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BIOTECH SECTOR AND TECHNOLOGY TRANSFER: THE EXAMPLE OF THE REGIONAL COMPETENCE CENTRES

by

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04-0112

I. INTRODUCTION AND DEFINITIONS

At the dawn of the 21st century, no new area of science and technology holds greater potential than biotechnology. The new biotechnologies are promising to have striking impact on the economic growth, contributing at the same time to a better quality of life and socio-economic development.

Biotechnology can be defined as a diverse collection of cellular and genetic techniques that manipulate cellular, subcellular and molecular components in living things to make products, discover new knowledge about the molecular and genetic basis of life, or modify plants, animals, and micro-organisms to carry desired traits. This general definition includes also productive technologies used long ago such as agriculture, zootechnology and the exploitation of fermentative activities of micro-organisms.

The so-called new biotechnologies include, but are not limited to, recombinant DNA methods, cloning, sequencing, polymerase chain reaction (PCR) amplification, oligonucleotide and protein synthesis, gene and protein markers, microarrays, RNA interference, monoclonal antibodies, transgenic organisms, bioinformatics, and biosensors.

These new techniques origin from various scientific fields as biology, chemistry, biochemistry, genetics, immunology, engineering and medicine, as well as other developing fields like informatics and material science. The biotechnologies' scientific base, therefore, is particularly rich and complex.

The same multidisciplinary origin of biotechnologies explains in part, their applications in different industrial sectors. Firms involved in biotechnologies are not separately classified as a single industry but are classified as working in different sectors such as human health, cosmetics, animal health, agriculture, food processing, energy and environmental management.

Despite this complex and multisectorial scenario, firms characterised by a strong influence of new biotechnologies in their products or processes, are defined as belonging to the biotech sector, and economic research is often focused on their evolution.

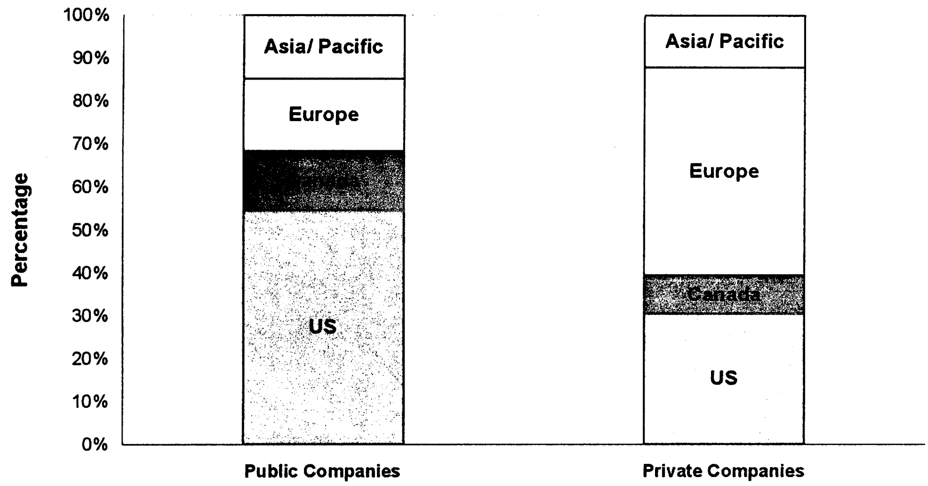
II. SECTOR EVOLUTION

Biotechnology is one of the most research and capital intensive industries. Therefore its growth, in the early stages, has been concentrated in the most developed economies. More than 85 % of global companies are from U.S and Europe[1].

U.S. biotechnology industry encompasses 1,457 companies and employs 191,000 people[2]. It has grown with a double-digit percentage annually, starting from the '90s.

In the past few years, the European biotech sector has been recovering a historical gap with U.S and is following close. As a matter of fact, the gap has been closed only in terms of number of enterprises since their number now (1,878) exceeds the American counterpart. The average size and turnover of European biotech is, in fact, still much smaller and the number of employees (around 82,000) is still much lower.

Geographical Distribution of Global Biotechnology Companies



Source: Ernst & Young, 2002

Although the European Biotechnological Industry is growing larger, individual countries represent different stages of biotech growth. Germany and the United Kingdom together account for nearly 40% European companies. If one calibrates the number of dedicated biotechnology firms (DBFs) using population or GDP numbers, it emerges that Sweden is ranked first according to both measures, followed by Switzerland, Ireland, Finland, and Denmark. The UK, Germany and France have similar values while Italy and Spain have the lowest ratios[3]. A fast growing biotech sector is also present in Canada (445 Companies[4]), Japan, Israel (160[5]), India and Australia.

Currently, the biotech sector is recovering after an evident crisis. It started from the slide of US biotech stocks at the beginning of 2000 and has spread globally in a couple of years. After a decade of 30-40% year-on-year growth in revenues, the biotech sector has in fact been stalling since the financing environment became harder. The amount of investment in biotech companies in Europe had for example

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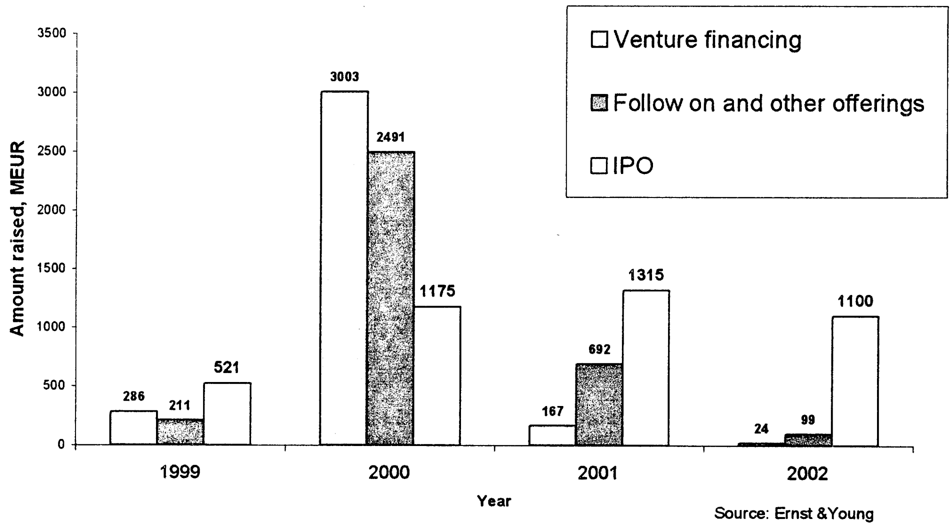
[1] *Beyond the Borders, The Global Biotechnology Report,* Ernst & Young, 2002.
[2] BIO's *Editors' and Reporters' Guide to Biotechnology,* Biotechnology Industry Organization, 2003.
[3] Allansdottir A., Bonaccorsi A., Gambardella A.,Mariani M., Orsenigo L., Pammolli F.,Ricccaboni M., *Innovation and competitiveness in European biotechnology,* Enterprise Paper of EU, 2002.
[4] Canadian Biotech News, 2003.
[5] Devlin A. , An *overview of biotechnology statistics in selected countries,* OECD working paper, 2003.

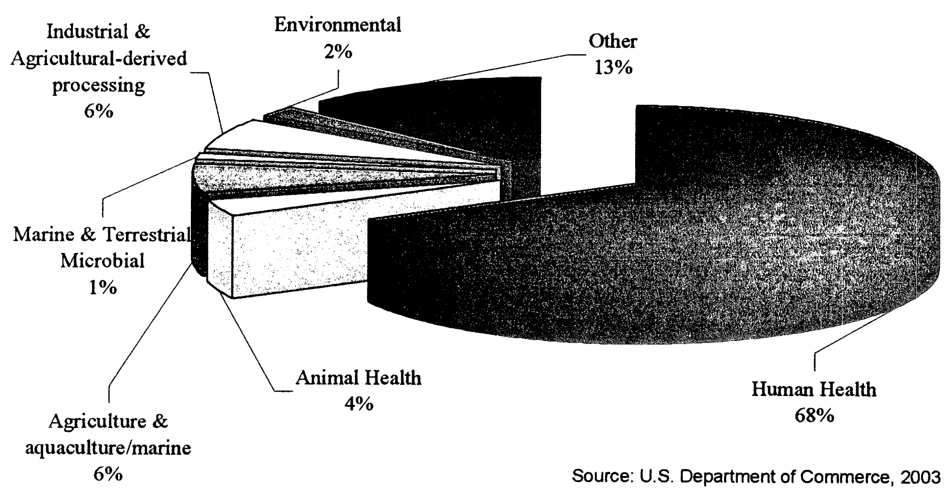
fallen from €6.7 billion in 2000 to just €1.2 billion in 2002. There were only three biotech IPOs in 2002, compared to nearly 40 in 2000. Venture Capitalists remained the only pillar of private funding as they continued to collect similar amounts of money[6]. Biotech start-ups were failing faster than ever before, with nearly a fifth of all biotechs that started in 2000 fallen by the wayside in a couple of years[7].

Summary of equity financing 1999-2002



Starting from 2002, signs of economic recovery are clear. The number of profitable biotech companies is increasing, the average loss per public company has halved over the past 4 years and the research is bringing new products in the market. In a recent survey conducted by the US Department of commerce, 68% of firms indicated that human health (HH) applications are their primary area of biotechnology-related activity[8].

