BioPolis - Inventory and analysis of national public policies that stimulate research in biotechnology, its exploitation and commercialisation by industry in Europe in the period 2002–2005

National Report of ITALY

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Summary

Although Italy has a population similar to France and the UK, and a total GDP only 5-15% smaller, its GERD, at 1.16% of GDP, is less than half that of those countries in absolute terms, with a only 50% invested by private firms. The biotechnology industry is heavily concentrated in the north of the country, especially around Milano, which has an industrial tradition in chemicals and pharmaceuticals.

The total public expenditure in biotechnology-related research, estimated at 250M EUR per year, is also much lower than that of France (estimated at 635M EUR per year). Most of this support (80% of the total) is allocated by block grants to public research organisations (PROs) (112M EUR per year) and rather unselective response mode grants both to basic research and to firms (95M EUR per year). These generic, non-policy-directed instruments that have dominated the Italian R&D system have yielded a biotech scientific base that is weaker but still comparable to the EU's average performance. However they have not succeeded in fostering knowledge transfer and industrial development, where Italian biotechnology indicators remain dismal. As a result, science policy priority-setting documents, legislation and some policy instruments have highlighted the need to foster technology transfer and the industrial development of biotechnology. Yet the fact that the Italian governance system is fragmented and rather unfocused makes implementation of the guidelines and measures uncertain.

Policy-directed funding for biotechnology amounts to about 45M EUR per year, two thirds of it through the national government and one third through regional governments. This is comparable to the contribution of two Italian charities for health biotechnology (almost 40M EUR per year). Among the policy-directed programmes the most important have been:

- Funds for investment in basic research (FIRB) in PROs, 10% of which was targeted at biotechnology (15M EUR per year in 2002-2005).
- The new Italian Institute of Technology (IIT), with one third of its budget for bionanotechnology (50M EUR in 2004 and 2005).
- The Technological districts initiatives, aimed to foster the creation of regional clusters focused on a specific technology, building on traditional Italian success in industrial districts. This has led to the creation of biotechnological districts in the regions of Lombardy (Lombardy, capital Milano) and Friuli Venezia Giulia (Trieste), supported with 17M EUR per year in 2004 and 2005 by the Ministry of Research (MIUR) and the regional governments.

In terms of application areas for policy-directed instruments, Italy appears to be less focused on health biotechnology (only 35% of expenditure) than other countries, but most of the specific support for plant, animal, food and environmental biotechnology is conducted through the PROs of the various ministries in charge of health, agriculture and energy policy.

The reform of the Italian institutional framework, with increased powers awarded to the regions since 2001, has led to the development of regional innovation plans, in some cases with a prominent place for biotechnology. Although still poorly funded in comparison to national non-directed policies (in 2005, in the order of 20-40M EUR versus 200M EUR), these regional policies seem better suited to the still nascent Italian biotechnology industry. Overall, the analysis of all the instruments reveals a diffuse, but not clear-cut pattern of specialisation between policies, with national and generic policies supporting the knowledge base and regional and specific policies supporting commercialisation and industrial development.

In conclusion, Italian policies for biotechnology appear to remain weak both in terms of expenditure and overall consistency, but recent trends suggest an improvement of commercialisation initiatives in terms of the types of policy instruments being developed, if not in the total expenditure on them.

1. Introduction and background

1.1 General introduction

With 58 million inhabitants, just 2 million less than France or the UK, and a GDP of 1 350 000M EUR, about 300-350 000M EUR smaller than France and the UK, Italy is the fourth largest European country in most respects (Eurostat, 2004). However, neither in technological or scientific terms, does Italy contribute as much as one might assume from its size and its historical relevance in Europe.

In economic terms, Italy has recently had one of the poorest growth rates in the EU (estimated to be below 0.5% in 2002, 2003 and 2005), which led to a decline in its relative GDP from 115% of the EU average to just 104% between 1995 and 2005 (Spain jumped from 87% to 99% in the same period) (Eurostat). The most common diagnosis for this decline is competition from emergent economies, in particular China, to Italian traditional strengths in manufacturing (e.g. textiles, leathers and clothing still contributed 13.5% of Italian exports in 2004[1]).

Although Italy devotes an important share of its wealth to education (about 5.9% of GDP, which is above the EU-15 average of 5.2% in 2002), its funding of higher education is low given its large university system, and its commitment to R&D is scant: in 2002 the country had a GERD of 1.16% of GDP, the same as in 1992, after a slight recovery from a 1.0% low point hit in the mid 1990s, during a period of public expenditure constraints that resulted from Italy adopting the Euro. This is a very low GERD figure – half the German (2.53%) and the French (2.26%) , and 60% of the British (1.87%) - for a country aiming to improve its competitiveness.

An important factor in the Italian economy is the predominance of small and medium-sized enterprises, which do not carry out formal R&D activities and whose innovative activities are related to learning-by-doing (Fulani et al. 2005). As a result, government gross expenditure on R&D (GOVERD) represented almost 50% of the total in 1997, compared to 31% in the UK, 36% in Germany and 40% in France. Thus, the innovation landscape appears to be split between scarce public research tilted towards higher education and basic science, and a private sector uncommitted to R&D, with poor communication between the two camps.

Another major feature is the extreme polarisation of economic activities between the northern and southern regions. Research in Italy is concentrated in the north. For example, just Lombardia, with 15% of the population, has 40% of the patents and 35% of Italian expenditure in R&D (24 Hore, 2004). Similarly, Italian biotechnology firms are heavily concentrated in this region, which has more than 1/3 of biotech firms and 2/3 of the biotech employees (Belussi and Di Bernardo, 2006, p.17). Most of firms are the result of spin out initiatives from big pharma, with other spin-out initiatives being more difficult

[1] *The Economist*, Factsheet of Italy. www.economist.com accessed 12-05-06.

to materialise given the lack of venture capital in Italy (Meldolesi, 2004). The main areas of research are vaccines, diagnostics and antibiotics.

The biotechnology industry in Italy is very small and focused on health biotech: there are only 65 companies compared to 370 in Germany, 340 in the UK and 245 in France (Fezzardini, 2004[2]). In spite of the small number of firms, many existing firms seem to have a sounder economic basis than the average in other countries, because as spin-offs of big *pharma*, they developed in a more mature way than academic spin-offs. The National Research Plan of 2005-2007 estimates that private R&D investment in biotechnology per year amounts to 190M EUR in total, about 90M EUR for health, 50M EUR for environment, 40M EUR for agro-food and 10M EUR for instrumentation (PNR, 2005).

1.2 Characteristics of national S&T and innovation system

The Italian S&T system is split into three types of organisations (universities, public research organisations and enterprises) that show a limited degree of interaction (Silvani and Sirilli, 2001). The 77 Italian universities absorb an important and growing share of the total expenditure on the R&D budget, with an increase from less than 0.25% of GDP in 1995 to more than 0.35% in 2002 (Wierzbicki, 2005). However, most of this expenditure is in the form of block grants in which the state has very little capacity to shape research priorities. The public research organisations, principally the National Research Council (Consiglio Nazionale delle Ricerche, CNR), have had responsibility for more mission-oriented type of projects since the mid 1970s.

The Italian government influences the research activities of these organisations mainly through response mode programmes and the public research organisations –described in detail in section 1.4 – are dependent on the following ministries:

- The Ministry of Education, University and Research (Ministero dell'instruzione, dell'universita et della ricerca, MIUR).
- The Ministry of Productive Activities (Ministero delle attività produttive, MAP).
- The Ministry for Innovation and Technology (Ministero per l'innovazione e le tecnologie, MIT).
- Ministry of Agriculture and Forestry Policies (Ministero delle Politiche Agricole e Forestali, MIPAF)
- Ministry of Health

The governance of public research is carried out through the Inter-ministerial Economic Planning Committee (Comitato Interministeriale per la Programmazione Economica, CIPE) who approves the National Plan of Research (Programmi nazionali di ricerca, PNR). Funding is decided by the national parliament in its annual budget law. The public

[2] The Italian organization for investment promotion, Investinitaly estimates 150 biotechnolgy firms, with an annual turnover of 300M EUR, but we believe this is due to the use of a less stringent definition of biotechnology (www.investinitaly.com accessed 17-01-06).

research system underwent an important reform in the late 1990s. Currently, the most important instruments are based on the legislative decrees 204/1998 and 297/1999, regulating public research organisations and the types of grants that can be awarded by the ministries (Baldini and Grimaldi, 2006). Unlike many other EU countries, Italy has developed very few indirect measures of support to firms through fiscal exemptions (Chiesa and Chiaroni, 2006b).

Given the dramatic north-south divide in Italy's economic activity, the Italian government devised a National Operative Programme (Programma Operativo Nazionale/Regionale, PON) and various Regional Operative Programmes (Programma Operativo Nazionale, POR), funded with EU Structural Funds[3] to promote scientific research, technological development and higher education in the southern regions.

Since 2001 regions have power to intervene in the process leading to the formulation of research and technological policies, which has led to the development of regional innovation plans that take local conditions into account (Fulani et al. 2005). The results presented below suggest that these regional policies are better suited to provide the linkages between public research and industry missing thus far in the Italian innovation system for biotechnology (Chiesa and Chiaroni, 2006b).

1.3 National support and framework conditions for biotechnology

Governmental support for biotechnology in Italy has been characterised by its weakness. The national government did not perceive the need for providing support until the mid 1980s, when it eventually passed a National Plan for Biotechnology in 1987. This plan distributed the load of applied research to various uncoordinated actors, but left to the CNR the task of collaborating with industry. Schmidt and Reiss (1999) estimated an annual expenditure of 20M EUR though policy-directed policies in the mid 1990s, focusing on health biotech. Chiesa and Chiaroni (2006b) estimate that between 1987 and 1996, 50-60M EUR per year was spent in biotechnology targeted projects. They also indicate that these resources were mainly channelled to a handful of academic and industrial groups in projects without a clear set of priorities. Thus, the targeted projects of the 1990s are considered to have led to poor scientific results and scarce industry-academia collaboration under a funding system that has been criticised as unfocused and fragmented.

In spite of this low support, Italian biotechnology has shown some strength. Although publication activities or impact are relatively poor, Italian basic research has some areas of excellence, as shown by the number of Italian projects funded by the biotechnology programmes of the 6th Framework Programme (FP) is only a bit lower than those awarded to the UK and France (PNR, 2005, p. 139). Moreover, data from 1998 to 2002 show a positive trend in the Italian biotechnology industry, with significant increases in the number of firms, industrial turnover and investment in R&D, whereas there have been

[3] In total Italy was allocated 3,744M EUR from structural funds for Objective 3 (Education, training and employment) in the period 2000-2006.

coordinated private initiatives, such as the Park San Raffaele in Milano, which suggest that, in spite of unsuccessful public intervention, Italian biotechnology industry seems to be developing.

At the same time, policies appear to have improved in the last five years. On the one hand, some of the response mode grant programmes awarded by the MIUR and the MAP, have chosen biotechnology as a priority – or propose to do so[4]. On the other hand, the system has become much more pluralistic with the entrance of the regional governments as important actors, which appears to favour technology transfer activities. The regional and local authorities have taken biotechnology specific initiatives to foster technology transfer, such as incubators and scientific parks, with the support of the national government. On top of this, the 6th FP of the EU, which funded biotechnology with 2 255 000M EUR between 2003 and 2006,[5] appears to have been another important instrument.

In terms of biotechnology-related legislation, Italy appears to be one of the strictest countries in Europe. Much research on embryonic stem cells is forbidden: only foetuses from abortion can be studied (Wirzbicki, 2005). In February 2004, a new law on assisted reproductive technology was passed. The regulations allow assisted reproduction but appear to be rather restrictive concerning a number of practices (Fineschi et al., 2005). A referendum in 2005 on artificial fertilisation was deemed invalid due to a high abstention rate, sponsored by the Vatican.. Genetically Modified (GM) Crops can only be planted under restrictive and controlled conditions.

The government has created a number of organisations to tackle bioethical and biosecurity issues. The National Bioethics Committee (Comitato nazionale per la bioetica) was created in 1988 with the mission of providing advice on legislative and administrative instruments for the regulation of biomedical practices. Moreover, it assumes the task of guaranteeing correct information to the public of the problematic aspects of biomedical research. In 2001 the National Observatory for Biosecurity and Biotechnology (Osservatore Nazionale per la Biosicurezza e le Biotecnologie[6]) was born within the National Committe for Biosecurity and Biotechnology (Comitato Nazionale per la Biosicurezza e le Biotecnologie, CNBB).

The Ministry of Environment has created an *Italian Biosafety Clearing House*[7] in order to deal with the legislation on deliberate release to the environment of GM organisms (Directive 2001/18/CE, brought into Italian law by the legislative decree number 224 of July 8th, 2003).

Perception of biotechnology among the Italian population tends to lie in the EU average, with a better perception of genetic engineering (which 70% of the population sees as

[4] The National Committee for Biosafety and Biotechnology (CNBB) suggested in a Working Document, that it would be convenient to have some biotech-specific instruments in the Funds for Industrial Support (FAR) (CNBB, 2005, p.8).
[5] Assuming that 5-10% of this funding is allocated to Italian institutions, this yields 25-50M EUR per year for Italian biotechnology.
[6] http://www.osservatoriobiotec.it/ accessed 15-05-06.
[7] http://bch.minambiente.it/index.html accessed 15-05-06.

positive compared to 65% of the EU average) than agricultural uses (65% of Italians with a positive view versus 66% of Europeans). Thus, Italy has one of the populations least opposed to human cloning for avoiding genetic disease (59% opposing it compared to the 75% in all EU) and accepting controlled application of genetic treatments for medical purposes (around 7% higher that the EU average for a number of genetic treatment or tests). Also for meat created in cell culture, the opposition only reaches 55% of Italians, as compared with 66% for the EU (EC, 2005).

