BioCT common tools for european biotech

WP5: Sharing Facilities

Deliverable 5.1:

From preclinical to phase 1: the bio cluster's needs for bio facilities – Experience of some European Clusters

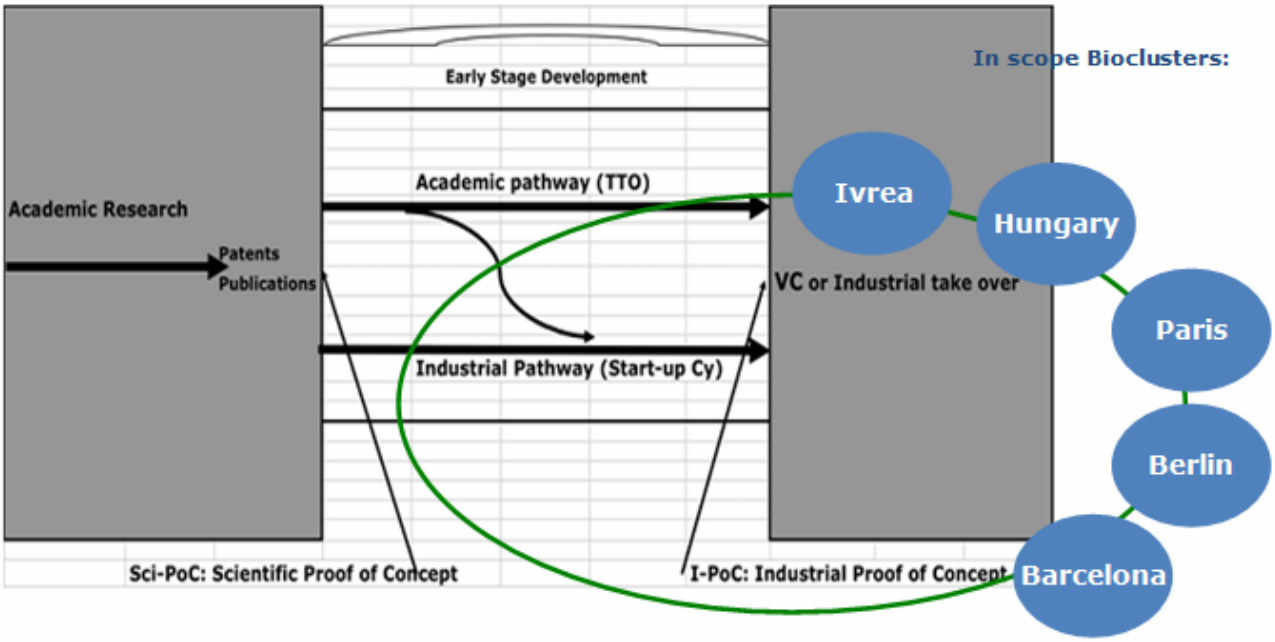
August 2010

Table of contents

1. Project Summary

1.1 Overall Project Objectives

Objective of the Bio-CT project is to deliver a Join Action Plan (JAP) in which the different Bio-Regions of the Consortium - alongside and hopefully together with other additional Bio-



Regions in future - will commit under sustainability conditions to open a good number of Facilities and Services.

