. Moreover, it does not account for those factors beyond the product-market relationships, such as industry collaboration, information flow, and tacit/informal knowledge exchange (Doeringer and Terkla, 1995; Jacobs and DeMan, 1996; Rosenfeld 1996, 1997).

According to these considerations, both a quantitative and qualitative analysis is required.

In the following sections the building of a model that could provide an answer to the research questions is developed.

CHAPTER 2 - METHODOLOGY

In order to investigate the issue a multiple-case study has been carried out (Eisenhardt, 1989; Yin, 1994). The choice of a quali-quantitative multiple-case approach is motivated (Yin, 1994) by the need to link theory with empirical evidence, in a context where:

- the analysis is based on few cases and does not permit a quantitative approach;
- it is not easy to control confounding variables: too many variables, that influence one another, have contributed to the start-up and the development of firms in the biotech sector;
- the analysis is based on different data, coming from different sources.

In order to define a framework for analysing the cases a preliminary literature review concerning the tools for local development has been performed. As will be further discussed, the literature review allowed identifying a framework of analysis with the aim of investigating the tools/strategies that have been adopted to develop biotech clusters. By performing this kind of analysis it could be possible to highlight the role of public administrations in this sense. Interviews have been considered the most appropriate data gathering technique, given the explanatory nature of the study (Strauss and Corbin, 1998).

The analysis of case-studies is based both on i) individual semi-structured interviews; and ii) documents available on the net and internal documents directly supplied by the respondents. The individual interviews were preferred rather than the focus group technique because of the susceptibility of the latter to be dominated by the single members of the group (Crabtree and Miller, 1992).

According to Patton's (1990) approach, a purposeful sampling of cases has been carried out. As Patton states:

The respondents were identified through a combination of purposive and snowball⁴ strategies (Patton, 1990). The main criteria used to select the interviewees were:

- i) the expected validity of their descriptions and knowledge of the cluster;
- ii) the will to take into consideration the perspective of public administrations, industry, university, and scientific community.

Interviews were carried out in two stages: from April to September 2006 and from February to March 2007.

As detailed in table 3, representatives from the academic, scientific, industrial and public sectors were identified and 22 interviews were performed: a representative of the Federal Ministry for Education and Research (*Bundesministerium für Bildung und Forschung* – BMBF) (who was interviewed twice either at the beginning and at the end of the survey), a representative of the Projektträger Jülich, 8 members of the BioRegion Rhineland, 6 members in the BioTech region Munich, and 5 of the BioRegion Berlin-Brandenburg.

On average each interview lasted 1 hour/ 1 hour and half and they were recorded (apart from one case, when the interviewee asked not to record the conversation).

⁴ The snowball process consists of asking a number of people who else to talk with. At the beginning the chain of recommended informants typically diverges but then it converges as a few names get mentioned over and over.

TABLE 3 – PROFILE OF RESPONDENTS ACCORDING TO THE CLUSTER AND THE TYPE

CLUSTER	TYPE OF ACTOR	INSTITUTION/ ORGANIZATION	CONTACT FUNCTION
Federal level	Public Administration	Federal Ministry for Education and Research (BMBF)	Assistant Head of Division Biotechnology
Federal level	Public Administration	Research center Jülich GmbH, Projektträger Jülich	Head of Dept. in the Division BIO
Berlin Brandenburg	Coordinating agency (Public organization)	BioTOP Berlin-Brandenburg	Public Relations
Berlin Brandenburg	Incubator (Public organization)	Metanomics GmbH	Manager Business Development
Berlin Brandenburg	Industry	Senate office for Economy, Labor and Women	
Berlin Brandenburg	Public Administration	BBB Management GmbH Campus Berlin-Buch	Project Development
Berlin Brandenburg	University	Charité Medicine University - Berlin	
Munich	Coordinating agency (Private organization)	BioM AG	Managing Director
Munich	Industry	Ludwig-Maximilians University - Munich	Contact for Research and Technology transfer
Munich	Industry	SuppreMol GmbH	Chief Executive Officer
Munich	Public Administration	Ingenium Pharmaceuticals AG	Senior Director Business Development, Licensing
Munich	Research Center	Max-Planck Institutes for Biochemistry and for Neurobiology	Public Relations
Munich	University	Bavarian Ministry of Economic Affairs, Infrastructure, Transport and technology	Biotechnology Innovation
Rhineland	Coordinating agency (No profit organization)	Life Science Agency	Location Marketing
Rhineland	Coordinating agency (Private organization)	BoRiver - Life Science im Rheinland e.V.	General Manager
Rhineland	Incubator (public organization)	Life Science Center	Center Manager
Rhineland	Industry	Bayer HealthCare AG	Local Public Relations
Rhineland	Industry	NewLab BioQuality AG	Director Operations
Rhineland	Local network (Non profit organization)	Ministry of Innovation, Science, Research and Technology of the NRW State	Head of the Innovation Policy Branch
Rhineland	Public Administration	Heinrich-Heine University - Düsseldorf	Prof. In Biophysics
Rhineland	University	Biocampus Cologne Grundbesitz GmbH	

The multiple case study approach has been evaluated according to four tests (Yin, 1994):

- construct validity, i.e. establishing the correct operational measures for the concepts being studied;
- internal validity, i.e. establishing a causal relationship, whereby certain conditions are shown to lead to other conditions, as distinguished from spurious relationships;
- external validity, i.e. establishing the domain to which the study's findings can be generalized beyond the immediate case study;
- reliability, i.e. demonstrating that the operations of the study can be repeated with the same results.

As the construct validity is concerned: i) multiple sources of evidence have been used, i.e. internal and public documentation, interviews and direct observation; ii) all interviews have been recorded and reported, a database of quantitative and qualitative data has been created, maintaining chain evidence (Yin, 1994).

In order to ensure internal validity, the cause – effect relationships have been judged by taking into consideration the effective and potential influence of confounding variables. Due to this reason both quantitative and qualitative analyses have been performed. In fact the former is not enough for evaluating the effect produced by public policies on clusters' performance. Not taking into consideration the qualitative information (such as social interactions structure) can be misleading (see §2.3.1). External validity has been satisfied by replicating the same methodological operations (data collection) in all analyzed cases. Moreover, in order to detect and correct any flaw in the framework of analysis, pilot-testing has been carried out with experts (from the university and the Ministry for research and education) who were not directly involved in the study.

In order to make the research reliable, all procedures adopted during the study have been documented.

2.1 Market versus policy-driven biotech clusters

By mapping world wide biotechnological clusters, Chiesa and Chiaroni (2005) draw a distinction between *spontaneous clusters* and *policy driven ones*. The former is characterized by the spontaneous aggregation of firms and research developer without the direct commitment of public actors. In this context the role of public administration is restricted to the definition of the legal framework. Examples of this kind are typically available in UK (e.g. Cambridge) and US (e.g. San Francisco). As it is hereafter detailed, in these realities the birth and growth of clusters has been determined by the market demand and structure, in this sense, these clusters can be denominated *market driven*. They represent a response to market dynamics.

The policy driven clusters are characterized by a direct commitment of public policy makers (Chiesa and Chiaroni, 2005). The main differences between the market driven model (typical of the American and British context) and the policy driven one (the experienced mainly in the Continental Europe) have been widely examined in literature. They can be outlined and summarized mainly according to the three following dimensions.

a) Technology transfer system and labour market

As already mentioned (§1.3.2) the American and European patent system largely differ. Whereas the former is based on the 'first to invent' rule, the latter is embedded into the 'first to file' one. This means that in Europe an invention that has already been published cannot be patented afterwards (Giesecke, 2000). Moreover technology transfer offices in US are run as for profit enterprises (Cooke, 2001). In fact they pay for fees for filing patents and, in return, gain a share of royalties (Giesecke, 2000). In the American context the technology transfer mechanism, and, hence the interaction between university and industry have always been perceived as a key issue for making biotechnology develop and flourish. For this reason, financial support and a supportive legislative framework for technology transfer have been enforced by the American government (Giesecke, 2000; Chiesa and Chiaroni, 2005). As abovementioned (§1.3.2) those realities where market driven clusters are located are characterized by a flexible labour market, informal corporate governance systems and a widespread ownership

(including banks and venture capitalists) that make them able to quickly adapt to changes of the environment (Casper and Matraves, 2003). The European model is characterized by a high degree of division of labour and specialisation between teaching and research (Allansdottir et al., 2002).

b) Public policy

In the market driven clusters public policies have played a marginal role. Here the main policies consisted of financial support for basic research and technology transfer, such as the Small Business Innovation Research (SBIR) (Cooke, 2005). In other words the American government undertook initiatives aimed at connecting academic and industry research, by passing laws on technology transfer during 1980s (the Bayh-Dole Act and its revisions are an example) (Giesecke, 2000). Furthermore in US there is not a central agency for coordinating science and technology policy (Owen-Smith et al., 2002). Since post World War II, all attempts made to create a central American agency failed. Instead of a central national agency, the Department of Health and Human Services (DHHS) and the National Institutes of Health (NIH) are responsible for science and technology policy on the sector of pharmaceutical biotechnology. However, in the US a specific program to support biotechnology development was never enacted (Giesecke, 2000). On the contrary, the policy driven clusters are characterized by an active commitment of public actors (Chiesa and Chiaroni, 2005). On the one hand, the public commitment can be determined by the response to an industrial crisis. In this case the public administration can intervene by leveraging the existing competences in the area in order to create new jobs and revitalize the industry. Examples in this sense are provided by the cluster of Uppsala after the merger of Pharmacia with Upjohn and by Biovalley after the merger between Ciba and Sandoz that generated a high unemployment rate. On the other hand public administrations can decide to intervene, by drawing *ad hoc* policies, in order to facilitate the development of the biotech sector (Chiesa and Chiaroni, 2005).

c) Financial market

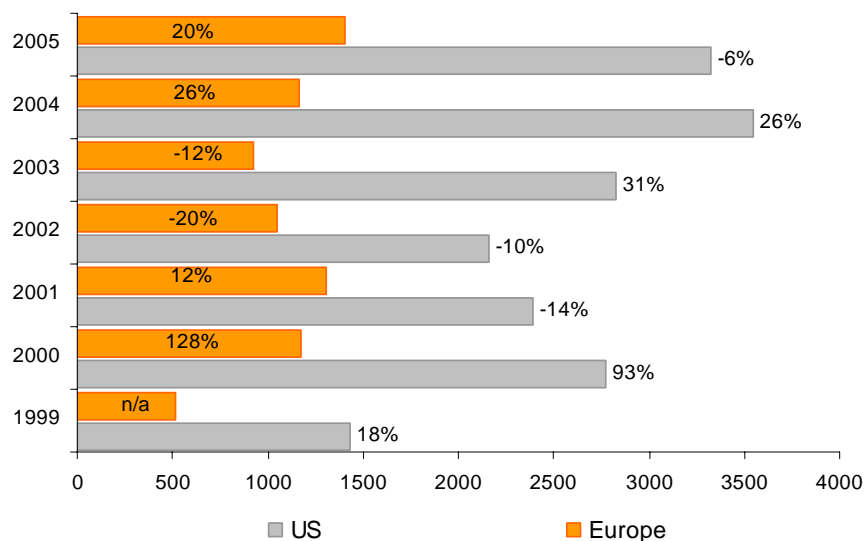
The market driven clusters are characterized by a structured venture capital industry (Allansdottir et al, 2002; Giesecke, 2000).

The Small Business Investment Act passed in 1958 supported venture capital companies, above all those that invested in high-tech companies. Venture capital, then, became the prevailing model for an alternative source of funding that supported the rise of many high-tech enterprises (Giesecke, 2000). Apart from providing financial support, venture capital offers «[...] managerial advice, organizational capabilities and “signals” to prospective investors about the potential of the new market» (Allansdottir et al., 2002).

On the contrary, the Continental European countries are characterized by a lack of venture capital. As Figure 7 shows, the European venture capital investment in biotechnology lags behind the US's one, at least in terms of absolute value. In fact, since 2004 Europe has been gaining the path and is recording positive growth rates in line with US in 2004, and greater than US in 2005.

As abovementioned (§1.3.2), above all during the past, Europe has mainly relied on public funding.

FIGURE 7 – VENTURE CAPITAL INVESTMENT IN BIOTECHNOLOGY IN EUROPE AND US (ABSOLUTE VALUE AND % GROWTH RATE)



Source: Data processing on Ernst&Young, 2005

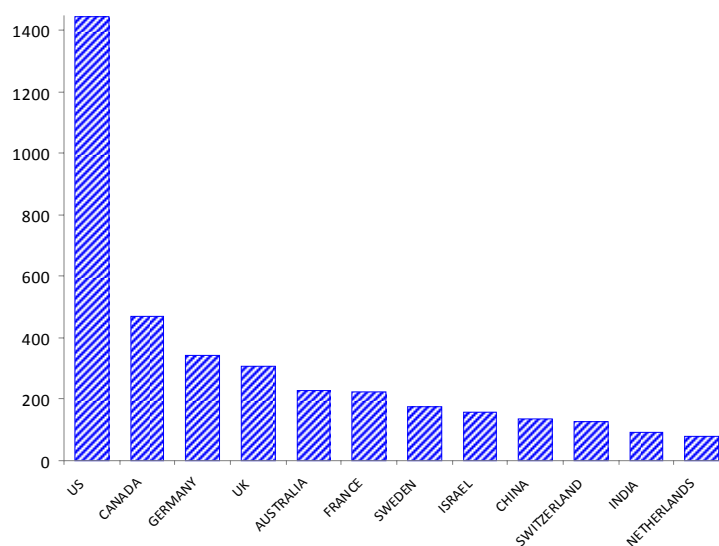
The combination of the three dimensions, made the US able to gain the first mover advantage. Since 1950s Europe developed a number of inventions and discoveries but

it wasn't able to commercially exploit them. In turn, US imported those inventions and exploited them, especially in places like Silicon Valley and Boston (Cooke, 2001).

The present research focuses on policy driven clusters, where public administration's intervention is not only regulatory but also actively participative into the cluster birth and development. Examples of this approach are the clusters located in Germany and France.

The cases analysed in this research were selected among the German clusters as Germany, if compared to France and other European policy driven clusters, is characterized by a longer history, and a wider range of information and availability of data. Moreover among the European policy driven countries, as the Ernst and Young (2005) report demonstrates (Figure 8), Germany is widely recognized as the best performing in terms of growth rate of biotech firms. Furthermore, Germany since mid 1990s has tailored *ad hoc* public initiatives, while France has started to invest in this respect late in 1990s and at the beginning of 2000. The German cases could in this way highlight the features that have influenced the successful and unsuccessful performance of the three policy driven clusters. The results could, hence, represent a benchmark for other realities (such as the Italian one) that are trying to invest in this sense.

FIGURE 8 – TOP 12 BIOTECHNOLOGY COUNTRIES ACCORDING TO THE NUMBER OF BIOTECHNOLOGICAL COMPANIES (2005)



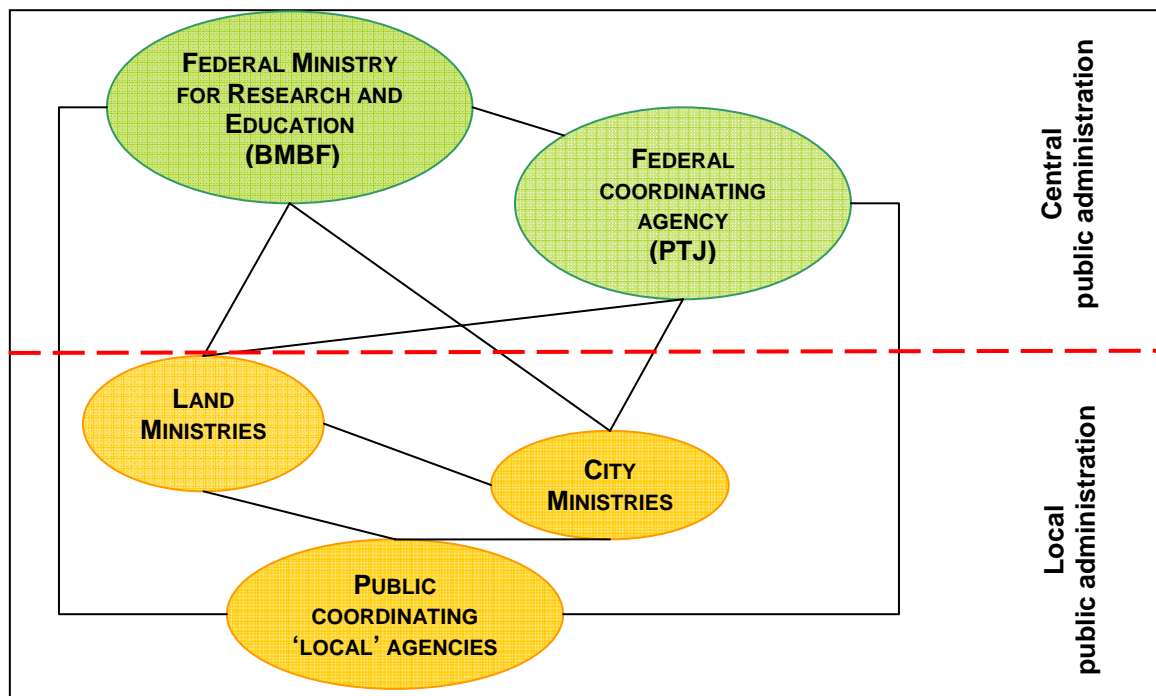
Source: Ernst&Young, 2005

2.2 The research model

As abovementioned (§1.4), the aim of this research is to analyze the role of public administration in sustaining the biotech clusters development. The analyses concerns three German cases. Before getting through the results, however, it is worthwhile to clarify what “public administration” means in such a context.

According to the purposes of the research, the role of the central public administration role has been firstly depicted. In the three analyzed cases, the central public administration is represented by the Federal ministry for research and education (BMBF). Its public policy is known and described by the literature as the starting point of the German investment in biotechnology (see chapter 3). Alongside the Federal Ministry, a Federal Agency (PTJ) functions as coordinator of the Federal funding programs addressed to stimulate the biotechnology sector (see chapter 3). While conducting interviews, local public initiatives (for instance, public funding programmes sponsored by Land and/or Cities Ministries, services provision etc) emerged and were included into the analysis. The inclusion of the local level of public administration is also justified by the thick interaction existing between the two levels and among the different public institutions that are detailed in chapter 3 (Figure 9).

FIGURE 9 – CENTRAL AND LOCAL PUBLIC ADMINISTRATIONS



The research model can be outline according to the scheme presented in Figure 10.

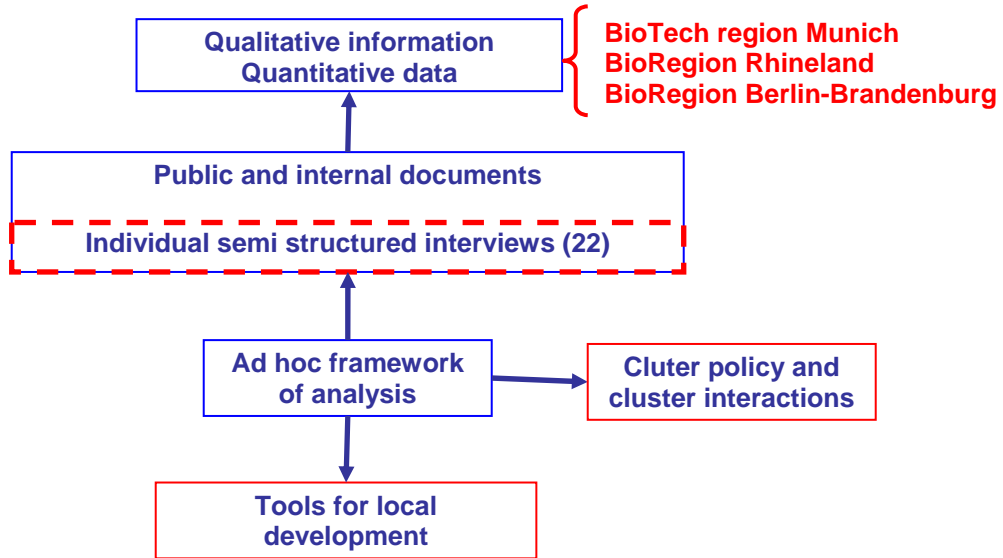
In order to investigate the three cases (the Biotech region Munich, the Bioregion Rhineland and the Bioregion Berlin Brandenburg), both quantitative data and qualitative information have been collected. It is worthwhile to remind that, according to the literature (§1.4) both a quantitative and qualitative analysis are required in order to investigate in depth the cluster dimension.

In order to collect this kind of data and information 22 individual semi structured interviews have been performed and public/internal documentation has been analyzed. The semi-structured interviews were based on a framework of analysis. The latter has been built on a literature review concerning the 'managerial tools' (better clarified in §2.3) for local development, i.e. a literature review on strategies and tools that can be used for local development in order to foster the localization of biotech R&D in general. This model, if applied to empirical experiences, leads to identify the tools that have been used to sustain the clusters development (see §2.3).

The application of this framework has also allowed:

- a) To highlight what kind of cluster policy central/local public administrations have activated (§2.4.1);
- b) To probe the interactions among the public, private and not profit players of each cluster, that, according the literature (as detailed in §2.4.1), are of great use to make the analyses complete.

FIGURE 10 – THE RESEARCH DESIGN



2.3 The framework of analysis

As no literature has investigated the issue from a managerial point of view, it is necessary to draw on appropriate references that could have investigated what managerial tools (strategies, decisions, organizations models etc) are needed to develop local territories, to attract and localize resources, regardless of the specific sector. This kind of review would allow to build a framework of analysis to support the identification of tools and strategies that have been adopted by biotech clusters in order to manage innovation process. The final purpose is to understand the role public administrations have had in this process.

Bovaird et al. (2001) provides a definition of 'local governance' that explicates, in simple words, what kind of contribution this literature can provide within this study:

«(...) the set of formal and informal rules, structures and processes by which local stakeholders collectively solve their problems and meet social needs. This process is inclusive because each stakeholder brings important qualities, abilities and resources. In this process it is critical to build and maintain trust, commitment and a system of bargaining».

According to this approach, the different qualifications (or, in other words, roles) of public administration can be investigated along an integrated cycle logic, split up into three main temporal and logical steps (Giaoutzi and Nijkamp 1993, Prahalad and Hamel, 1994, Kotler et al., 1993, Valotti, 2005):

- (a) strategy setting, i.e the development of the vision and of plans of action;
- (b) strategy enforcement/implementation, i.e the implementation of plans;
- (c) monitoring and evaluation of the strategy enforcement/implementation with respect to the strategy setting and a feedback process in order to improve and better off the performance.

This model of analyses, if applied to empirical experiences, leads to identify the "managerial tools" that have been adopted in biotech clusters in order to manage the innovation process. In this way, it allows to analyze what kind of role, if any, public administration play to facilitate the localization of R&D in their territories. Moreover, this kind of investigation, highlights how relationships between public administration and

private for profit and not for profit organisations affect the development of the biotech sector.

(a) Strategy setting

Van den Berg et al. (2001) conduct the analysis of clusters in nine urban regions in Europe and they conclude that the development of a strategy is necessary for a cluster to perform successfully.

In literature, strategy setting is widely analysed as an output of a negotiated planning process. It consists of three steps (Longo, 2005): the diagnostic recognition, the definition of objectives, and the setting of competences and responsibilities. As to the diagnostic recognition, Marelli (2002) defines the 'competitive strategy' as the identification of competitive arenas, the SWOT analysis of strengths, weaknesses, opportunities and threats, as a diagnostic recognition of the cluster and of the involved actors, i.e of the cluster boundaries . Moreover it is necessary to develop 'institutional strategy' (Marelli 2002), which aims at obtaining and maintaining over time consensus by institutional actors, i.e actors that take part to the cluster (such as enterprises, public administrations, non profit organizations). As already abovementioned, clusters are localized networks (van den Berg, 2001) and knowledge and competence networks (Carlsson, 1997). For this reason, as the literature about networks management states, to make solid and long lasting networks, a high level of internal consensus is required. The internal consensus can be obtained through either formal or informal ways. For instance, the sharing of objectives can be done either formally, through the stipulation of a contract, or informally, on the base of trust and reciprocal interest. Moreover, a further aspect that should be investigated is how and by whom cluster objectives are set up. In fact they can be decided according to a top-down procedure, or they can be shared among stakeholders; they can be chosen by public or private institutions.

Public and private institutions can be in charge of functions according to a balanced distribution, or same functions can be held by one (public or private) institution (Longo, 2005). Again, as in the case of objectives setting, the definition and setting of competences and responsibilities can be done according to a formal/informal procedure, and they can be either shared or hierarchically imposed.

(b) *Strategy implementation*: after the definition of a strategy, it has to be implemented. Strategy implementation involves the organizational structure level, the marketing activity and the financial cycle, i.e. the ability to attract funding.