Primary Activity of Biotech Industries in US, 2003



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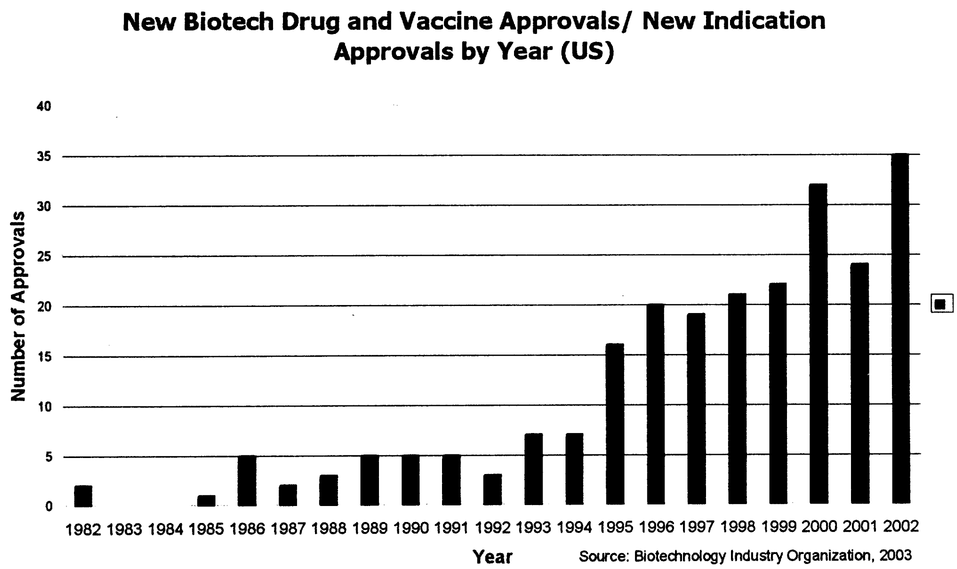
[6] Howell, M.; Trull M: Dibner, M. , *The Rise of European Venture Capital for Biotechnology*, Nature Biotechnology, 2003.
[7] Crocker, G., *Endurance,* Ernst & Young, 10th European Biotechnology Report, 2002.
[8] *A Survey of the Use of Biotechnology in U.S. Industry,* U.S. Department of Commerce, 2003.

More than 325 million people worldwide have been helped by the more than 155 biotechnology drugs and vaccines approved by the U.S. Food and Drug Administration (FDA). The number of new biotech medicines on the market has been constantly increasing. Another 350 drug products and vaccines derived from biotechnologies are into late-stage testing (1/3 of the overall pharmaceutical sector).



Biotechnologies are characterized by a number of advantages: biotechnology has brought hundreds of medical diagnostic tests, biotechnology foods hold increasing market shares, environmental biotechnology products make it possible to clean up hazardous waste more efficiently and industrial biotechnology applications have led to cleaner processes that produce less waste and use less energy and raw materials

So despite the current hardships, and the fact that the biotech sector is still a fragile young industry, its promises are only beginning to unfold and the future remains a very bright one.

III. TECHNOLOGY TRENDS

There are lots of different ways to classify the biotechnologies. They can be grouped, according to their final destination, in white, green and red biotechnologies.

The fourth annual meeting of experts from OECD member and observer countries in 2003 resulted in the agreement on the following statistical definition of biotechnology. The provisional single definition of biotechnology is as follows: "The application of Science & Technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services". The (indicative, not exhaustive) list of biotechnologies as an interpretative guideline to this single definition is:

- DNA (the coding): *Genomics, Pharmaco-genetics, Gene probes, DNA sequencing /synthesis /amplification, Genetic engineering*;

- Proteins and Molecules (the functional blocks): *Protein/peptide sequencing/synthesis, Lipid /protein engineering, Proteomics, Hormones, and Growth factors, Cell receptors /signalling /pheromones*;

- Cell and Tissue Culture and Engineering: *Cell/tissue culture, Tissue engineering, Hybridisation, Cellular fusion, Vaccine/immune stimulants, Embryo manipulation*;

- Sub-cellular Organisms: *Gene therapy, Viral vectors*;

- Process Biotechnology: *Bioreactors, Fermentation, Bioprocessing, Bioleaching, Bio-pulping, Bio-bleaching, Biodesulphurisation, Bioremediation, and Biofiltration.*

Genomics companies continue to play the lion's share of investment in Europe, although the business models have evolved from those offered a couple of years ago. The completion of the Human Genome Project in 2003 revealed that there are approximately 30,000 genes, and this knowledge has boosted the investments in this specific area. The results are applied both in Human Health Sector (these are often called Red Biotechnologies) and in the Plant Biotechnologies (Green Biotechnologies)

The completion of Human Genome Project itself is helping a lot in deciphering how these genes become half a million proteins. Not surprisingly, proteomics is an exploding area of research. Scientists are unraveling the complexity of biological systems by studying how proteins interact. The increasing knowledge about the physiological function of proteins explains, in turn, their effects on diseases. At present, the majority of drugs on the market and in development target proteins and, as a result, proteomics is expected to grow strongly over the next coming years

Improvements in cell culture technology have allowed us to better understand the molecular basis of the cell cycles. The research in this field is particularly conditioned by the ethical and societal debate on the use of embryonic stem cells, but the results in terms of new drugs and vaccines are already numerous on the market

Gene therapy and viral vectors has entered a phase of active clinical investigation in many areas of medicine, but so far there are no products that have entered the market

The last section of the OECD classification deals with lots of techniques with the help of which the modern biotechnologies serve industry and environmental protection. It is often referred to as White Biotechnology

Biotechnology in industry employs the techniques of modern molecular biology to reduce the environmental impact of manufacturing. Industrial biotechnology also works to make manufacturing processes more efficient for industries such as textiles, paper and pulp, and specialty chemicals.

This branch of biotechnology is already successfully competing with traditional manufacturing processes and has shown promise for achieving industrial sustainability.

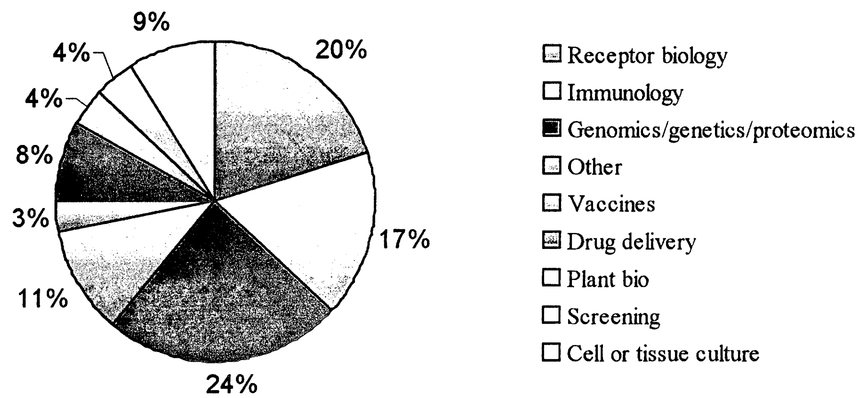
To industry, sustainable development means continuous innovation, improvement and use of "clean" technologies to make fundamental changes in pollution levels and resource consumption.

IV. KEY ELEMENTS OF BIOTECH FIRMS

Firms engaged in biotechnology activities vary greatly in size and scope.

Large, diversified firms, with well-established production and distribution systems and greater in-house resources have created biotech divisions or business lines. These companies were already operating in a traditional way in various market sectors, and have adopted modern biological technologies, as an innovation product element or as an improvement of ongoing production processes.

Venture investments in technology in Europe



Source: Ernst & Young, 2003

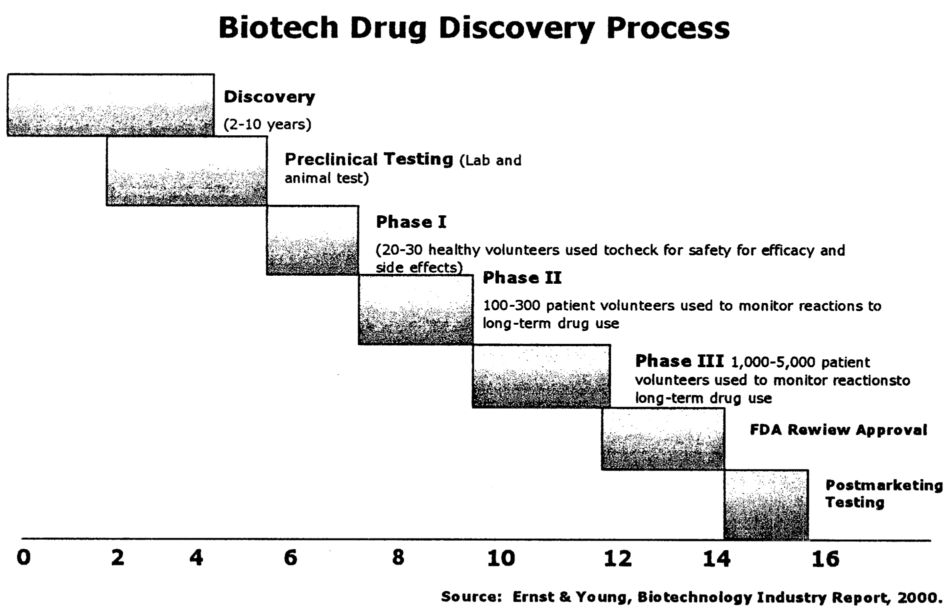
Small dedicated biotechnology firms (DBFs) that focus only on research or services to the research processes have been created during the last years. They operate primarily on venture capital, grants, initial public offerings and collaborative agreements and are often generated by university spin-offs that mobilize scientific and technological knowledge and transform it into potentially commercially useful techniques and products. These firms are usually formed through collaboration between scientists and professional managers, backed by venture capital. Their specific skills reside in the knowledge of new techniques and in research capabilities.