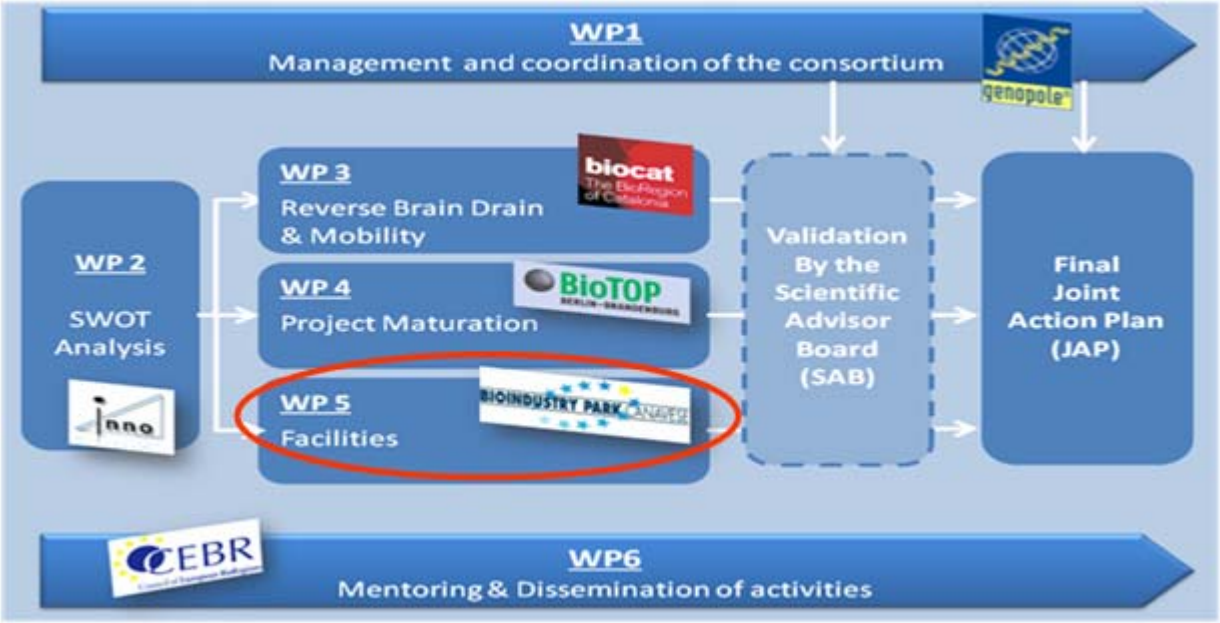
Such JAP will be studied in a limited area of the life Sciences: The Translational Medicine and for a specific stage of the companies' development: the I-PoC (Industrial Proof of Concept) stage, when companies need mostly to access said services and facilities.

The overall project is divided in 4 specific technical work packages:

- WP2 - SWOT Analysis of the mature research driven clusters: The SWOT analysis and competence mapping of the various clusters is the keystone of the project. It has been managed by a team composed of inno-TSD consultants, who have more than 15 years of experience in running such analyses, and has followed a bottom-up and homogeneous

methodology. The results of this comprehensive analysis have been colleted and published through the deliverables of this WP at the beginning of 2010.

- WP3 - Fostering reverse brain drain to European countries and improving inter-sectorial and cross-regional mobility. The WP3 will analyse different barriers in the EC for reversing brain drain including those affecting mobility between academia and industry, and existing schemes to overcome them. The WP3 aim is to create a tool, operated jointly, for detecting confirmed Biotech researchers, that would be candidates for new positions within the project consortium, and financing any form of salaries for them.
- WP4 - Development of technology selection and maturation model. The WP4 will provide a compendium of good practices in technology transfer and technology maturation models across Europe and a user guide for their mutual implementation throughout European Regions. The WP4 will enable any bio region partner to propose one development of new drug or a new device and benefit from all the expertise available within the consortium and create, among partners, a virtual incubating system which will enable any start-up company to beneficiate from all the skills present in the network.
- WP5 - Development of sharing network Facilities: many Bio-Regions are attempting to build attractiveness and excellence through heavy investments in research infrastructures whether in technical facilities or in human resources. The role of facilities is crucial: here a large part of the technical experimentation of the maturation process is done but sometimes such investments may appear as little justified, especially if seen from a trans-regional (or wider) point of view.
- WP6 lead by CEBR, is devoted to dissemination of the results issued from WP3-5. WP6 with the help of the Coordinator and the Project Manager will sustain the efforts of the bio cluster partners to ensure the most efficient way of dissemination.



The Bio-CT overall scheme, showing the relationships among the activities: WP5 is circled in red

1.2 WP5 scope: Development of sharing Facilities and deliverable

Through the development and testing of a model to share first phase clinical facilities, a JAP and dedicated guidelines to identify and share key facilities among different clusters will be produced. This will be reached through:

- Selection through a review of critical facilities needed, at regional level, then at consortium level, for upgrading cluster activities from preclinical to clinical phase 1 and likely to be shared.
- Definition of an implementation model of sharing facilities potentially applicable to any biotech cluster that aims to take the step from preclinical to clinical activity.
- Production of a Joint Action Plan chapter on how to share key facilities among different biotech clusters comprising: governance and financing schemes together with a contract model organising access of non local operators.