As to the organizational structure, the strategy implementation can require the establishment of *ad hoc* institutional forms, for instance the creation of a consortium among enterprises. Moreover, *ad hoc* bodies can also be found. Examples in this sense are provided by the literature (Marelli, 2002): *i*) a steering committee as a body provided with a wide overview of the cluster, *ii*) addressing bodies, more focused on single local realities, and *iii*) operative entities for concrete applications. Moreover Longo (2005) quotes the establishment of supporting infrastructures and offices for users.

As the framework of analyses used by Chiesa and Chiaroni (2005) in their study demonstrates, within clusters there can be a number of different forms of cooperations. The authors list, as possible forms of interactions: the intra and extra cluster collaborations (i.e. University-industry or industry – industry collaborations), and specific forms of industry-industry collaborations (such as project finance, alliances, joint ventures, and outsourcing). These collaborations can be managed either according to the formal stipulation of contracts or in informal ways. In the end, during the strategy implementation, human resources management is relevant (Chiesa and Chiarori, 2005). In fact, in order to be in tune with the planned strategy, it can be required the provision of training and educational services.

As to the marketing activity, it may consist of territorial marketing, i.e. of actions aimed at attracting and maintaining human and financial resources necessary to support a certain strategic positioning of the territory (Borgonovi et al. 2006). Examples of territorial marketing tools are the rating (as an autodiagnostic tool) and the territorial marketing plan, the supply of a stimulating net of professional relationships, and of cultural initiatives (Rebora, 1992). Another aspect of marketing activity is represented by the communication strategy, that can be aimed at sensitizing the public opinion about specific issues or activities. Examples in this sense are advertisement and propaganda (Caroli, 1999).

In order to be able to implement the cluster activity (and individual activity) the involved actors need funding. The sources of funding can be public or private. An example of public funding activity is represented by the federal funding programs activated by the

German federal ministry for innovation and education⁵. As to the private sources, funding can be provided by business angels, venture capitalists, banks, incubators and scientific and technological parks⁶ (these can also be public) (Chiesa, 2003; Casper and Kettler, 2001).

According to the literature (Borgonovi et al., 2006), public administrations can play a key role in promoting territorial marketing and fostering the collaboration within the territory, and, hence, the cluster. A possible intervention of public administrations can act through specialized agencies, whose task can be twofold: on the one hand, the attraction of investments and, on the other, the fostering of economic development.

(c) Monitoring and evaluation: Summing up, after:

- having analyzed the strengths, weaknesses, opportunities, and threats of the cluster and of the involved actors, the identification of strategic arena, and the definition of objectives as cluster strategy (strategy setting);
- having implemented the strategy through operative actions, in terms of cooperations, human resources management, marketing activity, and funding

the performance can be evaluated. This step requires the monitoring of the activity in order to collect data and information concerning actions, facts, decisions and so on (Longo, 2005). Every empirical experience, and in this specific study, every biotech cluster, can be evaluated according to its own objectives. However, from empirical studies and reports available in literature (such as the annual Ernst and Young report on biotechnology) it is possible to hypothesize some performance indicators, able to give an overview of the degree of success of a cluster, at least from a quantitative point of view:

- I. number of new firms according to source of generation (i.e. if they come from the business or science);
- II. amount of venture capital investments, which measure the ability of the cluster, and of its actors, to survive and, in case, to develop without the public sustain but by attracting external resources;

⁵ The first initiative in this sense of the German federal state was the BioRegio contest, according to which the winning regions got access to special federal funding for a period of five years.

⁶ Incubators and parks (sites where normally incubators are located) provide a mix of (non financial) resources to start up companies.

- III. number of patents, of new products, and of potential products in the pipeline, as indicator of the firms performance, outcomes, and the degree of production of innovations;
- IV. size of firms (in terms of number of employees) and growth rate of employees. This indicator has a twofold meaning, as, on the one hand, checks the presence of large firms, that, sometimes, act as catalysts for the development of clusters, by attracting new entries (Prevezer, 1997), and, on the other hand, as it measures the rate of success, in terms of the ability to increase skills within the cluster, of firms;
- V. revenues, net income.

The performance evaluation can be carried out with respect to each actor involved into the cluster and/or with respect to the whole cluster.

Moreover the monitoring, as well as the evaluation process, can be either performed by each actor or centralized for the cluster as a whole.

This literature review allow to define a framework of analysis (Box 2). This investigation tool can be used to gather data and information concerning biotech clusters. Through it the “managerial tools” that have been adopted by biotech clusters in order to manage the process of innovation can be mapped. The final purpose is to highlight the role public administrations have had in the clusters' birth and growth.

The sections concerning the strategy setting, the strategy enforcement/implementation, and the monitoring/evaluation retrace the contributions of literature, as above described. The ‘general information’ section has been added in order to have an overview of the entire cluster and a description of the context. For instance, the contents of legislative rules allow to assess to what extent public administrations assume, within each cluster, the qualification of regulator. Moreover, as the diagnostic recognition is concerned, a description of the composition of the cluster and the actors taking part to it has been included. As in Chiesa and Chiaroni (2005), the intent is to collect information on the role of each actor, the interactions between the actors, how the network is working, how the cluster evolution took place, the main problems to face, and the key decisions taken and how they have been taken. The purpose of this model,

however, is not only descriptive, but it also investigates if and how the public administration has been able to facilitate the localization of R&D in its territories.

Van den Berg et al. (2001), after their analysis and comparison of dynamics in clusters in nine urban regions in Europe, conclude that «*public-private co-operation is a prerequisite for the development of effective and efficient cluster policy*». This study goes beyond, by trying to investigate in what terms this cooperation is a prerequisite and focuses on the role of public administrations.

In detail, the model is aimed at understanding if the biotech cluster development has been influenced by the actual implementation of public policy. If so and where this has occurred, the gathered information and data could allow to define a path of managing the relationships between public administrations, biotech companies and possibly other organizations could.

Box 2: The framework of analysis of public actions in the three clusters

0. GENERAL INFORMATION

Item	Contents
GENERAL INFORMATION ON THE CLUSTER	<ul style="list-style-type: none"> ▪ Name ▪ Geographical area ▪ Starting year ▪ Activity – field of interest
CONTEXT	<ul style="list-style-type: none"> ▪ legislative references

1. STRATEGY SETTING

Item	Contents
DIAGNOSTIC RECOGNITION	<ul style="list-style-type: none"> ▪ Actors of the cluster and cluster boundaries ▪ Previous identification of competitive arenas ▪ SWOT analysis
OBJECTIVES PLANNING	<ul style="list-style-type: none"> ▪ Process according to which the cluster's objectives are defined ▪ Tools and ways for obtaining and maintaining over time consensus by institutional actors
COMPETENCES/RESPONSIBILITIES SETTING	<ul style="list-style-type: none"> ▪ Process of definition and setting of competences and responsibilities. It could be i) formal/informal, ii) shared or imposed decision, iii) defined according to specific organizational settings

2. STRATEGY ENFORCEMENT/IMPLEMENTATION

Organizational structure

Item	Contents
INSTITUTIONAL FORM	<ul style="list-style-type: none"> ▪ Type of institutional/legal form
AD HOC BODIES	<ul style="list-style-type: none"> ▪ Establishment of <i>ad hoc</i> bodies, such as strategic guide, steering committees, executive bodies, supporting/staff bodies, public relation office.
FORMS OF COOPERATION	<ul style="list-style-type: none"> ▪ Main collaborations (intra- and extra- cluster) ▪ Forms of industry-industry collaboration (intra- and extra- cluster) ▪ Public – private partnerships
HUMAN RESOURCES	<ul style="list-style-type: none"> ▪ Type of contracts ▪ Training services and education ▪ Intra-cluster mobility ▪ Extra-cluster mobility (attractiveness for key people from abroad)

Marketing

Item	Contents
TERRITORIAL MARKETING	<ul style="list-style-type: none"> ▪ Territorial marketing instruments in order to attract (capital and human) resources.
COMMUNICATION	<ul style="list-style-type: none"> ▪ Communication strategy ▪ Communication instruments ▪ Target

Financial cycle

Item	Contents
SOURCE OF FUNDING	<ul style="list-style-type: none"> ▪ Amount and conditions for public funding ▪ Ability to attract private funding: e.g. access to high risk finance/venture capital etc. ▪ Adoption of innovative finance
FUNDING MANAGEMENT	<ul style="list-style-type: none"> ▪ Institution in charge of managing the funding

3. MONITORING AND EVALUATION

Item	Contents/indicators
PERFORMANCE EVALUATION	<ul style="list-style-type: none"> ▪ Performance indicators: i) number of new firms according to source of generation; ii) amount of capital venture investments; iii) number of patents, of new products, and of potential products in the pipeline; iv) growth rate of employees; v) revenues, net income. ▪ How the performance evaluation is performed with respect to: i) each actor involved into the cluster; ii) the whole cluster
ORGANIZATION OF THE MONITORING AND EVALUATION PROCESS	<ul style="list-style-type: none"> ▪ Schedule ▪ Institution in charge of these processes ▪ Feedback with respect to strategy setting

2.3.1 Cluster public policies and social interactions

As abovementioned (§2.1) public policies have a key role in the birth and growth of policy- driven clusters. As it is hereafter further detailed (chapter 3), the German public policy on biotechnology has assumed a cluster dimension. For this reason, it is worthwhile to deepen the concept of 'cluster policy' that has a direct influence on clusters' birth and development.

Cluster policies deal with firms and industries as a system (Le Veen Plan, 1998). Cluster policy makers develop strategies in order to allocate their limited resources for urban and regional economic development, provide a tool for industry recruitment, and encourage diversification of the industry base. Cluster policies can be aimed at manifold purposes (Le Veen Plan, 1998; Rosenfeld, 2001 and 2002):

- For industry targeting and recruitment by filling the gaps of the production process and completing the overall production process.
- To stimulate competition, which, in turn, leads to economic growth.
- To supply infrastructure and services.

Porter (1997) proposed to incorporate industry cluster policies into inner city economic development. The author suggests that economic developers should identify firms that can gain competitive advantage by locating in inner city areas (in other words, in settling in a cluster dimension) and encourage their development. In so far, as clusters grow, they can be a mean to target industry recruitment, as well as to direct job training programs.

However, in order to be effective, cluster policies need to identify the clusters composition, their needs, strengths and weaknesses. Nowadays, a number of countries are trying to incorporate industry clusters into their economic development planning. For instance, both Oregon and Arizona have worked to identify key industry clusters, and have focused their economic development efforts on identifying the needs, strengths and weaknesses with the aim of promoting growth in these clusters (Rosenfeld 1996).

As already abovementioned (§ 1.4), the evaluation of the effect produced by a cluster policy aimed at fostering the clusters birth and growth has mainly been performed from

a quantitative point of view, i.e. by analyzing the growth rate of firms and employees, patents, product, amount of funding etc. On the one hand, the quantitative dimension is indispensable for evaluating the performance of a cluster, and, in turn, the effectiveness of a cluster policy. In fact this dimension can objectively provide a picture of the dimension, productivity and the human/financial resources status in a cluster and allows to measure the impact of the policy on these variables. On the other hand, quantitative variables are influenced by a number of confounding factors. According to Breschi and Malerba (2005), the economic geography and regional economics theories claim that:

« [...] Learning through networking and by interacting is seen as the crucial force pulling firms into clusters and the essential ingredient for the ongoing success of an innovative cluster. The ways firms learn in innovative clusters embrace user – producer relationships, formal and informal collaborations [...]. More generally, a key feature of successful high-technology clusters is related to the high level of embeddedness of local firms in a very thick network of knowledge sharing, which is supported by close social interactions and by institutions building trust and encouraging informal relations among actors».

According to these considerations, the system of interactions among actors of a cluster is of meaningful importance to evaluate the performance of a cluster, the effects of the related cluster policy and, hence, the role played by public institutions.

As Rosenfeld (2002) claims, the easiest relationships to map are the sector-based supply chains. But the actual supplier and institutional relationships are more difficult. «[...] Most maps are very general, showing cluster members as boxes but with little precise knowledge of the strength of the linkages, depicted as arrows connecting them. The most difficult relationships to map - but perhaps the most telling - are the flows of tacit knowledge and innovation, which requires information from individuals about forums for associative behaviour and personal relationships» (Rosenfeld, 2002).

In other words, Rosenfeld (1997) distinguishes clustering activities by the intensity of social infrastructure and firm interaction, placing social capital and trust as the basis of collaboration, information and knowledge flows in regional clusters (Braun et al., 2005).

Other authors share a similar vision:

- Swann et al. (1998) consider relational capital as a determinant of cluster strength and as the foundation of its knowledge base.
- Doeringer and Terkla (1995) consider clusters as dynamic phenomenon, where interactions and functional relationships between firms and industries characterize a cluster.

According to Rosenfeld (1996) even if quantitative data may show an “healthy”, growing cluster, it doesn't necessarily mean that it is an effective cluster. In order to be effective, a cluster must also include social interactions, trust, shared vision, and cooperation in determining the dynamic nature of a cluster.

According to the abovementioned literature, both a quantitative and a qualitative analysis have to be performed. As to the former, the following indicators for cluster performance have been collected (see chapter 3 and 4):

- number of companies, especially academic spin-off, that measures the performance in terms of ability to promote entrepreneurship;
- number of employees (and, consequently, evolution of the average scale of operations), that shows the effects of public policies in terms of employment;
- number of patents, that measures the effectiveness of innovativeness and technology transfer promotion;
- number of products per R&D phase (especially Phase III and commercialisation), that, if measured in the long run shows the ability to promote sustainable initiatives;
- private funds invested in local biotech companies (venture capital and private angels), that measures the attractiveness of local biotech companies.

As the qualitative analysis is concerned, the framework of analysis (Box 2) allowed to gather information on:

- the strategy setting: i.e. the development of the vision and of plans of action;
- the strategy implementation in terms of organizational structure, marketing, and financial cycle;
- the monitoring and evaluation activity of the strategy implementation with respect to the strategy setting and the related feedback process;
- the system of interactions among the actors of each cluster, by mapping the relationships among the main actors strictly within and outside the cluster itself. In particular, according to the three cases, four kinds of relationships have been taken into account:
 - I) Regular financial relationships, i.e. interactions on regular base, normally ratified through formal contracts;
 - II) Financial relationships connected to *ad hoc* funding programmes and/or private initiatives;
 - III) Financial relationships connected to the Bioregio contest;
 - IV) Provision of information and /or services (e.g. infrastructures).

Each relationship can assume either a formal or an informal connotation whether, respectively, the relationship is regulated by a contract or it isn't.

The information collected during the individual semi – structured interviews allowed also to highlight the added value of being part of a cluster and what can make a cluster successful as perceived by respondents. The respondents of the semi-structured interviews were asked, according to their perception, what added value they are gaining from being part of a cluster. These personal perceptions have enabled to assess the real value “socially” ascribed to the cluster dimension, in general, and interactions, in particular.

CHAPTER 3 – ANALYSIS OF DATA

3.1 The German biotech public policy

During the 80s, in most of European countries (apart from UK) there were some disadvantageous conditions for biotechnology development due to the regulatory systems and to the inter-institutional relationships (above all between enterprises and institutes for research). In particular, Germany was characterized by:

- an unfavorable regulation (the so called *Gentechnikgesetz*) for preventive protection against possible hazards in genetic engineering processes and products;
- the absence of relations between enterprises and institutes for research and a general lack of entrepreneurship within them;
- a lack of seed and venture capital. At that stage the only way for German investors to recoup their investments was through a public listing of a company on the Nasdaq stock market (New York), (Müller, 2002a);
- the absence of a fiscal policy able to foster the localization of R&D.

This context prevented, on the one hand, the growth of biotechnological enterprises and, on the other, the localization of R&D in Germany by multinational companies. Hence, large pharmaceutical companies, such as Bayer, Hoechst, and BASF moved their molecular biology research activities to US, and/or formed collaborations with US biotechnology companies and hospitals. This phenomenon had an important impact on public opinion: Germany had a strong and competitive chemical industry, thus the de-localisation process was rather shocking for the system. After the reunification in 1989, the German economy ran into stagnation and, consequently, into a high unemployment rate. As it became increasingly clear to the public and the German government that new

industries were needed to sustain high standards of living, the attitude towards biotechnology favorably changed (Müller, 2002a, 2002b).

The first step of this reform process concerned the regulatory system: in 1993 an amendment to the *Gentechnikgesetz* streamlined procedures, while leaving the protection for persons and environment unchanged. Moreover, in 1998, the amendment 98/81/EG to directive 90/219 simplified the administrative procedures for laboratory work (BMBF, 2002). Afterwards, the *Arbeitnehmererfindergesetz* (i.e. Worker inventor Act) was revised. In principle the ownership of an invention belongs to the inventor's employer. An exemption was made for university professors, who are considered the sole owners of their inventions. Under the reform, the professors' rights were limited and the technology transfer into the business community was encouraged. According to the new act, scientists have to notify their intention to their employer (the university) two months in advance of publication. The university can decide whether or not to endorse the invention. In case of endorsement the ownership of the invention is transferred to the university.

Apart from the regulatory intervention, public administrations invested in supporting infrastructures, such as technological parks (e.g. in Heidelberg) and incubators (e.g. IZB in Munich).

However, these actions were not considered sufficient. Hence, in order to overcome the situation, the German government made of the investment in biotechnology a strategic aim and some funding programmes were launched (Box 3). The first was BioRegio, addressed at fostering the creation of biotech clusters. BioProfile followed to foster firms as a system rather than as a single unit, under a logic of cluster policy (§ 2.3.1).

Box 3 - PUBLIC FUNDING PROGRAMMES

PROGRAMME	YEAR	DESCRIPTION
BioRegio	1995	Contest launched by the Ministry for Innovation and Research (BMBF). Each winner got a funding of 25 million of Euro over a 5-year period (1997-2001). A special grant of 15 million of Euro went to Jena located in the former East Germany.
BioFuture	1998	Funding initiative as support for young scientists. 75 million Euro have been provided by BMBF to winners between 1998 and 2010. During the first nine years of the programme 51 researchers have been selected and, hence, funded. In this way, each researcher could set up a team work with a maximum budget of 1,5 million euro.
BioChance BioChance Plus	1999	Funding programmes supporting the high-risk development of young biotech companies. Since 1999 about 100 million euro have been made available by BMBF.
BioProfile	2001	BioProfile is addressed to those regions which boast special strengths in future-oriented fields of application of modern biotechnology (e.g bioinformatics and genomic research). The three (out of 20 applicants) winning regions, that were granted 15-18 million Euro over a five-year period, were: Styttgard/Neckar-Alb (regenerative biology), Potsdam/Berlin (nutrition-related diseases) and Braunschweig/ Gottingen/ Hannover (improved diagnostics and therapy).

As Müller (2002a) states: «*One lesson learned from the successful development of biotech companies in the USA was the evolution of technology clusters, namely in Boston, North Carolina, San Diego and in the so-called BayArea around San Francisco. Although the US technology clusters evolved over more than 20 years under very specific conditions, they all consist of a close network of researchers from universities and from pharmaceutical companies, venture capitalists, patent attorneys, specialized consultants and politicians. Knowing the importance of these networks around strong research groups in universities, the BMBF launched the supraregional BioRegio contest in 1995*». The Bioregio contest was designed to work as the motor of the catch up process, stimulating biotech firm start ups, the growth of existing companies and the provision of venture capital (Dohse, 2000). A further objective of this competition was technology transfer from universities and other research institutes. The regions were encouraged to submit proposals for the commercial integration of concepts for biotechnological research. Those proposals pinpointed the strategic core competences of each region and how the network of research institutions, incumbent companies, public administration and service organizations foster entrepreneurship. Each region established a coordination agency (*Koordinierungsstellen*), which was (and still is) in

charge of strategically linking together all activities. Out of the 17 applicants, three winners were selected by an international and independent jury, chosen by the project agency of the BMBF (*Projekträger Jülich* - PTJ). This jury was made up of experts in natural science, economists, and coming from the industry and the trade unions representatives. Table 4 lists the criteria according to which the proposals were selected.

TABLE 4 - EVALUATION CRITERIA OF THE BIOREGIO CONTEST

1. Number and scale of existing biotechnology companies in the region
2. Number, profile and productivity of biotech research facilities and universities in the region
3. Interaction of different branches of biotechnology in the region
4. Supporting service facilities (patent attorneys, information networks, consulting)
5. Strategies to convert biotechnology know-how into new products, processes or services
6. Regional concept to help start-up biotech companies
7. Provision of resources (private and public) to finance biotech companies
8. Cooperation among regional biotech research institutes and clinical hospitals in the region
9. Local authorities approval practice concerning new biotech facilities and field experiments

Source: BMBF, 1996

As abovementioned, the applications were selected by a jury chosen by the PTJ. This agency, after the selection of winners, provided the winners with the funding, which, in turn, were transferred to PTJ by the BMBF. In other words, every year the BMBF grants a certain amount of funding to PTJ (for instance, for 2006 PTJ received 125 million Euro), that, in turn, finances the single projects.

To get the public funding the applicants had to find a 50% private co-funding. (Dohse, 2000; Müller, 2002a; Omland and Ernst, 2004). This condition is considered as a sort of guarantee for public authorities to fund solid enterprises, able to become independent from public support. According to this approach, public administrations, above all the local ones, often use the professional experience of VCs in order to judge the financial solidity of projects (business plans) that apply for public funding.

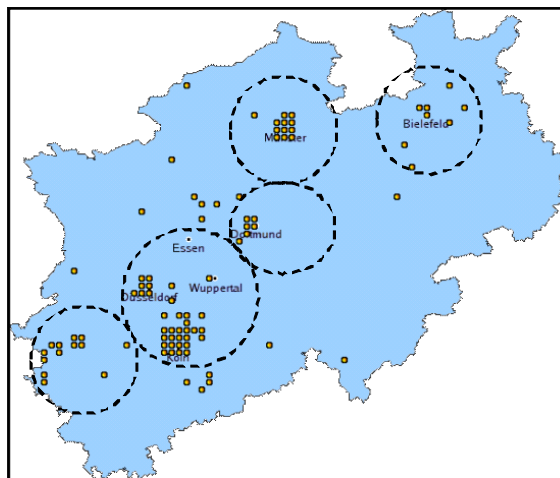
The next sessions analyze the results of the semi-structured interviews for each case according to the framework of analysis above described.

3.2 The Rhineland BioRegion

3.2.1 General information

The organization that managed the BioRegion contest for the Rhineland BioRegion (whose boundaries corresponded to the ones of Nord Rhein Westfalen - NRW – Land) was *BioGenTec NRW*. It was a federal state initiative, founded in 1994, to support the bio- and gene- technology in NRW.

In 2002 the Ministry of Economics in NRW decided to foster biotechnology together



with health care and medical technology, under the same label of 'Life Science'. According to this new approach, in 2002, on governmental initiative, *LSA* (Life Science Agency) was founded. This new organization was made up of three member associations, focusing on different fields: *Bio-Gen-Tec-NRW*, focused on biotechnological sector, *Health Care NRW*, concerning medical technology, and *MeTNet NRW*, focused on pharmaceutical industry. Employees from BioGenTec were moved to LSA and BioGenTec was no longer funded. While BioGenTec stopped to exist, five biotech regions developed and local coordination agencies (*Koordinierungsstellen*) were set up. Hence, the cluster split up into five smaller «regional initiative clusters»: i) *Biotech Region East Westphalia Lippe*, located in the north-east of NRW; ii) *Bioanalytik-Münster* developed around Münster; iii) *Life Technologies Ruhr*, in the Ruhr region, in the center of NRW; iv) *BioRiver-BioRegion Cologne/Düsseldorf*, around Bonn, Cologne, Düsseldorf e Aachen; v) *BioRegion Meuse-Rhine-Triangle*, in the south of NRW.

The cluster activity field of interest is wide. It comprises analytics, diagnostics, biomedicine, bio process technology, microstructure technology, chip technology, bioinformatics, genome and proteome research, enzyme technology, tissue engineering, stem cell therapy, nano-biotechnology, and plant biotechnology.

Item	Contents
GENERAL INFORMATION ON THE CLUSTER	<ul style="list-style-type: none"> ▪ <i>Name:</i> Rhineland Bioregion ▪ <i>Geographical area:</i> ▪ <i>Starting year:</i> 1994/1996 <p><i>Activity–field of interest:</i> Almost the 40% of companies are research and manufacturing biotech companies and the 60% are service companies and suppliers (LSA, 2005).</p> <p>Wide range of applications, among them analytics, diagnostics, biomedicine, bio process technology, microstructure technology, chip technology, bioinformatics, genome and proteome research, enzyme technology, tissue engineering, stem cell therapy, nano-biotechnology, and plant biotechnology.</p>

3.2.2. Strategy setting

The detailed information on both the strategy setting and implementation processes are discussed in the following section ('Strategy implementation'). In this one a schematization of the contents concerning the strategy setting is provided.