1.4 Main biotech policy and research actors

Unlike in many other European countries, which have specialised funding agencies at arms-length from the central government, in Italy grants are either given on a competitive basis directly by the Ministries or as block grants to public research organisations.

In terms of grants, the most important is the **Ministry of Education, University and Research** (Ministero dell'instruzione, dell'universita et della ricerca, **MIUR**), which grants the response mode **Funds for Supporting Industrial Research** (Fondo Agevolazioni Ricerca Industriale, **FAR**), the **Research Projects of National Interest** (Progetti di ricerca di interesse nazionale, **PRIN**), the policy-directed **Funds for Investment in Basic Research** (Fondo per gli investimenti della ricerca di base, FIRB) and the **Special Integrative Funds for Research** (Fondo Integrativo Speciale Ricerca, FISR) – the latter target specific interventions of general interest to the administration, but have not yet included biotechnology projects.

In addition, MIUR provides block grants to the **National Research Council** (Consiglio Nazionale delle Ricerche, **CNR**) and a list of smaller **Special Scientific Institutes** (Istituti Scientifici Speziale), including for example the National Consortium for Biotechnology Research and Development (Consorzio per le Ricerche e lo Sviluppo delle Biotecnologie).

Other relevant response mode grants for biotechnology are those awarded through the **Fund for Technological Innovation** (Fondo per l'innovazionne tecnologica, **FIT**), by the **Ministry of Productive Activities** (Ministero delle attività produttive, **MAP**) and those awarded by the **Ministry of Agriculture and Forestry Policies** (Ministero delle Politiche Agricole e Forestali, MIPAF) and the **Ministry of Health**.

Among the public research institutions, the **CNR** is the largest, with an annual block grants of almost 550M EUR. It the 1990s it had carried out big projects specially targeting biotechnology (Schmidt and Reiss, 1999) but currently its biotechnology research is independently conducted in some of its 105 research institutes.

The **National Agency for the New Technologies Energy and the Environment** (Ente per le nuove technologie, l'energia e l'ambiente, **ENEA**) is a Public Research Organisation (PRO) undertaking research on fields with possible industrial applications, such as renewable energy, environmental protection and agro-biotechnology, under the Ministry of Productive Activities.

The Italian Institute of Technology (IIT), established in 2004 by the MEF and the MIUR, targets research in bionanotechnology, with an estimated budget of 50M EUR for the first year and 100M EUR per year from 2005 onwards.

The **Council for Research and Experimental Agriculture** (Consiglio per la Ricerca e la Sperimentazione in Agricoltura, **CRA**) under the MIPAF, receive a block grants of about 80M EUR per year to distribute among its research institutes.

Similarly, the **Ministry of Health** allocates a block grant of about 180M EUR per year to various organisations undertaking medical research, most importantly to the **Higher Institute of Health** (Istituto Superiore Sanita, **ISS**).

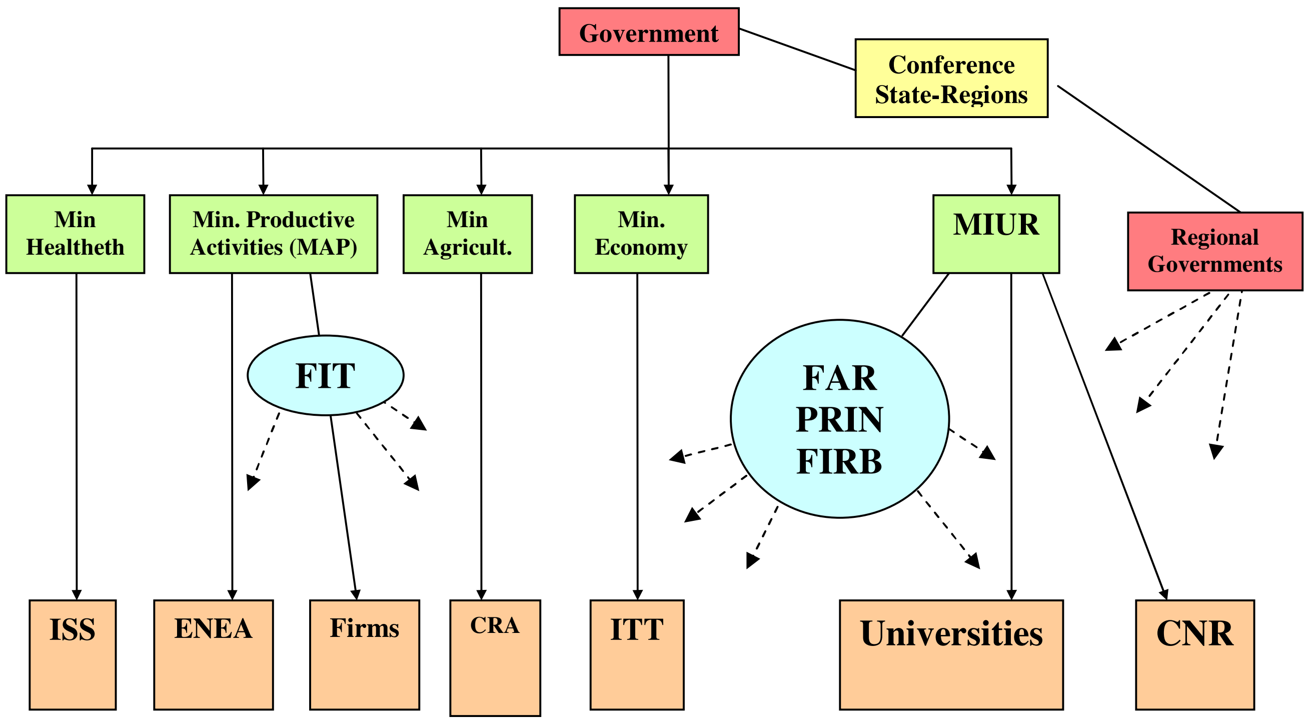
The charities **Italian Association for Research on Cancer** (Associazione Italiana per la Ricerca sul Cancro, **AIRC**) and the **Telethon** (Comitato Telethon Fondazione ONLUS) are major funders for biotechnology providing 38M EUR per year.

The **Department of Innovation and Technology** (Dipartimento per l'Innovazione e le Tecnologie, DIT) under the **Ministry for Innovation and Technology** does not seem to play a relevant role in biotechnology since its main role it to promote ICT use among the public and within the administration. Thus, surprisingly the Ministry for Innovation has no direct impact in policies for biotechnology, so far. However, this Ministry may play a role in the future, following the creation in October 2005 of a High Technology Fund (Fondo High Tech), providing 100M EUR of risk capital for 10 years.

The activities to support technological industrial development carried out by the **Institute of Industrial Promotion** (Istituto per la promozionne industriale, **IPI**) and the **Sviluppo Italia** (the national agency for enterprise and inward investment) concern technical advice and support and a variety of networking actions which, on some occasions, are helpful for biotechnology development. However, since these activities do not have a focus on biotechnology or do not involve funding to organisations conducting research in biotechnology, they will not be taken into account in this report.

Figure 0.1. Main biotechnology policy and research actors,

The Italian R&D funding system is based on response mode grants awarded by the Ministries (shown in circular) and the PRO receiving block grants to conduct research.



EC-BIOPOLIS, 2006

2. Funding for biotechnology R&D, transfer and commercialisation

2.1 Introduction

This report reviews the funding of biotechnology research and commercialisation. In the report we make a distinction between policy-directed funding and non-policy-directed funding of biotechnology.

Policy-directed funding includes funding which was directed by explicit policy decision making about installing a specific instrument, such as specific R&D programmes, programmes encouraging collaboration, industrial research grants, support for centres of excellence, support for commercialisation of research, support for start-ups, programmes encouraging mobility of researchers, programmes with open calls, etc. This policy-directed funding can include biotechnology specific policy instruments and generic policy instruments. Biotechnology specific policy instruments are instruments that have been specifically set up to stimulate biotechnology. Generic policy instruments are instruments that are not dedicated to a specific technology, but which in principle stimulate all technologies, also including biotechnology. In the BioPolis project, only those generic instruments are included if a reference is made to (the stimulation of) biotechnology activities in the policy of the funding organisation that runs the program, or of the ministry/government department that funds the funding organisations or that runs the program itself.

Non-policy-directed funding of research includes funding which is part of the structural governmental support for scientific education, research and research infrastructure. This type of funding is mainly given through block grants to universities and (government) research institutes, the open-call system of research councils etc. Research councils, research institutes and government research institutes develop their own programmes through which biotechnology may be supported. In the BioPolis project only the funds for block grants to (government) research institutes and through the open-call system of research councils are included.

In this chapter the funding of biotechnology research through policy and non-policy-directed instruments and of biotechnology commercialisation through policy-directed instruments is presented. Data were collected through desk research (publications, documents, websites of national and regional public funding organisations and/or governmental departments), from surveys completed by representatives of funding organisations that manage the generic and biotech specific programs, and/or interviews with representatives of organisations that are involved in non-policy-directed and policy-directed funding. The website of the funding organisations and their programs and the names of contact persons that participated in the survey and/or who have been interviewed can be found in Annex 3 (List of Contact Persons) and in footnotes and Annex 4 (References). Section 2.2 presents the non-policy-directed funding and section 2.3 the policy-directed funding. Charities also play an important role in funding of biotechnology research in some countries; they will be addressed in section 2.4. The final section provides a short overview of the European funding of biotechnology research in Italy through the 6th Framework Program.

2.2 Non-policy-directed funding for biotechnology research

The majority of funding for biotechnology research is Italy is non-policy-directed. It takes two forms: funding through response mode programmes managed by the Ministries and block grants to the big public research organisations. In the case of biotechnology, our estimates suggest that the amount allocated to each mode in the period 2002-2005 was approximately the same, as shown in Table 2.1.

Table 0.1 Non-policy-directed funding of biotechnology research.

Funding organisation	Name of programme/PRO	Period	Funds M EUR
Response Mode			
Min. Research (MIUR)	FAR	2002-2005	180.0
Min. Research (MIUR)	PRIN	2002-2005	53.8
Min Industry (MAP)	FIT	2002-2005	56.0
Ministry Health	Response Mode Grants	2002-2005	52.8
Min Agriculture (MIPAF)	Response Mode Grants	2002-2005	35.6
Subtotal			**378.2**
Public Research Organisation			
Min. Research (MIUR)	CNR	2002-2005	162.8
Min. Research (MIUR)	Special Institutes	2002-2005	3.7
Min. Industry (MAP)	ENEA	2002-2005	70.0
Ministry Health	ISS and other PROs	2002-2005	144.4
Min Agriculture (MIPAF)	CRA	2002-2005	68.2
Subtotal			**449.1**
TOTAL		**2002-2005**	**827.3**

Source: BioPolis Research

2.2.1 Funds for Supporting Industrial Research (FAR)

MIUR spent about 1 000M EUR in the Funds for Supporting Industrial Research (Fondo Agevolazioni Ricerca Industriale, FAR) for the period 2002-2005, of which an estimated 18% went to biotechnology. In our previous study in the 1990s, it was estimated that 10% of these funds[8] were spent of biotechnology research (Schmidt and Reiss, 1999). Therefore, we believe that the current estimate, provided by the MIUR, was less stringent concerning the definition of biotechnology than most Biopolis estimates.

FAR grants, usually lasting 3 years with 3-5M EUR per project, are response mode without stringent selection criteria: they are given to many of the applicants so long as their projects are industrial research in a pre-competitive stage of development. Around 65% of the FAR funds were used for industrial research, specially aimed at helping all types of SMEs to improve their technological base. The grants cover R&D personnel, instrumentation, consulting services, personnel training, teaching staff in the programme and related travelling. The rationale for this rather flexible and unselective granting mode of the FAR is to provide support to the many and varied SMEs that form the Italian industrial base.

[8] The equivalent grant to FAR was known as Fund for Applied Research (Fondo Ricerca Applicata, FRA).

In terms of application areas, 42% of the funding was used for health biotechnology, 37% for industrial and 21% to food biotechnology. FAR is supported by EU structural funds. Firms have to contribute 25% of the costs of a project.

2.2.2 Research Projects of National Interest (PRIN)

MIUR awards the grants of the Research Projects of National Interest (Progetti di ricerca di interesse nazionale, PRIN) on a competitive basis to any type of basic research project in PROs, without imposing priorities. Thus, this is a typical response mode programme for basic research. The total funding for PRIN has remained stable over recent years, with 133M EUR in 2002, 137M EUR in 2003, 137M EUR in 2004 and 131M EUR in 2005.

An examination of the projects awarded in 2005 reveals that 8M EUR went to agriculture research, 16M EUR to biology, and 24M EUR to medical sciences (PRIN, 2005). From this, we estimate an expenditure of 14M EUR on research closely related to biotechnology[9]. From this result, we may estimate about 10% of the PRIN funds are spent on biotechnology related research each year, yielding around 54M EUR for the whole 2002-2005 period (PRIN, 2005).