Some key elements can be identified as key success factors for firms of this sector:

- A strong techno-scientific base;
- A close relation with the basic research done in universities and research institutes;
- Flexible relations with integrated companies (joint ventures, commissioned research, etc.);
- An aptitude for the discovery of new products and new processes;

- Experience in transferring basic research to large corporations;
- Attractiveness for venture capital, investment banks and large corporations;
- Availability of highly skilled employees (university graduates and technicians);
- Belonging to international networks.

Investments in the field of new biotechnologies can be characterised by three relevant factors: a high techno-scientific content in rapid and continuous evolution, close links with basic research; therefore with Universities and other institutions, and the long time needed to introduce a new product on the market, which today varies between 5 to 20 years, depending on the sectors of application. In a study of economists at Tufts University[9], reported by Ernst & Young[10] it has been estimated that it takes 10 to 15 years to develop a new drug.



[9] *Pharmaceutical Research and Manufacturers of America, based on data from Center for the Study of Drug Development*, Tufts University, 1995.

[10] *Convergence*, Ernst & Young, Biotechnology Industry Report, 2000.

V. THE IMPORTANCE OF LEGISLATIVE ISSUES

The role of legislative aspects in the biotech sector is crucial.

First, drug development is the single most regulated human activity. The pharmaceutical and biotechnology sectors are the most regulated. Firms complain that the bureaucracy of the regulatory framework has a negative effect on research in European countries. In the US also more than half of the companies identified impediments to their firm's advancement regarding biotechnology research or product commercialization in regulatory approval process and costs (59%)[8].

The process for biotech drug approvals has slowed down in 2002, and the arduous task of getting a drug approved has become more difficult than ever before. Biotech product approvals have been lagging behind non-biotech drug approvals, and the situation doesn't appear to be improving[11].

Some applications of biotechnologies continue to raise ethical considerations. The cloning and stem cell research debates, alongside controversies over issues like gene therapy, genetic testing, clinical trial protocols and privacy, are increasingly putting the biotechnology industry itself under the microscope of scrutiny by the public, the media and elected officials.

There are many important legislative initiatives being developed in Europe and internationally in the area of healthcare biotechnology. Currently, EuropaBio, an organization made up of biotech industries in Europe, have created specialised working groups for key areas as human cell and tissue therapies, orphan drugs and regulatory rules.

The biotech firms and research institutes are also exercising a wide pressure for a more up to date and adequate system to patent products and processes. Firms have concerns over the continued delays in the full implementation of the European Directive on the Legal Protection of Biotechnological Inventions across all member states. So far, only 6 countries out of 15 have integrated the EU directive into the national legislation[12].

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[11] Crocker, G., *Endurance,* Ernst & Young, 10th European Biotechnology Report, 2002.
[12] *Ricerca biofarmaceutica: brevetti e blocco etico,* Forum per la ricerca biomedica, 2003.

VI. THE BIOCLUSTERS CONCEPT AND THE ROLE OF PUBLIC POLICIES

Biotechnology investments tend to concentrate within geographic regions: the biotech clusters[13]. Study of the leading biotech clusters have identified a number of key success factors.

The single most important factor is the proximity to leading and well-funded academic research institutions. Example of this can be found in the United States, where the oldest and largest bioclusters, as San Francisco Bay and Boston Areas, are close to important research laboratories, as well as in Europe (e.g. Cambridge/Oxford, in UK)

Another important factor is the proximity to the location of customers for biotech companies, in particular to pharmaceutical companies

Several other factors can favour the growth of such bioclusters[14][15]. The list is:

- Strong academic research institutions conducting basic research in the biosciences;
- Access to early-stage capital;
- Successful transfer of government-funded basic research to product commercialization;
- Specialized facilities, including wet laboratory space and specialized equipment;
- Highly skilled workforce;
- Stable and supportive public policy structure.

The most important bioclusters in Europe include Assia/Baden Wurttenberg and Munich Area in Germany, Sophia Anthipolis in France, the Medicon Valley in Sweden and Denmark and several region in Benelux and Finland. Bioclusters are present also in Western Asia (Tel Aviv-Haifa), Australia (Queensland), Japan (Kyoto) and India (Bangalore)

In this context states and regions are releasing strategic plans and are developing initiatives in order to foster an environment in which biotech companies can succeed and grow. Especially in the Far East, there's a push to jump start a biotech industry.

Incentives to drive the formation of biotechnology centers include investment in biomedical research and facilities, fast-track application procedures, tax incentives and streamlined technology transfer procedures.

Several case studies show government incentives work, particularly in an environment of world-class academic institutions with streamlined rules for technology transfer.

A major impediment for the development of the sector is the access to start-up capital, both private or public, through institutional incentives. Governmental policy and commitment can make the difference in the support of biotechnological sector moving beyond the traditional R&D tax credit programs to provide substantial funding for incubator facilities and even for venture capital and grant funds.

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[13] *The Dynamics of Industrial Clustering – International Comparisons in Computing and Biotechnology*, ed. G.M. Peter Swann, Oxford, 1998.

[14] Battelle Memorial Institute and US State Science and Technology Institute - *State Government Initiatives in Biotechnolog,y* 2001.

[15] *Commercial Attractiveness of biomedical R & D in Medicon Valley – The role of R & D in Attracting Regional Investments,* Boston Consulting Group, 2002.

VII. THE REGIONE CAMPANIA INITIATIVE

The Regione Campania has a strong scientific base in the field of Life Science and launched, between the end of 2002 and the beginning of 2003, three Projects for the creation of Regional Competence Centers in this field. The aim is the creation of networks of resources and competences in order to increase the transfer of knowledge to industrial applications in the field of functional genomics, diagnostics and molecular drugs and industrial biotechnologies. The total number of researchers involved in these Projects is around 700. The budget for these three projects exceed 60 Million EUR.

In particular, the project to establish the Regional Competence Center for the "Technological and industrial transfer of structural and functional genomics of higher organisms", (also named GEAR, GEnomics for Applied Research), is funded by 70% from EC, through the Regione Campania, and by the remaining 30% from several regional academic and research Institutions, such as the University of Naples Federico II, the Second University of Naples, two Italian National Research Council Institutes, and three non profit research Centers, Biogem, Ceinge and Tigem.

The Center is focused on the human health applications of biotechnologies and will be constituted by four Sections:

- Drug discovery and analysis;
- Diagnostic tool development;
- Discovery management;
- Technological development.

The Technological Development Section will coordinate six Facility Platforms:

- Bioinformatics for functional genomics;
- Facilities for cell biology and morphology;
- Gene targeting and animal facilities;
- Gene therapy;
- Nucleic acid facilities;
- Protein facilities.

The research activity during the following three years, which precede the self-government of the Center, will focus on a "demonstration" project entitled "Industrial spin-off of experimental models of functional genomics" that consists of 4 Work Packages:

- WP1. Functional genomics applied to the development of diagnostic methodologies;
- WP2. Generation through genetic manipulation of a multifunctional murine model for preclinical evaluation of innovative therapeutic protocols;
- WP3. Development of vectors and of innovative methods for gene therapy;
- WP4. Development of in vivo and in vitro integrated systems for the analysis, screening and identification of molecules with relevant biological activity.

The core idea of this "demonstration" project is to transform experimental models used in basic research in functional genomics into tools for industrial research and, in some cases, into prototypes of commercial products.

The aim of WP1 is to identify diagnostic and prognostic markers of disease through the definition of mRNA and protein expression profiles in neoplastic tissues and cell lines, particularly thyroid tumors, and/or through the identification of profiles of genetic polymorphisms suitable to assess the sensitivity/resistance to antiblastic chemotherapy.

WP2 will generate a multifunctional transgenic animal system that will be used for the generation new mouse models of human diseases. These studies will lead to industrial research tools for the development of innovative therapeutic strategies that cannot be directly assessed in humans. In particular the system will allow us to generate tumors in the mammary gland and in the prostate, and it will allow us to express secretory proteins in both breast and prostate.

The aim of WP3 is to develop viral vectors and a protocol for their large-scale production. These vectors and protocols will be tested for their efficacy in animal models of eye diseases and atherosclerosis.

The aim of WP4 is to develop cellular and animal experimental models that are well-studied by the researchers of the Center. Some of these models are already in an advanced phase of development and can be used on an industrial scale in the near future.

Each product of the four WPs could represent the basis for the development of a spin-off enterprise.