Item	Contents
DIAGNOSTIC RECOGNITION	<p>A diagnostic recognition (in terms of identification of <i>actors</i>, <i>competitive arenas</i> and <i>strengths/weaknesses</i> of the region) was performed in occasion of Bioregio, when the cluster wrote the concept to apply to the contest.</p> <ul style="list-style-type: none"> ▪ <i>Actors of the cluster and cluster boundaries:</i> the Rhineland Bioregion has developed at different levels. At the time of the application and of the win of the contest the boundaries of the Rhineland Bioregion corresponded to those of NRW Land. Afterwards, five regional initiative clusters were created. Hence a twofold (State and local) level of coordination and management of the cluster/s was developed. <p>The main actors of the cluster are:</p> <ol style="list-style-type: none"> i) biotech companies, mainly spin offs of the university; ii) pharmaceutical companies, such as the multinational chemical and pharmaceutical company Bayer (that has its headquarter in Wuppertal, near Dusseldorf) and several mid-sized pharmaceutical companies, like Schwarz Pharma, that have their headquarters in the NRW Land; iii) the first German gene center was founded, in 1984, in Cologne, due to the long standing history of the town in this field; iv) a number of research centers, such as the Max-Planck-Institute for Plant Breeding, the Center for Molecular Medicine in Cologne, the Jülich Research Center, the Fraunhofer Institute for Molecular Biotechnology; v) VCs, private investors, private banks and the NRW Bank.

	<ul style="list-style-type: none"> ▪ <i>Competitive arenas and strengths/weaknesses of the region:</i> the decision to apply for the competition was based on the long lasting history of research of the region and of the potentials in terms of industrial developments, thanks to the wide presence of pharma and biotech enterprises. According to this view point, it was clear that a strengthening of the networking between research and industry was necessary.
<p>OBJECTIVES PLANNING</p>	<ul style="list-style-type: none"> ▪ <i>Process according to which the cluster's objectives are defined:</i> regular meetings among the actors of the cluster: (State and local) coordinating agencies, companies, universities, research centers and public institutions (i.e. with representatives of the Cities, Land, and Federal Government). ▪ <i>Tools and ways for obtaining and maintaining over time consensus by institutional actors:</i> through regular meetings and the involvement into the decision making and objective setting process. For instance, i) Bioriver involves, through meetings and questionnaires, its members into the objectives planning; ii) LSA receives directions from the State government, that participated to its foundation.
<p>COMPETENCES/ RESPONSIBILITIES SETTING</p>	<ul style="list-style-type: none"> ▪ <i>Process of definition and setting of competences and responsibilities.</i> Mainly on an informal way

3.2.3 Strategy implementation

a) Organisational structure

Whereas each *regional initiative cluster* is coordinated by its own local coordination agency, **LSA**⁷ acts for the entire NRW Land. During the foundation of LSA, the Government of NRW i) participated at the definition of its business plan; ii) participated at LSA Board; iii) provided LSA with directions and funding. Even if publicly funded, LSA is a *GmbH*⁸, non-profit service company and, hence, acts as a private company. During the last years, due to the change of Government, LSA has been under a re-focusing process and a re-definition of its tasks. In fact, under the past Government, LSA referred to the Ministry of Economics, while nowadays, under the new government, it refers to the Ministry of Science and Innovation.

LSA has two major tasks:

⁷ Information concerning LSA have been mainly provided by Mr Zschunke (Location Marketing) of LSA.

⁸ GmbH stands for "Gesellschaft mit beschränkter Haftung", i.e. limited liability company

1. the marketing activity: events on scientific themes are organized in collaboration with the Ministry. LSA acts as an *information point* on research activities and on infrastructures for those entrepreneurs who are interested in establishing their activity/business in NRW. Moreover LSA organizes workshops and courses on different topics.
2. Consultancy – service provider: LSA provides firms with consultancy about subsidies and funding (regional, national, EU etc). Moreover it created (and is expanding) a database of companies and biotech actors in the cluster. It helps to develop business plans, and supports developers in finding licensing partners.

The members of the LSA Supervisory Board are representatives of:

- *Bayer Vital GmbH*, Leverkusen;
- *Ministry for Economic Affairs and Energy NRW*, Düsseldorf;
- *Medice GmbH & Co. KG*, Iserlohn Chairman of the Board Health Care NRW e. V.;
- *NewLab BioQuality AG*, Erkrath Member of the Board of Bio-Gen-Tec-NRW e. V.;
- *FH Gelsenkirchen*, Abt. Bocholt Chairman of the Board MeTNet NRW e. V.

LSA is often the intermediary between companies and the Ministry by meeting the former and discussing with them if there are necessities to be satisfied by the latter (e.g. an increasing in infrastructure etc). Then LSA discusses these requests with the Ministry. All these interactions are informal.

Among the five *regional initiative clusters*, the **BioRiver⁹-Bioregion**, represents two third of all firms in NRW and the 80% of all employees in NRW. This *regional initiative cluster* is organized, as normally all biotechnological cluster, according to four pillars:

- i) *science*, there are 11 universities/universities of applied science and outstanding research institutes (e.g. the Max Planck Institute);
- ii) *companies*, the *BioRiver-Bioregion* is made up of 74 biotech companies and more than 50 pharmaceutical/chemical companies;
- iii) *parks*, there are 20 biotechparks and incubators;
- iv) *cities*, the Bioregion develops around four international business hubs, i.e. Cologne, Düsseldorf, Aachen, and Bonn.

⁹ Information concerning BioRiver have been mainly provided by Dr Kretschmer (General Manager – BioRiver - Life Science im Rheinland e.V)

The organization in charge of managing this cluster at local level is *BioRiver - Life Science im Rheinland e.V.*¹⁰, a private association founded in 1995 and financed by the members' fees (mainly private companies) that are proportional to their size. It has limited resources, as its activity is managed only by a full time person and a part time one. Its objectives are:

- *providing network for companies and the Region*, i.e. to create added value in the Region (business to business, science to business)
- *communication/regional marketing*, i.e. to promote potential and opportunities of Companies and Region and to support marketing activities of companies
- *promoting innovations*, i.e. to strengthen technology transfer (science to business) and to support spin-off opportunities
- *optimizing framework conditions*, i.e. to help to optimize the Government policy on Life Sciences in NRW and to support opportunities for funding (VCs, Regional Banks).

Bioriver stipulates with the member companies formal contracts with a framework of rules between the parties. The companies are supposed to pay an annual fee. The amount varies according to the size of the company: the smallest companies – i.e those with incomes lower than 1,5 million euros - pay 200 euro per year, the biggest pay 5.000 euro per year.

Bioriver provides member companies with the following services:

- platform for contacts and networking;
- platform for technology transfer (industry und science);
- lobbying and consultancy for politics;
- 'BioRiver Academy': workshops, seminars, symposiums;
- networking and partnering by arranging national and international events; public relations/regional marketing (companies and region), trade fairs, and exhibitions.

Each University, located in the BioRiver region, leads a "collaborative Science Network" according to a specialization field:

- Aachen: medical technology, biomaterials;
- Bonn: Neuroscience, ethics;
- Cologne: inflammation, infection and tumours;

¹⁰ e.V. stands for "eingetragener Verein", i.e. both membership corporation and registered association.

- Düsseldorf, Jülich: biotechnology platform (from this university there have been many spin offs).

The Board of Directors of Bioriver meets every 2 or 3 months and is made up of a managing board and an advisory one. The former is mainly composed of members coming mostly from companies, i.e. Qiagen GmbH (the Chairman), Newlab BioQuality AG, Coley Pharmaceuticals GmbH, the University of Cologne, Bayer Industry Services, Madaus Capital Network GmbH¹¹. The latter is formed by representatives of Aplagen GmbH¹², Life Science Center Dusseldorf (see hereinafter), Research center of Jülich, City of Dusseldorf, NRW Bank (see hereinafter), the Cologne Chamber of Commerce and Industry (IHK Cologne), Miltenyi Biotec GmbH¹³, the Association of the Chemical Industry in NRW (VCI NRW), and Phytowelt Greentechnologies GmbH¹⁴.

As to BioRiver's objective planning:

- Once a year there is a meeting among all Bioriver members in order to discuss contract contents, i.e. the general objectives;
- In order to set more specific objectives, questionnaires/interviews are administered by Bioriver to its members, in order to identify their needs/requests and what BioRiver can do for them. According to the results of questionnaires, members consider networking, lobbying, and marketing as the most important/useful services provided by Bioriver.

The Ministry for Innovation in NRW is planning to establish a new coordinating agency for NRW, an *Innovation Agency*, which is not going to focus on life sciences but on all the field of innovation. In fact according to the State Ministry opinion, the performance of the current organizational structure of the cluster is not satisfactory, as the cluster is split up into many smaller local clusters, generating fragmentation and inefficiencies. The purpose of the new agency is to promote innovation in NRW, to provide a platform for events, to improve international contacts, and to set up a big knowledge data base. The Innovation Agency should be a 100% public agency. The idea of establishing such an agency has been imported from foreign experiences, such as the one in Singapore.

¹¹ An asset management service company.

¹² A biopharmaceutical company.

¹³ A biotech company that develops, manufactures, and sells products and services in the fields of cell biology, immunology, regenerative medicine, and molecular biology.

¹⁴ It is a biotech company whose core business is agricultural science and plant biotechnology.

Among the members of the cluster there are 'local networks' that support, autonomously and in collaborations with BioRiver, communication, marketing activity and creation of contacts among the actors of the cluster. They are five: i) BioCologne, ii) Netzwerk Bonn, iii) BioTecRheinErft, iv) LifeScienceNet Dus, v) LifeTec Aachen/Jülich. Among them, **BioCologne**¹⁵, founded in 2002, is a not profit organization and, as the others, a member of BioRiver. Its members are companies, banks, venture capital companies, consulting companies, scientific organizations, technological parks, and individuals interested in biotech. Its aim is to support the area around Cologne, by creating a network able to support companies' activity within and outside the area. Decision making and objective setting are shared with local actors (public institutions included, e.g. the Economic departments of the City of Cologne, of Dusseldorf) by arranging meetings both locally in the Cologne network, and broadly at regional level. Local networks try not to overlap initiatives/activities among each other. BioCologne has no contact at the federal and *Projäktträger Jülich* (PTJ) levels; it works mainly on the base of informal contacts.

Public and private institutions support BioCologne activity by providing human resources (and paying them): in practice, BioCologne hasn't any employee.

Within the Rhineland BioRegion the role of the **University**¹⁶ is

- to support the technology transfer, bringing the science from university to business: at Heinrich Heine University there is a department of technology transfer with 3-4 employees and 3-4 consultants (who are professors). They provide advices for patents, to find partners for licenses, and organize lectures of 1-3 days on 'how to create a start-up'. The University would like to increase this department by improving the business and managerial expertise.
- to try to set up a combination of study programmes, e.g. chemistry-business, science-business.

¹⁵ Information concerning BioCologne have been mainly provided by Dr Susen (BioCologne)

¹⁶ Information about the University role within the cluster have been mainly provided by Prof. Riesner.

The University has also collaborated with politics and business to develop initiatives in order to support biotechnology in NRW. Among the results of these collaborations there are, for instance, the foundation of BioGenTec NRW and of Life Science Centers. Among them, the **Life Science Center Düsseldorf** (LSC) is a technology center, an incubator established in Düsseldorf. It offers to start ups a place to develop, in practice it provides them with lab spaces. LSC acts as a moderator between science and industry in the area of Dusseldorf. In the other cities of NRW, such as Cologne and Munster, there are similar technology centers.

Together with the Heinrich Heine University, the City of Düsseldorf and a network of partners, LSC aims at supporting founders, young enterprises, and research institutions in turning their scientific know-how into a marketable product or process. Moreover it provides the already established companies with the opportunity (above all in terms of space) to expand.

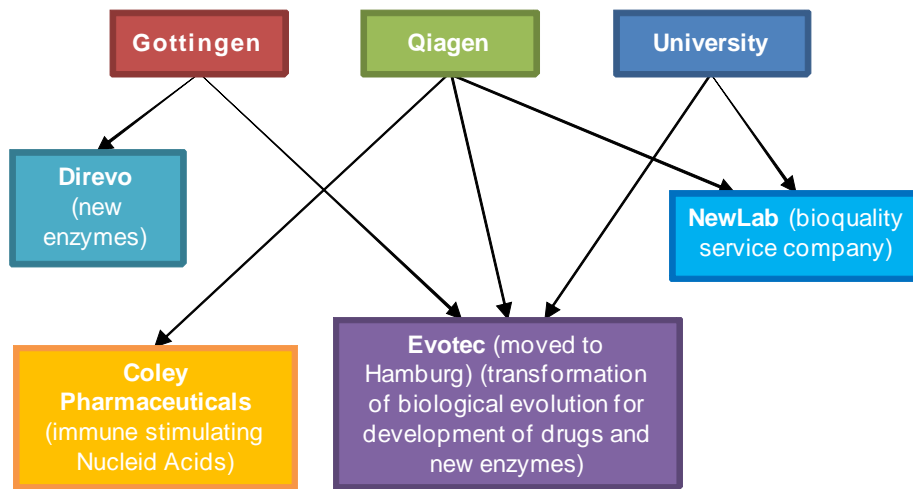
LSC mainly collaborates i) with the Land Government, the Chamber of Commerce, Bioriver, LSA and the City in an informal way, that means, no contracts have been signed; ii) with the Heinrich Heine University through a long term cooperation contract. LSA provides a marketing support to LSC by making the interested actors informed about their existence and offers.

Among the **companies** of the cluster, *QIAGEN* represents the starting point of the cluster. It is a spin off of the science faculty of the Heinrich Heine University in Düsseldorf and it was founded in 1985. Nowadays, it has 1400 employees and it is defined as the leading provider of enabling technologies and products for separating and purifying nucleic acids (DNA and RNA) over the world.

In the area of Düsseldorf there are many examples of academic spin offs¹⁷:

- Rhein Biotech is a spin off from the Microbiology Institute of the Heinrich Heine University working on methods to transform yeast to produce vaccines.
- The Science Faculty of the Heinrich Heine University contributed to the foundation of other firms, as the following scheme shows:

¹⁷ Information concerning spin offs have been mainly provided by Prof. Riesner (of Heinrich Heine University); for this reason they mainly refer to the Heirich Heine University experience.



Coley Pharmaceuticals, in particular, has been established by the University of Iowa in US and Qiagen.

Other firms originated from the medical faculty:

- Cardion: whose activity concerns genetherapy, immunomodulators. This company was sold to Roche;
- Kourion: whose activity concerns adult stem cells. It was sold to Viacell (US);
- Neuraxo: whose activity deals with the treatment of Paraplexia and, in the near future, clinical trials;
- Ortogen: whose activity concerns cell treatment.

Among the companies of the cluster, that are also members both of LSA and BioRiver, there are *Bayer HealthCare*¹⁸ and *NewLab BioQuality*¹⁹.

The headquarters of *Bayer HealthCare* (BHC) is in Leverkusen, while the research, development and production units are in Wuppertal. BHC has been part of the cluster since the origins. Among the companies in NRW, BHC is the largest in terms of both size (4300 employees in Germany) and production (8.5 billion euro of sales in 2004). This firm is interested in the field of biotechnology as a player of the biotech society,

¹⁸ Information about Bayer HealthCare, as member of a biotechnological cluster, have been provided by Dr Dellweg (Local Public Relations at Bayer HealthCare AG in Wuppertal – Germany) and downloaded by the LSA website (www.liscia.de).

¹⁹ Information about NewLab BioQuality , as member of a biotechnological cluster, have been provided by Dr Richter (Director Operations at NewLab BioQuality AG in Erkrath – Germany) and downloaded by the LSA website (www.liscia.de).

through production activity and in order to find potential partners for biotech activities and partners for the pharmaceutical-chemical park, which has been set up since 3 years in its site.

Due to its long experience in the field, BHC was involved into the foundation of BioRiver. The involvement of the firm into three of the four abovementioned Bioriver's founding pillars, i.e. science, industry, and parks, justifies its participation to the Board of Bioriver Association. Also the production activity triggers BHC interest in being part of Bioriver. The competition of those products that are produced in countries with low cost of labor, led Bayer HealthCare (as many other companies) to loose job and work places. Hence, under this perspective, cooperation with other companies is important. The number of corporations as partners has increased during the last years but, it is not clear how much this is due to Bioriver or not. Bioriver is not considered the only activity/way for BHC to promote Bayer's activity. The same considerations are made as concerns the technology transfer: there are strong relationships between Bayer HC and Science Institutions, not necessarily related to Bioriver. According to his issue, Bioriver activity is considered to be more useful and strategic for small enterprises.

NewLab BioQuality is a service provider of quality control analysis for biopharmaceutical drugs. This firm performs analytical services for biotech and pharmaceutical services. It tests the quality (purity, safety etc.) of biopharmaceuticals. It has 60 employees and was founded in 1993 as a spin off of QIAGEN. It is located in Erkrath (near Dusseldorf), Cologne, and Bielefeld. NewLab BioQuality is focused on: i) effective process development for new biotech products; ii) comprehensive integrated processes to shorten the developmental phases of biopharmaceuticals; iii) high-quality individual customer care and a close interdisciplinary cooperation of project teams.

The founder of NewLab was a chairman of the *Landes Initiative*, BioGenTec.

The main collaborations of NewLab BioQualities are with:

- LSA and Bioriver: the founder of the firm is a member of the Board of Directors of LSA and Bioriver. NewLab organized, in collaboration with LSA, and participated to the *BioQuality Tag* (BioQuality Day), that involved actors active in the field of biotechnology of the Bioregion and from outside. Moreover it is involved in the training of technical assistants organized by Bioriver.
- the Ministry: through informal connections.

- Universities and Centres for Research: informal collaborations on scientific base.
- Technology transfer: NewLab acts as an intermediary between science and industry. It has informal and personal connections with scientists as it is considered not easy to get information about technology development in Universities.
- Labs (within and outside Universities): these collaborations are managed through long term contracts (more than 3 years). Labs provide NewLab BioQuality with special analytical services that cannot be performed within the firm. E.g. for Electron microscopy, NewLab BioQuality collaborates with the University of Bielefeld, in particular with the Institute of Information/Technology Transfer, where scientists can privately provide services through instruments of the Universities.

Item	Contents
INSTITUTIONAL FORM	<ul style="list-style-type: none"> ▪ <i>Type of institutional/legal form:</i> 1996-2002: an informal sort of consortium, whose boundaries corresponded to NRW ones, steered by the coordinating agency (BioGenTec/LSA). Since 2002: coexistence of the former consortium and five regional initiative clusters that repeated, at local levels, the structure of the former.
AD HOC BODIES	<ul style="list-style-type: none"> ▪ <i>Establishment of ad hoc bodies:</i> i) BioGenTec and LSA (public initiative); ii) BioRiver (private initiative); iii) local networks (e.g BioCologne); iv) financial entities (e.g. NRW Bank)
FORMS OF COOPERATION	<ul style="list-style-type: none"> ▪ <i>Main collaborations</i> (intra- and extra- cluster, industry-industry and PPP): a) Between LSA/BioRiver and i) companies and incubators of the cluster; ii) other coordinating agencies of other German Bioregion; iii) Bioriver/LSA; iii) public institutions (BMBF, PTJ, Land Ministries, Cities Ministries, Chamber of Commerce), iv) financial entities (single investors, VCs, banks). b) Among companies and between them and financial entities (single investors, VCs, banks). c) Between the University and i) companies and incubators of the cluster and outside it; ii) BioRiver/LSA; iii) public institutions (BMBF, PTJ, Land Ministries, Cities Ministries, Chamber of Commerce).
HUMAN RESOURCES	<ul style="list-style-type: none"> ▪ The main collaborations within the cluster are informal ▪ <i>Training services and education:</i> organized by the coordinating agencies in collaboration with Universities / Research Centers / Public Institutions (e.g. BioEurope)/ Single Companies.

b) Marketing

As abovementioned, the marketing activity for all the NRW biotechnological sector is managed by LSA, the one at BioRiver region level by the BioRiver association.

Marketing is performed through the publication of brochures, the creation of web sites, database, the arrangement of events, fairs, and meetings. Moreover, above all in order to attract new resources, personal and informal contacts seem to be a key factor.

Also the Government does marketing, through publications and conferences at national and international level.

The planned Innovation Agency should also be in charge of managing the international marketing.

Item	Contents
TERRITORIAL MARKETING	<ul style="list-style-type: none"> ▪ <i>Territorial marketing instruments in order to attract (capital and human) resources:</i> arrangement of events, trade fairs, meetings/conferences at national and international level, platform for contacts and technology transfer (mainly provided by coordinating agencies).
COMMUNICATION	<ul style="list-style-type: none"> ▪ Publication of brochures, creation of web sites, exhibitions, events.

c) Financial cycle

In 1982-1990 University research in Gene Technology, single projects developed in spin-offs have been funded. The former mainly by the government, while the latter both by the government and the local banks (as *Sparkasse*). Then the local banks reduces the investments and in 1995 the Bioregio contest was launched.

After winning the Bioregio contest, BioRegion Rheinland received almost 25 millions of euro from the BMBF and 30 millions of euro from the Land Government of NRW. Moreover around 25 million were provided by private sources. At that time BioGenTec was in charge of managing the funding received through PTJ by the BMBF.

In particular, as the application process for public BMBF funding is concerned, the regional coordinating agencies have:

- to prepare the research projects, by supporting scientists and enterprises. These projects have to be, then, approved by PTJ.
- to provide information to the actors of the clusters.

The coordinating agencies need to find alternative sources of funding for their activity business rather than the ones granted by PTJ, as the latter have to be dedicated to support projects. They can play as an intermediary between the PTJ and the companies that have applied for public funding but they cannot use these funds for their own managerial activity/organization.

In some cases, when firms don't need the agencies' support to develop the concept, funding are directly provided to firms, without the intervention of the agencies.

Apart from the BMBF and PTJ programmes, also the State (*Land*) can launch funding programmes. In this case the coordinating agencies are not directly involved into the funding management. In fact, they support firms in preparing the application and in finding partners but then the funds are directly provided to applicants. For instance, the City of Düsseldorf financially supported the Bioriver Bioregion, having provided firms with funding for the start up period (3 years) and a further 3-year-period.

Other sources of funding are the NRW Bank, VC companies, and Business Angels.

With effect from March 31st 2004, *Landesbank NRW* has become *NRW.BANK*, the development and municipal bank for North Rhine-Westphalia. In August 2002, *Westdeutsche Landesbank Girozentrale* was split up into West LB AG, which continues the activities of a competition-exposed bank, and *Landesbank NRW*, which is responsible for economic and structural development under a public mission. This split-up was effected against the background of an agreement, the so-called "*Verständigung*", between the EU Commission and the Federal Government on July 17th 2001, according to which Germany's public banks ceased to benefit from institutional liability and guarantor liability in mid-July 2005 (www.nrw-bank.de).

NRW.BANK is owned by the State of North Rhine-Westphalia (64,74%) and the Regional Associations of the Rhineland and Westphalia-Lippe (17,63% each) (www.nrw-bank.de). In practice, it was created on public initiative but it acts as a private VC company. It has set up a seed and a venture fund, and it has 70 million euros at disposal to support start ups.

There is a VC State company: TechnoMedia (of Sparkasse Cologne-Bonn) that supports companies located in NRW (mainly the big ones).

In order to help firms in getting private funding, in November 2006 the State Ministry of Innovation, Science, Research and Technology (*MIWFT - Ministerium für Innovation, Wissenschaft, Forschung und Technologie des Landes Nordrhein-Westfalen*) organized BioEurope: an event that involved European, American firms and VC companies. Two days before, 3 young biotech companies were selected to get professional training by VCs. The former had to be able to convince the latter to provide them with funding.

Item	Contents
SOURCE OF FUNDING	Public sources: BMBF (as winner of BioRegio contest), NRW Government, City of Dusseldorf. Private source: single investors and VCs. Mix sources: NRW BANK.
FUNDING MANAGEMENT	<i>Institution in charge of managing the funding:</i> at the time of the BioRegio contest, the coordinating agency (BioGenTec) that arranged and managed the application process.

3.2.4 Monitoring and evaluation

Once a year **Bioriver** has to provide its members with a written report concerning the actions it has conducted. The performance evaluation is done by the Board of Directors according to the four formal objectives abovementioned. The controlling process is not strictly detailed: specific indicators have not been set.

Whereas **BioGenTec** had to monitor the number of new firms, new products and patents, in order to justify how public funding had been spent, Bioriver does the same for private interest and for marketing and statistical purposes. In reality these statistics seem to be not available, due to lack of human resources that can be dedicated to this task in Bioriver.

The monitoring and reporting activity, once done by BioGenTec, is now managed by **LSA**: it provides public institutions (in particular local governments, the PTJ and BMBF) with reports containing data and general information concerning the cluster development. Moreover, LSA, as funded by the State, is compelled to report about its own activity to public institutions.

When **LSC** received the grant in occasion of Bioregio, they were required to provide data to the regional coordinating agency (BioGenTec at the beginning and LSA afterwards) for performance evaluation. They had to write an annual report, summarizing the scientific results, costs and revenues. Afterwards, they went on writing an annual report during the further 5 years in order to describe the implementation stage, the technology development and to demonstrate the effects of the projects in the long term.

Now, LSC provides to LSA and Bioriver data concerning the growth of NewLab (e.g. number of employees).