2.2.3 Funds for Technological Innovation (FIT)

The Funds for Technological Innovation (Fondo per l'Innovazione Tecnologica, FIT) of the Ministry of Productive Activities (MAP) are meant to support firms in the later stages of development of a technology. As in the case of the FAR, the selection procedure is not very stringent, funding 25%-50% of the applicants. About 85% of the funds are directed to firms and 15% to research centres and universities.

During the period 2002-2005, FIT amounted to 800M EUR of which an estimated 56M EUR (7%) fell in the area of biotechnology. Before 2005, the calls of the FIT were completely generic, but in 2005 technological priorities were included with one call of 180M EUR targeted to five technological areas, of which biotechnology was one. Since the aim of the FIT is helping technological development in firms, its policy goals fall into support to applied technology (30%), business investment (30%), adoption of biotechnology in industry (25%) and transfer from academia to industry (15%).

2.2.4 Ministry of Health

The National Health Plan 2003-2005 (Piano Sanitario Nazionale) includes as one of its ten priorities, the 'promotion of biomedical research and biotechnology'. The Ministry of Health (Ministero della Salute) implements this priority by funding the following biomedical research institutions through both block and competitive grants:

1. Higher Institute of Health (Istituto Superiore Sanita, ISS)

[9] We assume that 30% of medical sciences and 25% of biology and agriculture are closely related to biotechnology. Many more biology projects contain the terms listed in our definition of biotechnology, but only part of them have foreseeable applications.

2. Institutes for Recovery and Healing of a Scientific Character (Istituti di ricovero e cura a carattere scientifico, IRCCS), conducting applied biomedical and clinical research.
3. Experimental Zoo-prophylactic Institutes (Istituti Zooprofilattici Sperimentali (IZS).
4. Higher Institute for the Prevention and Labour Safety (Istituto Superiore per la Prevenzione e la Sicurezza del Lavoro, ISPESL).

The competitive grants have been reduced in recent years, from 73M EUR in 2002, to 59M in 2003, and 22M EUR in 2004. Assuming a similar trend for 2005, this would give a total of around 175M EUR for the period 2002-2005. An inspection of the research projects funded reveals that about 30% use keywords included in our definition of biotechnology. This yields 53M EUR in fields closely related to biotechnology in 2002-2005. On the other hand, the Ministry of Health awards about 180M EUR per year[10] in block grants to these institutions. Assuming that at least 20% of this funding goes to research closely related to biotech (in countries such as Ireland we have obtained estimates of 30%), we can make a conservative estimate for the total expenditure of 144M EUR on block grants in the period 2002-2005.

2.2.5 Ministry of Agriculture (MIPAF)

The Ministry of Agriculture (Ministero delle Politiche Agricole e Forestali) has 20 research institutes that in October 2004 were grouped into a Council for Research and Experimentation in Agriculture (Consiglio per la Ricerca e la Sperimentazione in Agricoltura, CRA). CRA funds are allocated in response to proposals by its research institutes.

The budget for the CRA is 81M EUR in 2005. Before the CRA, it is estimated the budget for the 20 institutes was also around 80M EUR in 2002 and 2004, with a 100M EUR in 2003. About 20% of the activities of CRA fall into biotechnology, 70% in plant, 15% in animal and 15% in environmental biotechnology. In terms of research goals, the main priority (60%) is applied research, the second priority being experimental development in collaboration with firms and regional authorities. Basic research (10%) and training of human resources (5%) are complementary goals. Given the restrictive legislation of Italy on Genetically Modified (GM) organims, CRA emphasises research on diagnostics and traceability.

In 2002-2005, the Ministry of Agriculture has directly awarded another 137M EUR to collaborative projects with industry on a competitive basis which are used by a diversity of institutions, including research groups in the CRA, ENEA, CNR and universities. Of these, 36M EUR were awarded to biotechnology-related projects. Plant biotechnology received 20M EUR, Animal and Food 5M EUR each, Environment 4M EUR and ELSA, 2M EUR. In spite of a doubling from 26M EUR to 55M EUR of the response mode research budget from 2002 to 2005, there is no trend of increasing biotechnology expenditure. The majority of this funding is allocated on a targeted basic to projects with various institutions participating.

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[10] Exactly: 179M EUR in 2004, 179M EUR in 2003 and 185M EUR in 2002.

2.2.6 National Research Council (CNR)

The National Research Council (Consiglio Nazionale delle Ricerche, CNR) is the biggest research organisation in Italy with 7,220 personnel, of which 3,895 were researchers and 5,454 associated students in 2003. It is funded through a stateblock grant of 540M EUR[11], and 224M EUR from other sources, mainly from the EU, contract research and consulting activities (Baldini and Grimaldi, 2006). Since we are concerned with national public policies only the block grants will be considered here.

In the recent years the CNR has gone through two reform processes, in 1999 and 2003, with the first reform pushing its accountability to national science and technology policy and the second one making it more involved in knowledge and technology transfer to the Italian industry. Moreover, between 1999 and 2002 its 314 research institutes and centres were re-organised into 107 institutes. The reform of 2003 should finally result in the creation of a few macro-area departments, one of which will be biotechnology.

We estimate that about 30% of the current 105 CNR institutes fall in the life science area[12].We have estimated that 17 of the institutes carry out at least some research closely related to biotechnology, using around 7.5% of the expenditure. Considering that block grants amount to about 540M EUR, this yields around 40M EUR per year. This figure is smaller than the figures in the CNR triennial plan 2003-05, which estimates biotechnology expenditure at almost 10% of the total, without including the percentage of biotechnology within research from agricultural technology (6% of total) and biomedical technology (19% of total) (CNR, 2005, www.cnr.it). We believe that the difference between CNR and our estimate is due to the stringent definition of biotechnology used in Biopolis.

In relation to application areas, we estimate that of CNR biotechnology research 50% is basic, 25% health, 13% plant, 5% food biotechnology and the remainder is split between animal and ELSA

2.2.7 National Agency for the New Technologies Energy and the Environment (ENEA)

The National Agency for the New Technologies Energy and the Environment (Ente per le nuove technologie, l'energia e l'ambiente, ENEA) was born in the 1950s as the National Committee for Nuclear Energy, a name that carried on until 1982. It is one of the instruments for national policy on energy, including research on renewables. In the late 1980s its mission was widened to include environmental research and promote industrial innovation. It employs about 3000 people and has a budget of about 370M EUR (2004).

ENEA has a department specialised in research on biotechnology, health and ecosystem protection focusing on applied research. Its research agenda covers the areas of environmental (25% of its activities), health (30%), food (20%) and industrial biotechnology (20%), although it also carries out some research on ethical legal and

[11] For 2002: 544M EUR, 2003: 533M EUR; 2004: 547M EUR; for 2005, we estimate 547M EUR.
[12] This estimate is consistent with data concerning the share of Life Sciences of the total CNR's personnel (27%) and expenses (36%).

social aspects of biotechnology (ELSA). In 2005 the department for biotechnology had funds of 25M EUR, of which 80% were from the Italian government. ENEA was not able to provide accurate data, but it may be assumed from data of other Italian PROs that about 30% of the funds are response mode programmes or contract research, and the other 70% block grants. This yields support to biotechnology in ENEA from block grants at 70M EUR for 2002-2005.

2.2.8 Special Scientific Institutes

The MIUR also funds a number of minor institutions that under the banner of Special Scientific Institute (Istituto Scientifico Speciale) conduct a variety of activities, some of which are specifically to carry out or coordinate biotechnology research. We estimate that MIUR funding to the institutes related to biotechnology amounts to a total of 0.9M EUR per year, mainly targeting basic and medical research.

An example of the type of organisations funded, is the National Centre for Biological Resources (Centro Nazionale per le Risorse Biologiche, CNRB), created by MIUR in 1999 and granted about 0.12M EUR each year. The current members of the CNRB are the following, some of which are also Special Institutes on their own:

- Consorzio de Ricerca Apllicata alle Biotecnologie (CRAB) L'Aquila, Abbruzo.
- CEINGE Biotechnologie Avanzate, Naples.
- Consorzio Interuniversitario Biotecnologie (CIB), Trieste.
- Istituto Superiore di Oncologia (ISO), Genoa.
- Parco Tecnologico Padano, Milano.
- Bioindustry Park del Canavese, Torino.

2.3 Policy-directed funding for biotechnology research and commercialisation

Policy-directed instruments in Italy comprise two types of programmes: (i) those created by the MIUR in order to promote its research priorities; (ii) a number of small initiatives carried out by regional governments, of which we have only included the most important regions. The regional initiatives reflect the growing decentralisation in the Italian R&D governance since 2001.

It should be noted that expenditure in policy-directed instruments, 46.6M EUR per year, is just one fifth of the total public expenditure in biotechnology, an amount comparable to the contribution by charities, 38.2M EUR per year.

Table 0.2 National public policy-directed biotechnology stimulating instruments in 2002-2005.

Instrument	Funding organisation	Budget M EUR	% of total	Use of DF/SF
National				
Generic				
FIRB	MIUR	60.0	32.2%	No
Biotech specific			0.0%	
Technological districts	MIUR	15.5	8.3%	No

Instrument	Funding organisation	Budget M EUR	% of total	Use of DF/SF
IIT	MIUR	50.0	26.8%	No
CNR Target projects	CNR	0.7	0.4%	No
Subtotal national		**126.2**	**67.7%**	
Regional				
Generic				
Meta-clusters	Lombardia	10.0	5.4%	No
Delibera CIPE	Piemonte	10.2	5.5%	No
Biotech specific				
Tech. Districts (Friuli VG)	Friuli VG	10.7	5.7%	No
Tech. Districts (Lombardia)	Lombardia	18.0	9.7%	No
Bioindustry Park	Piemonte	7.4	4.0%	No
Bio-incubator	Piemonte	4.0	2.1%	No
Subtotal regional		**60.3**	**32.3%**	
Total		**186.5**	**100.0%**	

Source: BioPolis Research

2.3.1 Funds for Investment in Basic Research (FIRB)

The Fund for Investment in Basic Research (Fondo per gli investimenti della ricerca di base, FIRB) is meant to supplement basic research carried out in universities and other public research organisations in those topics considered to be of strategic importance, in particular generic technologies or big infrastructure investments. A total of 600M EUR have been devoted to FIRB in 2002-05, of which 10% (60M EUR) were targeted to biotechnology, with most of the funding going to basic and health biotechnology (25M EUR each).

2.3.2 Technological Districts

Given the very relevant contribution of sectoral industrial districts to the development and the competitiveness of Italian economy, since 2003 MIUR has started a policy of supporting existing or incipient districts focused on a specific technology[13]. This strategy aims to upgrade the technological capabilities of Italian small and medium sized enterprises (SMEs), which invest less in R&D than firms in other European countries. Since technological districts are expected to build on local and regional strengths the funding and the policies are coordinated and funded both by the MIUR and the regional governments. The instruments for technological districts may include various technological transfer activities managed by regional agencies.

Of the 21 technological districts developed thus far, five have an important biotechnology focus, but only two of them had fully started within the period 2002-2005 examined by BioPolis.

Technological district Lombardia (Milano): This district was awarded 26M EUR in total for biotechnology in 2004-2006, with 8M EUR funded by MIUR and 18M EUR by the regional government. The district also includes expenditure targeted at ICT and new materials, with 22M EUR provided by MIUR and 42M EUR by the region.

[13] See the webpage of the National Observatory of Technological Districts: http://www.distretti-tecnologici.it/home.htm.

Technological district Friuli Venezia Giuilia (Trieste): Focusing on molecular biomedicine, it was awarded 36.4M EUR for 2004-2006, with 15M EUR by MIUR and 21.4 M EUR by the region.

The other three districts are still in their initial development phase, after agreements concerning the framework plans were signed between the MIUR and the regions in 2005. Puglia (Bari, 6M EUR committed by CIPE) will focus on agri-industrial biotechnology, Sicilia (22M EUR committed by CIPE) in agro-bio industry and Sardegna (Cagliari, 16M EUR committed) in biomedicine and health technologies[14].

The technological district initiative is still gathering momentum, and for the period 2004-2005, MIUR has only awarded 34M EUR to two regions. In terms of application areas, we estimate that 75% these funds have concentrated on health biotechnology and the remaining is used in generic biotechnologies.

2.3.3 Italian Institute of Technology (IIT)

In 2004, MIUR and the Ministry of Economy and Finance established the Italian Institute of Technology (Istituto Italiano de Tecnologia, IIT) in Genoa, with the mission of becoming a centre of excellence in research that is not necessarily applied but has possible avenues of commercial application. The IIT includes amongst its targets higher education programmes and collaboration with industry (IIT, 2005).

The contribution from the central government was 50M EUR in 2004 and 100M EUR from 2005 to 2014, which includes expenditure for renewing the infrastructure and building laboratories. The project is at its very initial phase, planning the research and building the infrastructure. The region of Liguria contributed the 20 000 m^2 facilities. IIT strategy will be implemented through three technological platforms: (i) nanobiotechnology, (ii) neural sciences and (iii) automation and robotics. Since nanobiotechnology will receive about 1/3 of the funding, we have a biotechnology expenditure of about 50M EUR for 2004-2005. The main goal of the IIT is strategic and applied research, but it also includes training, collaboration with industry and creation of start-ups among its aims. Since the focus of nanobiotechnology is in instrumentation, it falls mainly into basic and industrial biotechnology.