VIII. TECHNOLOGY TRANSFER MODALITIES

Among the objectives of the Regional Competence Centers is the management of technology transfer activities related to biotechnology like:

- patent policy;
- licensing in/out;
- creation of biotechnology start-up companies and joint-ventures;
- attraction of investment of large companies with high technological content;
- definition of research and development contracts and project management;
- promotion of biotechnology transfer from basic research to private companies or directly to the market;
- assistance in the marketing and commercialisation of products and activities generated by the various research projects;
- promotion of technical cooperation and partnerships with academic and applied research institutions and enterprises.

A useful distinction must be underlined between vertical technology transfer and horizontal technology transfer. Vertical technology transfer occurs when information is transmitted from basic research to applied research, from applied research to development, and from development to production. Such transfers occur in both directions, and the form of the information changes as it moves along this dimension. Horizontal transfer of technology occurs when technology used in one place, organisation, or context is transferred and used in another place, organisation, or context[16].

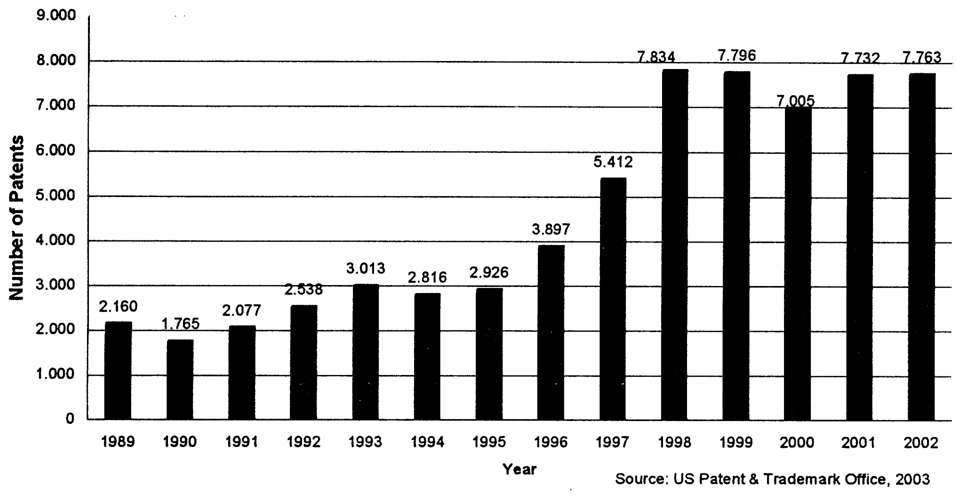
Generally, the challenge in the relationship between business and universities is said to be to devise ways that create appropriate conversion of public discoveries and inventions into commercial products[17]. That is a tipical example of vertical technology transfer. To cope with this task, intellectual property rules and management are crucial to move from laboratory to commercialization.

Discovery management and intellectual property protection is a strategic issue for all the research centers of biotech sector. Careful patent drafting is important for obtaining long-lasting patent protection in

[16] Mansfield, E., *Technology Transfer, Productivity, and Economic Policy*, W. W. Norton &Co., New York 1982.
[17] Alberghina L., Chiesa V., *Per lo sviluppo delle biotecnologie in Italia: il ruolo dell'università*, Economia & Management, 2002.

Europe and related costs are substantial. The trend of increase of patent's activity is underlined by the analysis of data from US and European Patent Offices

Total Biotechnology Patents Granted per Year (US)



Firms' business strategies are in fact often focused on developing technologies that can be licensed to others, or acquiring technologies through licensing arrangements or joint venture arrangements. There are a number of reasons why a bio-industry company may enter into a licensing arrangement and universities must be able to deal with companies and find the proper negotiating terms.

Another way to deal with vertical transfer is through the creation of new firms. As previously reported, many small dedicated biotechnology firms (DBFs) in the sector are university 'spin-offs.

Many other biotech companies collaborate with academics in universities and/or hospitals. The reasons for biotech companies to collaborate are often very similar to those for licensing. Timing is a key element in the agreement terms with a small biotech or a large pharmaceutical company for product development[18]. Taking a product candidate through the early stages of development will involve substantial investment and risk up-front, but is likely to result in higher royalty rates in the long term. The earlier in the development process a collaboration partner becomes involved, the lower the returns are likely to be for the biotech company, because of the greater risk that the product will never reach the market and the greater level of investment made by the partner.

[18] Middlemiss S., Sadlleir R., *Collaborations and Licensing - Key Legal Issues,* Bio-Science Law Review, 2001.

Innovation process for biotech (*adapted from* [17])

Step	Main Actors	Output	Evaluation Criteria	Burn Rate and Time (for each project)
Basic Research	University and public research centers (PRC)	Publications	Quality of scientific publications, innovativeness	50-100 K€/year ?
Pre-competitive research	University, PRC, Incubators, Tech transfer centers,(TTC)	Patents	Innovativeness, patentability, transferability	100-250 K€/year 2-3 years
Competitive research (i)	TTC, Small companies	New projects, Start-ups	Competitiveness of potential products, attractiveness for investors	250-500 K€/year 3-4 years
Competitive research (ii)	Small companies, Start-up	Potential new products	Competitiveness of potential products, attractiveness for financial markets	1-10 M€/year 3-4 years
Development and commercialization	Large Companies, Multinationals	New products	Profits	100-150 M€/year

For what concerns horizontal transfer, partnerships of all kinds have long been the lifeblood of the biotech industry the rate of partnering is growing.

In a communication from the European Commission[19], it is suggested that Europe's biotechnology communities facilitate open access to knowledge, skills and best practises, and create a close community of actors and institutions involved in biotechnology. Research cooperation and technology transfer among regions and with foreign countries must be enhanced. There is a need to promote and facilitate different forms of networking and linking-up to overcome current fragmentation. Benchmarking allows the sharing of knowledge of good practises. An intelligent management of diversity may exploit the network benefits of regional clusters that are specialized in specific technologies.

In this scenario the Regional Competence Centers are promoting technical cooperation and partnerships with academic and applied research institutions and enterprises, mainly in the Mediterranean Area.

[19] European Commission. *Life Science and Biotechnology – A strategy for Europe*, 2002.

GEAR Regional Competence Center

BIOTECH SECTOR AND TECHNOLOGY TRANSFER:

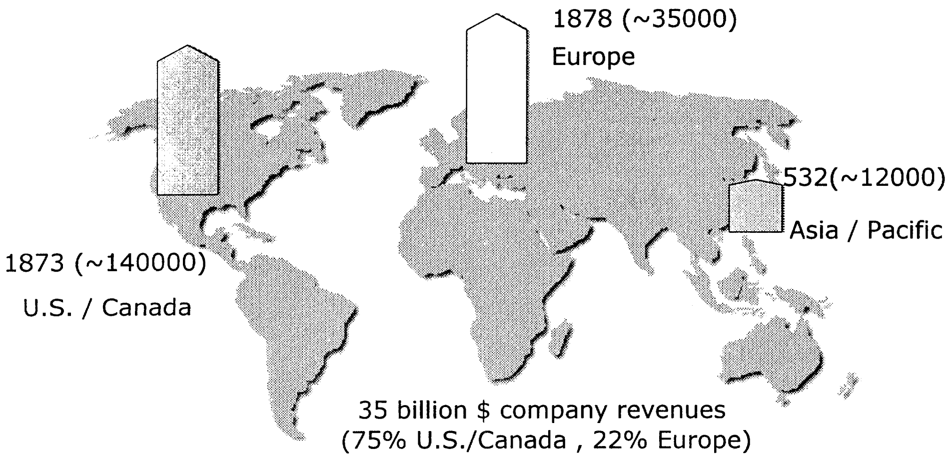
THE EXAMPLE OF THE REGIONAL COMPETENCE CENTERS

Antonio Balestrieri

Beirut, 12 March 2004

GEAR Regional Competence Center

Biotech – a global industry



Distribution of global biotechnologies companies (employees)

Source: Ernst & Young

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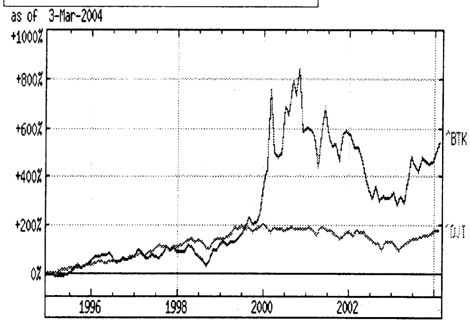
Biotech – a growing business

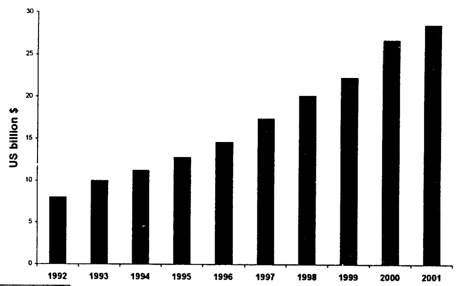
Biotech stocks back on the rise



AMEX Biotech (BTK) vs. Dow Jones (DJI)

Source: Yahoo Finance website

Biotech revenues always growing



Source: Biotech Industry Organization (US)

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Biotech - a risky business

Survivability of a Biotechnology Company

Average biotechnology company survival	3.2 years
Average survival of 50 smallest companies	1.0 year
Number of biotechs with < 1 year of cash	17 %
Number of biotechs with < 4 year of cash	56 %
Average market cap of these companies	$81 M (1998)