BioCologne doesn't collect data on cluster performance at the moment. However, it is developing a database on companies of the local network. During interviews it emerged that many companies, on the one hand, are reluctant in providing the number of products, and the pipeline; on the other hand, they declare, without any problem, the number of employees.

The level of satisfaction of the 40 members for the services provided by BioCologne, often seems to encounter difficulties. For this reason it is informally done during regular meetings.

Bayer Health Care doesn't provide Bioriver with specific data (i.e. number of products etc.) as they consider all other companies as business competitors. BHC just provides data that are already public: Bayer Hc is an AG²⁰; hence it quarterly has to publicly disclose data concerning its sales and its activity.

According to the **State Ministry** opinion, the activity of monitoring cannot be successfully performed, as the regional initiatives do not cooperate with LSA. This is another reason why the local Ministry doesn't want to continue funding LSA and aims at establishing a new Innovation Agency. As to the evaluation of the cluster performance, it is mainly done according to the formal requirements claimed in case of public funding programmes.

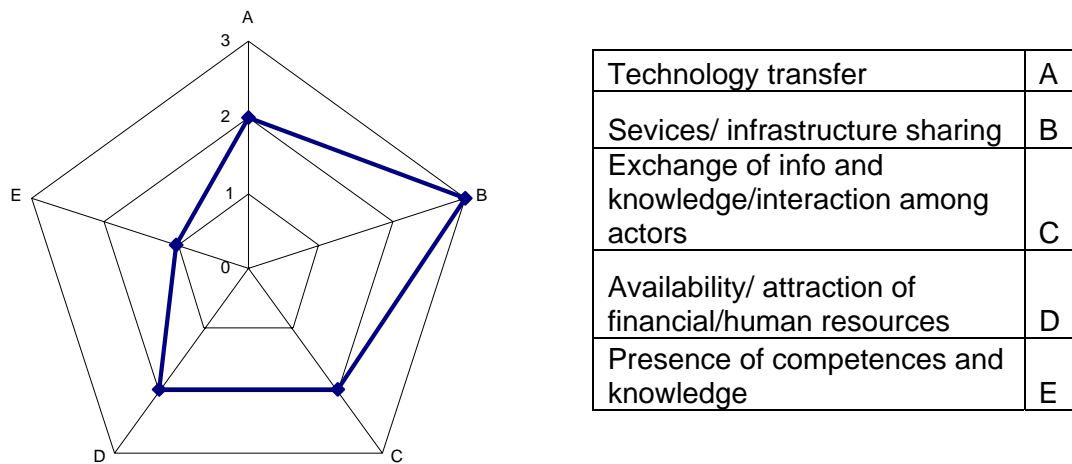
Item	Contents/indicators
PERFORMANCE EVALUATION	<ul style="list-style-type: none"> ▪ <i>Performance indicators:</i> i) number of companies; ii) number of employees; iii) number of products ▪ <i>How the performance evaluation is performed with respect to:</i> <ul style="list-style-type: none"> a) regular reports were provided by BioGenTec to public institutions (in particular to BMBF) in order to demonstrate the performance of the cluster and justify the obtained funding. b) LSA, as funded by the State, is compelled to provide public institutions with regular reports. c) BioRiver has to keep its members informed of its performance and the cluster development.
ORGANIZATION OF THE MONITORING AND EVALUATION PROCESS	<p><i>Schedule:</i> Reporting - once/twice a year; informal meetings are not strictly scheduled.</p> <p>Institution in charge of these processes: The coordinating agencies (BioGenTec/LSA and BioRiver).</p> <p><i>Feedback with respect to strategy setting:</i> mainly through informal meetings.</p>

²⁰ AG stands for *Aktiengesellschaft*, i.e. a private limited company

3.2.5 Interaction system

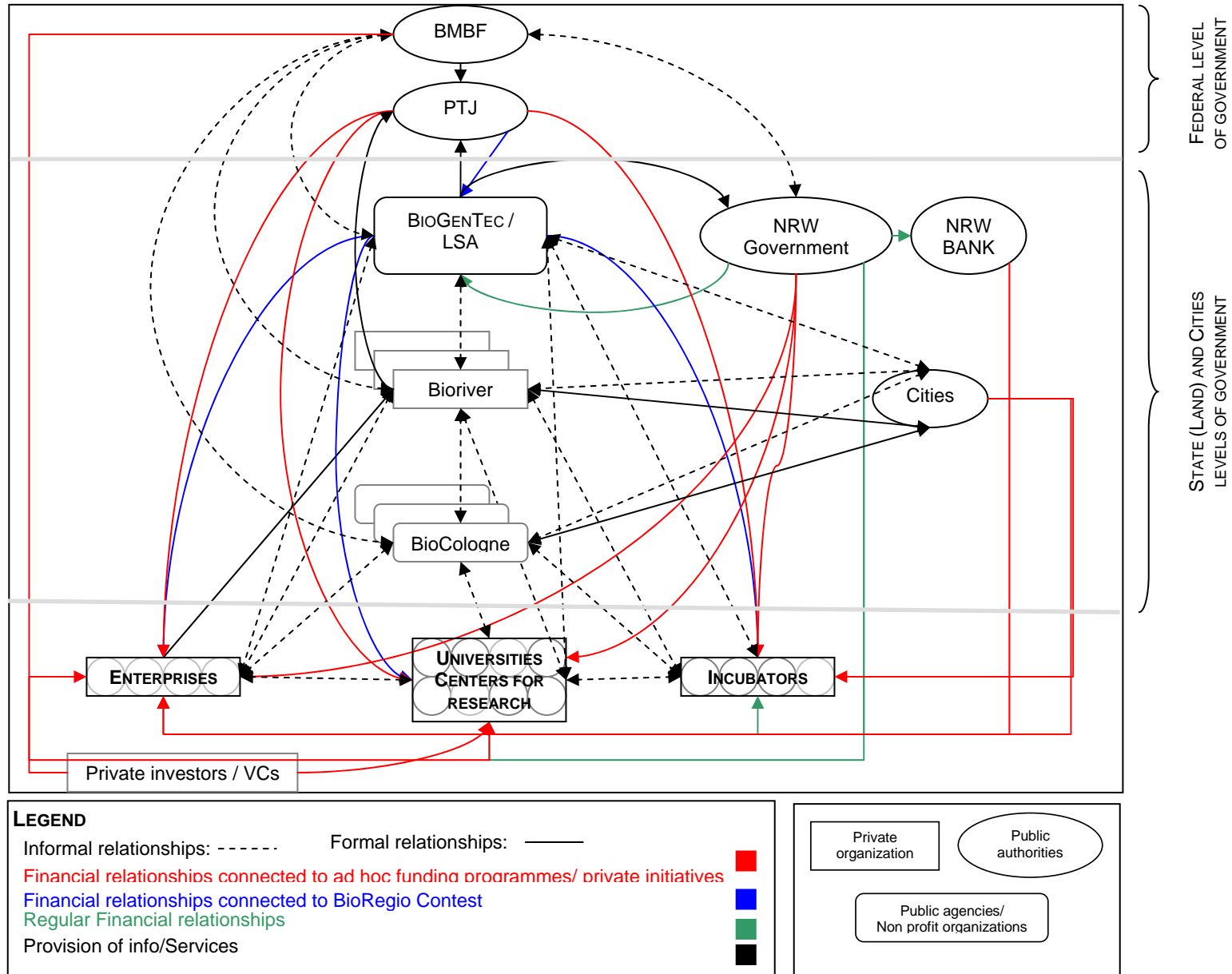
Figure 11, depicted according to data/information gathered by interviews and available documentation (§ 2.3.1), shows the most relevant interactions among the main members of the cluster. The figure shows a sizeable number of informal interactions as far as the provision of information and services is concerned. Just in few cases this kind of interaction is formally regulated by a contract in private-private and private – public interactions. In case of public-public relationships the interactions are mainly informal.

FIGURE 11– PERCEIVED ADDED VALUE OF BEING IN THE RHINELAND BIOREGION



The respondents of the semi-structured interviews were also asked what, according to their opinion, can be considered as the added value of being part of the cluster (§2.3.1). According to performed interviews, in the Rhineland cluster the most valuable added value is represented by the opportunity of sharing services and infrastructures. This opportunity allows above all the small and new companies to lower costs, focusing their resources either on production or R&D activities. Secondly, technology transfer, the exchange of information and knowledge and the interaction among actors are highly considered. Only one respondent mentioned also the presence of competences and knowledge.

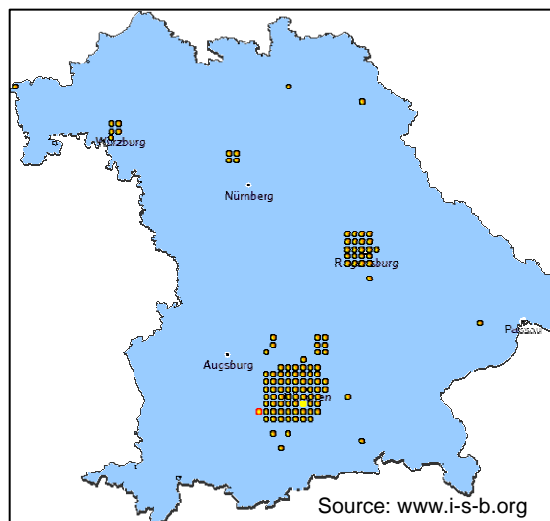
FIGURE 12 MEMBERS AND RELATIONSHIPS IN THE RHINELAND BIOREGION



3.3 The Munich BioTech region

3.3.1 General information

In 1994, the Bavarian Land Government launched the *Zukunftsoffensive Bayern* ("Future offensive for Bavaria"): an initiative aimed at improving the technological competitiveness of the Land and promoting science and research. Under this initiative, Bavaria launched several biotechnology promotion programs financed by the privatization of public assets. In this way, the Land was able to invest 4,05 million euro (1,5 in a



first phase in 1994, other 1,25 in a second one in 1996, and 1,3 in a third one in 2000). A policy of localization of the technological activity in Martinsried, near Munich, was performed. In this location important institutions of basic research, such as the gene center, the Max-Planck-Institute for Biochemistry and other centers, were set up. A further step of this process of localization was the establishment of the Biotech Innovation and of Start-up Center Martinsried (IZB), the Clinic Großhadern and the shift of a large part of the natural sciences faculties of the university, such as chemistry, pharmacy, biology, medicine and physics, to Großhadern (which is located in close neighbourhood of Martinsried). The IZB, built in 1994 and extended afterwards, offers laboratory space for start-up companies, internal and external infrastructure and facilitates formal cooperation and informal networking activities (Zeller, 2001). Apart from biotechnological companies, the Bioregion counts two universities, two university hospitals, two universities of applied science, the National Center for Environment and Health (GSF), three Max Planck Institutes with competences in Biology, and 26 pharmaceutical companies. The activity of the Bioregion is focused on the development of therapeutic and diagnostic products for oncology, dermatology and cardio-vascular diseases, reagents, DNA and bioinformatics.

Item	Contents
GENERAL INFORMATION ON THE CLUSTER	<ul style="list-style-type: none"> ▪ <i>Name:</i> BioTech Region Munich ▪ <i>Geographical area:</i> Munich and surroundings ▪ <i>Starting year:</i> 1994/1996 ▪ <i>Activity–field of interest:</i> Development of therapeutic and diagnostic product for oncology, dermatology and cardio-vascular diseases, reagents, DNA and bioinformatics.

3.3.2 Strategy setting

When the Bioregio contest was launched, the Government of Bavaria decided to participate for the whole State. But then the federal state suggested to focus on smaller areas. According to this suggestion, the Government of Bavaria decided to apply for the Munich area, by creating a sort of steering committee (made up of scientists and representatives of the Ministry, and the current director of Bio^M, the coordinating agency of the cluster - see hereinafter).

In the application for Bioregio contest a generic diagnostic recognition was traced. In particular, the steering committee, that managed the application process, detailed what was present in the area, in order to highlight its strengths and weaknesses. At that time the area was characterized by: i) «strong science» (two universities, university hospitals, three biologically oriented Max Planck Institutes, the National Center for Environment, two universities for applied science); ii) few pharmaceutical and chemical companies, most of which were subsidiaries of bigger pharmaceutical and chemical companies; iii) some biotech companies as spin off from the pharmaceutical and chemical companies already present in the territory. Moreover the committee established that “to provide start up companies with financial support to develop their business” was the medium term objective to be reached through the development of the cluster. The idea was to make available to entrepreneurs, coming from universities, seed funds that could support the start up of the company. A further goal was to create a network. At the time of the contest, according to Bio^M director’s experience, it was easier to have a network because everybody could be involved (including secretaries and technicians) as they were few. But then, when the sector started to grow, the

network had to be changed. It needed to become a “multidimensional network”, which means that experts from different fields and at different level (e.g. business developers, scientific directors, clinical leaders, human resources and companies' PR managers) had to be put in contact.

Item	Contents
DIAGNOSTIC RECOGNITION	<ul style="list-style-type: none"> ▪ <i>Actors of the cluster and cluster boundaries:</i> the main actors of the cluster are: i) biotech companies, mainly spin offs of the university; ii) pharmaceutical and chemical companies; iii) two universities, two university hospitals, two universities of applied science; iv) National Center for Environment and Health (GSF), three Max Planck Institutes with competences in Biology; v) VCs, private investors, private banks and the Bayern Capital GmbH. ▪ <i>Competitive arenas and SWOT analysis of the region:</i> performed by an ad hoc steering committee. When the Bioregio contest was launched, the Government of Bavaria decided to participate for the whole State. According to the federal State suggestion, the Government of Bavaria decided to apply for the Munich area.
OBJECTIVES PLANNING	<ul style="list-style-type: none"> ▪ <i>Process according to which the cluster's objectives are defined:</i> regular meetings among the actors of the cluster: coordinating agency, companies, universities, research centers and public institutions (i.e. with representatives of the State and, in some cases, the Federal Government). ▪ <i>Tools and ways for obtaining and maintaining over time consensus by institutional actors:</i> coordination of relationships by the coordinating agency both on formal (by contract) and informal base by creating a “multidimensional network”.
COMPETENCES/ RESPONSIBILITIES SETTING	<ul style="list-style-type: none"> ▪ <i>Process of definition and setting of competences and responsibilities:</i> mainly informal (e.g. stammtisch and personal relationships and knowledge of the area). The investment/supervisory board of the Bio^M represent the interests of many actors (companies, research institutes, and university); the Government of Bavaria is regularly involved into the decision making process as founder of the agency.

3.3.3 Strategy implementation

a) Organizational structure

After the Munich BioTech region won the Bioregio contest, a coordinating agency, **Bio^M AG**, was founded. The founders (the abovementioned steering committee) decided to set an AG²¹ to be able to raise funds for financing start up companies.

The State of Bavaria decided to provide Bio^M with the 25% (1,75 million euro) of the capital it needed to become operative and the other 75% was collected from the private sector (i.e. banks, pharma and chemical companies).

Nowadays, Bio^M team is made up of 10 persons, moreover an investment board and a supervisory one meet regularly in order to take decisions and monitor the agency activity and performance. The investment board is made up of representatives from the Consortium for the electro-chemical industry, GPC Biotech AG²², the 3i Technologieholding²³ and of the Technische Universität Munich. The supervisory board consists of representatives from the GSF –(Forschungszentrums für Umwelt und Gesundheit – Research center for Environment and Health), Siemens AG, Aventis Pharma Deutschland GmbH, Roche Diagnostics GmbH, and Max-Planck-Institut für Biochemie Martinsried.

Bio^M has mainly three objectives:

- to help the start of 5 new biotech companies per year;
- public relations in terms of international visits, local press;
- to find out what is important for companies and how the agency can help them. In this way it helped companies to write good applications: 20-25% of grants distributed overall in Germany went to Munich.

It offers services and financial support to Munich-based biotechnology firms and provides international institutions or companies with assistance to look for business partners in the area. In particular, Bio^M offers:

- i) information and consultancy (it helps founders to start and conducts studies on the industry for agencies and governmental bodies);
- ii) networking by organizing conferences and bringing business partners together;

²¹ AG stands for Aktiengesellschaft, i.e. shareholder company

²² It is a biotechnological company.

²³ It is a private equity and venture capital company

- iii) public relations, i.e. Bio^M provides the press with information and represents the region at national and international conferences and exhibitions. Moreover Bio^M finances companies with seed capital. Its venture capital activities have been expanded with the establishment, in December 2001, of **Bio^M VC fund**, that, even if legally independent of the Bio^M, is managed by the same team. The fund performs co-investments with lead investors and arranges long-term partnerships with the promising biotechnological companies.

As abovementioned, Bio^M is financially supported by the Bavarian government with which it has stipulated a three-year contract, according to which the State pays 700 thousand Euros per year.

According to the snowball strategy (Patton, 1990; chapter2), within the Bioregion, the **University**²⁴ aims at supporting the commercialization of research activity/results. According to this purpose, in 1992 the Technology Transfer Center was founded. At the beginning of its activity it was managed only by one person, now the team is made up of 15 persons. Each year there are 1-3 new firms generated by the academic environment. The task of the center is to support these firms in writing the business plan and bring them in contact with Bio^M to get some advices for finding project and financial partners. According to this task the LMU and the university of Munich, in collaboration with the industry and venture capitalists, have launched the *Business plan competition (Münchener Business Plan Wettbewerb)*. This competition aims at encouraging researchers, engineers and business people to start new companies. During the last ten years, the three stage competition has supported the start up of 381 companies (of which the 84% are still alive), selected by a jury (that includes entrepreneurs, business angels and venture capitalists): venture capitalists have invested 285 million Euros, business angels have invested 25 million, and all together the 381 companies employ 2900 persons.

According to the increasing importance paid to life sciences in the last ten years (i.e. since the Bioregio contest), dedicated new departments and chairs were developed

²⁴ Information concerning the Ludwig-Maximilians University have been mainly provided by Mr Zinser (LMU – Technology Transfer Center)

within the university. In the mean time, universities have been asked by the Bavarian State to write concepts, to highlight their field of excellence and potential development.

With the support of Bio^M, two companies were chosen: *Ingenium AG* and *Supremol GmbH*. The former is a medium – size company and the latter a small one. They were chosen as they are different in size, market and field of interest and, hence, they can provide complementary perspectives on the same cluster and on the potential benefits that they can gain from being part of it.

Among the **companies** of the bioregion, *Ingenium*²⁵ AG was founded in 1998 as a spin off of the German Human Genome Project. Ingenium counts about 50 employees and discovers and develops novel therapeutics to treat pain and inflammatory diseases. Within the Bioregion, Ingenium mainly collaborates with

- companies, by doing some tests/experiments with/for local companies
- Bio^M that organizes visits and meetings to which Ingenium participates
- the Max Planck Institute and the universities for research activity and exchange of knowledge.

Moreover, some persons of Ingenium are regularly involved in round table organized within the cluster by Bio^M and research institutes.

The main benefits that Ingenium gains from being part of the cluster are the availability of infrastructures (e.g kindergardens), of platforms for discussions/meetings and the visibility through the PR activity performed by Bio^M.

*Supremo*²⁶ GmbH is focused on the development of novel therapeutics for the treatment of autoimmune diseases. It is a spin off from the laboratory of Prof. Huber (Nobel Prize for Chemistry in 1988) in the Max Planck Institute for Biochemistry. Supremol was founded in 2002 and up to October 2005 it was still located at Max Planck Institute, but then it moved to Martinsried campus. The company counts 9 employees and mainly collaborates with:

- the University: they have stipulated a 1 to 3 year contract for clinical research;

²⁵ Information concerning Ingenium AG have been mainly provided by Mr Ade (Senior Director Business Development, Licensing – Ingenium AG)

²⁶ Information concerning Supremol GmbH have been mainly provided by Dr Buckel (Chief Executive Officer – Supremol GmbH)

- Bio^M: the Chief executive officer at Supremol was personally involved in the foundation of BioM, moreover the agency provides services (in terms of marketing/ PR / territorial marketing activities) without having stipulated any contract;
- Max Planck Institute: for spin offs from Max Planck Institute, as Supremol is, patents are managed by an agency of the Institute; hence the company and Max Planck Institute are co-owners of inventions;
- The Chief executive officer of Supremol is member of the Board of Trustees of Max Planck Institute, teacher at the University, and member of the action team of Martinsried (a team interested in the evolution of the campus).

Another member of the cluster is the **Max Planck Institute in Biochemistry**²⁷, founded in 1974 and located in Martinsried. This Institute is part of the Max Planck Society, a non profit research organization dedicated to basic research. The Institute has ten totally independent departments and each department has a director, appointed by the Chairman. Each department has its own budget decided by the Board of directors. The Institute was involved into the Bioregio contest. In particular the professors of the institute have been directly involved into the writing of the application. The Institute has a limited budget and limits in terms of employment: there are few permanent positions and many Phd students.

The Max Planck Institute mainly collaborates with:

- the university: there are close connections between professors and the university. There is a Max Planck international school (that opened 2 years ago) where a Phd programme is shared with the university;
- firms: on informal base, mainly with spin offs coming from the Institute, and formal collaborations between the Institute and companies (e.g. Proteros and Supremol);
- Bio^M in an informal way, for PR activity;
- hospitals: in particular those for neuron immunology, neurology, biochemistry both for projects and educational programmes.

The Institute has also a Board of Trustees (appointed by the president) whose main members are Bio^M, the firms (Max Planck spin offs), the media and politicians. It meets

²⁷ Information concerning Max Planck Institute in Biochemistry in Munich have been mainly provided by Prof. Diehl (Public Relations – Max Planck Institute in Biochemistry).

once a year to discuss different and specific issues addressed at understanding how to improve the collaboration in the bioregion.

In order to encourage innovation, to be attractive as a high-tech and science location, and to create jobs, at the beginning of 2006, the economy experts of the Bavarian government launched a strategy, the so called *Cluster Initiative*. In Bavaria were identified 19 high-tech clusters for which the Bavarian government has earmarked 50 million Euro. There is the intention to commit the management for biotechnological clusters (of which the Munich one is the biggest) to the responsibility of Bio^M. The activities should be commissioned and controlled by the Bavarian State Ministry of Economic Affairs, Infrastructure, Transport and Technology.

Item	Contents
INSTITUTIONAL FORM	<ul style="list-style-type: none"> ▪ <i>Type of institutional/legal form:</i> an informal sort of consortium, whose boundaries corresponded to Munich and surroundings, steered by the coordinating agency (Bio^M).
AD HOC BODIES	<ul style="list-style-type: none"> ▪ <i>Establishment of ad hoc bodies:</i> i) the coordinating agency (Bio^M), ii) Bio^M VC fund, iii) Bayern Kapital GmbH; iv) Board of Trustees at Max Planck Institute
FORMS OF COOPERATION	<ul style="list-style-type: none"> ▪ <i>Main collaborations</i> (intra- and extra- cluster, industry-industry and PPP): <ol style="list-style-type: none"> a) Between Bio^M and i) companies and incubators of the cluster; ii) other coordinating agencies of other German Bioregion; iii) public institutions (BMBF, PTJ, Land Ministries), iv) financial entities (single investors, VCs, banks), v) its shareholders. b) Among companies and between them and financial entities (single investors, VCs, banks, BioM VC fund). c) Between the University and i) companies and incubators of the cluster and outside it; ii) Bio^M; iii) public institutions (BMBF, PTJ, Land Ministries).
HUMAN RESOURCES	<ul style="list-style-type: none"> ▪ Type of contracts: between Bio^M and the Bavarian Government has been stipulated a three-year contract. Moreover, Bio^M is a shareholder company. ▪ Training services and education: organized by the coordinating agencies in collaboration with Universities / Research Centers / Public Institutions / Single Companies.

b) Marketing

The marketing within the Munich Biotech region is mainly managed by Bio^M, that produces publications and brochures, organizes events, conferences and fairs, and issue interviews on newspapers. In fact, according to Bio^M director, « *It is important to be in the perception of the public*» and « *It's important to keep knowledge and resources within the cluster*». In this sense, Bio^M plays as moderator of official and unofficial information.

Marketing and PR activities are also managed by research departments of the Universities, mainly by organizing events and seminars.

Among the companies, Ingenium, according to the director of business development and licensing, has a limited service business and it concentrates its financial resources in research rather than marketing.

At Max Planck Institute every two years an Open Day is organized. Moreover, seminars and scientific conferences are performed and press releases are done.

Item	Contents
TERRITORIAL MARKETING	▪ <i>Territorial marketing instruments</i> : events, conferences and fairs.
COMMUNICATION	▪ Publications and brochures hoc interviews on newspapers

c) Financial cycle

The Bioregions that won the contest didn't receive a direct funding of 25 million Euro, but a promise that the funding would have been provided to research projects in the area that could match the same amount of money from the private. In other words, these funding were reserved only for biotech companies (not pharmaceutical/chemical ones) that could provide the other 50% of the funding. Hence, the Munich Bioregion got the prize, established Bio^M that, through a strong evaluation process, selected research projects. These projects were then suggested to the federal ministry, which agreed on all of them. Moreover, unlike other parts of Germany, the steering committee decided to get seed fund in order to support entrepreneurs from universities to start a company. According to the experience of the steering committee fifteen members, the communication between scientists and business people is difficult, as «they use

different languages and have different priorities». Their idea was to use seed funds in order to train the scientists to become entrepreneurs/ business people at the very early stage of a company start up. According to this approach, Bio^M had provided one third of the capital and the other two third were offered by the state owned bank and the federal owned one, both in terms of long term loan. For instance, Bio^M provided the companies with 200 thousands Euro and each bank gave other 200 thousands Euro and so on.