2.3.4 CNR Target Project

In the 1990s biotechnology was one of the four Target Projects (Progetti finalizzati) where the CNR concentrated its efforts. It had a total expenditure of 121M EUR exclusively in biotechnology and 100M EUR for innovation in agricultural systems between 1989 and 2001 (Schmidt and Reiss, 1999). However, biotechnology target projects were awarded only 0.9M EUR in 2000, 2.6M EUR in 2001, 0.7M EUR in 2002 and negligible amounts thereafter.

2.3.5 Regional government of Lombardia (Lombardy)

[14] The Autonomous Region of Sardina is present through the Consorzio ventuno (the regional agency for support to SMEs and innovation: www.consorzioventuno.it accessed 10/05/06) and Polaris, the technological park of Sardegna, which has already 25 firms and includes one bioincubator (http://www.consorzioventuno.it/polaris_presentazione.php accessed 10/05/06).

As explained in the introduction, the small but growing biotechnology industry in Italy is heavily concentrated in Milano, which has not only the most dynamic economy but also the one with the strongest chemical and pharmaceutical tradition in Italy[15]. Given this background, the regional government has devised both generic technology transfer programmes and biotechnology focused initiatives to help consolidate the industry. The three main projects in 2002-2005 have been the technological district (funded with 18M EUR by the region as explained above), the Meta-clusters *(Mettadistretti)* and the Bioinitiative (Bioiniziativa) (Chiesa and Chiaroni, 2006a).

Bioinitiative (BioIniziativa) is a small programme aimed to accompany (*scout*) biotechnology basic research into entrepreneurial activities. It is carried out by Assolombarda (Lombardia Industrial Association) and the regional public agency Finlombarda (Financial Development Agency of Lombardia Region). Since its start in 2003, it has identified 94 projects with potential for 'translation' into commercial activities, with 20 projects ready for the *start-up* phase, that are now searching for financing. Its expenditure is only 0.13M EUR for 2003-2005 (so small that we will not include it in the total expenditure summary tables), but it is viewed as an important instrument.

Metaclusters (Mettadistretti) is a programme to develop networks of firms in Lombardia. The idea is to favour the creation of clusters in several sectors[16]. The programme lasts for three years 2004-2006, with a commitment of 60M EUR and supports one cluster for pharmaceuticals and one cluster on agro-food technology, involving various activities. Up to 2005, there was a call for proposals with 25M EUR for funding SMEs, both independently or in collaborative projects (particularly with PROs). About 10M EUR are estimated to have been awarded to biotechnology projects.

Some of the funds of Meta-clusters may be expected to support other existing private or academic initiatives, which appear to have preceded governmental activities:

- The **Parco Tecnologico Padano**[17] focuses on agro-food biotechnology is an initiative of the University of Milano with the support of the Region of Lombardia. It hosts university research centres as well as a business park and an incubator.
- The **Science Park San Raffaele**, in Milano, was born from a private hospital that moved from being an organisation carrying out many clinical trials to a research centre in biotechnology (1992) and later a higher education institution, including international doctoral programmes (1996). A the end of 2007, there will be an expansion of park, with a total investment of 140M EUR.
- The new **Scientific-Technological Pole Multimedica** was opened in December 2005 as a centre of excellence in biomedical research. It was created with the involvement of the University of Milano and the CNR. Research Pole 'Renato Dulbeco', born through collaboration between private and public institutions, the group Multimedica and the Centro Interdisciplinare

[15] See Chiesa and Chiaroni (2005) for a description of the industrial biotechnology cluster of Milano.
[16] See http://www.metadistretti-lombardia.it/ accessed 10/05/06.
[17] See http://www.tecnoparco.org accessed 19/01/06.

Studi Bio-molecolari e Applicazioni Industrialli (CISI, Interdisciplinary Centre of Biomolecular Studies and Industrial Applications).

Lombardia also participates through the technological agency Cestec in the EU funded programme REGINS[18], which involves the regions of West Pannon (Hungary), Stuttgart (Germany) and Upper Austria. REGINS supports technological collaboration between SMEs in these four regions in the automotive, biotechnology and logistics industry. No data were available for the expenditure on biotechnology.

2.3.6 Regional government of Friuli Venezia Giulia

At the north-east corner of Italy, Trieste, capital of Friuli Venezia Giulia region has had historically a multinational dimension which has clearly helped its scientific base in recent decades: Trieste is host to the International Centre for Theoretical Physics (part of UNESCO) and the International Centre for Genetic Engineering and Biotechnology, an institute funded by the United Nations, with the other seat in New Delhi. Building on these assets, the regional R&D strategy focuses on biotechnology and pharmaceuticals. It has hosted the national laboratory of the Inter-University Consortium of Biotechnology (Consorzio Interuniversitario per le Biotechnologie, CIB), since the mid 1990s and the Trieste science park, AREA, has been active in searching for funds for biotechnology research from a variety of sources, including AIRC, Telethon and multinational firms.

In this context, the Technological District in molecular biomedicine funded by MIUR (15M EUR) and the regional government (21.4M EUR) in 2004-2006, aims to support technology transfer through various measures in a field in which the region has scientific excellence. The initiative is managed by a public-private consortium including the AREA science park and other PROs as well as private research firms. The scientific areas prioritised are:

- Cellular therapies
- Regenerative medicine
- Oncology
- Hepatology
- Neuroscience
- Vascular cardiology

Given these priorities we estimate that about 50% of the research activities may fall under the definition of biotechnology used in this study.

2.3.7 Regional government of Piemonte (Piedmont)

Piemonte, one of the other economic locomotives of Italy, is also striving to create a biotechnology industry. The regional policy instruments have focused on technology transfer through the creation of scientific parks, bioincubators and funds for applied research.

Bioindustry Park Canavese was created around 2000 by Finpiemonte (the agency for regional development), the Province of Torino, Confindustria Piemonte (the regional federation of industry) and some private firms (e.g. the pharmaceutical firm Serono).

[18] See http://www.regins.org/en accessed 10/05/06.

From its initial stages in 1996 to 2005 the regional government has spent 35M EUR on the project, with a total of 7.1M EUR between 2002-2005. The regional government also funds two incubators, the Schuola Biotechnologie and Ediscuole, 4.0M EUR between 2003 and 2005.

The programme Delibera CIPE n.20/2004, resulting in an agreement between the regional government and the ministries involved in the Inter-ministerial Economic Planning Committee (CIPE), awarded 15M EUR per year in 2004 and 2005 to research in PROs. The topics funded are basic research with possible applications within the broad fields of life sciences, safety and quality of food products, sustainable development, nanotechnology and aeronautics. In total 12.8M EUR was targeted at life sciences, and it is estimated that 80% of this (10.2M EUR) went to basic health biotechnology.

2.4 Charities

2.4.1 Comitato Telethon Fondazione ONLUS

Telethon is an Italian charity founded in 1990 whose mission is to fund research on muscular dystrophy and all other human genetic diseases. Fundraising depends primarily on a yearly television marathon and on Italian private donations. In total, Telethon raises about 20-25M EUR each year.

Since 1991, Telethon has awarded over 1800 external grants (for research projects, fellowships and research facilities) and has established three major initiatives: the Telethon Institute of Genetics and Medicine (TIGEM), the San Raffaele-Telethon Institute for Gene Therapy (HSR TIGET) and the Dulbecco-Telethon Institute (DTI) for career development of young investigators. About two thirds of its funding is for external grants and about one third for internally created laboratories.

Funded activities span from (1) the identification of genes causing genetic diseases, to (2) studies of mechanisms by which genetic alterations cause the disease, to the study of therapeutic strategies in (3) cellular and (4) animal models of the disease, up to (5) therapeutic clinical trials. In addition, (6) diagnostic, observational and palliative clinical trials are also performed within Telethon grants. All of the projects funded by Telethon entail biotechnological techniques to a varying degree, the aim being to produce knowledge enabling translation of the research into a cure. Telethon research can therefore be roughly classified as basic, for activities 1-4 above, and applied, for activities 5 and 6 above. Between 2002-2005, it allocated 74.6M EUR to research in the area of basic health biotechnologies.

2.4.2 Italian Association for Research on Cancer (AIRC)

The Italian Association for Research on Cancer (Associazione Italiana per la Ricerca sul Cancro, AIRC) and its sister Italian Foundation for Research on Cancer (Fondazione Italiana per la Ricerca sul Cancro, FIRC) spent 130M EUR on research and fellowships in 2002-2005 (33M EUR in 2002, 30M EUR in 2003, 30M EUR in 2004 and 37M EUR in 2005). About 65% of this is basic and translational research, with the remaining 35% in clinical and epidemiological research. An estimate of the percentage of biotechnology involved in cancer research is very problematic: they may oscillate between about 10% of projects making pure technological development to 90% of projects making an important use of biotechnological tools. From an examination of the project titles, we make a prudent estimate of about 60% of projects as strongly biotechnology-related. This would yield 78M EUR for the period considered.

Table 0.3 Overview of biotechnology stimulating instruments by charities

Charity	Duration	Budget (M EUR)
Telethon	2002-2005	74.6
AIRC	2002-2005	78.0
Total	2002-2005	152.6

Source: BioPolis Research

2.5 Participation in 6th FP and use of development funds

Table 0.4 Involvement of Italy in biotechnology/life sciences programmes of the 6th Framework Programme

Sixth Framework Programme[1] Thematic priority	Participation as project manager (% of total)	Participation as member of project teams (% of total)
1. Life sciences, genomics and biotechnology for health	76(10)	869 (10)
2. Nanotechnologies, section bionanotechnology	1 (8)	9 (8)
5. Food quality and safety	10 (11)	139 (9)

[1] First and second call, all types of projects
Source: BioPolis Research

The participation of Italy in the 6th FP is a bit lower than its demographic weight in the EU (13%), but it is remarkably high considering the situation of most Italian R&D indicators. Moreover, EU Structural Funds are an important source of funding, with a total of 3 744M EUR allocated to education, training and employment for 2000-2006. These funds are particularly important in relation to the National Operative Programme 'Safety in the Development of the Italian South' (PON, Programma Operativo Nazionale "Sicurezza per lo Sviluppo del Mezzogiorno d'Italia") which is the funding source of regional initiatives for innovation, such as the biotechnology districts in Puglia or in Cagliari (Sardegna).

3. Performance indicators

3.1 Introduction

This section analyses the performance of the Italian biotechnology innovation system for two or three time periods (depending on data availability) as shown by a range of indicators for scientific and commercialisation performance[19]. Each time period includes several years, to avoid capturing erratic trends. National trends are benchmarked against the performance of the EU-25 Member States and the US.

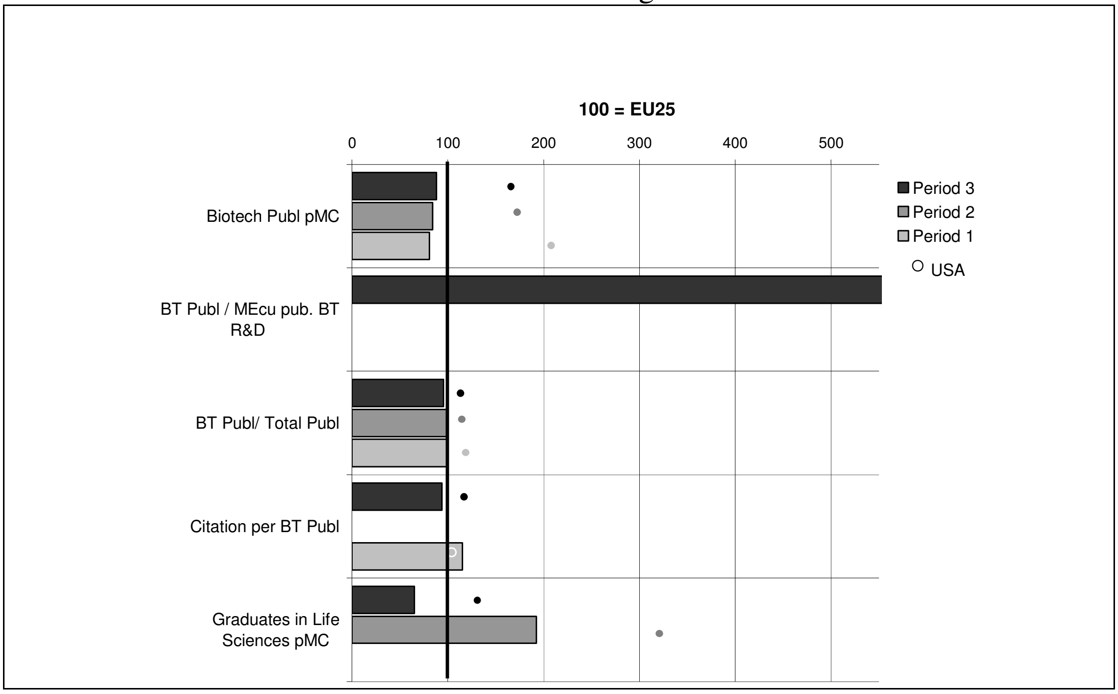
The presentation of performance is structured along the four main areas of the Innovation System: the knowledge base, processes of knowledge transmission and application, industrial development and markets for biotechnology based products. For each area data are shown for a number of different indicators for Italy, the USA and EU25. The values of EU25 have been chosen as a reference for each indicator. The absolute figures that are used to calculate the values for the indicators presented and the sources for the data can be found in Annex 5. In principle, for each indicator data are presented for three periods. The periods chosen can vary considerably between the indicators; table A.5.1 presents for each indicator the specific years of each period.