Source: Ernst & Young

The main reason is that length and complexity of R&D processes are always increasing

"of approximately 5000 compounds screened for their potential as new medicines only one will be approved by the US FDA and reach the pharmacy shelf"

"PhRMA (Pharmaceutical research and manufacturers of America) estimates that on average it costs 800 MUS$ to discover and develop one new medicine"

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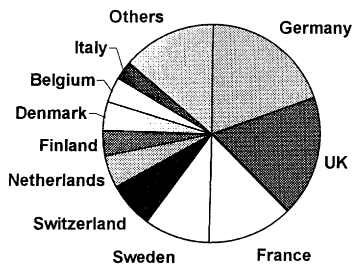
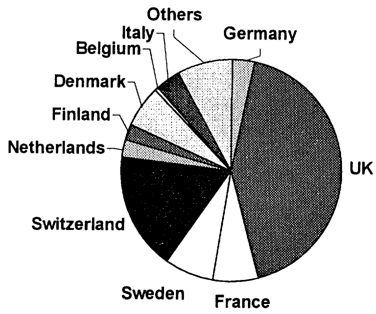
European Biotech distribution

European companies by country



European products in the pipeline by country



Source: Ernst & Young

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Biotech Applications

Health Care	Agriculture & Food Processing	Industrial & Environmental
Therapeutics	**Transgenic Crops**	**Biocatalysts**
Diagnostics	**Forestry**	**Renewable Energy Prod.**
Vaccines	**Aquaculture**	**Waste Treatment**
Regenerative Medicine	**Food Processing**	**Biopolymers**

Traditional sectors are being transformed by biotech applications

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Biotechnologies and Tools

- Cloning
- Monoclonal Antibodies
- Cell Culture
- Microarrays
- Recombinant DNA Technology- Genetic Engineering
- Protein Engineering
- Biosensors
- Bio-nanotechnology
- Bioprocessing Technology
- Anti-sense and RNA interference
- Stem Cell Technology
- Gene knock-out
- Genomics
- Proteomics
- Bioinformatics

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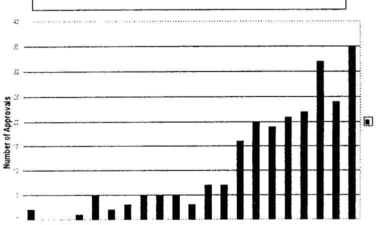
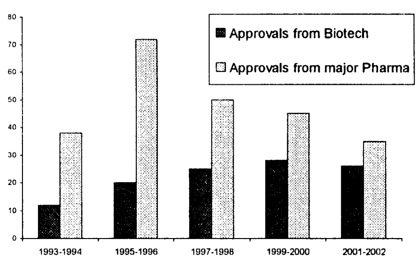
Pharma industry relies on biotech for innovations

New Biotech Drug and Vaccine Approvals



Source: Biotech Industry Organization (US) website

Increasing importance of Biotech in New Product Launches



Source: FDA Database

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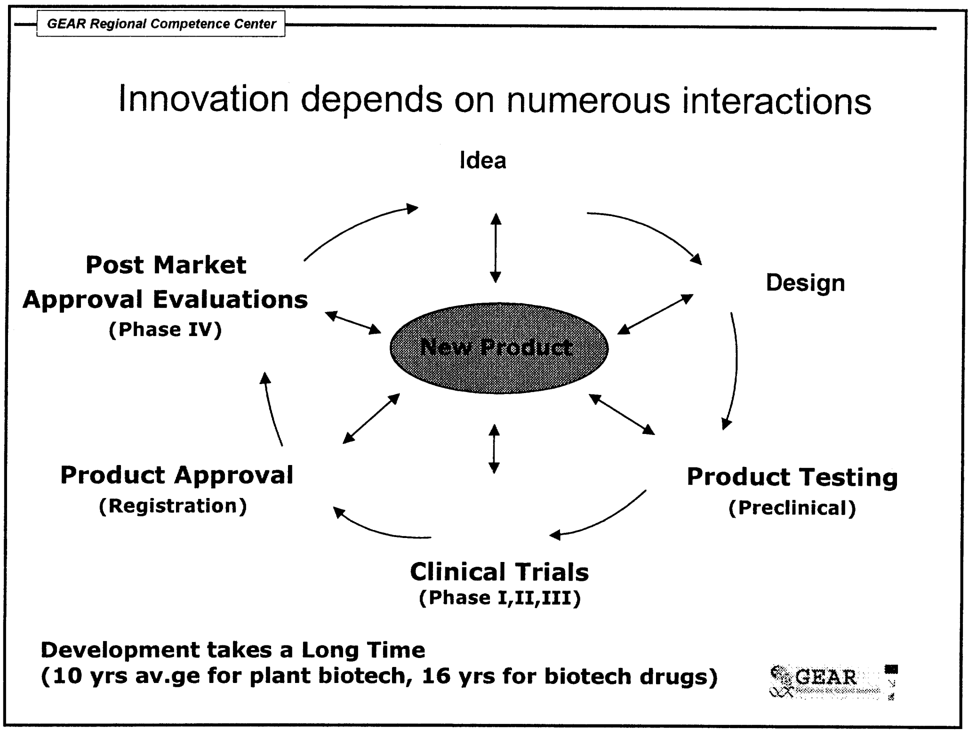
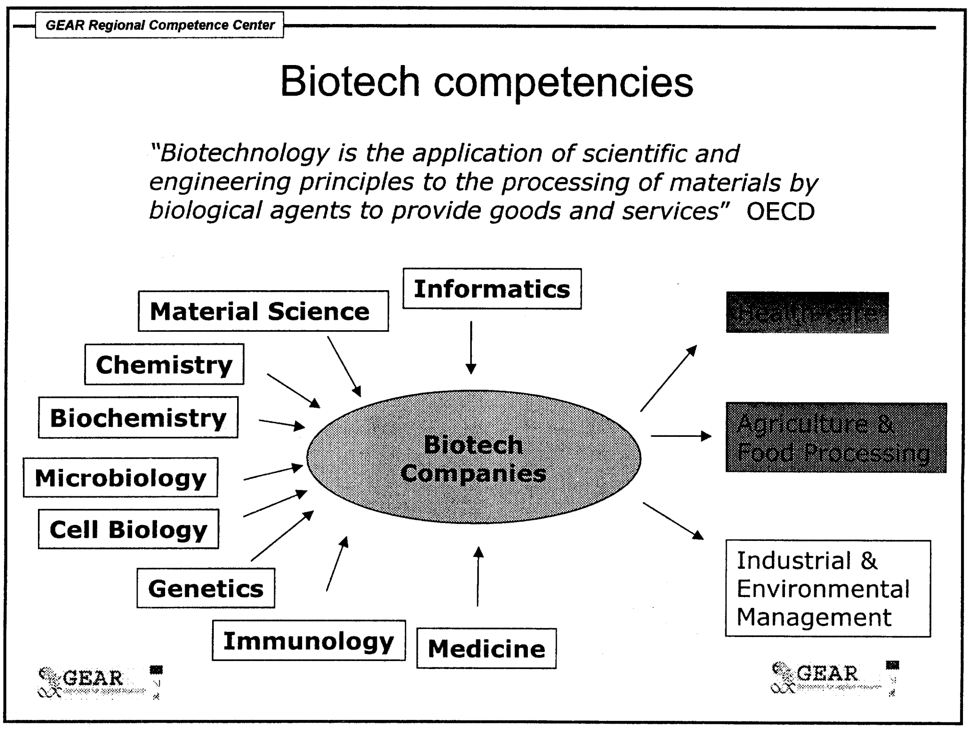
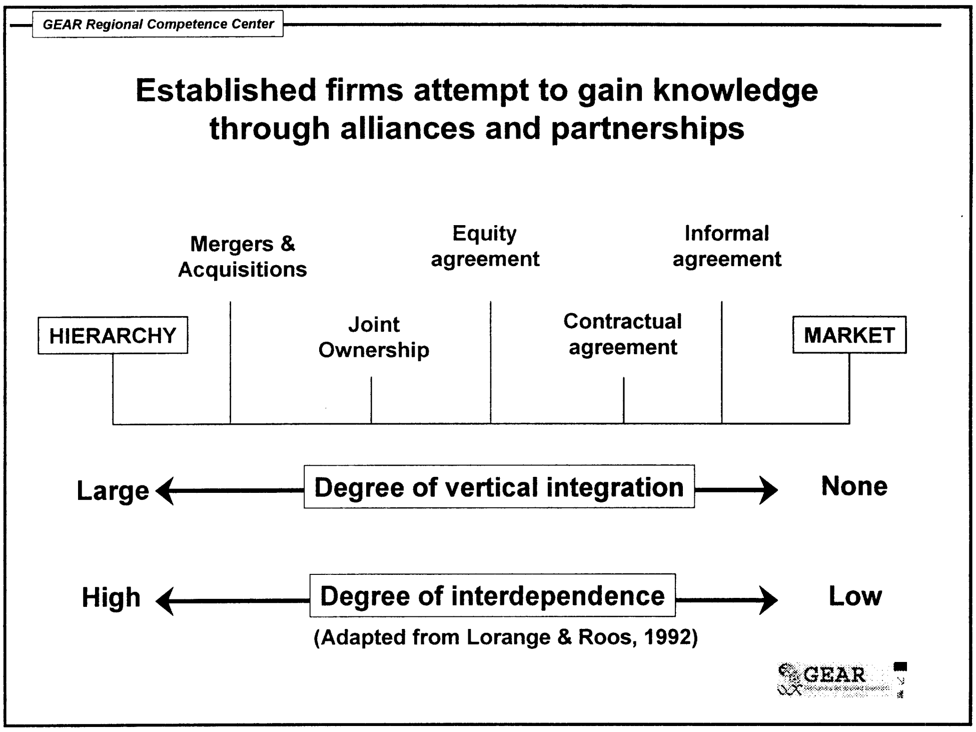