Through this procedure probably too many start ups were funded and many of them couldn't survive. Some of them had strong technology but the time needed to get it to the market was too long and too much private funding was needed. Probably, the situation was due to inexperience, i.e. to not enough training in running a business. Also for this reason, Bio^M decided to work on another programme that is supposed to support scientific projects still in the academic environment and commercially oriented (it's a kind of pre-seed fund). Business idea is developed in the academic surrounding and only at a rather late stage the company is founded and receives money from private investors. This programme tries to bridge this gap. It was funded by the federal ministry of research; in particular, it is the result of the interaction among all the 25 German biotech clusters. After the financial market crash in 2000-2001, they joined the efforts in order to find funds for the early stage companies. Then they formulated their concept and submitted it to the BMBF. According to this proposal the Federal state activated a program to support young researchers.

The university normally waits for public contests and then applies, being supported by Bio^M in writing the application and the letter of intent. In most cases the contests are launched by the Federal Ministry, the Bavarian State and the City of Munich (mainly not concerning research rather than employment).

Funding for start ups are also provided by Bayern Kapital GmbH. This is a Bavarian venture capital company founded at the end of 1995 as part of the "Bavarian Future Initiative" as a wholly-owned subsidiary of the *LfA Foerderbank Bayern* (Bavaria's development bank). The objective of *Bayern Kapital* is to finance research, development and market introduction of new products. In this effort *Bayern Kapital* usually acts as co-investor in cooperation with a lead investor. In 2002 *Bayern Kapital* set up two new funds. It joined forces with the *LfA Foerderbank* (Bavaria's development

bank) and *tbg-Technologie-Beteiligungs-Gesellschaft mbH* (now *KfW* – a bank sponsored by the German federal government), to create:

- i) *seed funds Bayern* with a volume of 22 million euro for financing startups in the medical technology, environmental technology and information / communication / software sectors;
- ii) *echnofonds Bayern II* with a volume of 60 million euro;
- iii) a target volume of 75 million euro, was also set up with the same partners and the European Investment Bank. The fund aims at facilitating the emerging Bavarian firms to get venture capital.

Bayern Kapital now manages a fund volume of almost EUR 190 million. The investments are mainly concentrated in the information technology, measuring and control equipment, medical technology and pharmaceutical industries (www.bayernkapital.de).

The Max Planck Institute's funding can be provided by the Federal State, the Bavarian Government, the EU and the private (e.g. Cancer organizations, companies etc.). Another source of funding can be represented by the *Deutsche Forschung Gemeinschaft* (DFG), which is the central, self-governing research funding organization that promotes research at universities and other publicly financed research institutions in Germany. The DFG provides long term funds to research projects and facilitates cooperation among researchers.

Item	Contents
SOURCE OF FUNDING	Public sources: BMBF (as winner of BioRegio contest), Bavaria Government. Private source: single investors and VCs. Mix sources: Bayer Capital (at State level), KfW (at federal level), Bio ^M VC fund.
FUNDING MANAGEMENT	<i>Institution in charge of managing the funding:</i> At the time of the BioRegio contest, the coordinating agency (Bio ^M) that arranged and managed the application process. Bio ^M as manager of the biotech clusters in Bavaria for State funding cluster initiative. In case of public programmes it depends on the involved partners, Bio ^M is often involved in the application process and funding management/distribution.

3.3.4 Monitoring and evaluation

According to the interviews, indicators needed to evaluate the cluster performance are:

- the number of companies (even if considered not so important)
- the number of employees (considered very important)
- the amount of sales
- money spent in R&D
- how much money come into the region
- collaborations started by companies with other companies and with research institutes.

These data are collected through questionnaires by Bio^M. A report is edited once a year. The respondents are really supportive; in some cases they provide confidential data concerning the products that cannot be published.

The evaluation by the Bavarian State of Bio^M activity is performed twice a year: there are agreed milestones (i.e. goals, e.g. increase of space...) and the State controls the achievement of them (through reports). These milestones are very flexible: the agency and the State agreed on general aspects but the agency can ask to change them from one day to another according to necessities.

At the university, performance evaluation depends on the projects: the projects financed by public institutions require an evaluation. Whenever public funding are provided, regular reports (at least one at the end of the project) are required in order to demonstrate/justify, in terms of results of the research project, how the funding have been invested. There is also a feedback: the reports seem to be critically read by the public institutions.

In case of DFG funding, a regular evolution/publication of results is required: the ministry funds the projects for 2 – 3 years and then, after a check of middle results, can continue to fund.

In case of public funding also the companies are asked of providing very detailed reporting. For instance KFW asks for a monthly report. In this case data concerning the

financial situation, salaries, number of employees and turn over rate, number of patents and of publications are mainly requested.

Item	Contents/indicators
PERFORMANCE EVALUATION	<ul style="list-style-type: none"> ▪ <i>Performance indicators:</i> i) the number of companies; ii) the number of employees; iii) the amount of sales; iv) money spent in R&D; v) how much money enter the region; vi) collaborations started by companies with other companies and with research institutes. ▪ <i>How the performance evaluation is performed with respect to:</i> <ul style="list-style-type: none"> a) regular reports provided to public institutions (BMBF and State Government) in order to demonstrate the performance of the cluster and justify the obtained funding. b) Bio^M, as funded by the State, is compelled to provide public institutions with regular (twice a year) reports according to agreed milestones. c) Publication Bio^M, once a year, of reports according to data collected through questionnaires and concerning the development and performance of the cluster.
ORGANIZATION OF THE MONITORING AND EVALUATION PROCESS	<p><i>Schedule:</i> Reporting - once/twice a year; informal meetings are not strictly scheduled.</p> <p><i>Institution in charge of these processes:</i> The coordinating agencies (Bio^M).</p> <p><i>Feedback with respect to strategy setting:</i> mainly through informal meetings.</p>

3.3.5 Interaction system

In the Bioregion Munich interactions are mainly formal, even if a number of services and information are provided and shared on an informal base, above all when managed by the coordinating agency Bio^M.

The importance of the exchange of information, knowledge and interactions among actors is confirmed by the results of the interviews (Figure 13). Even if less mentioned as the former, the sharing of services and infrastructures and the availability/ attraction of financial/human resources are considered substantial factors. The least mentioned added values are technology transfer and the presence of competences and knowledge. A possible explanation can be that these factors are taken for granted as already well structured and integrated.

FIGURE 13 – PERCEIVED ADDED VALUE OF BEING IN THE MUNICH BIOREGION

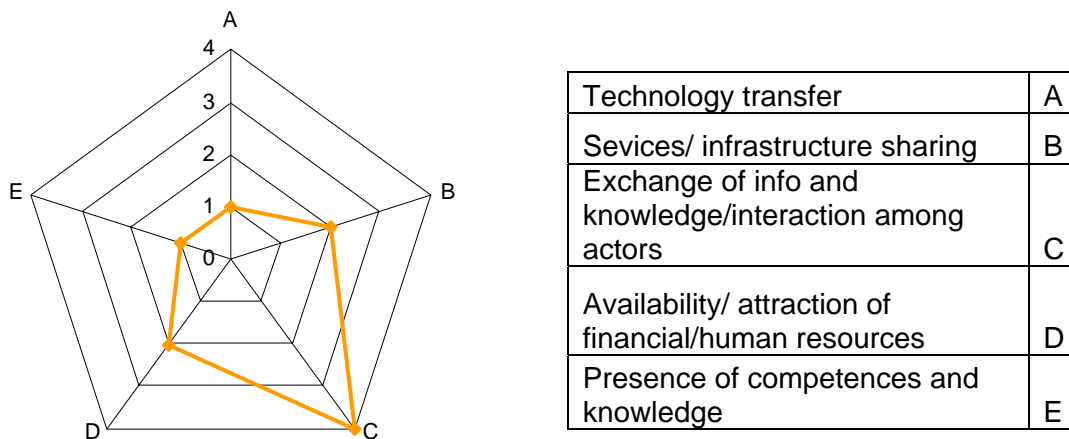
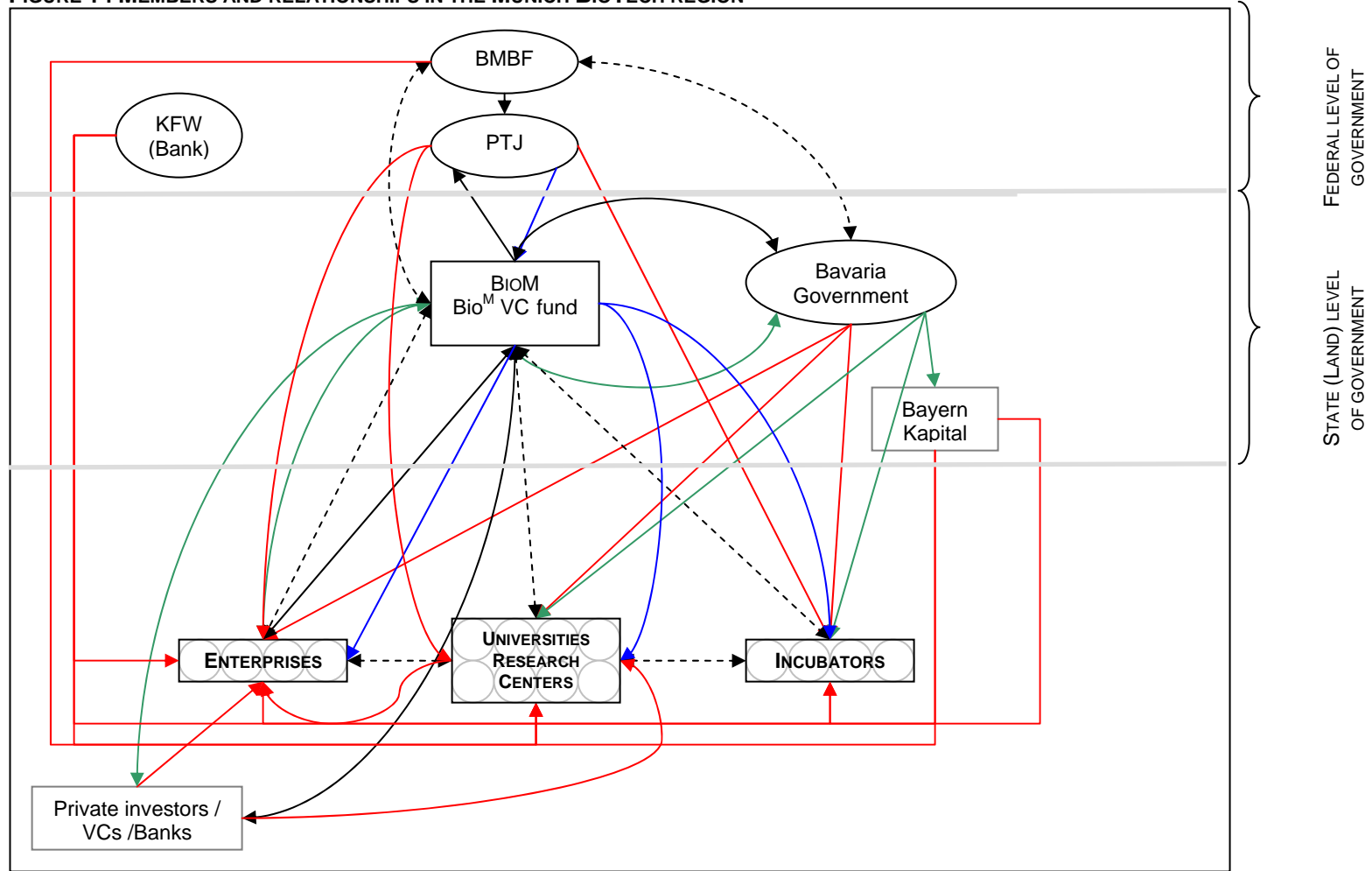


FIGURE 14 MEMBERS AND RELATIONSHIPS IN THE MUNICH BioTECH REGION



LEGEND

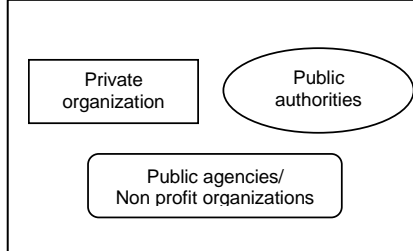
Informal relationships: - - - - - Formal relationships: ———

Financial relationships connected to ad hoc funding programmes/ private initiatives ■

Financial relationships connected to BioRegio Contest ■

Regular Financial relationships ■

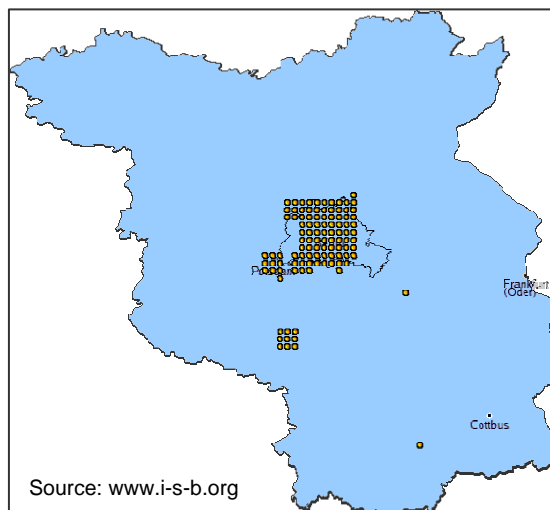
Provision of info/Services ■



3.4 The Berlin-Brandenburg Bioregion

3.4.1 General information

The Berlin-Brandenburg Bioregion got the fourth place in the Bioregio contest. In 2001 the cluster won the Bioprofile contest and got 18 million Euro over a five-year period. BioProfile was addressed to those regions that aim at investing in future-oriented fields of application of modern biotechnology. In particular, in the Berlin-Brandenburg Bioregion, this funding aimed at supporting the development of research in the field of



nutrition related diseases. In detail, the research activity of the cluster focuses on metabolic syndromes, obesity, cardio vascular diseases, diabetes, cancer, allergies and technology. Other fields of activity of the bioregion are genome and proteome research, biohybrid technologies, e.g. biochips for analysis and diagnostics, new therapies in the field of regenerative medicine, glycobotechnology, and bioinformatics. Apart from the biotechnological companies, the cluster counts: i) 25 centers for research, among which the Max Delbrück Center for Molecular Medicine, several Max Planck Institutes, the Fraunhofer Institutes, the German Institute of Human Nutrition and the German Resource Centre for Genome Research; ii) five universities, among which the Charité university hospital (that is the largest in Europe); iii) six scientific parks (the Biotechnologiezentrum Hennigsdorf, the Campus Berlin Buch, the Berlinbiotech park, the Focus Mediport, the WISTA/UTZ Zentrum für Umwelt-, Bio- und Energietechnologie, the Biotech Campus Potsdam, and the Biotechnologiepark Luckenwalde). Within the cluster, during time, thirteen scientific networks have been formed (*Biohybrid Technologies, Bioinformatics, Functional Genomics, Glycobotechnology, Nutrigenomics, Personalised Medicine, Plant Genome Research, Protein Structure Research, Regenerative Medicine, RNA Technologies, Tumor Diagnostics, Ultrastructure Research, and White Biotechnology*). The process of

formation of 'scientific networks' consists in the localization of research centers, universities and companies with common competences in specific fields of research/activity (e.g. white biotechnology, nutrigenomics and so on) into the same geographical area of the cluster.

The State of Berlin and the one of Brandenburg decided to participate to the Bioregio contest and to the Bioprofile one together, as a single applicant. The reasons underlying this decision are that, on the one hand, Brandenburg strongly depends on Berlin to attract investments and, on the other, Berlin depends on Brandenburg as the latter is less expansive than the former.

Item	Contents
GENERAL INFORMATION ON THE CLUSTER	<ul style="list-style-type: none"> ▪ <i>Name:</i> Berlin - Brandenburg ▪ <i>Geographical area:</i> States of Berlin and Brandenburg ▪ <i>Starting year:</i> 1996 <p><i>Activity-field of interest:</i> Genome and proteome research, biohybrid technologies, e.g. biochips for analysis and diagnostics, new therapies in the field of regenerative medicine, glyco-biotechnology, nutrigenomics and bioinformatics.</p>

3.4.2 Strategy setting

The governments of Berlin and Brandenburg at the time of Bioregio were aware of the strong research potential present in the area. There was a clear idea that the creation of a cluster was needed to become more effective. In particular, the creation of collaborations/contacts to get technologies, information, projects and financial partners were perceived as essential. The coordinating agency of the Bioregion, BioTop, has constantly monitored the strengths and weaknesses of the region. Among the latter, the economic difficulties of the two States are related to the deep changes that interested important areas of their territories after the German reunification. In order to overcome these problems, the two States, as abovementioned, decided to join their forces.

BioTop has contributed to identify the potential of the Bioregion. The most rooted strength of Berlin and Brandenburg is considered their potential in science and research, thanks to the high number and importance of research centers there located. For instance, BioTop identified the potential of the region in the development of tissue

engineering and hence supported the growth of a tissue engineering lab, established in 1994 and developed between the end of 1990s and 2000.

The cluster's objective planning is defined through regular meetings mainly between the BioTop board and the two governments of Brandenburg and Berlin. BioTop regularly meets representatives of the industry and the research in order to collect their opinions and needs and discuss them with public authorities.

Item	Contents
DIAGNOSTIC RECOGNITION	<ul style="list-style-type: none"> ▪ <i>Actors of the cluster and cluster boundaries:</i> the main actors of the cluster are: i) biotech companies, mainly spin offs of the university; ii) pharmaceutical and chemical companies; iii) five universities; iv) 25 centers for research; v) six scientific parks; vi) thirteen scientific networks; vii) VCs, private investors, private banks; viii) Investitions Bank Berlin (IBB) and the Technology Coaching Center (TCC). ▪ <i>Competitive arenas and SWOT analysis of the region:</i> performed by BioTop. According to it the two States of Berlin and Brandenburg decided to join their forces and form a unique biotech cluster.
OBJECTIVES PLANNING	<ul style="list-style-type: none"> ▪ <i>Process according to which the cluster's objectives are defined:</i> regular meetings mainly between the BioTop board and the two governments of Brandenburg and Berlin. BioTop regularly meets representatives from the industry and the research in order to collect their opinions and needs and discuss them with public authorities. ▪ <i>Tools and ways for obtaining and maintaining over time consensus by institutional actors:</i> coordination of relationships by the coordinating agency both on formal (by contract) and informal base.
COMPETENCES/ RESPONSIBILITIES SETTING	<ul style="list-style-type: none"> ▪ <i>Process of definition and setting of competences and responsibilities:</i> the first steps towards the cluster development were decided by the States Governments, that took the first key decisions (i.e., for instance, joining the forces into a unique cluster, to found BioTop as manager of the cluster activities).

3.4.3 Strategy implementation

a) Organizational structure

The coordinating agency of the cluster is BioTop. It was founded in 1997 under the initiative of the Technology Foundation Innovation Center²⁸ (*Technologiestiftung Berlin* – TSB) Berlin and it is financed by the States of Berlin and Brandenburg whose relationship is regulated by a three year contract. Its original aim was to apply for Bioregio and then its range of activity widened and it became responsible of the growth of the cluster and supported the governments to enforce their policy in biotechnology.

In particular, BioTop tries to support biotech in a broad sense, by:

- organizing applications for contests, such as Bioprofile and Innoregio
- getting people to know each other and trying to create networking among scientific centers
- supporting scientists interested in start new companies to write business plans, to find partners and public/private funds and spaces
- coordinating the 6 parks of the bioregion
- collaborating with the bio-campus and scientific networks' representatives in order to coordinate the activity and have an exchange of info
- doing lobbying activity towards the public authorities
- arranging regular meetings with representatives of the industry in order to collect their requests and needs
- providing services to existing companies: once a month there is a meeting concerning legal issues and patents, contracts, cooperations (the so called BioTop forums).

BioTop team is made up of 6 persons. In its advisory board there are representatives of:

- the Freie University in Berlin, Institute for Biochemistry
- the Charité – University of Medicine Berlin
- Metanomics GmbH (see hereinafter)

²⁸ The TSB technology foundation is a Berlin centre of innovation. It sponsors the applications-oriented science (www.technologiestiftung-berlin.de).

- the Max-Planck-Institute for Molecular Genetic and the the one for Molecular Plant physiology, Berlin
- the Humboldt University in Berlin, Institute for Clinical Pharmacology
- the Institute for Biochemistry and Biology Universität Potsdam
- the Berlin-Brandenburgischen Academy of Sciences
- B·R·A·H·M·S corporation²⁹

As abovementioned, between 1997 and 2006 within the cluster thirteen scientific networks have been formed: *Biohybrid Technologies*, *Bioinformatics*, *Functional Genomics*, *Glycobiotechnology*, *Nutrigenomics*, *Personalised Medicine*, *Plant Genome Research*, *Protein Structure Research*, *Regenerative Medicine*, *RNA Technologies*, *Tumor Diagnostics*, *Ultrastructure Research*, and *White Biotechnology*. In Box 4 a short overview of the networks is presented.

Box 4 Scientific networks in the Berlin – Brandenburg cluster

Name of the network	Field	Year of foundation	Source of funding	Coordinating institution
PTD (Pre-symptomatic tumor diagnostics)	Technologies and strategies for early tumor detection	1997	BMBF (BioResponse) Federal Ministry of Economics and Labour (NEMO)	Non profit 'Association Pre-symptomatic Tumor Diagnostics'
RiNA	RNA technology	1998	Senate of Berlin BMBF European Regional Development Fund Local companies	RiNA Network for RNA technologies GmbH
Nutrigenomics	Nutrigenomics	1999	BMBF (BioProfile) Contributions from local companies involved in R&D projects	Society for the Promotion of Nutrigenomics Research in cooperation with BioTop
GABI (Genome Analysis of the plant Biological System)	Plant genome	1999	Public private partnership between BMBF and local companies	GABI Managing Office at the Max-Planck-Institute of Molecular Plant Physiology
(PSF) Protein Structure Factory	Protein structure	1999	BMBF (NGFN-2), EU, Research Institutions, Industrial partners	Max Delbrück Center for Molecular Medicine
BioHyTec (Biohybrid Technology Network)	Interface between biosensor development and microsystems	2000	BMBF (InnoRegio Program) State funds	BioHyTec Association for Bioanalysis and BioHybrid Technologies (non profit)

²⁹ Company that develops and produces diagnostic test procedures.

	technology			
BCB (Berlin Center for Genome Based Bioinformatics)	Bioinformatics	2001	BMBF (Biotechnology Advancement Program 2000')	Coordinating committee formed by scientists
CFFG (Center for functional genomics)	Functional genome and proteome	2002	State of Berlin European Regional Development Fund Max Planck Institute for Molecular Genetics	Executive Office at Max Planck Institute for Molecular Genetics
Personalised Medicine (in Campus Berlin-Buch)	Molecular causes of cancer, coronary diseases, and degenerative neurological diseases	2002	BMBF (Innoregio Program)	InnoRegio Office in the BBB Management GmbH Campus Berlin - Buch
RMIB (Regenerative Medicine Initiative Berlin)	Regenerative medicine	2002	University Science Program	CellNet.Org (the interdisciplinary research association for regenerative medicine) at the Charité University of Medicine Berlin
UltraStruktur	Structural proteomics	2002	EU, Berlin Senate Administration for Science, Research and Culture	Max-Planck-Institute for Molecular Genetics Berlin
Glycobiotechnology	Glycobiology	2003	Technology Foundation Berlin (Future Fund)	Institute for Biochemistry and Molecular Biology of the Charité University of Medicine Berlin
White Biotechnology	Industrial biotechnology	2006	Under development/definition	

Source: *Biotech Networks Berlin Brandenburg*, BioTop.

Unlike the five sub-clusters developed in NRW, the scientific networks in Berlin – Brandenburg are not coordinated by *ad hoc* agencies but by associations with specific tasks focused on the networks itself rather than on the whole cluster.

In the Berlin Brandenburg cluster there are six parks, even if there is the intention to reduce this number. The Biocampus association, organization made up of the managers of the different parks, regularly meets in order to coordinate their activity.

Among the parks, the **Biotech Park Berlin-Buch**³⁰ is the biggest (with a surface of 26.000 m²). The Biotech Park Berlin-Buch is part of the campus Berlin- Buch, whose history and structure are described in Box 5. In the BiotechPark 36 companies are located and approximately 470 persons are employed. The park, as all the campus, is managed by *BBB Management GmbH Campus Berlin-Buch* (BBB). Between 1996-2006 funding by the EU, the Federal and Länder governments (overall 50 million Euro) have been raised for the foundation and expansion of the park. In the mean time, 183 million Euro (of which 139 million privately financed and 44 million as grants) have been invested by 50 companies.