Expected WP5 results:

- The bio cluster's needs for bio facilities – Experience of some European Clusters: overview of the clusters experience regarding the transition from preclinical to phase in terms of facilities need assessment.
- General guidelines for bioclusters development: report on clusters needs and selection of possible shared facilities. The report will integrate all outcomes of the activities performed in task 5.2 with the goal to summarize and integrate needs of different clusters in a common conceptual framework.
- JAP module on a common initiative to build & share a key facility in a trans-cluster environment. Results of the activity will be the development of the common model for management and use of a trans-cluster shared facility. The JAP module will analyse the different aspects (technical, legal, economic, etc) that will affect the life of the shared facility in order to develop both a proposal to be implemented and guidelines useful to help the implementation of similar actions in other regions. This report will include sections dedicated to governance and financing schemes together with a contract model (business model proposal) organising access of non local operators.

2. Sharing Facilities: needs assessed

2.1 Introduction

In recent years, biotech has experienced an increase in the number of instruments, tools and equipment needed to explore the living organisms at the gene, protein and even nanoscale level. Therefore, the instrumentation is more and more resources consuming (mainly money and skills), and the distribution of research facilities becomes a growing problem for an effective development of the biotechnology sector in the different EU bio-regions. Academic labs, start-ups, SMEs and some large companies require access to large scale facilities such as synchrotron, hi-throughput screening, clean rooms, or production facilities in order to be able to conduct research and even to start their production (Micro-arrays, lab-on-chips, dedicated or value added research materials, etc.).

Large-scale research facilities are generally defined as a set of experimental tools and components that are available for academics and to some extent to industrial players but can also be places in which technological entrepreneurship can initiate the production process. However, technology platforms or large facilities not simply means up to date instrumentation and facilities for scientific research: they are also embodied by a wide scientific and technological community, developing skills in a specific geographical area, or bio-region.

2.2. Why facilities are so important in Life Sciences

Working at the genetic level, modern biotechnology aims at understanding the mechanisms of life by reducing uncertainty in the exploration and manipulation living materials. This involves the design of new tools for data generation and their mass analysis and improving the efficiency of research and production in the field. Progress in this direction largely improved the ability of researchers to increase the predictive power of R&D activities based on mass data production (high-speed sequencing, etc), and the calculation of the functional properties of certain molecules (mainly proteins). For example, new techniques such as DNA sequencing, high-performance functional genomics, bioinformatics and proteomics have

become essential tools in modelling structure of nucleic acids and proteins, thereby providing researchers in the pharmaceutical industry with new tools for rational drug design and development. Today, it is clear that the converging knowledge of molecular biology and genetic engineering represents a discontinuity with respect to technological and scientific knowledge, artefacts, knowledge and practices earlier in life science.

The emergence of technology platforms in the field of Life Science is a direct expression of this historical evolution, which heavily relies on instrumentation and equipment for the generation, storage, analysis and representation of large amounts of data. So technology platforms can be broadly defined as research and / or production facilities for exploration and exploitation of new knowledge. These facilities are complex sets of instruments and knowledge, whose importance, cost and power structures the scientific community often need decision-making at regional (while not at national) level and multi-annual funding.

Technology platforms have traditionally been associated with the large scale research facilities (eg CERN or similar) and are engaged in "community based" scientific information systems production, based on extensive trans-national collaborations within a large number of scientists. For the production of knowledge, they heavily rely on single, large-scale and high complex tools that require very high initial investment and show high maintenance costs. In addition, these facilities are located in specific places, in environments where scientific and technical knowledge are specialised in order to properly manage and exploit the tools and their potential.

With the introduction of new ways to explore living organisms, heavy instrumentation not only altered the technological methodologies to develop new products (therapeutic, diagnostic equipment, etc) but also the way technological innovation is organised and takes place, since laboratories became more dependent on public financing both for investment and for the day-by-day management and operations.