GEAR Regional Competence Center
Innovation depends on numerous interactions
Idea
Design
New Product
Post Market
Approval Evaluations
(Phase IV)
Product Approval
(Registration)
Product Testing
(Preclinical)
Clinical Trials
(Phase I,II,III)
Development takes a Long Time
(10 yrs av.ge for plant biotech, 16 yrs for biotech drugs)
GEAR


GEAR Regional Competence Center
Biotech competencies
"Biotechnology is the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services" OECD
Informatics
Material Science
Chemistry
Biochemistry
Microbiology
Cell Biology
Genetics
Immunology
Medicine
Biotech Companies
Healthcare
Agriculture & Food Processing
Industrial & Environmental Management
GEAR
GEAR


GEAR Regional Competence Center
Established firms attempt to gain knowledge through alliances and partnerships
Mergers & Acquisitions
Equity agreement
Informal agreement
HIERARCHY
Joint Ownership
Contractual agreement
MARKET
Large
Degree of vertical integration
None
High
Degree of interdependence
Low
(Adapted from Lorange & Roos, 1992)
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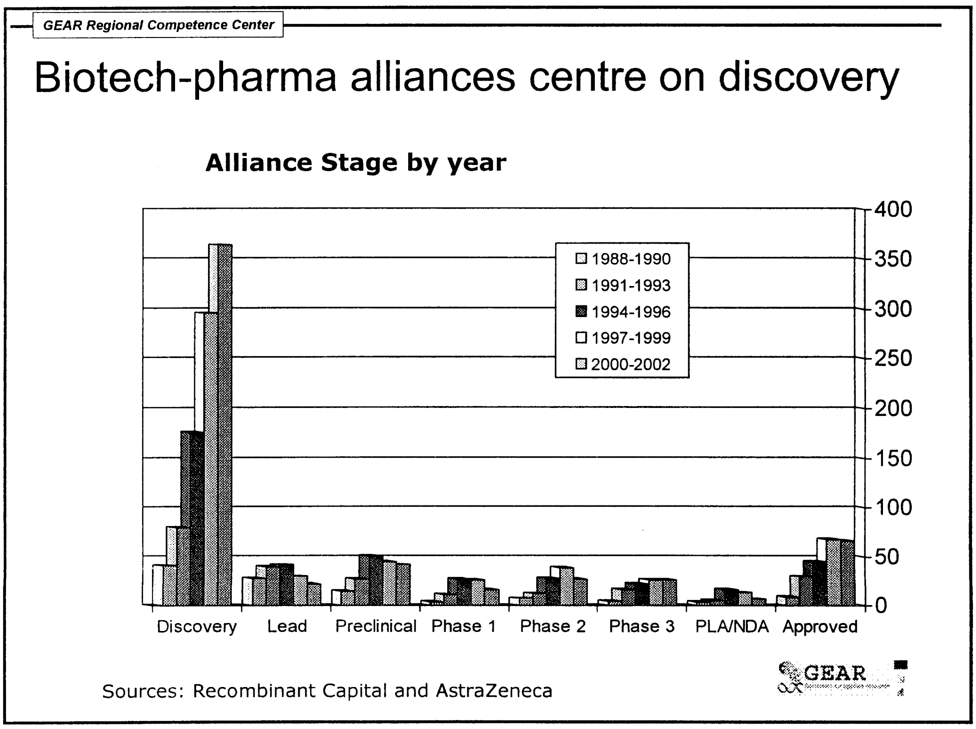
GEAR Regional Competence Center
Biotech-pharma alliances centre on discovery
Alliance Stage by year
1988-1990
1991-1993
1994-1996
1997-1999
2000-2002
400
350
300
250
200
150
100
50
0
Discovery
Lead
Preclinical
Phase 1
Phase 2
Phase 3
PLA/NDA
Approved
Sources: Recombinant Capital and AstraZeneca
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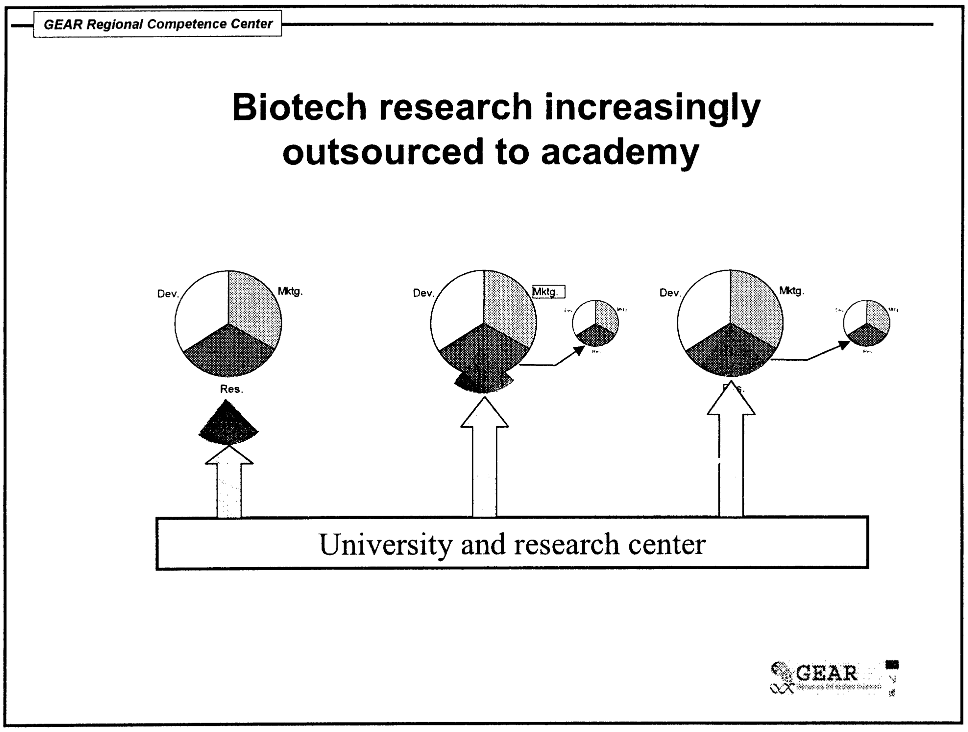
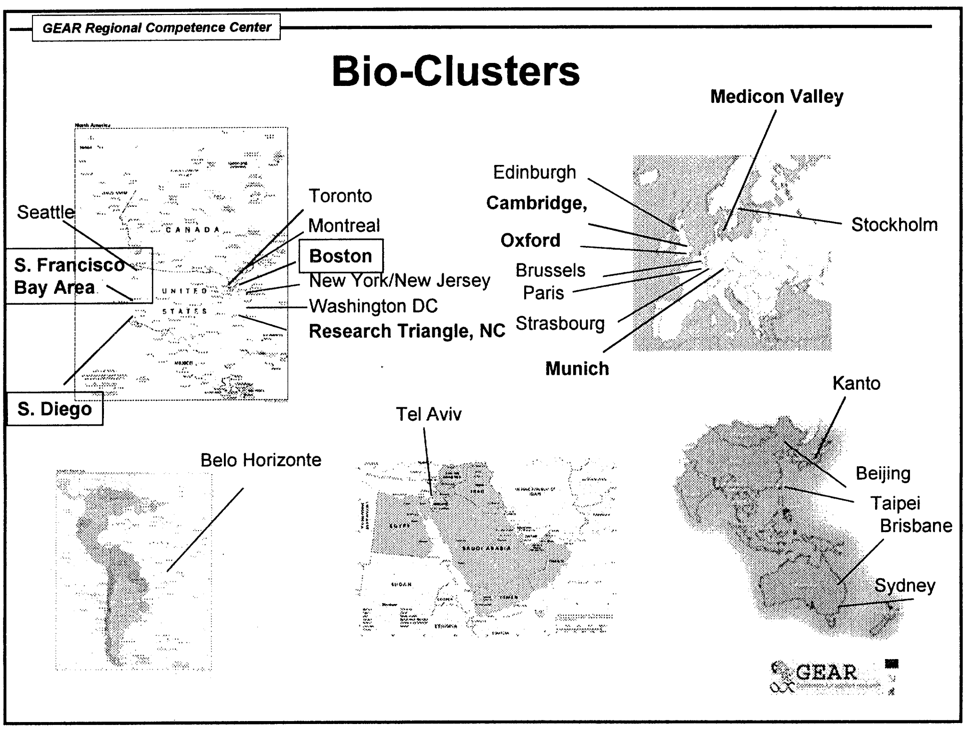

GEAR Regional Competence Center
Biotech research increasingly outsourced to academy
Dev.
Mktg.
Res.
Dev.
Mktg.
Dev.
Mktg.
University and research center
GEAR


GEAR Regional Competence Center
Bio-Clusters
Seattle
S. Francisco Bay Area
S. Diego
Toronto
Montreal
Boston
New York/New Jersey
Washington DC
Research Triangle, NC
Medicon Valley
Edinburgh
Cambridge,
Oxford
Brussels
Paris
Strasbourg
Munich
Stockholm
Kanto
Beijing
Taipei
Brisbane
Sydney
Tel Aviv
Belo Horizonte
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10 Critical Success Factors for Biocluster Development

I. **Strong science base**
II. **Entrepreneurial culture**
III. **Growing company base**
IV. **Ability to attract key staff**
V. **Premises and infrastructure**
VI. **Availability of finance**
VII. **Business support services and large companies in related industries**
VIII. **Skilled workforce**
IX. **Effective networking**
X. **Supportive policy environment**

Source: Battelle Memorial Institute

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Factors that encourage biocluster development (1)

I. **Strong science base** Leading research organizations: university departments, hospitals/medical schools and charities; critical mass of researchers; world leading scientists.