BBB has a public mandate and is a not profit organization; its shareholders are the Max Delbrück Center for Molecular Medicine (MDC) Berlin-Buch (60 %), the Leibniz Institute for Molecular Pharmacology (20 %) and Schering AG (20 %). BBB:

- i) provides biotechnological firms with a location and facilities within the campus, in particular in the BiotechPark and an Innovation and Foundation Center with specialised infrastructure;
 - ii) fosters and coordinates the collaboration and interaction among all members of the campus;
 - iii) acts as a lobbyist with public authorities in the interest of the campus members.
- The BBB board of directors includes representatives of the shareholders, the Charité Univeristy of Medicine of Berlin, the Berlin Research Association, the Senate Office for Economics and the one for Science. They meet once a year to set objectives and discuss data.

The development of the whole campus is organized by its 'users' who meet once a month. BBB works with BioTop on a regular base, for instance, they cooperate on some EU projects. Between 2000 and 2001 BioTop, in collaboration with the State governments, arranged an initiative, the BIOFUTURE, that put together enterprises, venture capitalists, banks. Afterwards, this kind of initiatives was abandoned as they were considered less effective than one-to-one meetings.

BBB collaborates also with Charité Medicine University for the installation of experimental clinical research

³⁰ Information concerning the Biotech Park Berlin-Buch have been mainly provided by Mr Mätzold (Manager – Biotech Park Berlin-Buch)

There is an organization, called 'Regional development cooperation', that involves BBB, shareholders and other institutions and meets quarterly in order to discuss how to develop the area of the campus and to obtain the support of public authorities.

Box 5 HISTORY AND STRUCTURE THE CAMPUS BERLIN- BUCH

Campus Berlin-Buch is a science, health and biotechnology park with a focus on biomedicine. In particular, major areas of activity include the study of the molecular causes of cancer, cardiovascular and neurodegenerative diseases, as well as interdisciplinary basic research to develop new drugs, patient-oriented clinical research and the commercial realization of biomedical insights. The campus hosts research institutes, clinics and biotechnology companies. The history of the campus originates between the 30s and 40s, when academy institutes were established in the area of Berlin-Buch. Then, after the re-unification of Germany, under the unification agreement, according to which the east and west research capacity had to be merged, the academy institutes of the Berlin-Buch area were phased out.

The campus activity basically started in 1992, when the Max Delbrück Center for Molecular Medicine (MDC) Berlin-Buch was founded in its area. The whole Berlin-Buch Campus is made up of i) 5 hospitals (the Robert Rössle Clinic for Tumor Diseases – RRK, the Franz Volhard Clinic for Cardiovascular Diseases – FVK, the HELIOS Clinic Berlin-Buch, the Specialist Hospital for Pneumology and Thoracic Surgery – FLT, and the Rheuma Clinic Berlin-Buch) where clinical and scientific activity is performed by combining medical treatment and clinical research; ii) outstanding research centers (the MDC and the Leibniz Institute for Molecular Pharmacology - FMP), iii) the BiotechPark, founded in 1996, as a spin off of the MDC Berlin-Buch, with the Innovation and Incubation Center (IGZ).

The Campus has been developed and managed by the BBB Management GmbH Campus Berlin-Buch (BBB). The campus has been financially supported through investments of more than 200 million euros by the federal government, the state government of Berlin and the EU.

The area of the campus is property of the State of Berlin. Nowadays the BBB is made up of 27 persons.

The area of the campus is approximately 320.000 m² where 48 companies are located and the number of employees of all the campus institutes/companies are 2.200.

Note: information concerning the Campus Berlin Buch have been provided by Dr Mätzold (Project Development – BBB Management GmbH Campus Berlin-Buch) and downloaded from the websites www.bbb-berlin.de and www.campus-berlin-buch.de

In the cluster there is a good collaboration between the industry and the **university**³¹. For instance, Charité was supportive in setting up new companies. Moreover, the university often looks for commercial partners in order to apply for funding programmes,

³¹ Information concerning the Charité University have been provided by Mr Sittinger (director of Gene engineering lab at Charité University) .

as companies are considered to be more effective than university to collect private funding.

Among the **companies** of the cluster, *Metanomics* is a spin off from Max Planck institute of Molecular Plant Physiology. The decision of interviewing a Metanomics representative is due to the fact that the company is a member of the advisory board of BioTop and has a wide and long knowledge of the cluster structure and evolution. It was founded in 1998 as a joint venture between scientists from the Max Planck Institute of Molecular Plant Physiology and BASF AG. Nowadays Metanomics is a member of the international BASF Plant Science platform. It provides the technology to metanomics Health which is a mass-spectrometry based metabolite profiling companies. The two companies work as one and have the same CEO. Metanomics mainly cooperates with:

- the Max Planck Institute and the Charité University.
- the Board of BioTop as Metanomics' CEO is a member
- With the German Institute for Nutrition
- With IT companies.

Item	Contents
INSTITUTIONAL FORM	<ul style="list-style-type: none"> ▪ <i>Type of institutional/legal form</i>: an informal sort of consortium, whose boundaries corresponded to the States of Berlin and Brandenburg.
AD HOC BODIES	<ul style="list-style-type: none"> ▪ <i>Establishment of ad hoc bodies</i>: i) the coordinating agency (BioTop); ii) Technology Coaching Center (TCC); iii) Investitions Bank Berlin (IBB).
FORMS OF COOPERATION	<ul style="list-style-type: none"> ▪ <i>Main collaborations</i> (intra- and extra- cluster, industry-industry and PPP): <ul style="list-style-type: none"> a) Between BioTop and i) companies and incubators/parks of the cluster; ii) other coordinating agencies of other German Bioregion; iii) public institutions (BMBF, PTJ, States Ministries), iv) financial entities (single investors, VCs, banks), v) coordinating institutions of the scientific networks. b) Among companies and between them and financial entities (single investors, VCs, banks). c) Between the University and i) companies and incubators/parks of the cluster and outside it; ii) BioTop; iii) public institutions (BMBF, PTJ, Land Ministries).

	d) Between the coordinating institutions of the scientific networks and i) public authorities, ii) BioTop, iii) each other.
HUMAN RESOURCES	<ul style="list-style-type: none"> ▪ Type of contracts: between BioTop and the Berlin and Brandenburg Governments has been stipulated a three-year contract. ▪ Training services and education: organized by BioTop in collaboration with Universities / Research Centers / Public Institutions / Single Companies.

b) Marketing

Public relations and marketing activity for the Bioregion is mainly performed by BioTOP. It participates at the major fairs at national and international level; they offer a space in their pavilion to smaller/young enterprises. They have different publications, promotional material and the website. BioTop organizes seminars: at the moment only from time to time, but in future there is the intention to make them more regular.

The BBB has its own communication system. It manages the PR activity by providing quarterly newsletters, by participating at fairs, and organizing workshops.

Item	Contents
TERRITORIAL MARKETING	▪ <i>Territorial marketing instruments</i> : seminars, workshops and fairs at national and international level.
COMMUNICATION	▪ Publications, promotional material, website, newsletters

c) Financial cycle

During the last ten years the funds for the Bioregion have mostly been issued by the two States of Berlin and Brandenburg (mainly the Ministry of Economics) and the BMBF (e.g. BioProfile and InnoRegio). These public funding always require a private co-payment, that has been is mainly provided by VCs (BioTop has contacts with the most important VCs), public VC Banks (e.g. Berlin Investment Bank, and the national one, the KFV) and the National High Tech Start ups Fund (set up in April 2005)³².

³² This fund offers public venture capital to founders of technology-based start-ups for financing seed and start-up stages. A main target group are spin-offs from public research institutions, universities and companies.

Public administrations, in particular the State of Berlin, have widely intervened to support the biotechnology development with the aim of increasing the number of firms. The main actions in this sense have been the building of technological centers (for instance Berlin Buch) and the creation of institutions with the task of providing enterprises with *ad hoc* services, for instance BioTop, the *Investitions Bank Berlin (IBB)*, and the Technology Coaching Center (TCC). IBB, that is an investment bank, has an 'agency agreement' (*Geschäftsbesorgung*) with the State of Berlin according to which the Bank provides its opinion on the financial feasibility of a project. TCC provides services to enterprises: financial advices, business plans writing and so on. It operates in collaboration with BioTop.

Bioprofile grants have supported the research on nutrigenomics by funding application-based projects in the region. In this way the activity of the Berlin-Brandenburg Nutrigenome Research Network has been fostered.

BioTop supports enterprises that want to apply for a public funding. Moreover BioTop provides its services and experience to banks to support the evaluation of companies. This evaluation process aims at assessing the feasibility/solidity of the business plan of each company and if it fit within the cluster.

The main sources of funding for the BBB are public programmes, banks, the earnings from rents and the services provided to the institutes located into the campus.

BBB was involved in the BioProfile contest as the companies of the campus were involved into the interdisciplinary networks (i.e. Nutrigenome Research Network) of the Bioregion.

Metanomics participated to the Bioprofile contest as interested in Nutrigenomic research. Hence it was provided with the funding made available by BMBF. As to the private funding, they have been provided by BASF, that is the mother company and through short and long term contracts with other companies.

A further source of funding for the cluster members was the InnoRegio Program launched by the BMBF in April 1999. The program aimed at strengthening innovative and economic competitiveness in selected regions of East Germany. This funding

allowed the development of two biotech networks: the BioHyTec (that got 9,18 million Euro) and the one focused on personalized medicine.

Item	Contents
SOURCE OF FUNDING	Public sources: BMBF (as winner of Bioprofile and InnoRegio contest), Berlin and Brandenburg Government, National High Tech Start ups Fund. Private source: single investors and VCs. Mix sources: Investitions Bank Berlin (IBB).
FUNDING MANAGEMENT	<i>Institution in charge of managing the funding:</i> At the time of the BioProfile contest, the coordinating agency (BioTop) that arranged and managed the application process. BioTop as manager of the biotech clusters in Bavaria for State funding cluster initiative. In case of public programmes it depends on the involved partners, BioTop is often involved in the application process and funding management/distribution.

3.4.4 Monitoring and evaluation

As abovementioned, the original and broad goal of BioTop is the growth of the cluster. More specific objectives are negotiated with the States. It is according to these goals that BioTop is evaluated by them. The indicators used to measure the success of BioTop activity are: the number of companies, the number of new companies, the amount of private funding, the amount of funding invested in research institutions, the number of products in the pipeline and the performed clinical research. These indicators show how 'good' the cluster is even if BioTop cannot directly influence them. If the results are not considered satisfactory, after the 3 year contract period, the States can decide not to finance BioTop any more.

As the monitoring of the cluster development is concerned, BioTop administers the companies and the other members of the cluster (such as research institutes) questionnaires to collect data about the size of companies, the number of employees, turnover, and the products in the pipeline.

In case of funding provided by IBB the performance evaluation is done at the end of each project by financial and research experts.

As to BBB, the public authorities are interested to know the economic development of the campus in terms of number of jobs and public/private investments.

In case of BMBF funding (e.g. BioProfile), three reports a year have to be provided. Moreover, once a year, there is a meeting to show and discuss the status of the project (in presence also of project partners).

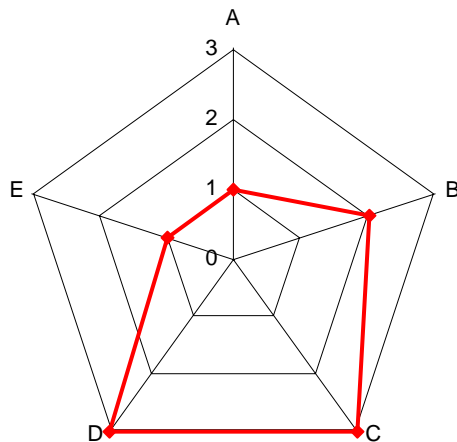
Item	Contents/indicators
PERFORMANCE EVALUATION	<p><i>Performance indicators:</i> i) the number of companies, ii) the number of new companies, iii) the amount of private funding, iv) the amount of funding invested in research institutions, v) the number of products in the pipeline and vi) the performed clinical research.</p> <ul style="list-style-type: none"> ▪ <i>How the performance evaluation is performed with respect to:</i> <ul style="list-style-type: none"> a) regular reports provided to public institutions (BMBF and State Governments) in order to demonstrate the performance of the cluster and justify the obtained funding. b) BioTop, as funded by the States of Berlin and Brandenburg, is compelled to provide public institutions with regular (once a year) reports according to specific flexible objectives. c) Publication by BioTop, once a year, of reports according to data collected through questionnaires and concerning the development and performance of the cluster.
ORGANIZATION OF THE MONITORING AND EVALUATION PROCESS	<p><i>Schedule:</i> Reporting – once/three times a year; informal meetings are not strictly scheduled.</p> <p>In case of funding provided by IBB the performance evaluation is done at the end of each project by financial and research experts.</p> <p>Institution in charge of these processes: The coordinating agencies (BioTop).</p> <p><i>Feedback with respect to strategy setting:</i> mainly through informal meetings.</p>

3.4.5 Interaction system

FIGURE 15, depicted according to data/information gathered by interviews and available documentation, shows the most relevant relationships among the main members of the cluster. Again, as for the other two clusters, the information and services are mainly provided on an informal base and involve any kind of institution/organization (public, private, not profit).

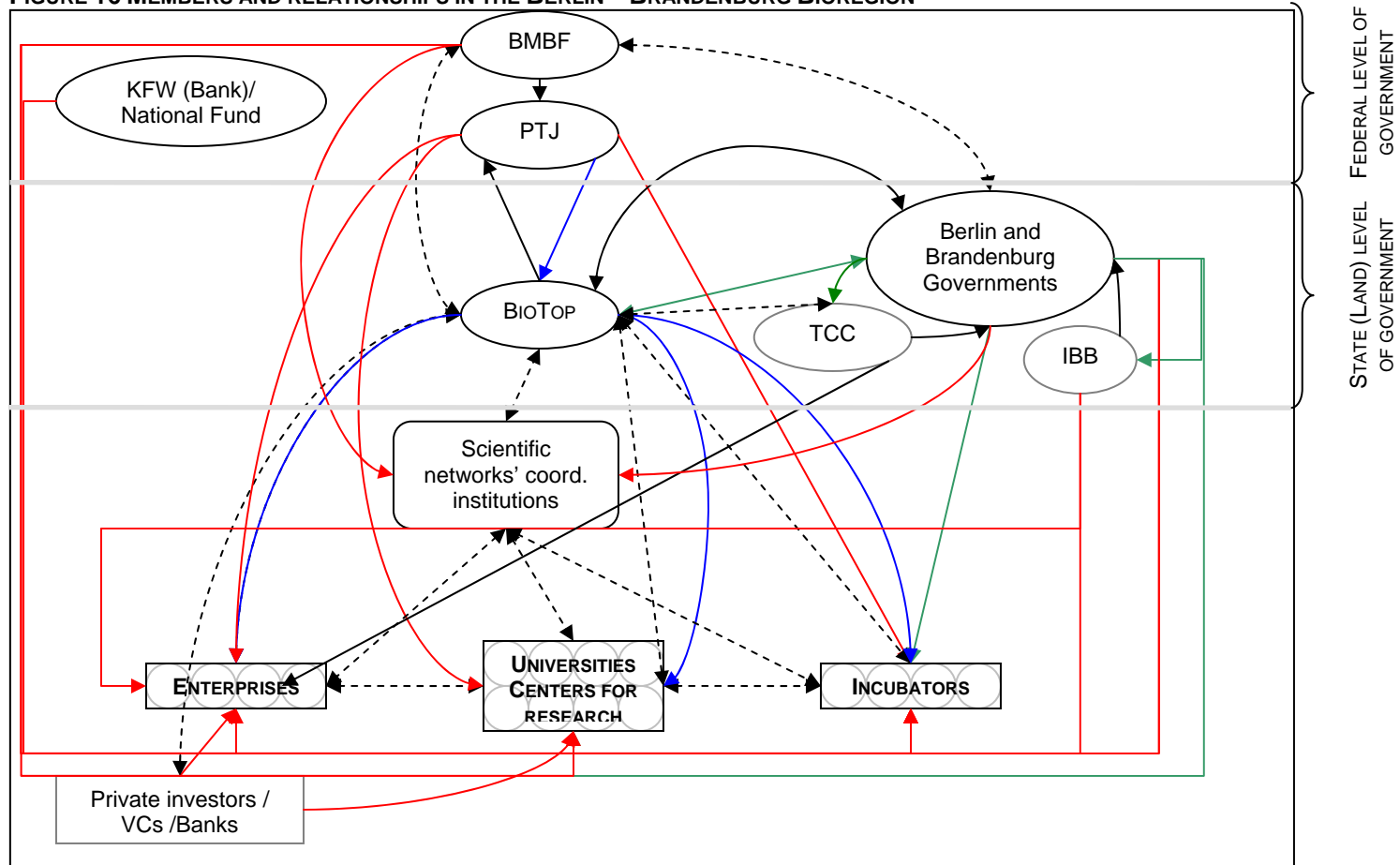
According to respondents, asked on their perceived added value of being part of a cluster, the most important issues are, on the one hand, the exchange of information/knowledge and the interaction among actors and, on the other, the availability/attraction of financial and human resources. Second, the sharing of services and infrastructures. In the end, technology transfer and the presence of competences and knowledge.

FIGURE 15— PERCEIVED ADDED VALUE OF BEING IN THE BERLIN – BRANDENBURG CLUSTER



Technology transfer	A
Services/ infrastructure sharing	B
Exchange of info and knowledge/interaction among actors	C
Availability/ attraction of financial/human resources	D
Presence of competences and knowledge	E

FIGURE 16 MEMBERS AND RELATIONSHIPS IN THE BERLIN – BRANDENBURG BIOREGION



LEGEND

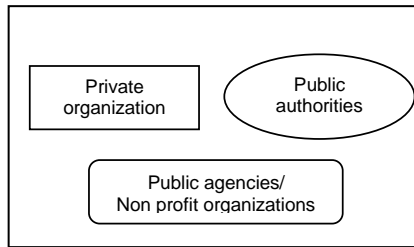
Informal relationships: - - - - - Formal relationships: ———

Financial relationships connected to ad hoc funding programmes/ private initiatives ■

Financial relationships connected to BioRegio Contest ■

Regular Financial relationships ■

Provision of info/Services ■



CHAPTER 4 – DISCUSSION OF RESULTS

Germany has made a great effort in promoting biotech industry. Public administration has played a major role in such an action, recognizing the risk, from an industrial perspective, of a delocalization of research-based industry. This risk was even higher taking into account the important role played by the German pharmaceutical industry in the past and the presence of important German-based companies (such as Bayer and Boehringer Ingheleim). The general aim of these policies have been to foster entrepreneurship, making more efforts in the direction of technology transfer and relationships between the industry and the research institutes (BioRegio and BioChance); further develop scientific and industrial – if any - competitive advantages already present (BioProfile) and make Germany more attractive for young scientists (BioFuture) (§ 3.1).

Evaluating the success of these public policies is not easy. Performance evaluation of clusters financed by these policies can be firstly based (and has traditionally based) upon quantitative variables (see §§ 1.4 and 2.3.1). The framework of analysis (see § 2.3) illustrates those variables generally used to evaluate the performance of a cluster: i) number of new firms according to source of generation; ii) amount of capital venture investments; iii) number of patents, of new products, and of potential products in the pipeline; iv) growth rate of employees; v) revenues, net income.

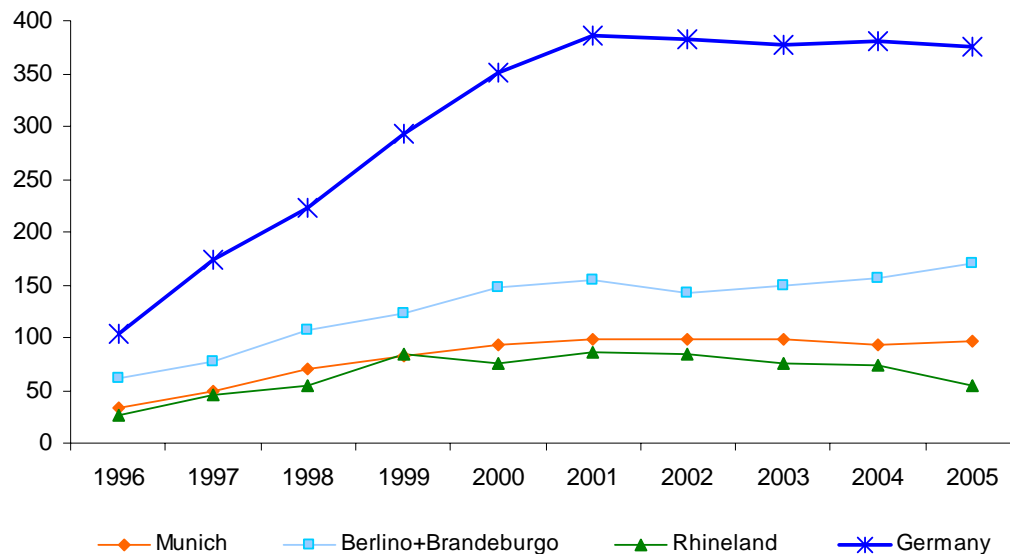
However, more qualitative factors have emerged from the analysis of the three case-studies. These factors can be extremely useful, even more than quantitative ones, if similar public policies were approached by other countries, where the biotech industry is not very developed so far (such as Italy).

According to the results of the research, from a quantitative point of view, clusters can be evaluated in terms of:

- number of companies, especially academic spin-off, that measures the performance in terms of ability to promote entrepreneurship;
- number of employees (and, consequently, evolution of the average scale of operations), that shows the effects of public policies in terms of employment;
- number of patents, that measures the effectiveness of innovativeness and technology transfer promotion;
- number of products per R&D phase (especially Phase III and commercialisation), that, if measured in the long run shows the ability to promote sustainable initiatives;
- private funds invested in local biotech companies (venture capital and private angels), that measures the attractiveness of local biotech companies.

Data have been collected for Germany as a whole and the three clusters that have been scrutinised.

FIGURE 17 - NUMBER OF BIOTECHNOLOGICAL FIRMS



Sources: Ernst and Young 2002-2006; BioTop; Bio^M; BMBF

TABLE 5 - INDEX NUMBER OF BIOTECHNOLOGICAL FIRMS

Bioregion	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	CAGR 96-01	CAGR 01-06
Munich	100	147	206	244,1	274	291	291	288	274	282	274	24%	-1,2%
Berlin-Brandenburg	100	126	173	198,4	237	250	228	240	252	274	281	20%	2,3%
Rhineland	100	173	212	323,1	292	331	327	288	281	212	215	27%	-8,2%
Germany	100	166	213	281,7	338	371	367	363	365	361	376	30%	0,3%

Source: data processing on Ernst and Young 2002-2006; BioTop; Bio^M; BMBF

Note: CAGR is the compound average growth rate

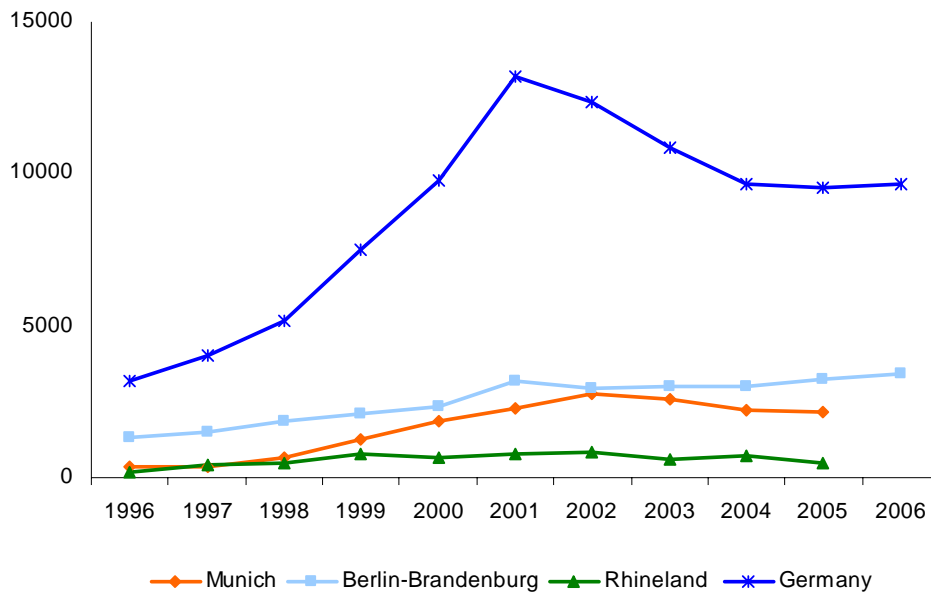
Up to 2001, at national level, the number of biotechnological firms constantly increased. Since 2001, in correspondence to the crash of financial markets, the number of enterprises has slightly decreased, with exception of Berlin-Brandenburg Bioregion that received the funds of BioProfile Program (FIGURE 17, TABLE 5). Whereas the Berlin-Brandenburg and the Munich Bioregions have a similar trend, since 2002, in the Rhineland BioRegion the number of firms has constantly decreased. Generally speaking, the advent of BioRegio seems to have favoured the creation of new companies. However, there is not any evidence of an important difference between those regions that won the contest (Munich and Rhineland) and those who didn't. In addition, after BioRegio has produced its effects, Rhineland started worsening its position compared to the other two clusters. This trend could be explained by the split up of the cluster into the five sub clusters.