3.2 Performance in creating a knowledge base and supporting the availability of human resources

The Italian knowledge base performance is only slightly below the EU average, which is quite remarkable considering the low Italian expenditure on R&D in general, and its lack of focus on biotechnology. The high number of publication per expenditure in biotechnology (second row) is only very high given the low investment that Italy put into biotechnology in the mid 1990s. But the denominator does not reflect expenditure on biotechnology in the universities, where most of the publications were produced. Finally, Chart 3.1 indicates a small decrease in the number of graduates in biotechnology (from 9306 in 1998 to 6987 in 2002.

[19] For a detail discussion on the strengths and limitations of science and technology indicators see Moed, H.F., Glänzel, W., Schmoch, U. (eds.) (2004) *Handbook of Quantitative Science and Technology Research. The Use of Publication and Patent Statistics in Studies of S&T Systems*, Dordrecht, Kluwer Academic Publishers.

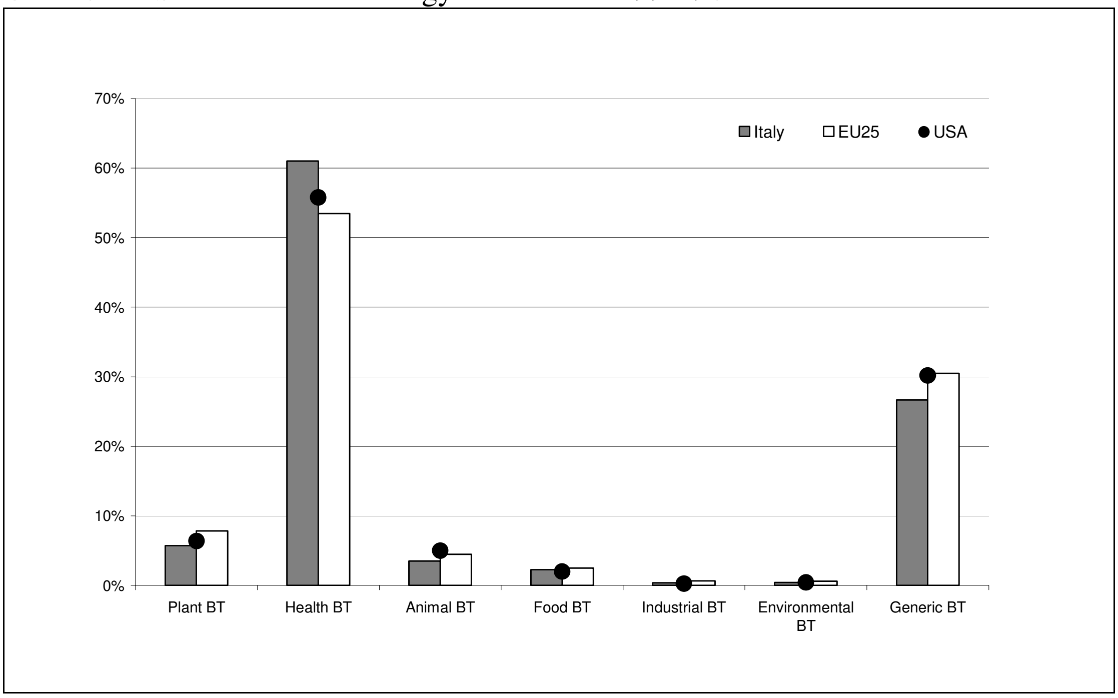
Chart 0.1 Performance Indicators. The knowledge base



Source: BioPolis Research

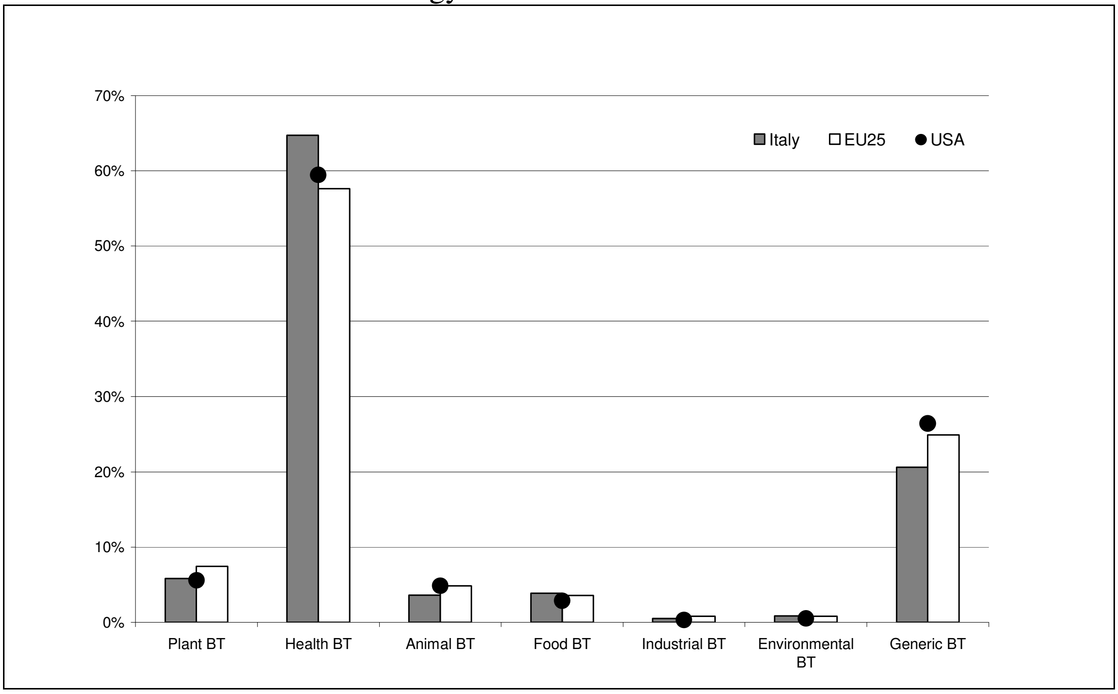
Chart 3.2.1 and 3.2.2 show the biotechnology sub-fields in which publication has occurred in 1994-96 and 2002-2004. The concentration on health biotechnology is even greater in Italy than it is for the EU average. Publication in industrial and environmental biotechnology is extremely low.

Chart 0.2.1 Share of biotechnology subfields in 1994-96



Source: BioPolis Research

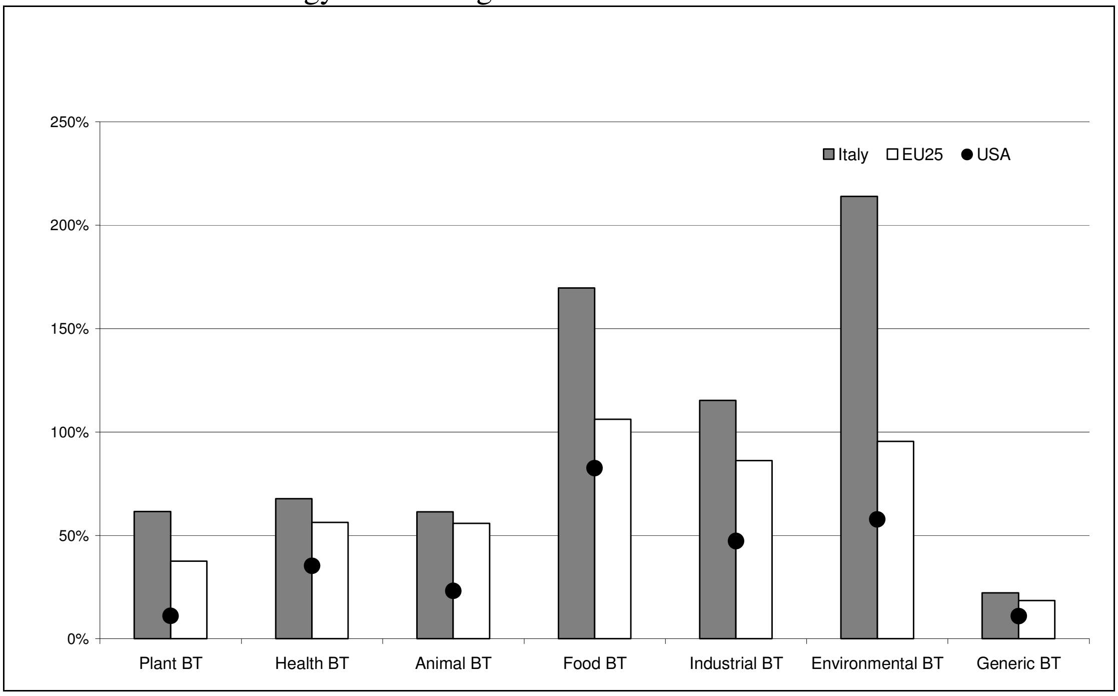
Chart 3.2.2 Share of biotechnology subfields in 2002-04



Source: BioPolis Research

The growth rates in each sub-field are shown in Chart 3.3. As is the case in several other countries, some of the areas with the smallest shares of publications show the highest increases. This is the case in Italy in Food, Industrial and Environmental biotechnology.

Chart 0.3 Biotechnology subfields: growth rates between 1994-1996 and 2002-2004

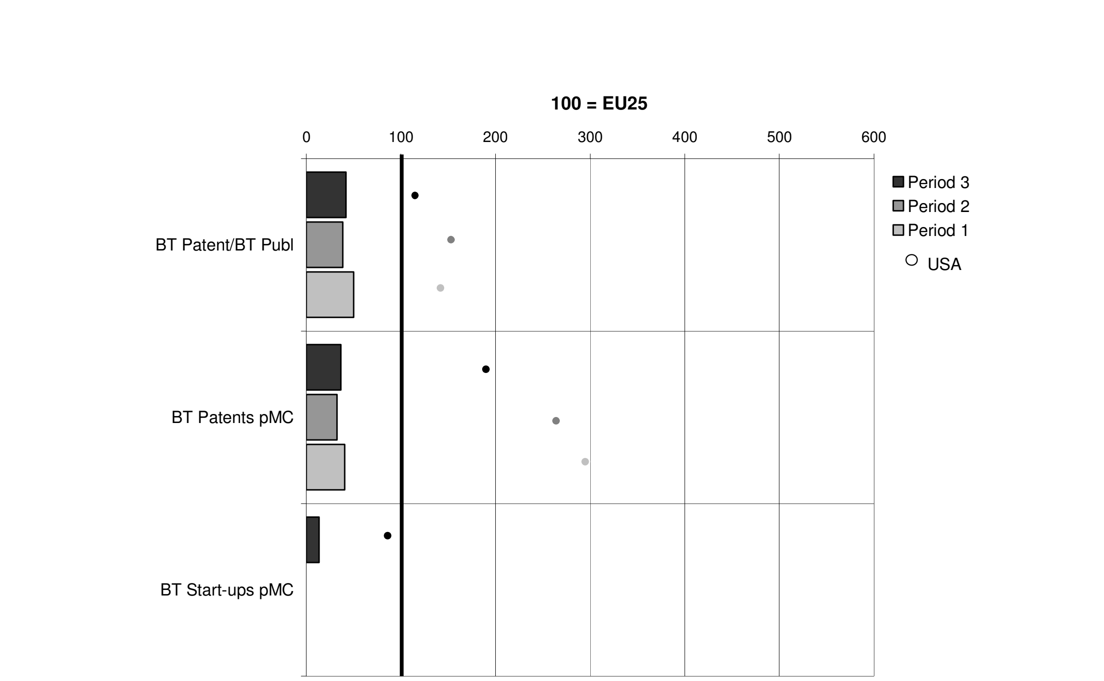


Source: BioPolis Research

3.3 Performance in knowledge transmission and application

Whereas the knowledge base indicators show figures below but close to the EU average, the indicators for knowledge transmission and application remain extremely low and without any tendency to improve.

Chart 0.4 Performance indicators. Knowledge transmission and application.