II. **Entrepreneurial culture** Commercial awareness and entrepreneurship in Universities and research institutes; role models and recognition of entrepreneurs; second generation entrepreneurs.

III. **Growing company base** Thriving spin-out and start up companies; More mature 'role model' companies

IV. **Ability to attract key staff** Critical mass of employment opportunities; image/reputation as biotechnology cluster; attractive place to live.

V. **Premises and infrastructure** Incubators available close to research organisations; premises with wet labs and flexible leasing arrangements; space to expand; good transport links: motorways, rail, international airport.

Source: Ministry for Science (UK)

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Factors that encourage biocluster development (2)

I. **Availability of finance** Venture capitalists; business angels.

II. **Business support services and large companies** Specialist business, legal, patent, recruitment, property advisors; large companies in related sectors (healthcare, chemical, agrifood).

III. **Skilled workforce** Skilled workforce, training courses at all levels

IV. **Effective networking** Shared aspiration to be a cluster; regional trade associations; shared equipment and infrastructure; frequent collaborations

V. **Supportive policy environment** National and sectorial innovation support policies; proportionate fiscal and regulatory framework; support from RDAs and other economic development agencies, sympathetic planning authorities

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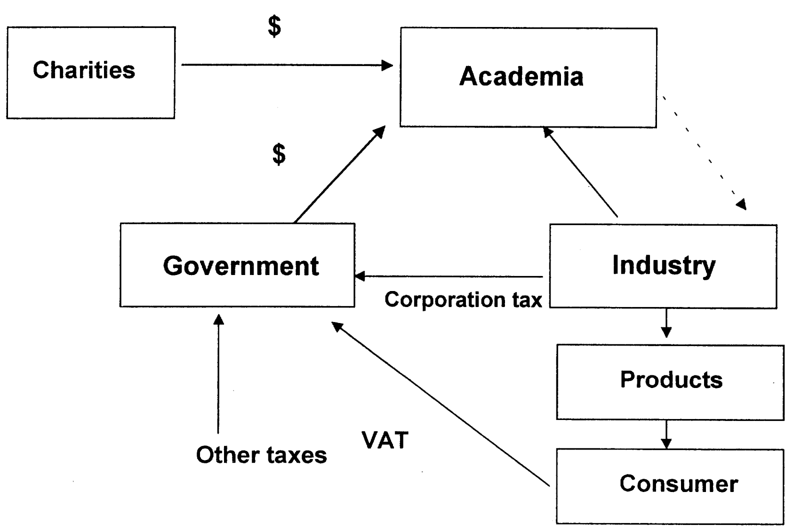
Triple Helix view of technology transfer



Sources: Etzkowitz H., Leydesdorff H.

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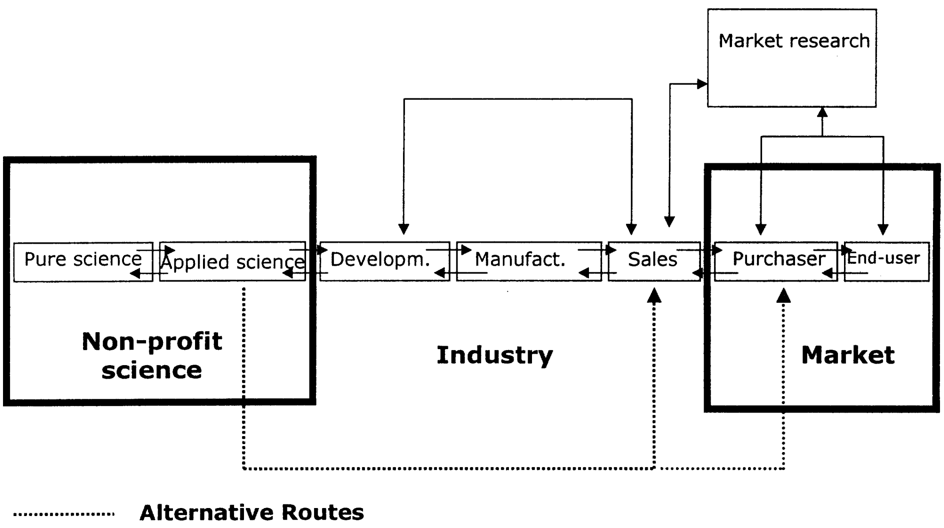
Linear view of technology transfer



Source: Pannenborg, A. E.

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Third mission for universities

1	**Teaching**	→	**Graduates**
2	**Research**	→	**Publications**
3	**Application**	→	**Intermediate Activities** Consultancy, embedded labs, executive education
		→	**Licensing** Packaged Knowledge
		→	**Spin-outs** New companies

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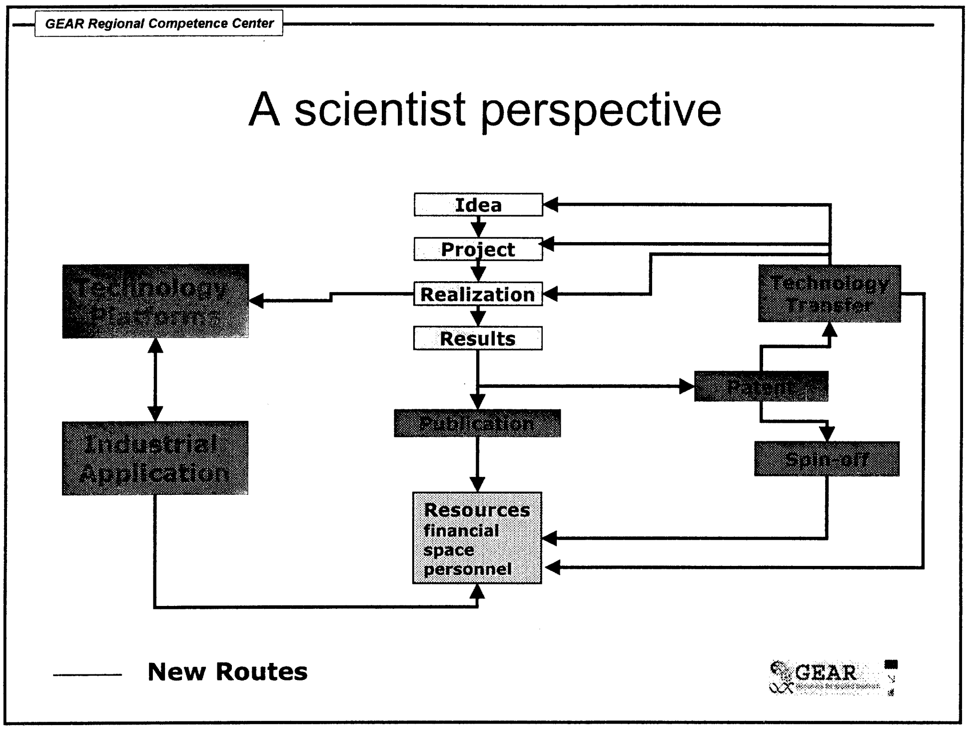
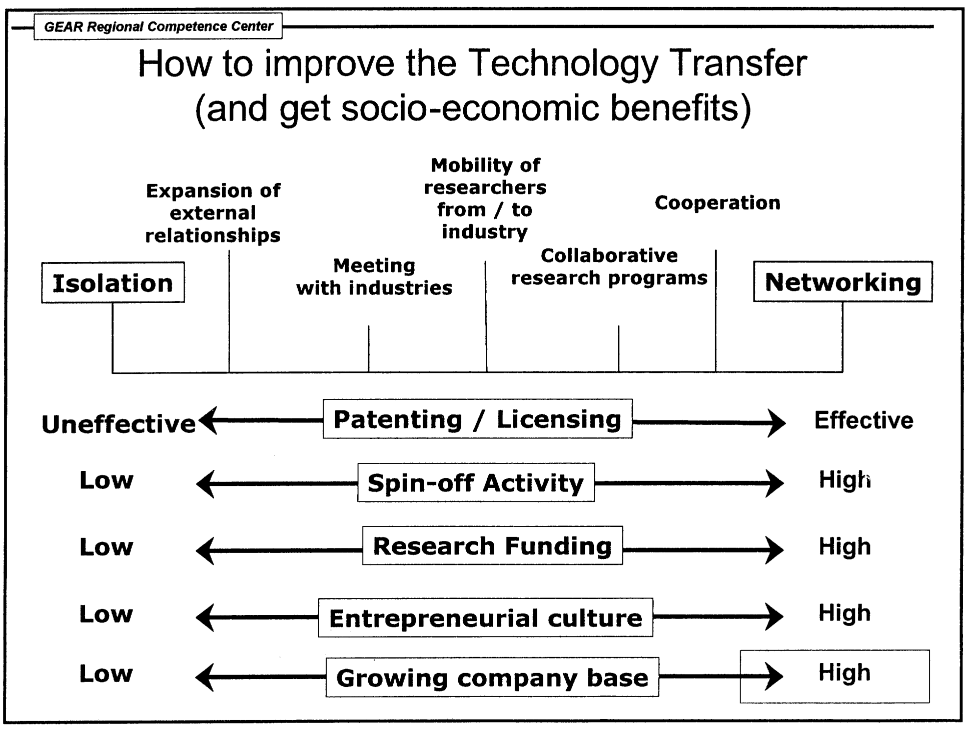