TABLE 6 - INDEX NUMBER OF EMPLOYEES IN BIOTECHNOLOGICAL FIRMS

Bioregion	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	CAG R 96-	CAG R 01-	CAG R 01-
Munich	100	109	188	371	550	668	812	762	656	632	n.a	46%	-1%	n.a
Berlin-Brandenburg	100	114	141	160	181	242	225	230	230	246	263	19%	0%	2%
Rhineland	100	213	241	397	359	408	431	328	386	260	n.a	32%	-11%	n.a
Germany	100	127	164	236	309	417	390	342	305	301	305	33%	-8%	-6%

Sources: data processing on Ernst and Young 2002-2006; BioTop; Bio^M; BMBF

Note: CAGR is the compound average growth rate

FIGURE 18 - NUMBER OF EMPLOYEES IN BIOTECHNOLOGICAL FIRMS

Sources: Ernst and Young 2002-2006; BioTop; Bio^M; BMBF

Data concerning i) Rhineland (for the periods 1996 – 2000 and 2004 – 2005); ii) Munich (for 1996); and iii) Berlin – Brandenburg (for 1997 – 1999) have been approximated according to information provided by respondents, as official data were not available.

Data concerning the number of employees in biotechnological firms (Figure 18, table 6) confirm the trend of the number of firms in the period 1996-2001, with an important increase in the number of employees in the Munich BioRegion that has continued in 2002. However, after 2001, the two clusters that won BioRegion have shown a constant decrease in the number of employees, whereas the Berlin-Brandenburg Bioregion, that won BioProfile, was not particularly hit by the 2001 crisis. According to Bio^M, this trend could be justified by the fact that «*Due to mergers, utilization of synergies and focusing on core activities the additional personnel requirement of existing companies was more or less unchanged, start-ups were launched with very few employees, and a number of firms were forced to reduce their headcounts once more, if only slightly*» (Bio^M Annual Report 2005, p. 12).

Patents filed by each cluster show a very similar pathway. The number of patents has hugely increased till 2001-2002. Afterwards they fell in all regions, with a higher drop in

Rhineland and Berlin. Differences among Bioregions cannot be considered enough to be attributed to the role played by the public programmes.

As far as products are concerned, available data cover a very limited period of time (2000-2005) and are not complete for the Rhineland BioRegion. These data are not enough to demonstrate that public policies have supported the development of successful products. What is clear is a tremendous difference between Munich and Berlin-Brandenburg on the one hand and NRW on the other in terms of production referred to the period under analysis, thus confirming that the latter was less successful than the formers. In fact, even if the number of companies and filed patents can be considered a good indicator for a start-up cluster, after a certain number of years is much more important the productivity of R&D in terms of new products in the pipeline or launched into the market.

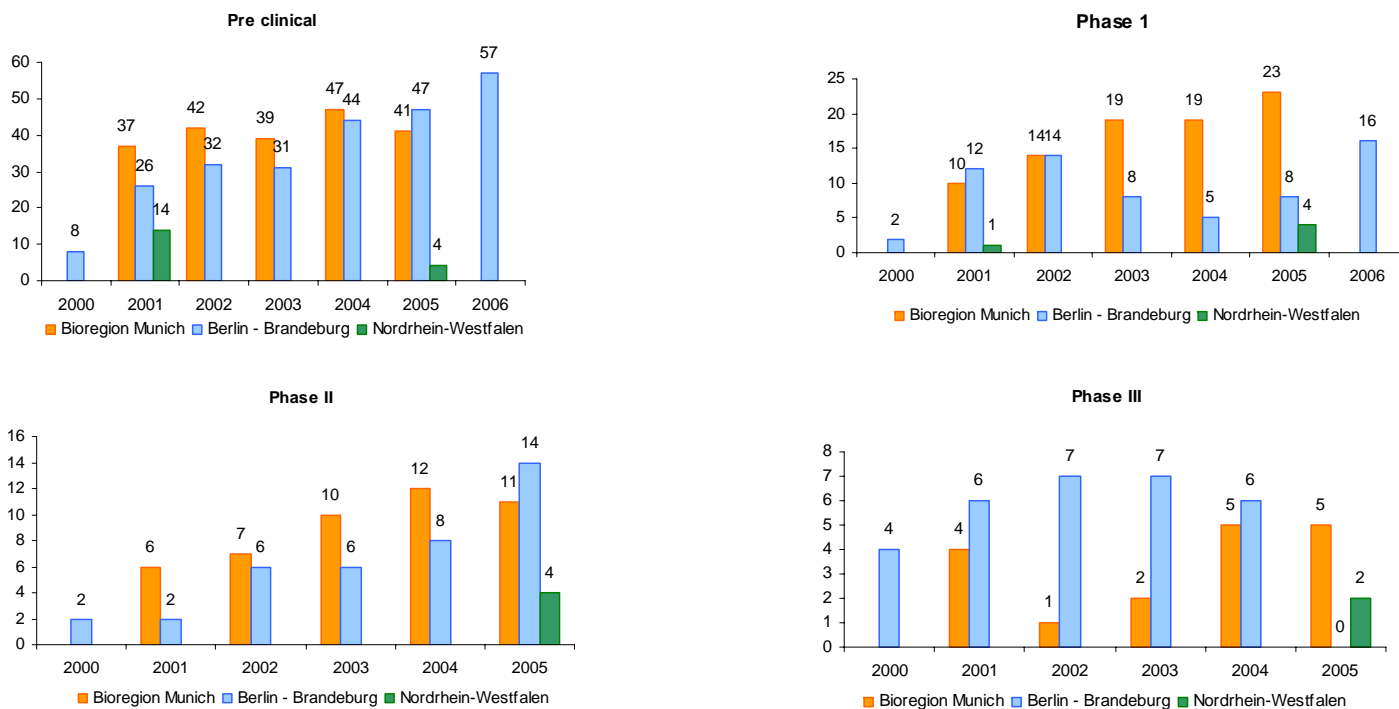
TABLE 7 - AVERAGE NUMBER OF PATENT REGISTRATIONS IN BIOTECHNOLOGY PER YEAR

Bioregion	1996-2000	2000			2001			2002			2003			2004			2005								
	Tot	Ec	Sc	IP	Tot	Ec	Sc	IP	Tot	Ec	Sc	IP	Tot	Ec	Sc	IP	Tot	Ec	Sc	IP	Tot				
Bayer	35	57	15	29	101	67	14	33	114	80	17	36	133	95	14	31	139	92	22	11	125	74	14	18	106
Berlin - Brandenburg	27	25	19	13	57	45	12	16	72	52	17	12	81	56	14	10	79	38	16	10	64	33	18	3	54
Nordrhein-Westfalen	40	49	13	25	88	68	18	31	116	140	14	23	178	111	12	28	151	90	17	15	121	91	11	17	119
Germany	n/a	235	112	124	472	313	121	146	580	500	102	123	725	507	89	132	728	426	122	68	616	384	113	62	559

Source: DPMA, 2006

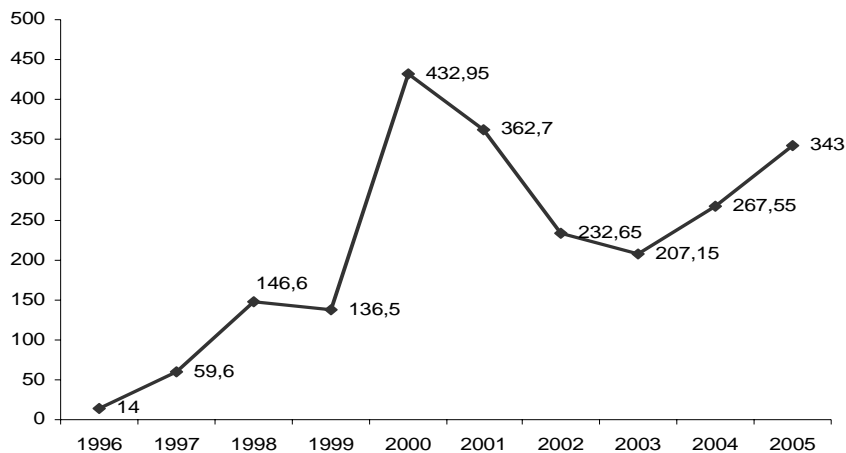
Note: 'Ec' stands for 'Economy'; 'Sc' for 'Science'; 'IP' for 'Individual person', in this case applicant and the inventor coincide.

FIGURE 19 - PRODUCTS DEVELOPMENT (SOURCES: BIOM, BIOTOP, BMBF)



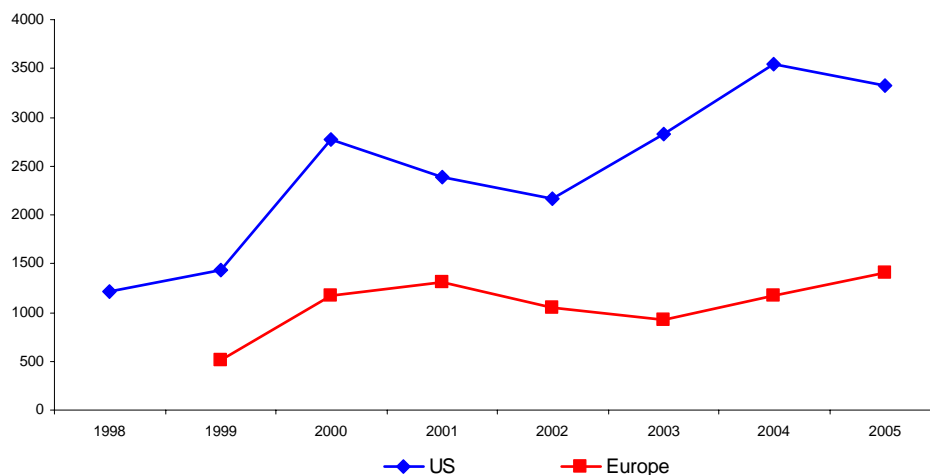
As to the VCs investment in Germany, FIGURE 20 shows that these funds have constantly increased since 1996 and till 2000, in part as a consequence of BioRegio request of co-funding for projects. However it cannot be denied that the investment inflow could also be motivated by the capital stock bubble. Investments faced a crisis in correspondence of the market crash between 2001 and 2002 that has affected the world wide markets (FIGURE 21 shows the trend of venture capital in the US and Europe markets).

FIGURE 20 - VC INVESTMENTS IN BIOTECHNOLOGY IN GERMANY



Source: Schudy, 2006

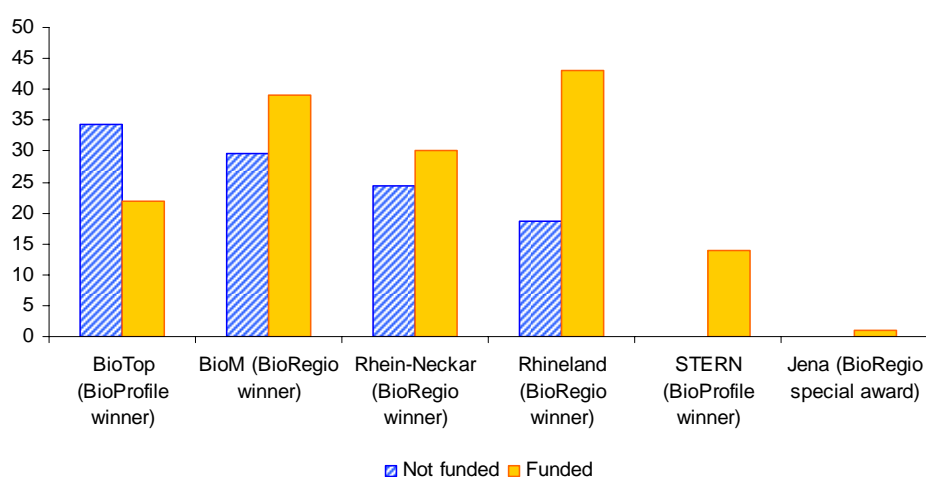
FIGURE 21 - VC INVESTMENTS IN BIOTECHNOLOGY IN US AND EUROPE



Source: Data processing on Ernst&Young, 2005

Figure 22, figure 23, and table 8 show the trend of venture capital investments distinguished according to the type of cluster (funded by Bioregio, by Bioprofile, and not funded by public programmes launched by the Federal Ministry). During the first years after the launch of a public funding programme the winners of the related contests have been characterized by high levels of VC investments. This could have produced a sort of “surprise effect”. In the middle-long term the differences between “funded” and “not funded” clusters decrease.

FIGURE 22 - AVERAGE VENTURE CAPITAL INVESTED PER FIRM DISTINGUISHED BETWEEN “FUNDED” AND “NOT FUNDED” BY BIOREGIO AND BIOPROFILE PROGRAMMES (MILLION EURO).



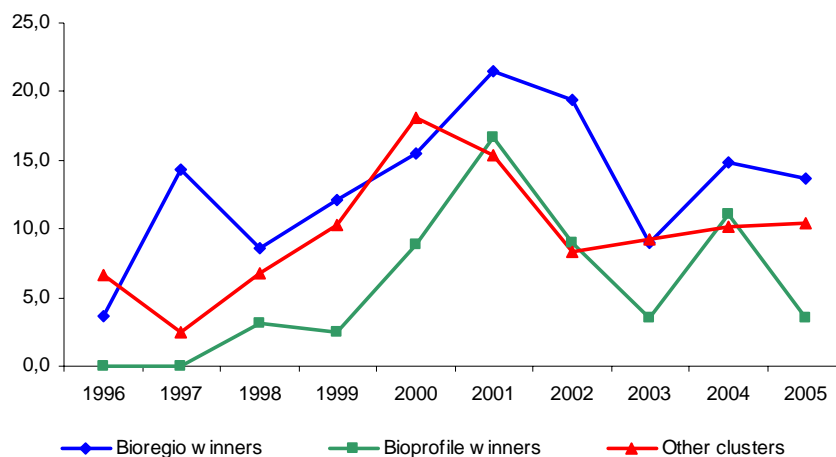
Source: Schudy 2006

TABLE 8 - VENTURE CAPITAL PER FIRM AND PER YEAR AS PERCENTAGE ON TOTAL VC (MILLION EURO).

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Bioregio funded	52,9%	95,8%	46,9%	53,0%	25,1%	35,5%	41,7%	25,9%	33,3%	18,9%
Bioprofile funded	0,0%	0,0%	6,5%	1,8%	8,2%	13,8%	11,5%	5,2%	12,5%	10,3%
Not funded	47,1%	4,2%	46,6%	45,2%	66,7%	50,8%	46,8%	68,9%	54,3%	70,9%

Source: Schudy 2006, p. 27

FIGURE 23 - INVESTMENTS IN BIOTECHNOLOGICAL CLUSTERS IN GERMANY BY VCS IN THREE GROUPS OF CLUSTERS (AVERAGE INVESTMENT PER FIRM, MILLION OF EURO)



Source: data processing on Schudy, 2006

A second important performance evaluation can be traced from **qualitative** information that have directly or indirectly emerged from the interviews. These interviews have evidenced both advantages and critical aspects of public policies (Table 9, Table 10 and Table 11).

Firstly, different actors have complained that objectives assigned to clusters were too general and not measurable. This was particularly true for BioRegio, unless it has to be pointed out that this public programme was launched to generally foster biotechnology in Germany. Subsequent initiatives (essentially BioProfile) were more tailored to already existing competitive advantages of regions.

Another key problem has been the presence of un-coordinated agencies with overlapping functions. In principle, public actions have been designed to avoid this problem and involve all public actors in the definition, implementation and control of clusters' objectives. The central public administrations (i.e BMBF) have been involved into the strategic objectives setting of clusters. In occasion of Bioregio and Bioprofile contests the clusters were required to share with the Ministry the expected goals of their activities in the field of biotechnology, in order to justify the way in which they intended to invest the public funding. Monitoring of strategic objectives of each cluster were left to the "ad hoc" clusters' coordinating agencies. Regional and public authorities (i.e. the

Land ministries and cities) met, on a regular base, the coordinating agency of each cluster in order to discuss the cluster development and evaluate its strengths and weaknesses. In some cases this complex, but rationally designed system has worked well. In some other cases it turned into a complex and un-coordinated system, with too many actors with overlapping function and, definitively, to a waste of resources. The Rhineland Bioregion was complicated by the presence of a twofold level of coordination: the one managed by LSA (which is publicly funded) and the second by local regional initiatives, managed by local agencies like Bioriver, which is a private organization. In order to overcome this duplication, the local Ministry for Innovation, Science, Research and Technology has the intention to create a unique public agency, named 'Innovation Agency', with the task to manage the development of biotechnology in the overall region, that should incorporate all previous agencies. The presence of a two-fold coordination and the creation of different clusters within the same one have been recognized as one of the most important causes of NRW poor performance.

Some interviewed actors, namely the pharmaceutical companies and some universities – e.g. the Heinrich Heine University in NRW, criticized public funds allocation criteria. They mentioned that allocation was not selective, did not take into account the already existing competences and was mostly driven by political issues. These actors do recognize that public actors should be aware of political aspects, such as, for example, the exigency of promoting clusters in the East Germany, and that these issues should be included into the decision making process. However they felt that political variables have definitively prevailed, thus frustrating those actors that have been promoting technology transfer and entrepreneurship in the academia and research centers well before public programs have done. In addition, there is a general perception that this non-selective and political-driven allocation failed to spread a larger consensus over biotechnology.

All actors have unanimously recognized that German public initiatives on biotech have (i) enhanced informal relationships within the clusters and (ii) indirectly produced virtuous behaviour among actors that were and still are very sceptical on public policies. Regarding the first effect, informal relations emerged on the common interest in the development of the field. Few formal contracts have been signed between scientific parks/incubators and universities, between public administrations and the (public) coordinating agencies and among enterprises for the services provision. This informal

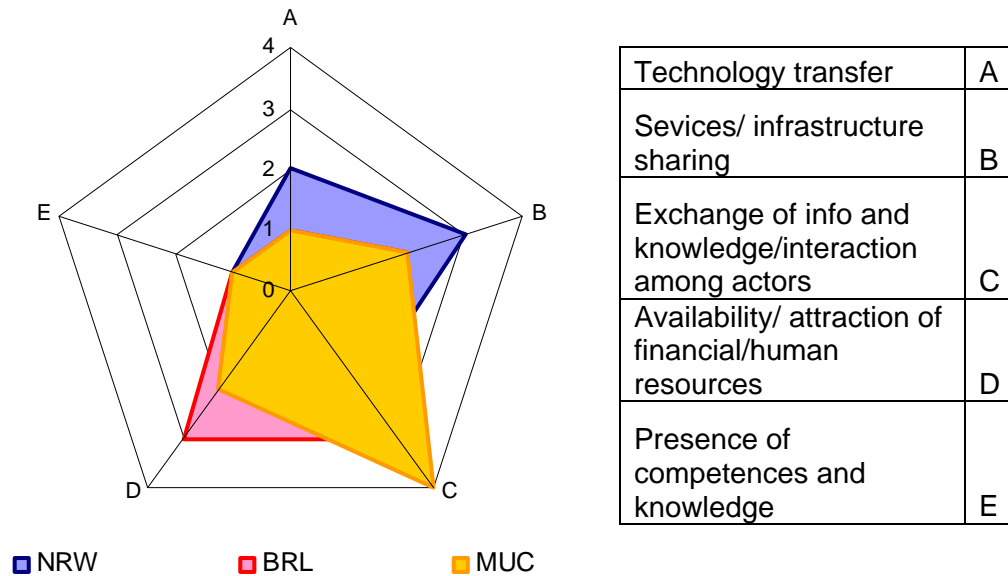
approach could appear weak, because non-enforced, but in practice has promoted contacts among actors, that proved to be in other more advanced contexts the key success factor for the development of the cluster (Veltman, 2003). As far as the second effect is concerned, it can be quoted that a private company, Bayer Health Care, has funded the creation of an incubator, that elsewhere were generally promoted by the public administrations or private not for profit research centres.

The attraction of venture capital required by BioRegio contest was considered a key success factor. In order to stimulate the investment of VCs, the coordinating agencies and/or the Land arrange meetings between Vcs and enterprises. An example of this kind of initiative is the *BioEurope* initiative, sponsored by NRW: young biotechnological firms are selected and are offered professional training by VCs on how to get a private VC funding. Actually, in many clusters, the co-funding rule turned into the creation of “ad hoc” public bank, perceived as very far from a venture capital company.

Most of the interviewed have also stressed the necessity to enlarge the completeness of the horizon of public policies: e.g. some experts have complained the absence of true incentives for other risk-taker investors (like business angels), that have been introduced elsewhere (e.g. in France).

Furthermore respondents have underlined the importance of exchanging information/knowledge and interacting with other actors (figure 24). Some respondents have mentioned as added value of being part of a cluster, the presence of competences and knowledge. However, if compared with the other issues, this one seems to be less considered. A possible reason can lie on the fact that competences and knowledge in this kind of clusters are taken for granted. Moreover, probably, competences and knowledge are not strictly related to the cluster dimension and not hardly available also outside the boundaries of the clusters.

FIGURE 24 – PERCEIVED ADDED VALUE OF BEING IN A CLUSTER



The combination of the quantitative information and qualitative analysis allows to draw conclusive consideration on what the strengths and weaknesses of each cluster are and the opportunities and threats that the German context offer as a whole (table 12).

The SWOT analysis highlights the factors that can contribute to the success (or failure) of a cluster.

In this way the analysed German experiences prove how preparing a favourable regulatory context, defining the right policy and offering public funds is not sufficient. What is even more important is to implement policies in a coordinated way, recognizing the competitive advantages of different territories, but also promoting a broader diffusion of knowledge, exploiting indirect effects if them and promoting self-sustained organisations.