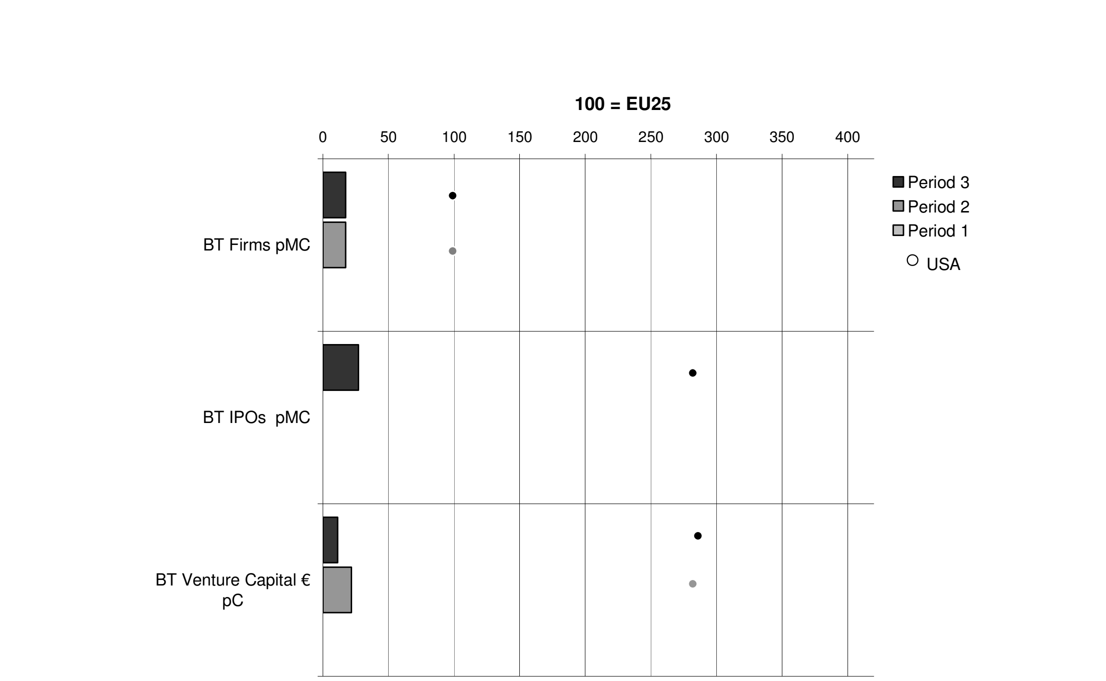


Source: BioPolis Research

3.4 Industrial development

Chart 3.5 shows poor industrial development, both in the number of biotechnology firms and the extremely low investment in them in comparison to the EU average. However, with one public company, it is among the small number of European countries with biotech companies listed on the stock market in the period 2002-2005.

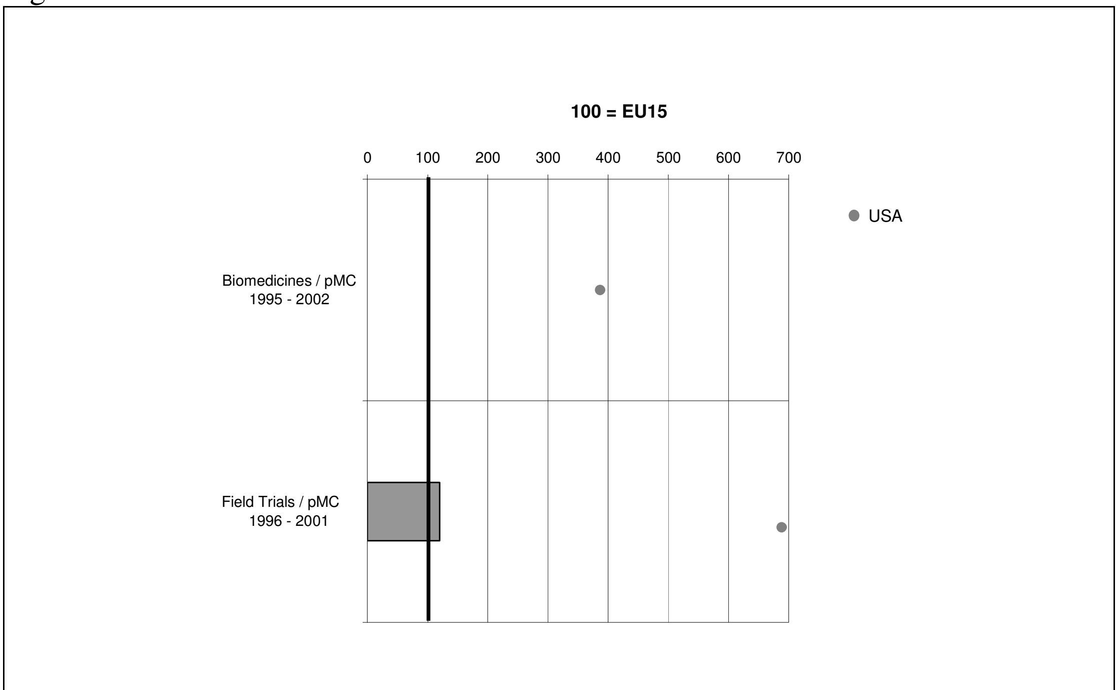
Chart 0.5 Performance indicators. Industrial development.



Source: BioPolis Research

3.5 Market conditions

Figure 0.6 Performance indicators. Market conditions.



Source: BioPolis Research

Italy's number of field trials is above the EU average despite public opposition and legislation that is viewed as restrictive.

4. Conclusions

4.1 Introduction

As in the 1990s, Italian policies for biotechnology appear to remain weak both in terms of expenditure and overall consistency, but recent trends suggest an improvement, if not in the total expenditure, at least in the type of instruments used.

Support for basic and applied research through block grants and rather unselective response mode grants is still the dominant characteristic of the system. Thus generic and non-policy-directed instruments still take more than 80% of the total expenditure on biotechnology. This support has yielded a scientific base that is a weaker but still comparable to EU's average performance.

However, given that in terms of knowledge transfer and industrial development, Italian indicators remain dismal, science policy legislation and the new policy instruments highlight the need to foster technology transfer and industrial development of biotechnology. Building on Italian success in industrial districts, new policy instruments have been developed to support specific technology transfer and commercialisation activities at the technological-industrial cluster level. Although not yet very well funded in comparison to non-policy grants, they seem a positive development.

The analysis of all the instruments reveals a (diffuse, not clear-cut) pattern of specialisation between policies, with national and generic policies supporting the knowledge base and regional and specific policies supporting commercialisation and industrial development. These latter policies in terms of science parks and bioincubators appear to point in the right direction in those regions (Lombardia and Piemonte) where a small but growing biotechnology industry (often rooted in former chemical or pharmaceutical groups) is developing. It remains to be seen if they will be capable of creating and consolidating commercial activities in those other regions that do not thus far have scientific excellence and/or technological industry.

4.2 Public funding of biotechnology through policy instruments

From 2002 to 2005, public funding for non-policy-directed instruments remained roughly constant, whereas policy-directed instrument quickly increased during these years. We have to remember that during the mid 1990s, policy-directed policy was also important (to the order of 20M EUR per year) but managed centrally by the CNR and the ministries. Therefore the increase between 2002 and 2005 of policy-directed instruments has to be put in the context of a funding system undergoing a decentralisation process: as the regional authorities begin shaping R&D policies and funding (or even the national authorities in the case of technological districts), the number of policy-directed measures increases.

Funding for commercialisation also shows an upwards trend – in fact, probably to a higher degree than shown in Table 4.1, since some of the instruments that mainly support research, such as the technological districts, also have some important commercialisation aspects, but this is not reflected in the commercialisation total.

Table 0.1 Public funding of biotechnology through non-policy-directed and policy-directed instruments in the period 2002-2005 (in M EUR)

	2002	2003	2004	2005	Total
RESEARCH					
1. *Non-policy-directed*					
Public Research Institutions	112.2	110.3	115.1	111.5	449.1
Response Mode	91.9	92.8	103.2	90.3	378.2
Total	**204.1**	**203.1**	**218.3**	**201.8**	**827.3**
2a. *Policy-directed Generic*					
National	15.0	15.0	0.0	30.0	60.0
Regional	0.0	0.0	5.1	5.1	10.2
Total	**15.0**	**15.0**	**5.1**	**35.1**	**70.2**
2b. *Policy-directed Biotech-specific*					
National	0.0	0.0	24.4	41.1	65.5
Regional	0.0	0.0	14.4	14.4	28.7
Total	**0.0**	**0.0**	**38.8**	**55.5**	**94.2**
COMMERCIALISATION[20]					
1a. *Policy-directed Generic*					
Regional	0.0	0.0	0.0	10.0	10.0
1b. *Policy-directed Biotech specific*					
Regional	0.7	5.5	1.5	3.7	11.4
Total commercialisation	**0.7**	**5.5**	**1.5**	**13.7**	**21.4**
GRAND TOTALS	**219.8**	**223.6**	**263.7**	**306.1**	**1013.1**

Source: BioPolis Research

4.3 Specific features of the instruments

Most of policy-directed instruments for biotechnology in Italy have a technology transfer rationale and thus either promote or require participation of PROs and firms.

Table 0.2 Participants/recipients and co-financing requirements of policy-directed programs that fund biotech activities in the period 2002-2005

Instrument	Funding agency	Participants/ Recipients			Financial contribution required (%)	
		PRO's	SME's	LFs	Recipients	Other Public authorities
National						
Generic						
FIRB (MIUR)	MIUR	√	√	√	√	
Biotech specific						
Technological districts (MIUR)	MIUR	√	√	√	n.a.	√
ITT (MIUR)	MIUR	√				
CNR Target Project	MIUR	√			n.a.	
Regional						

[20] The total for commercialisation policies is lower than that shown in Table 4.3 for commercialisation policy goals 5,6,7 and 9 because it reflects those instruments that were solely or mainly oriented towards commercialisation. However, many of policy-directed research instruments had many policy goals, including some minor commercialisation activities.

Instrument	Funding agency	Participants/ Recipients			Financial contribution required (%)	
		PRO's	SME's	LFs	Recipients	Other Public authorities
Generic						
Meta-clusters (Lombardia)	Lombardia		√		√	
Delibera CIPE (Piemonte)	Piemonte	√			n.a.	
Biotech specific						
Tech. Districts (Friuli VG)	Friuli VG	√	√	√	n.a.	
Tech. Districts (Lombardia)	Lombardia	√	√	√	n.a.	
Bioinitiative (Lombardia)	Lombardia	√				
Bioindustry Park (Piemonte)	Piemonte	√	√	√	√	
Bio-incubator (Piemonte)	Piemonte		√		n.a.	

Legend: PROs Public Research Organisation. SME: Small and Medium Enterprise. LF: Large Firm.
Source: BioPolis Research

4.4 Policy goals

In terms of policy goals, there appears a consistent though not clear-cut division of functions between national versus regional, and generic versus specific instruments. National and generic instruments focus on upstream goals (basic research, availability of human resources, etc.), whereas regional and specific instruments focus on the promotion of technology transfer and commercialisation. Given that the lack of linkage between academia and industry is one of the Achilles heels of the Italian innovation system, these regional and specific instruments may constitute a positive development.

Table 0.3 Coverage of policy goals and funding by goal by policy-directed instruments for the period 2002-2005 (in M EUR)

	Policy goals								
	1*	2	3	4	5	6	7	8	9
National									
Generic									
FIRB	√	√	√	√					
Subtotal National Generic	**19.8**	**10.2**	**10.2**	**19.8**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Specific									
Tecnological Districts (National)		√			√	√			√
ITT	√	√	√	√	√	√			
CNR Target Project		√							
Subtotal National Specific	**10.0**	**10.7**	**7.5**	**7.5**	**12.6**	**12.6**	**0.0**	**0.0**	**5.3**
Regional									
Generic									
Meta-clusters (Lombardia)		√							√
Delibera CIPE (Piemonte)		√							
Subtotal Reg. Generic	**0.0**	**15.2**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**5.0**
Specific									
Tech Districts (Friuli VG)		√			√	√			√

	Policy goals								
	1*	2	3	4	5	6	7	8	9
Tech Districts (Lombardia)		√			√	√			√
Bioinitiative (Lombardia)					√		√		
Bioindustry Park (Piemonte)	√	√	√	√	√	√			
Bioincubator (Piemonte)		√			√	√			
Subtotal Reg. Specific	**6.3**	**2.2**	**0.4**	**0.1**	**10.7**	**10.7**	**0.0**	**0.0**	**9.8**
Total	**36.1**	**38.3**	**18.1**	**27.4**	**23.3**	**23.3**	**0.0**	**0.0**	**20.0**

* Legend:
1 = High level of biotechnology research
2 = High level of industry-oriented (and applied) research
3 = Knowledge flow and collaboration among scientific disciplines
4 = Availability of human resources
5 = Transmission of knowledge from academia to industry and its application to industrial resources
6 = The adoption of biotechnology for new industrial applications
7 = Firm creation
8 = Social acceptance of biotechnology
9 = Business investment in R&D
10= Bio-safety, Risk assessment
Source: BioPolis Research

4.5 Biotech research applications areas

As it is the case in most countries, health biotechnologyreceives most funds, with one third of the policy-directed expenditure. Industrial biotechnology takes a large part here, because we have classified the investment in nanobiotechnology of IIT as such. Basic biotechnology and general biotechnology take most of the remaining funding. Funding for plant, animal, food and environmental biotechnology are covered through the CRA and ENEA and appear to be negligible in the policy-directed instruments.

Table 0.4 Coverage of biotech application areas and funding through policy-directed instruments by biotech application area for the period 2002-2005 (in M EUR)

	Biotech application areas								
	1*	2	3	4	5	6	7	8	9
National									
Generic									
FIRB	√	√	√	√	√	√	√	√	√
Subtotal Nat. Generic	1.0	1.0	4.0	25.0	1.0	1.0	25.0	1.0	1.0
Specific									
Tecnological Districts (National)				√					√
ITT						√			
CNR Target Project									√
Subtotal Nat. Specific	0.0	0.0	0.0	11.6	0.0	50.0	0.0	0.0	4.6
Regional									
Generic									
Meta-clusters (Lombardia)	√	√		√	√	√			
Delibera CIPE (Piemonte)				√					√
Subtotal Reg. Specific	1.3	1.3	0.0	12.2	2.5	1.0	0.0	0.0	2.0
Specific									
Tech Districts (Friuli VG)				√					

	Biotech application areas								
	1*	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Tech Districts (Lombardia)									√
Bioinitiative (Lombardia)									√
Bioindustry Park (Piemonte)				√	√			√	√
Bioincubator (Piemonte)									√
Subtotal Reg. Specific	0.0	0.0	0.0	16.8	0.1	0.0	0.0	0.4	22.7
Total	**2.3**	**2.3**	**4.0**	**65.6**	**3.6**	**52.0**	**25.0**	**1.4**	**30.3**

Figures in the table should be understood as rough estimates of expenditure in a given application area.