GEAR Regional Competence Center
A scientist perspective
Idea
Project
Realization
Results
Publication
Resources
financial
space
personnel
Technology Platforms
Industrial Application
Technology Transfer
Patent
Spin-off
New Routes
GEAR


GEAR Regional Competence Center
How to improve the Technology Transfer
(and get socio-economic benefits)
Expansion of external relationships
Mobility of researchers from / to industry
Cooperation
Meeting with industries
Collaborative research programs
Isolation
Networking
Uneffective
Patenting / Licensing
Effective
Low
Spin-off Activity
High
Low
Research Funding
High
Low
Entrepreneurial culture
High
Low
Growing company base
High

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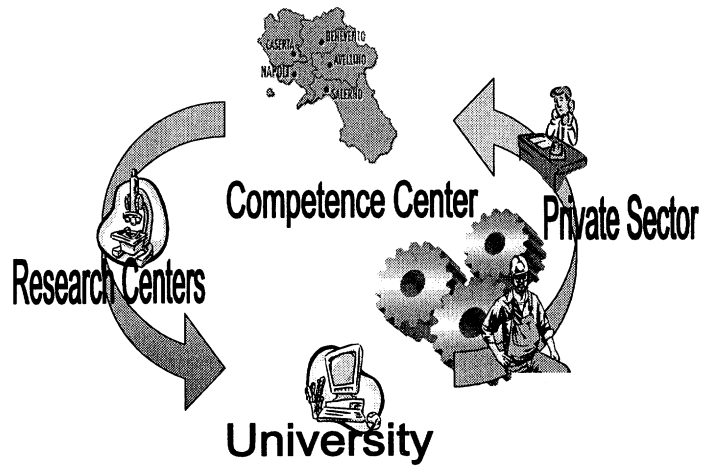
Regional Competence Centers Reference Model



Source: Nicolais L.

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Biotech Regional Competence Centers in Campania

24 University Departments

- Università degli Studi di Napoli Federico II (15)
- Seconda Università di Napoli (7)
- Università di Salerno
- Università del Sannio

2 Scientific Parks

- Consorzio Technapoli
- PST di Salerno e Aree Interne della Campania

9 Research Institutions

- Consiglio Nazionale delle Ricerche (CNR) (5)
- Ceinge
- Tigem
- BioGeM
- Stazione Zoologica A. Dohrn

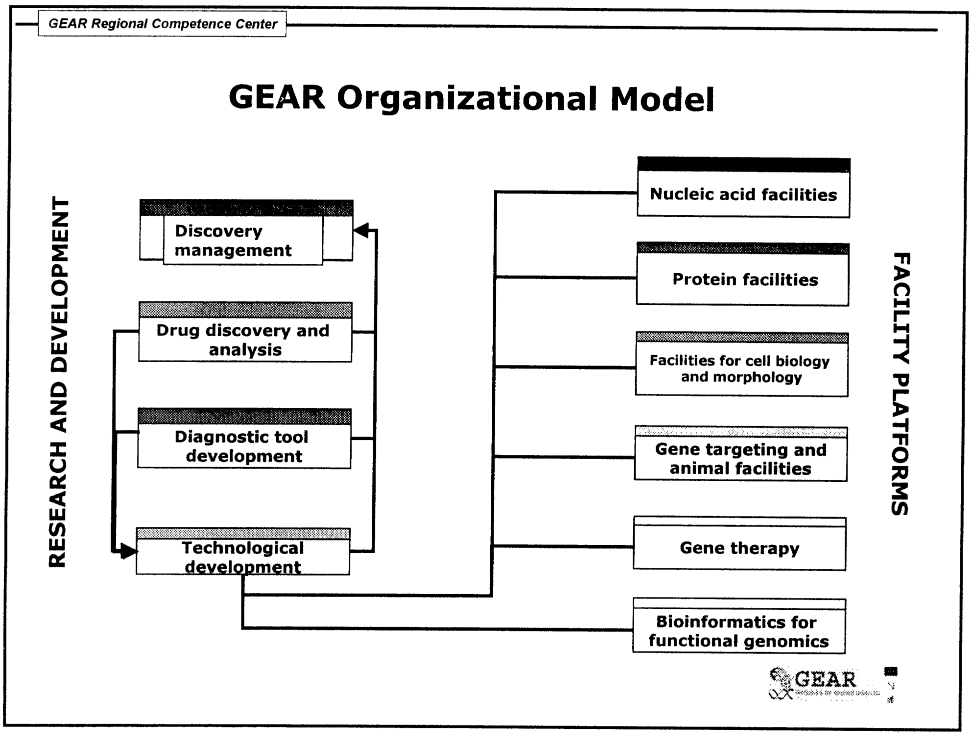
2 Hospitals

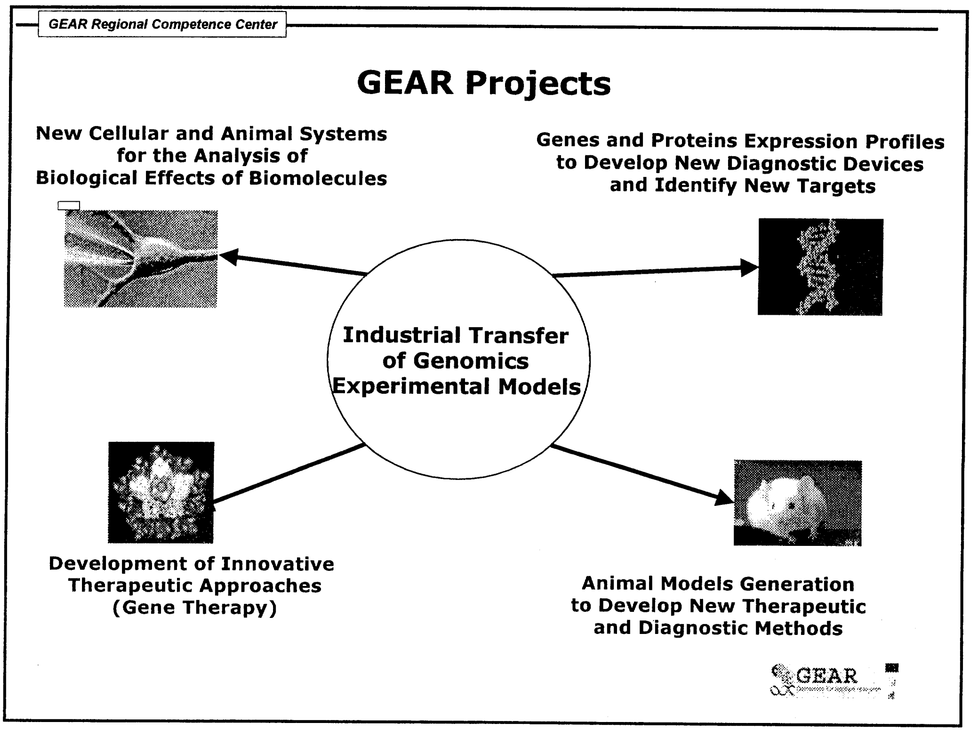
- Azienda Ospedaliera "A. Cardarelli"
- Fondazione "G.Pascale"

GEnomics Applied Research (GEAR)

Diagnostics & Molecular Pharma (DFM)

Industrial Biotech (BIOTEKNET)


GEAR Regional Competence Center
GEAR Organizational Model
RESEARCH AND DEVELOPMENT
Discovery management
Drug discovery and analysis
Diagnostic tool development
Technological development
Nucleic acid facilities
Protein facilities
Facilities for cell biology and morphology
Gene targeting and animal facilities
Gene therapy
Bioinformatics for functional genomics
FACILITY PLATFORMS
GEAR


GEAR Regional Competence Center
GEAR Projects
New Cellular and Animal Systems for the Analysis of Biological Effects of Biomolecules
Genes and Proteins Expression Profiles to Develop New Diagnostic Devices and Identify New Targets
Industrial Transfer of Genomics Experimental Models
Development of Innovative Therapeutic Approaches (Gene Therapy)
Animal Models Generation to Develop New Therapeutic and Diagnostic Methods
GEAR