TABLE 9 – STRATEGY SETTING IN THE THREE GERMAN CLUSTERS

1. STRATEGY SETTING		Rhineland Bioregion	BioTech Region Munich	Berlin - Brandenburg Bioregion
Diagnostic recognition	<i>Actors of the cluster and cluster boundaries:</i>	The Rhineland Bioregion has developed at different levels. At the time of the application and of the win of the contest the boundaries of the Rhineland Bioregion corresponded to those of NRW Land. Afterwards, five regional initiative clusters were created. Hence a twofold (State and local) level of coordination and management of the cluster/s was developed. The main actors of the cluster are: i) biotech companies, mainly spin offs of the university; ii) pharmaceutical companies; iii) a number of research centers; iv) VCs, private investors, private banks and the NRW Bank.	The main actors of the cluster are: i) biotech companies, mainly spin offs of the university; ii) pharmaceutical and chemical companies; iii) two universities, two university hospitals, two universities of applied science; iv) National Center for Environment and Health (GSF), three Max Planck Institutes with competences in Biology; v) VCs, private investors, private banks and the Bayern Capital GmbH.	The main actors of the cluster are: i) biotech companies, mainly spin offs of the university; ii) pharmaceutical and chemical companies; iii) five universities; iv) 25 centers for research; v) six scientific parks; vi) thirteen scientific networks; vii) VCs, private investors, private banks; viii) Investitions Bank Berlin (IBB) and the Technology Coaching Center (TCC).
	<i>Competitive arenas and SWOT analysis of the region:</i>	The decision to apply for the competition was based on the long lasting history of research of the region and of the potentials in terms of industrial developments, thanks to the wide presence of pharma and biotech enterprises. According to this view point, it was clear that a strengthening of the networking between research and industry was necessary.	Performed by an ad hoc steering committee. When the Bioregio contest was launched, the Government of Bavaria decided to participate for the whole State. According to the federal State suggestion, the Government of Bavaria decided to apply for the Munich area.	Performed by BioTop. According to it the two States of Berlin and Brandenburg decided to join their forces and form a unique biotech cluster.
Objectives planning	<i>Process according to which the cluster's objectives are defined:</i>	Regular meetings among the actors of the cluster: (State and local) coordinating agencies, companies, universities, research centers and public institutions (i.e. with representatives of the Cities, Land, and Federal Governments)	Regular meetings among the actors of the cluster: coordinating agency, companies, universities, research centers and public institutions (i.e. with representatives of the State and, in some cases, the Federal Government).	Regular meetings mainly between the BioTop board and the two governments of Brandenburg and Berlin. BioTop regularly meets representatives from the industry and the research in order to collect their opinions and needs and discuss them with public authorities.
	<i>Tools and ways for obtaining and maintaining over time consensus by institutional actors:</i>	Through regular meetings and the involvement into the decision making and objective setting process. For instance, i) Bioriver involves, through meetings and questionnaires, its members into the objectives planning; ii) LSA receives directions from the State government, that participated to its foundations.	Coordination of relationships by the coordinating agency both on formal (by contract) and informal base by creating a "multidimensional network".	Coordination of relationships by the coordinating agency both on formal (by contract) and informal base.
Competences/ responsibilities setting	<i>Process of definition and setting of competences and responsibilities:</i>	Mainly on an informal way	Mainly informal (e.g. stammtisch and personal relationships and knowledge of the area). The investment/supervisory board of the Bio ^M represent the interests of many actors (companies, research institutes, and university); the Government of Bavaria is regularly involved into the decision making process as founder of the agency.	The first steps towards the cluster development were decided by the States Governments, that took the first key decisions (i.e., for instance, joining the forces into a unique cluster, to found BioTop as manager of the cluster activities)

TABLE 10 – STRATEGY IMPLEMENTATION IN THE THREE GERMAN CLUSTERS

2. STRATEGY IMPLEMENTATION		Rhineland Bioregion	BioTech Region Munich	Berlin - Brandenburg Bioregion
Organizational structure				
Institutional form	<i>Type of institutional/legal form:</i>	1996-2002: an informal sort of consortium, whose boundaries corresponded to NRW ones, steered by the coordinating agency (BioGenTec/LSA). Since 2002: coexistence of the former consortium and five regional initiative clusters that repeated, at local levels, the structure of the former.	An informal sort of consortium, whose boundaries corresponded to Munich and surroundings, steered by the coordinating agency (BioM).	An informal sort of consortium, whose boundaries corresponded to the States of Berlin and Brandenburg.
Ad hoc bodies	<i>Establishment of ad hoc bodies:</i>	i) BioGenTec and LSA (public initiative); ii) BioRiver (private initiative); iii) local networks (e.g BioCologne); iv) financial entities (e.g. NRW Bank)	i) the coordinating agency (BioM), ii) BioM VC fund, iii) Bayern Kapital GmbH; iv) Board of Trustees at Max Planck Institute	i) the coordinating agency (BioTop); ii) Technology Coaching Center (TCC); iii) Investitions Bank Berlin (IBB).
Forms of cooperation	<i>Main collaborations (intra- and extra-cluster, industry-industry and PPP):</i>	a) Between LSA/BioRiver and i) companies and incubators of the cluster; ii) other coordinating agencies of other German Bioregion; iii) BioRiver/LSA; iii) public institutions (BMBF, PTJ, Land Ministries, Cities Ministries, Chamber of Commerce), iv) financial entities (single investors, VCs, banks). b) Among companies and between them and financial entities (single investors, VCs, banks). c) Between the University and i) companies and incubators of the cluster and outside it; ii) BioRiver/LSA; iii) public institutions (BMBF, PTJ, Land Ministries, Cities Ministries, Chamber of Commerce).	a) Between BioM and i) companies and incubators of the cluster; ii) other coordinating agencies of other German Bioregion; iii) public institutions (BMBF, PTJ, Land Ministries), iv) financial entities (single investors, VCs, banks), v) its shareholders. b) Among companies and between them and financial entities (single investors, VCs, banks, BioM VC fund). c) Between the University and i) companies and incubators of the cluster and outside it; ii) BioM; iii) public institutions (BMBF, PTJ, Land Ministries).	a) Between BioTop and i) companies and incubators/parks of the cluster; ii) other coordinating agencies of other German Bioregion; iii) public institutions (BMBF, PTJ, States Ministries), iv) financial entities (single investors, VCs, banks), v) coordinating institutions of the scientific networks. b) Among companies and between them and financial entities (single investors, VCs, banks). c) Between the University and i) companies and incubators/parks of the cluster and outside it; ii) BioTop; iii) public institutions (BMBF, PTJ, Land Ministries). d) Between the coordinating institutions of the scientific networks and i) public authorities, ii) BioTop, iii) each other.
Human resources	<i>Type of contracts</i>	The main collaborations within the cluster are informal	Between BioM and the Bavarian Government has been stipulated a three-year contract. Moreover, BioM is a shareholder company.	Between BioTop and the Berlin and Brandenburg Governments has been stipulated a three-year contract.
	<i>Training services and education:</i>	Organized by the coordinating agencies in collaboration with Universities / Research Centers / Public Institutions (e.g. BioEurope)/ Single Companies.	Organized by the coordinating agencies in collaboration with Universities / Research Centers / Public Institutions / Single Companies.	Organized by BioTop in collaboration with Universities / Research Centers / Public Institutions / Single Companies.
Marketing				
Territorial marketing	<i>Territorial marketing instruments</i>	Arrangement of events, trade fairs, meetings/conferences at national and international level, platform for contacts and technology transfer (mainly provided by coordinating agencies)	Events, conferences and fairs.	Seminars, workshops and fairs at national and international level.
Communication	<i>Communication instruments</i>	Publication of brochures, creation of web sites, exhibitions, events.	Publications and brochures hoc interviews on newspapers	Publications, promotional material, website, newsletters
Financial cycle				
Source of funding	<i>Public sources</i>	BMBF (as winner of BioRegio contest), NRW Government, City of Dusseldorf.	Public sources: BMBF (as winner of BioRegio contest), Bavaria Government.	BMBF (as winner of Bioprofile and InnoRegio contest), Berlin and Brandenburg Government, National High Tech Start ups Fund.
	<i>Private sources</i>	Single investors and VCs.	Private source: single investors and VCs.	Single investors and VCs.
	<i>Mix sources</i>	NRW BANK.	Mix sources: Bayer Capital (at State level), KfW (at federal level), BioM VC fund.	Investitions Bank Berlin (IBB);
Funding management	<i>Institution in charge of managing the funding</i>	At the time of the BioRegio contest, the coordinating agency (BioGenTec) that arranged and managed the application process.	At the time of the BioRegio contest, the coordinating agency (BioM) that arranged and managed the application process. BioM as manager of the biotech clusters in Bavaria for State funding cluster initiative. In case of public programmes it depends on the involved partners, BioM is often involved in the application process and funding management/distribution.	At the time of the BioProfile contest, the coordinating agency (BioTop) that arranged and managed the application process. BioTop as manager of the biotech clusters in Bavaria for State funding cluster initiative. In case of public programmes it depends on the involved partners, BioTop is often involved in the application process and funding management/distribution.

TABLE 11 – MONITORING AND EVALUATION IN THE THREE GERMAN CLUSTERS

3. MONITORING AND EVALUATION		Rhineland Bioregion	BioTech Region Munich	Berlin - Brandenburg Bioregion
Performance evaluation	<i>Performance indicators</i>	i) number of companies; ii) number of employees; iii) number of products	i) the number of companies; ii) the number of employees; iii) the amount of sales; iv) money spent in R&D; v) how much money enter the region; vi) collaborations started by companies with other companies and with research institutes.	i) the number of companies, ii) the number of new companies, iii) the amount of private funding, iv) the amount of funding invested in research institutions, v) the number of products in the pipeline and vi) the performed clinical research
	<i>How the performance evaluation is performed with respect to:</i>	a) regular reports were provided by BioGenTec to public institutions (in particular to BMBF) in order to demonstrate the performance of the cluster and justify the obtained funding. b) LSA, as funded by the State, is compelled to provide public institutions with regular reports. c) BioRiver has to keep its members informed of its performance and the cluster development.	a) regular reports provided to public institutions (BMBF and State Government) in order to demonstrate the performance of the cluster and justify the obtained funding. b) BioM, as funded by the State, is compelled to provide public institutions with regular (twice a year) reports according to agreed milestones. c) Publication BioM, once a year, of reports according to data collected through questionnaires and concerning the development and performance of the cluster.	a) regular reports provided to public institutions (BMBF and State Governments) in order to demonstrate the performance of the cluster and justify the obtained funding. b) BioTop, as funded by the States of Berlin and Brandenburg, is compelled to provide public institutions with regular (once a year) reports according to specific flexible objectives. c) Publication by BioTop, once a year, of reports according to data collected through questionnaires and concerning the development and performance of the cluster.
Organization of the monitoring and evaluation process	<i>Schedule</i>	Reporting - once/twice a year; informal meetings are not strictly scheduled.	Reporting - once/twice a year; informal meetings are not strictly scheduled.	Reporting – once/three times a year; informal meetings are not strictly scheduled. In case of funding provided by IBB the performance evaluation is done at the end of each project by financial and research experts.
	<i>Institution in charge of these processes</i>	The coordinating agencies (BioGenTec/LSA and BioRiver).	The coordinating agencies (BioM).	The coordinating agencies (BioTop).
	<i>Feedback with respect to strategy setting</i>	Mainly through informal meetings.	Mainly through informal meetings.	Mainly through informal meetings.

TABLE 12 - SWOT ANALYSIS OF THE THREE GERMAN BIOTECH CLUSTERS (OPPORTUNITIES AND THREATS FOR THE WHOLE GERMANY)

Bioregion	Strengths	Weaknesses	Opportunities	Threats
Rhineland	<p>Presence of four Business Hubs close one other (Cologne, Dusseldorf, Aachen, and Bonn). Long lasting history of research. Financial support by State bank (NRW Bank).</p>	<p>Duplication of un-coordinated initiatives. As a consequence, limited resources in the State and local coordinating agencies. Difficulty in collecting data. Split up of the Bioregion into five regional initiative clusters. Lack of sense of affiliation to the community of the cluster</p>	<p>Availability of public funding both at Federal and State level. Requirement of private - co-funding in case of public funding (in order to foster the ability of enterprises to become independent from public financial support). High autonomy of State and local decision makers.</p>	<p>Venture capitalists less risk-taker than elsewhere. Lack of tax incentives for other investors (e.g. business angels). High number of biotech cluster (25 in all Germany). Barriers to the collaboration among clusters, often due to a strong focalization on local interests.</p>
Munich	<p>Long lasting history of research. Localization of most activity into dedicated areas (e.g. Martinsried). Financial support by State bank (Bayer Capital). Financial support by the State of Bavaria. Strong sense of affiliation to the community of the cluster.</p>	<p>Lack of infrastructures, above all for connecting the center of Munich with Martinsried.</p>		
Berlin-Brandenburg	<p>Financial support by the States of Berlin and Brandenburg. BMBF funding (InnoRegio Programme) dedicated to regions in the former East Germany. Localization of actors according to research/activity field.</p>	<p>Economic difficulties. The cluster is spread on a huge area and this makes difficult the connection among actors of the cluster that are localized in different areas according to the research/activity field.</p>		

CHAPTER 5 – CONCLUSIONS AND IMPLICATIONS

The comparative analysis of the three German clusters provides some interesting observations concerning the role of public administration in supporting the clusters' development. In this sense, the following conclusions can be traced, even being aware that, on the one hand, successful cases cannot be uncritically translated into a different context, and, on the other unsuccessful factors can depend on contingent issues.

RQ1 – Have the birth and development of biotech clusters been influenced by the actual implementation of public policy?

According to results (chapter 3) and their discussion (chapter 4), the first research question can be answered as follows.

First, a favorable regulatory framework, the activation of public resources according to a cluster policy, i.e. the allocation of resources on the base of regional projects (as the Bioregio contest did) able to set global goals for developing clusters, are not a sufficient condition for success.

In some cases, the cluster dimension has been perceived as the reaction to globalization and the increasing demand for innovation and flexibility (UNCTAD 1998). This reasoning explains the underlying factors that led to the advent of market driven clusters, i.e. the ones that represent a response to the market demand and needs (§2.1). According to this perspective, competition deals not only with prices but also with the ability to innovate that brought firms to geographically concentrate, by establishing interactions and sharing services, infrastructures and knowledge with the final aim of increasing their competitive advantage, gaining power and overcoming problems related to isolation.

On other cases, the definition of a cluster policy, as the German one, has been considered necessary for stopping the delocalization of research based industry. Along this perspective, the cluster dimension is considered the solution to the incapacity of any other kind of strategy (mainly local development policies aimed at supporting single enterprises or pool of firms) to gain the expected outcome (Doeringer and Terkla 1996; Scott 1992, 1998; OECD, 2001).

In this respect, a key role can be played by Public administrations in setting and implementing *ad hoc* cluster policies, i.e. policies targeted to firms and industries as a whole. However, even if public cluster policies can foster and/or facilitate the clusters' development, they are not a sufficient condition.

RQ2 – Where this has occurred, is there any structured path of managing the relationships between public administration, biotech companies and possibly other organisations?

The conducted research can contribute to enrich the public administration and management discipline. In fact, according to the results of this research a new way of relationship can be shaped between public administration and industry.

In order to make the birth and growth of clusters a strategic tool for local development, a number of issues are necessary. As hereafter detailed, the role of Public administration is manifold: i) to provide start up conditions, ii) to set conditions necessary for long term sustainability of the cluster, and iii) to face braking events.

The results of the research show how, in order to accomplish this role, the public administration need a set of competences.

First, public administration needs *strategic competences* able to activate and influence the environmental variables. In this sense it is worthwhile to identify the competitive advantages of each territorial reality and the already existing experiences of entrepreneurship promotion (for instance, the technology transfer centers). The allocation of public resources according to general indicators (i.e. not specifically tailored on the features of a territorial reality) can be initially useful but then, in the middle-long term, it can generate negative performances.

After evaluating the strategic importance of the cluster dimension for the development of its territory, the public administration, can decide to set start up conditions, i.e. to prepare the ground for the birth of the cluster at time zero (Figure 25):

- i) Definition of a favorable regulatory framework. In case of biotechnology, for instance, the patent filing and protection system and the tax incentives.
- i) Definition of a cluster policy aimed at fostering the creation of clusters. The German experience shows how the creation of a competitive mechanism can encourage to seriously invest in the preparation of the project. Competition mechanisms among the territorial areas for getting public funding (through the launch of federal/land funding programmes) can lead the applicants to define competitive projects involving the whole cluster. This mechanism can moreover induce and strengthen the sense of affiliation to the community of the cluster. Whereas the Munich Biotech region is an enlightening example of strong affiliation to the community, the Rhineland bioregion suffers from the lack of affiliation that weakened the cluster and led to its fragmentation.

Even if some authors (§ 1.3.2) consider the role of public administration limited to the framework regulatory setting, this research provides empirical evidence of a broader active role of public administration. In fact, according to the results of this research, the Public administration is required to adopt a new attitude of managing the relationship with industries. The levels of public administration these considerations refer to depend on the institutional asset of the case taken into consideration. According to the results of this research, the start up conditions can imply the intervention of the central public administration level (e.g. the German Federal Ministry). The accomplishment of the other conditions can imply the intervention of local levels but it depends on their degree of autonomy.

In order to clarify the role of public administration in this respect, it is necessary to tackle the concept of *long-term sustainability of clusters*. According to the fundamental propositions of the Italian approach to management theory (Zappa, 1927: 30, 40; Zappa, 1957: 37; Masini, 1979: 10-11; Airoldi, Brunetti and Coda, 1994: 39; Anessi Pessina, 2002):

«An institution³³ is a durable entity, composed of individuals as well as tangible and intangible resources, operating under a stable set of cultural norms and of behavioral rules and structures, and performing a set of coordinated activities; with the final goal of satisfying human needs».

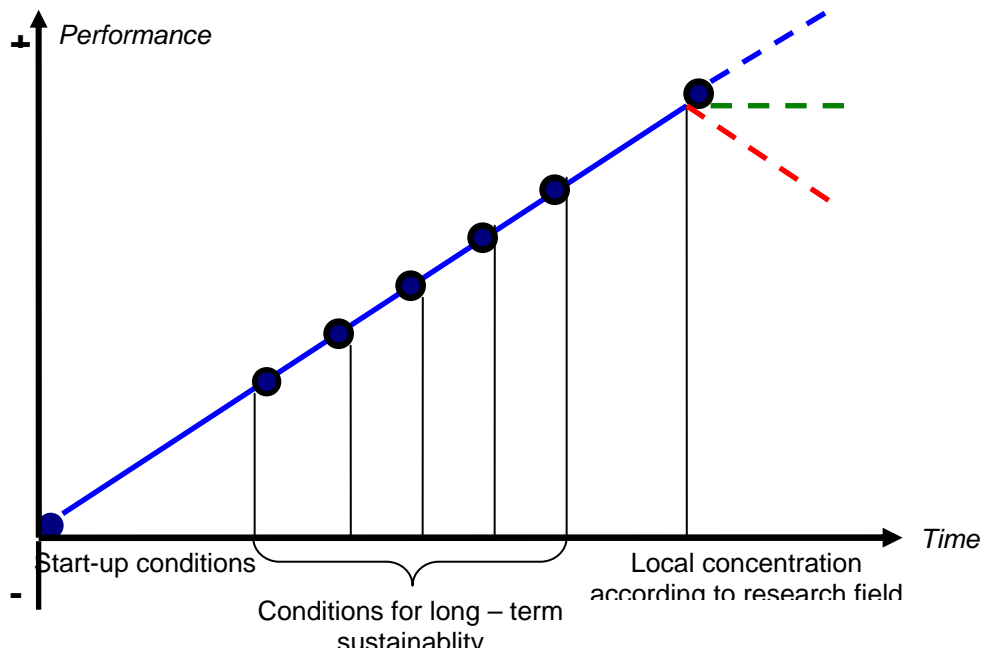
Management theory defines institutions as durable entities, operating under a stable context. During time, globalization undermined this stability and institutions have been operating under highly dynamic contexts and they have had to improve a remarkable degree of flexibility in order to be able to survive in the long run (Airoldi, Brunetti and Coda, 1994). Hence, during time the concept of durability, or long-run sustainability, has been tried hardly out. The characteristics of clusters (§ 1.3) demonstrate how they are constantly exposed to hard dynamics that can undermine their ability for a long-term sustainability. The long-term sustainability of a cluster depends on a number of conditions.

Taking into consideration the characteristics of biotechnological clusters (§§ 1.2 and 1.3) in particular, and innovative industry clusters in general, and trying to lay clusters within the public management fundamental proposition a question arises: how can public administration affect the long-term sustainability of clusters? In other words, what are the necessary conditions that can allow a cluster to be sustainable in the long run? This kind of question can be answered by deepening the considerations on the results of this research. Foremost, an answer to this question outlines the structured path of managing the relationships between public administration, and other organizations operating in a cluster.

Clusters are characterized by high instability: they are influenced by the long term sustainability of their members (that are public, private and non profit institutes) and on the changes of the environment. It is intrinsic for a cluster that its boundaries can change, as far as members and institutional/geographic contexts change.

³³ In the Italian approach to management theory 'institution' is defined as «political bodies, economic bodies, social bodies, and educational bodies. They are group of individuals bound by the common purpose to achieve objectives» (North, 1990; Anessi Pessina, 2002).

FIGURE 25 – THE ROLE OF PUBLIC ADMINISTRATION IN THE CLUSTERS' DEVELOPMENT



The public administration can influence and, in some cases, provide the conditions necessary for the long-term sustainability of a cluster:

- a) The presence of competences and knowledge, and, foremost, rather than the solely presence, the ability to recognize and exploit the distinctive competences and knowledge of a certain area. As abovementioned the public administration should develop strategic competences that could allow to exploit the existing (scientific, cultural, research etc) heritage of the territory. After having enhanced the birth of the cluster, the public administration can influence its growth by tailoring *ad hoc* programmes that can provide financial, infrastructural, and service support. The German experience shows how, after Biotechio, a number of funding programmes addressed at fostering specific competences, have been launched by the Federal ministry. In this case the central public administration has perceived the necessity of investing on certain issues, such as providing support for young scientists (BioFuture) and specific research fields (Bioprofile). In order to exploit territorial specific competences, a commitment by the local public

administration can be more effective than the central one as better aware of the potentials of the area.

- b) Activation of mechanisms of technology transfer and exploitation of the already existing ones. The strategic competences required to the public administration concern also the ability of recognizing and exploiting the already existing experiences of technology transfer. For instance, technology transfer in the three analyzed cases is often performed both by university offices and by the public coordinating agencies. This situation has sometimes generated duplication of procedures, leading to a slowdown of the technology transfer process. The public administration can avoid this situation by identifying the already existing experiences. If the latter are well functioning, the public coordinating agencies can be charged with complementary tasks. On the contrary, if the already existing experiences are ineffective, they can be substituted or supported by the agencies' intervention.
- c) Availability and attraction of financial and human resources. The availability of human resources basically depends on the composition of the cluster. However, the public administration can intervene on the attractiveness of human resources by activating territorial marketing leverages. The three German cases have shown that the main territorial marketing means to attract human resources consist of letting the cluster be known for its working opportunities, technology transfer experiences and the net of available contacts and research/project partners. As the financial resources are concerned, the public administration intervention can be twofold, by: i) providing public funding (launching public funding programmes), ii) asking, as in the German case, a mandatory co-funding as necessary condition for getting public funding. An important issue concerns the ability of public policies in upgrading, on the one hand, the growth of the sector and, on the other, the autonomy of firms rather than supporting allocative inefficiencies. In this sense the rule of co-funding by private sources in case of public funding programmes represent a positive feature. Against a public funding of 90 million Euro, during the period 1996 – 2005, the Bioregio contest has been able to attract 185 million Euro of private investments. More critical is the

- establishment of hybrids, such as banks with a mixed nature having the task to run as venture capitalists for start ups and new projects. This decision is due to the lack of venture capital market but it doesn't actually solve the difficulties of the market.
- d) Sharing of infrastructures and services able to minimize and optimize costs by enabling economies of scale. In this respect, the public administration can build spaces, infrastructures, communication networks, participate to the establishment of incubators and scientific parks (e.g. the Berlin-Buch biocampus in Berlin), supply water, energy and so on for shared spaces etc . The task of managing the shared infrastructures and services can be assigned to either the already existing local coordinating agency or, as in the Berlin – Buch campus, by establishing an *ad hoc* agency service provider.
- e) Exchange of information/knowledge and interaction among actors strictly within and outside the cluster. The exchange of knowledge, information and the interaction among actors is considered on average as the first added value of being part of a cluster (chapter 4). This consideration represents the ground and reason for the creation of a cluster: its members geographically concentrate their businesses and activities in order to reduce distances and exploit the neighborhood for interacting and exchanging information and knowledge without waste (or, at least, the lowest waste) of resources. In this sense, the public administration is called to enhance the interactions and collaborations. Its intervention in Germany has produced the establishment of the local coordinating agencies, that arrange round tables, provide platforms etc. In this sense the local public administrations have played a key role of coordination, by creating/managing public (and in some cases also private) *coordination agencies* with a wide range of tasks: e.g. institutional marketing, provision of services (technological and managerial support), technology transfer. In two of the three analysed cases the public local agencies have actually promoted cooperative intra-regional strategies. Difficulties emerged where there is a high level of fragmentation. This is the case of the cluster in NRW, where the presence of five sub – clusters (and, hence, of five local agencies) has generated problems in

coordinating the five with each other and them with the coordinating agency of the whole cluster (LSA).

After having set the start up conditions and contributed to the long term sustainability of the cluster (figure 25), a further condition needs to be accomplished. Changes that occur within and outside the cluster can undermine its long-term sustainability. An example is provided by the Rhineland bioregion and the Berlin- Brandenburg one. The former was characterized, since 2002, by a fragmentation process that led to the creation of five sub-clusters. This was the result of a progressive specialization of certain areas. The low degree of affiliation to the cluster and the absence of a strong coordinating power brought to the fragmentation of the cluster and to a progressive negative performance (see chapter 4).

The Berlin – Brandenburg cluster experienced the same situation since late 1990s, when a process of geographic concentration in certain areas of the cluster (and above all of Berlin) according to the research field started and created the so called “scientific networks”. In this case, this process didn’t lead to a fragmentation of the cluster because the scientific networks became highly integrated to the cluster. In this situation the public administration was able to anticipate the events and actively sustained the creation of these scientific networks by providing public funds, services, infrastructures and keeping a certain degree of control in the steering coordinating agencies of the networks.

A progressive geographical concentration can follow different paths:

- fragmentation, by decreasing the performance and risking to lead during time the end of the cluster life;
- creation of local networks that represent an evolution of the cluster and require the public administration a further organizing effort;

if the concentration fails a static phase could follow and the cluster require time to recover and re-starting its growth.

Figure 25 depicts the role of the public administration during the cluster development and how it can influence its performance³⁴ and long term sustainability. At time zero, when the cluster is originating, the public administration define the start up conditions (regulatory framework and competitive mechanisms). During time the positive performance that characterizes the short term life of a cluster and the potential long term sustainability are supported by further interventions of the public administration.

In all these steps the public administration plays an active role. According to this interpretation a new way of managing the relationship between public administration and industry emerges. The former provides the latter with start up conditions that lay the foundation for developing a cluster. Then, during the cluster life time, the public administration contributes to its long-term sustainability by intervening on specific conditions and dealing the so-called breaking events.

This research paves the way for further studies. In fact, it could be expanded at the supra national level. The present research focuses on the relationship among national central, local levels of public administration and industry but it could be expanded to the relationship between supranational governments (e.g. European Union) and the national level. Furthermore, the methodological research design can be generalized and adopted for further investigations in other innovative industries if the role of public administration (even at different levels than the ones here studied) would be investigated.

³⁴ Performance is intended as discussed in chapter 4, i.e. according to the quantitative indicators there mentioned and the qualitative issues taken into consideration.

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