* Legend:

1 = Plant biotechnology
2 = Animal biotechnology
3 = Environmental biotechnology
4 = Health biotechnology
5 = Food biotechnology
6 = Industrial biotechnology
7 = Basic biotechnology
8 = Ethical, legal, social aspects of biotechnology
9 = General biotechnology (covers all areas or is not area-specific)

Source: BioPolis Research

4.6 Stimulation of biotech activities through the instruments

Table 0.5 Coverage of biotech activities in the period 2002-2005 through policy-directed instruments

	Biotech activities																
	1*	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**
National																	
Generic																	
FIRB (MIUR)	√			√	√	√	√	√								√	√
Biotech specific																	
Technological districts (MIUR)								√		√			√		√		
ITT	√	√	√		√	√											
CNR Target Project		√			√												
Regional																	
Generic																	
Meta-clusters (Lombardia)		√						√									
Delibera CIPE (Piemonte)	√	√															
Subtotal Reg. Specific																	
Specific																	
Tech Districts (Friuli VG)								√		√			√		√		
Tech Districts (Lombardia)								√		√			√		√		
Bioinitiative (Lombardia)												√	√				
Bioindustry Park (Piemonte)									√	√	√		√	√			
Bioincubator (Piemonte)														√			

Ticks in this table aim to highlight those activities deemed more important although most instruments also cover to some extent many other activities.

Source: BioPolis Research

* Many different types of activities are supported by biotech instruments:
1 Basic research
2 Applied research
3 Centres of excellence
4 Research network
5 Mobility of researchers among disciplines
6 Biotechnology training
7 Mobility of researchers between academia and industry
8 Collaborative research between industry and public research organisations
9 Set up research institute/centre of industrial interest
11 Science and technology park
12 Protection of IPR in public research organisations
13 Financial support for start-ups
14 Non-financial support for start-ups
15 Creation of incubators
16 Awareness of biotech by companies not yet active in it
17 Grants for industrial research
18 Other incentives for business investment

4.7 Dynamics: comparison with 1994-1998

Unlike many other countries in the BioPolis reports, for Italy we do not have data to make a comparison between biotechnology expenditure in 1994-1998 and 2002-2005. Considering only national policy-directed instruments, it appears that funding has increased from an average of 21.4M ECU to 31.4M EUR per annum. In relation to non-policy-directed instruments, which are linked to block grants to large organisations, one would not expect dramatic changes given the inertia of organisations such as CNR, even during the period of re-organisation it has recently undergone. For regional expenditure, although no data is available for the 1990s, it is safe to assume that it was very low, since the regions had not yet been given the mandate to support R&D. We may therefore conclude that the biggest change in funding has resulted from the contribution by regional governments to policies that are directed and often specific to biotechnology.

Table 0.6 Comparison of biotechnology research funding through non-policy-directed and policy-directed instruments in the periods 1994-1998 and 2002-2005

Funding	Average total funding per annum for biotechnology research in 1994-1998	Average total funding per annum for biotechnology research in 2002-2005
National	21.4M ECU (only policy-directed)[21]	238.2M EUR
Regional	Not available	15.0M EUR
Total	21.4M ECU	253.2M EUR

Note: For the period 2002-2005, table 4.6 combines total data of non-policy-directed funding and policy-directed instruments.
Source: BioPolis Research

In the period 2002-2005, it appears that the policies in place guarantee a more thorough coverage of various policy goals than in 1994-1998. This has been achieved by regional policies which, through measures like science parks, aim to provide support to the various stages of development of biotechnology.

Table 0.7 Coverage of policy goals by the policy-directed instruments in the periods 1994-1998 and 2002-2005

Presence of instruments					
Policy areas	**Policy goals**	**1994-1998**		**2002-2005**	
		G	**S**	**G**	**S**
1. Creation of knowledge base and human resources	1. To promote high level of biotechnology basic research	√	√	√	√
	2. To promote high level of industry-oriented (and applied) research	√	√	√	√
	3. To support knowledge flow and collaboration among scientific disciplines		√	√	√
	4. To assure availability of human resources		√	√	√
2. Knowledge transmission and application	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes	√	√	√	√

[21] From Schmidt and Reiss' report (1999) we may estimate a biotechnology expenditure of 21.4 M EUR per year but this covers only policy-directed instruments.

Presence of instruments					
Policy areas	**Policy goals**	**1994-1998**		**2002-2005**	
		G	**S**	**G**	**S**
	6. To stimulate the adoption of biotechnology for new industrial applications	√	√	√	√
	7. To assist firm creation	√		√	√
3. Market	8. To monitor and improve the social acceptance of biotechnology				√
4. Industrial development	9. To encourage business investment in R&D	√		√	√

Source: BioPolis Research

In terms of application areas, whereas in the 1990s, about 80% of policy-directed funding was targeted at health biotechnology, in recent years, there has been an increase in the funding of industrial and basic biotechnology. This tendency is in accordance with that shown in

Chart 0.3 concerning the publication growth per area between 1994-1996 and 2002-2004.

5. Future developments

The guidelines for S&T policy for 2002-2006[22] singled out agro-food and health as strategic areas (2 out of 8 areas listed) and biotechnology and biomedical as technological priorities (2 out of 11 technologies listed). Moreover they list among the ten programmes to be developed, four programmes that are related to biotechnology, though not always in a very direct manner: health, pharmaceutical industry, biomedical industry and agro-food and food safety. Thus, it seems that biotechnology forms part of the vision for the future development of Italian R&D, but that the prioritisation is not very focused.

In terms of concrete commitments, the main research policy developments with the potential to impact on biotechnology are:

- The National Research Programme 2005-2007, with a commitment of 800M EUR to be spent on research focused in the improvement of well-being, competitiveness and sustainable development.
- High Technology Fund (Fondo High Tech), created in October 2005 by the Ministry of Innovation and Technology (MIT), endowed with 100M EUR for a decade to promote the emergence of risk capital to fund SMEs in under-invested areas.
- The consolidation of the technological districts already started (Lombardia and Friuli Venezia Giuilia), and the development of those in their initial stages during late 2005 and early 2006 (Sicilia, Sardegna, Puglia).
- The possible incorporation into the response mode grants FAR and FIT of a selection priority for biotechnology projects.

[22] See *Linee guida per la politica scientifica e tecnologica del governo* (2002), pp. 12-18: http://www.governo.it/GovernoInforma/Dossier/riforma_ricerca/lineeguida.pdf accessed 19-05-06.

Annex 1 List of tables

Annex 2 List of figures and charts

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Annex 5 Performance

Introduction

This Annex includes the data that was used to develop the indicators discussed in Chapter 3. Chapter 3 describes four sets of indicators used to measure the performance of the national biotechnology system of innovation, in terms of:

1. Creating a knowledge base and supporting the availability of human resources: Charts 3.1, 3.2.1, 3.2.2 and 3.3
2. Knowledge transmission and application: Chart 3.4
3. Industrial development: Chart 3.5
4. Market conditions: Chart 3.6

The indicators aim to capture trends in performance and compare the national situation with that of a reference region. To present trends in performance, most indicators are provided for three or two different time periods, depending on data availability. To avoid capturing erratic trends, each time period includes several years, again depending on data availability. Information on which years have been captured for each period and comments concerning the index used can be found in the last two columns of Table A5.1.

Table A5.1. Performance indicators, charts, comments and time periods

	Indicator	Chart	Comments	Time periods
Ind. 1	Biotech publications per million capita (pMC)	3.1	Index: Reference Region EU25 =100 and US data for comparison	(1) 1994-1996, (2) 1998-2000, (3) 2002-2004
Ind. 2	Biotech publications per BT public R&D expenditure	3.1	Only for those countries included in the inventory Index: Reference Region EU25 =100	BT Pub. 2002-2004 / Total Pub. Expenditure 1994-1998 M Ecu
Ind. 3	BT patents / BT publications	3.4	Index: Reference Region EU25 =100 and US data for comparison	(1) 1994-1996 (2) 1998-2000 (3) 2001-2003
Ind. 4	BT publications / Total pub.	3.1	Index: Reference Region EU25 =100 and US data for comparison	(1) 1994-1996 (2) 1998-2000 (3) 2002-2004
Ind. 5	Citations to BT publications	3.1	Index: Reference Region EU25 =100 and US data for comparison Small country effect	(1) 1994-1998 (3) 2000-2004
Ind. 6	Graduates in life sciences pMC	3.1	Index: Reference Region EU17 =100 and US data for comparison	(2) 1998 (3) 2002

	Indicator	Chart	Comments	Time periods
Ind. 7	BT publications in subfields, as % of total BT publications	3.2.1	Data in % EU25 and US data for comparison	1994-1996
		3.2.2		2002-2004
Ind. 8	Growth rate of BT publications in subfields	3.3	EU25 and US data for comparison Small field effect	Growth rate between 1994-96 (period 1) and 2002-04 (period 3)
Ind. 9	Biotech patent applications pMC	3.4	EU25 and US data for comparison	(1) 1994-1996 (2) 1998-2000 (3) 2001-2003
Ind. 10	Number of biotechnology companies pMC	3.5	European (data available) and US data for comparison	(2) 2001 (3) 2004
Ind. 11	Number of biotech start-ups pMC	3.4	European (data available) and US data for comparison	(3) 2001-2003 (only one period)
Ind. 12	Number of biotech IPOs pMC	3.5	European (data available) and US data for comparison	(3) 2002-2005
Ind. 13	Venture capital in € pC	3.5	European (data available) and US data for comparison	(2) 2002 (3) 2004
Ind. 14	BT acceptance index	No Chart - Discussed in text of chapter 3	Source: BT Policy Benchmarking 2005. The biotechnology acceptance index is a composite index and draws on questions Q.12, Q.13.1 and Q14.01 and Q14.09 of the Eurobarometer 58.0	2002
Ind. 15	Eurobarometer 225	No Chart - discussed in text of chapter 3	See section 3.3 and sections 3.4.1, 3.4.2, and 3.4.3 of the Special Eurobarometer 225[23]	2005
Ind. 16	Biomedicines	3.6	Source: BT Policy Benchmarking 2005 Index: Reference Region EU15 =100 US data for comparison	1995-2002
Ind. 17	Field trials	3.6	Source: Biotechnology Innovation Scoreboard 2002 Index: Reference Region EU15 =100 US data for comparison	1996-2001

[23] http://europa.eu.int/comm/public_opinion/archives/ebs/ebs_225_report_en.pdf

The following methodological issues are related to some of the indicators:

- Indicator 3 (Patent BT / Publications BT) replaces the indicator *BT publications basic research/ BT publications applied research*. Results of the EPOHITE project have shown that the original indicator does not differ significantly in the case of old EU member states. This might be the result of methodological problems associated with the indicator, since the definition of basic and applied research is based on a journal classification made by SCI. The explanatory power of this indicator is therefore questionable.
- To calculate the citation rate first the publications for the period 1994-1996 (set 1) were searched and all the publications in 1994-1998 that cited any publications in set 1 (set 2). Citation rate has been calculated by (number of publications in set 2) / (number of publications in set 1). However, many of the articles in set 2 cited not only one article in set 1 and these duplicated citations are not taken into account in our calculation. For example, if there are 2 articles in set 1 and they each has one citation but cited by the same article, there is only 1 article in set 2. The citation rate for the 2 articles in set 1 is 0.5 instead of 1. This depreciation is more obvious in countries with more publications such as USA and EU25 since the possibility to cite multiple articles in set 1 is large. Accordingly the citation rates of USA and EU25 are a bit underestimated.
- The indicator 'Citations to BT publications' seems to have a 'small country effect' bias. Small countries show a relatively large citation rate. A possible explanation might be that, as far as number of publications is concerned, larger countries usually have a larger 'middle quality' share of research results (in terms of impact) while smaller countries usually have a 'low in number but good in quality' publications impact. This can be explained by the concentration of resources allocated to selected research groups in small countries. Small countries may concentrate resources in outstanding research units. Accordingly, fewer publications may have greater impact.
- The EU25=100 index is applicable in the indicator 'Graduates in life sciences pMC' since data was only available for 17 member states.
- For those countries starting from zero in period 1 (1994/1996), the growth rate of BT publications in subfields was set to 100% if the number of publications in period 3 (2002-2004) was larger than zero. On the other hand, if the country reduced the number of publications to zero in the period 2002-2004, the growth rate was -100%.Given that a relative growth rate was used, small fields tended to have relatively larger growth rates.
- To benchmark each country we chose EU25 (or EU15 if data was not fully available) as the reference region. In those cases where data for EU25 or EU15 were not available, the reference corresponds to the sum of national data available. Moreover, to ease the presentation of indicators with different scales in a given chart, an index value was used.

Raw data for the Charts in chapter 3

Raw data for Chart 3.1. BT publications per million capita (pMC): absolute and indexed values

	BT publications			Population (million)		
	94-96	98-00	02-04	1996	2000	2004
EU25	97521	128716	145646	447	451	457
Italy	10030	13678	16295	57	57	58
USA	119802	135508	154402	264	276	292
	BT publications/pMC			Index EU25=100		
	94-96	98-00	02-04	94-96	98-00	02-04
EU25	218	285	319	100	100	100
Italy	176	240	281	81	84	88
USA	454	492	529	208	172	166

Source: BIOPOLIS research
Publication data: Science Citation Index (through online database vendor STN International)
Population data: EUROSTAT and OECD

Raw data for Chart 3.1. BT publications per BT public R&D expenditure

	BT publi-cations	Non-policy-directed funding	Policy-directed funding		Total public spending on BT (Mecu)	BT publications/ Mecu BT public expenditure	Index
			Biotech specific	Generic			
	2002-2004	1994-1998	1994-1998	1994-1998	1994-1998	2002-2004/ 1994-1998	
EU25	145646				n.a.		
Italy	16295		77.9	19.5	97	167	1042
USA	154402				n.a.		n.a.

Source: BIOPOLIS research
Publication data: Science Citation Index (through online database vendor STN International)
BT public expenditures in research: Inventory Project, Table 3.4 Executive Summary

Raw data for Chart 3.1. BT publications, as share of total publications: absolute and indexed values

	BT publications			Total publications		
	94-96	98-00	02-04	94-96	98-00	02-04
EU25	97521	128716	145646	860652	1024327	1117392
Italy	10030	13678	16295	88476	110186	130865
USA	119802	135508	154402	889506	941191	1045894
	Share of BT publication			Index EU25=100		
	94-96	98-00	02-04	94-96	98-00	02-04
EU25	11%	13%	13%	100	100	100
Italy	11%	12%	12%	100	99	96

USA	13%	14%	15%	119	115	113

Source: BIOPOLIS research
Publication data: Science Citation Index (through online database vendor STN International)

Raw data for Chart 3.1. Citations to BT publications: absolute and indexed values

	Citations to BT publications		Index EU25=100	
	94-98	**00-04**	**94-98**	**00-04**
EU25	6,14	7,28	100	100
Italy	7.07	6.85	115	94
USA	6,39	8,54	104	117

Source: BIOPOLIS research
Ciatations data: Science Citation Index (through online database vendor STN International)

Raw data for Chart 3.1. Graduates in life sciences pMC: absolute and indexed values

	Graduates in Life Sciences		Population (million)	
	1998 / 1999	**2002**	**1998 / 1999**	**2002**
EU17	46,859**	81,316	552**	431
Italy	9306	6987	57	57
USA	75,253*	70,950	276*	288
	Graduates pMC		**Index EU17=100**	
	1998 / 1999	**2002**	**1998 / 1999**	**2002**
EU17	85**	189	100	100
Italy	164	123	192	65
USA	273*	246	321	131

Index EU17=100 for 1998 is EU-16, because for Portugal no data available
* data for 1998; ** data for 1999
Source: BIOPOLIS Research
Graduates data OECD Education Database
Population source for US is the OECD

Raw data for Chart 3.2.1. BT publications in subfields, as share of total number of BT publications for the period 1994-1996

	1994-1996							
	Total	**Plant**	**Health**	**Animal**	**Food**	**Indus-trial**	**Environ-mental**	**Generic**
EU25	100%	8%	53%	5%	3%	1%	1%	30%
Italy	100%	6%	61%	4%	2%	0%	0%	27%
USA	100%	6%	56%	5%	2%	0%	0%	30%

Source: BIOPOLIS Research
Publication data: Science Citation Index (through online database vendor STN International)

Raw data for Chart 3.2.2. BT publications in subfields, as share of total number of BT publications for the period 2002-2004

	2002-2004							
	Total	Plant	Health	Animal	Food	Indus-trial	Environ-mental	Generic
EU25	100%	7%	58%	5%	4%	1%	1%	25%
Italy	100%	6%	65%	4%	4%	1%	1%	21%
USA	100%	6%	59%	5%	3%	0%	1%	26%

Source: BIOPOLIS Research
Publication data: Science Citation Index (through online database vendor STN International)

Raw data for Chart 3.2.1 BT publications in subfields for the period 1994-1996

	1994-1996							
	Total	Plant	Health	Animal	Food	Indus-trial	Environ-mental	Generic
EU25	97217	7629	51944	4375	2434	624	576	29635
Italy	10006	571	6104	352	227	39	43	2670
USA	111686	7118	62274	5580	2230	296	459	33729

Source: BIOPOLIS Research
Publication data: Science Citation Index (through online database vendor STN International)

Raw data for Chart 3.2.2 BT publications in subfields for the period 2002-2004

	2002-2004							
	Total	Plant	Health	Animal	Food	Indus-trial	Environ-mental	Generic
EU25	140984	10494	81220	6821	5017	1162	1126	35144
Italy	15823	922	10239	568	612	84	135	3263
USA	141680	7910	84234	6872	4070	436	724	37434

Source: BIOPOLIS Research
Publication data: Science Citation Index (through online database vendor STN International)

Raw data for Chart 3.3. Growth rate of BT publications in subfields between 1994-96 and 2002-04

	1994-1996/2002-2004						
	Plant	Health	Animal	Food	Industrial	Environ-mental	Generic
EU25	38%	56%	56%	106%	86%	95%	19%
Italy	61%	68%	61%	170%	115%	214%	22%
USA	11%	35%	23%	83%	47%	58%	11%

Source: BIOPOLIS Research
Publication data: Science Citation Index (through online database vendor STN International)

Raw data for Chart 3.4. BT Patents pMC: absolute and indexed values

	BT patents			Population (million)		
	94-96	98-00	01-03	1996	2000	2003
EU25	4924	8921	10119	447	451	455
Italy	254	366	464	57	57	57
USA	8590	14396	12348	264	276	292*
	BT patents/pMC			Index		
	94-96	98-00	01-03	94-96	98-00	01-03
EU25	11	20	22	100	100	100
Italy	4	6	8	41	33	36
USA	33	52	42	295	264	190

Source: BIOPOLIS Research
Publication data: Science Citation Index (through online database vendor STN International)
Patent data: `EPPATENT, WOPATENT` (online database vendor Questel Orbit)

Raw data for Chart 3.4. BT Patents per BT publications: absolute and indexed values

	BT patents			BT publications		
	94-96	98-00	01-03	94-96	98-00	01-03
EU25	4924	8921	10119	97521	128716	140219
Italy	254	366	464	10030	13678	15305
USA	8590	14396	12348	119802	135508	148853
	BT patents/ BT publications			Index EU25=100		
	94-96	98-00	01-03	94-96	98-00	01-03
EU25	0.05	0.07	0.07	100	100	100
Italy	0.03	0.03	0.03	50	39	42
USA	0.07	0.11	0.08	142	153	115

Source: BIOPOLIS research
Publication data: Science Citation Index (through online database vendor STN International)
Patent data: `EPPATENT, WOPATENT` (online database vendor Questel Orbit)

Raw data for Chart 3.5. Number of BT companies pMC for the period 2001 – 2004: absolute and indexed values

	BT companies				Population (x1,000)			
	2001	2002	2003	2004	2001	2002	2003	2004
Europe	1879	1878	1861	1815	452016	452641	454580	456863
EU Available	1643	1650	1782	1605	319337	319484	408602	322210
Italy	51	51	50	50	56968	56994	57321	57888
USA	1457	1472	1473	1444	285102	287941	290789	291685
	BT companies pMC				Index			
	2001	2002	2003	2004	2001	2002	2003	2004
Europe								
EU Available	5	5	4	5	100	100	100	100
Italy	0.90	0.90	0.87	0.86	17	17	20	17
USA	5.11	5.11	5.06	4.95	99	99	116	99

Note: EU Available is the result of the sum of available EU member states
Source: BIOPOLIS Research

Biotech companies data: Ernst and Young 2002-2004, EuropaBio

Raw data for Chart 3.5. BT start-ups pMC for period 2001-2003 and year 2003: absolute and indexed values

	BT start-ups		Population (x1,000)	
	2001-2003	2003	2003	
Europe (EU 15 - Cyprus - Greece + Norway + Switzerland)	523	132	367051	
Italy	11	4	57321	
USA	355	83	290789	
	Biotech start-up/pMC	Index	Biotech start-up/pMC	Index
	2001-2003	2001-2003	2003	2003
Europe (EU 15 - Cyprus - Greece + Norway + Switzerland)	1.4	100	0.36	100
Italy	0.07	19	0.2	13
USA	1.2	86	0.29	79

Source: BIOPOLIS Research
Start-ups data: EuropaBio

Raw data for Chart 3.5. Number of BT IPO's pMC: absolute and indexed values

	BT IPO	Population T				
	2002-2005	2002	2003	2004	2005	2002-2005
EU Available	29	452927	454869	457154	461593	456636
Italy	1	56994	57321	57888	58462	57666
USA	52	287941	290789	291685		290138

	IPO /pMC	Index
	2002-2005	2002-2005
EU Available	0.00	100
Italy	0.00	27
USA	0.00	282

Note: EU Available is the result of the sum of available EU member states
Source: BIOPOLIS Research
IPO data: Ernst and Young 2002-2004, London Stock Exchange, Frankfurt Stock Exchange, Euronext, Nasdaq, Burril & Company

Raw data for Chart 3.5. Venture capital pC: absolute and indexed values

	Venture capital in biotechnology companies M€			**Population (x 1,000)**		
	2002	**2002**	**2002**	**2002**	**2003**	**2004**
Europe	1100	920	2800			
EU Availiable	890	883	1111	315584	319663	325131
Italy	35	18	22	56994	57321	57888
USA	2288	2498	2855	287941	290789	291685
	Venture capital in €/pC			**Index**		
	2002	**2003**	**2004**	**2002**	**2003**	**2004**
Europe						
EU Availiable	2.8	2.8	3.4	100	100	100
Italy	1	0.3	0.4	22	11	11
USA	8	9	10	282	311	286

Source: BIOPOLIS Research
VC data: E&Y Beyond Borders 2002, 2003, 2004

Raw data for Chart 3.6. Number of Biomedicines pMC

	Biomedicines	**Population (Million)**	**Biomedicines / pMC**	**Index**
	1995-2002	**2002**		**1995-2002**
EU15	39	378	0.10	100
Italy	0	57	0.00	0
USA	115	289	0.40	387

Note: EU 15 is the result of the sum of the 15 old EU member states
Source: BIOPOLIS Research
Number of medicines: Benchmarking of public biotechnology policy 2005

Raw data for Figure 3.6. Number of field trials pMC

	Field trials	**Population in M**	**Field trials pMC**	**Index**
	1996-2001	**2001**	**1996-2001**	**1996-2001**
EU15	1334	379	4	100
Italy	245	58	4	120
USA	6745	278	24	688

Note: EU 15 is the result of the sum of the 15 old EU member states
Source: BIOPOLIS Research
Field trials: Biotechnology Innovation Scoreboard 2002

Raw data for biotechnology acceptance.

BT acceptance index 2002		
	Index Average	**N (sample size)**
EU - 15*	100,29	16828
Italy	100.58	976

*Weighted Average according to the weight "W13" of the Eurobarometer 58.2, which considers population differences among countries and corrects for inconsistencies in the national samples
Source: BIOPOLIS Research
BT acceptance index: Benchmarking of public biotechnology policy 2005

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EuropaBio	http://www.europabio.org/
EUROSTAT	http://epp.eurostat.cec.eu.int/
OECD Education Database	http://www.oecd.org/
OECD Statistics	http://www.oecd.org/
STN International	http://www.stn-international.de/
Questel Orbit	http://www.questel.orbit.com/index.htm

Annex 6 Abbreviations

AIRC	Associazione Italiana per la Ricerca sul Cancro (Italian Association for Research on Cancer)
CIPE	Comitato Interministeriale per la Programmazione Economica (Inter-ministerial Economic Planning Committee)
CNR	Consiglio Nazionale delle Ricerche (National Research Council)
CNRB	Centro Nazionale per le Risorse Biologiche (National Centre for Biological Resources)
CNBB	Comitato Nazionale per la Biosicurezza e le Biotecnologie (National Committee for Biosafety and Biotechnology)
CRA	Consiglio per la Ricerca e la Sperimentazione in Agricoltura (Council for Research and Experimental Agriculture)
ELSA	Ethical Legal and Social Aspects
ENEA	Ente per le nuove technologie, l'energia e l'ambiente (New Technology, Energy and Environment)
FAR	Fondo Agevolazioni Ricerca Industriale (Funds for Supporting Industrial Research)
FIRB	Fondo per gli investimenti della ricerca di base (Funds for Investment in Basic Research)
FP	Framework Programme
IIT	Istituto Italiano de Tecnologia (Italian Institute of Technology, IIT)
ISS	Istituto Superiore Sanita (Higher Institute of Health)
MAP	Ministero delle attività produttive (Ministry of Productive Activities)
MIPAF	Ministero delle Politiche Agricole e Forestali (Ministry of Agriculture and Forestry Policies)
MIUR	Ministero dell'instruzione, dell'universita et della ricerca (Ministry of Education, University and Research)
PON	Programma Operativo Nazionale/Regionale (National Operative Programme)
POR	Programma Operativo Nazionale (Regional Operative Programmes)
PRIN	Pogetti di ricerca di interesse nazionale (Research Projects of National Interest)
PRO	Public Research Organisation
MEF	Ministero dell'Economia e delle Finanze (Ministry of Economy and Finance)
SME	Small and medium sized enterprise