2.3 The necessity to share and to smartly combine

This "modern" model of functioning of large scale facilities, does not completely explain the real situation of life sciences technology platforms, where the "big" presence of a large scale facility or instrument is not enough for producing high level scientific knowledge: the expertise and instrumentations required are diversified and complementary. One facility alone simply "*doesn't do the job*" and also their average size is not so large in its strict sense.

What is useful is the (smart) combination of different powerful tools and instruments that are used for the collection of data and their processing. This is typical of the first, initial, discovery phase, very often performed in academia and sometimes "spill-overed" in the industrial sector, where the first industrial projects and the start-ups dominate the scene.

On the other hand and at a different development stage, we find the privately owned technology platforms, which are specialized in a segment of the production cycle, such as contract research organizations (CRO), offering production services for the pharmaceutical industry. If the technology is mature enough to be exploited without further investigation, it can be outsourced to private companies. Some technology platforms are highly stabilized, fully operational tools which run on a routine basis (eg sequencing platforms) while, on the other hand, some other areas are still to develop technologies that require greater investment in costly research and implementation before one can expect routine work (eg proteomics platforms). These elements clearly emerged also during the discussion of first CEBR Special interest Group on Sharing Facilities, held at the Bioindustry Park (Colleretto Giacosa – IT) in May 2009, a starting point for our the further developments on the topic.

In real life the fact is that, for each technology platform, the user is not the same. When the research facilities can run on a routine basis, a set of services can be offered to customers and the production of services can be made with a standardized quality and low uncertainty of delivery time. By contrast, when platforms are constructed and used for research purposes at the same time, two types of uncertainties arise: uncertainty of science, technology and platform development and the scientific uncertainty under investigation.

Scientists studying through life sciences platforms and those who work in the development of the platform itself are co-producers of scientific results, even if they are not clients of the platforms, but rather the users. Therefore, the degree of maturity of scientists and the technological advances of the instruments may influence the choice of the internal organization. In different cases, performance criteria might not be the same and the platform manager may assign different levels of priority between different types of customers / users. While platforms are run on a commercial basis, the propensity to pay is a key criteria to select customers, when the platforms are still in development, scientific and technological criteria prevailing for prioritizing.

So, to summarize, the results of our desk analysis, of our discussions with several professionals, culminated in the BioCT workshop held in Torino on February 2010, is that research in life sciences increasingly depends on expensive equipment and on the highly trained team of specialists required for their operation. This implies a new strategy for the entire infrastructure of transnational research, to create and support the international community to share the facilities and the technology platforms that are needed. The trend towards shared research infrastructure is recommended not only by economic pressures, but also by a new focus on research activities in smaller groups with greater interdisciplinary cooperation. There are strong reasons to believe that the core shared facilities and technology platforms that will be used for both business and scientific purposes will be a standard feature in universities and research institutes in the next future. There are indications that the main facilities can represent an important tool of regional policy, as companies locate their facilities wherever the best research infrastructure for their projects are. Since specific studies on the sharing of research infrastructures for life sciences do not exist, for this document we rely on information gathered from various sources, with the cooperation and advice of the project partners and the results of many interactions with dedicated professionals.

2.4. Need n.1: Platforms and services

If we look at the entire Europe, we can see that the facilities that are available are covering almost the entire range of the latest technologies. We are here dealing with the technologies and services that require particularly large investment and usually, very long and specialised training or familiarization, so it is necessary that they are operated by specially trained personnel (and this also applies to the interpretation of resulting data).

There is a general upward trend in response to requests from industry to research facilities that are capable of providing scientific services. This usually involves higher costs of operation and the services have to meet the business needs (speed, efficiency, price, standard regulations, LPG, etc), but this is considered as a positive trend because it helps to reach a higher level of use of their own equipment and also encourages a positive dynamics (cooperation, but also the transfer of technology) with industry.

While easy access to the equipment only requires low-level support, high added value consulting activities may involve rather complex issues of time, going all the way to develop new methods. The young companies, in particular start-ups and spin-offs, often approach the facility managers with new open challenges and state of the art topics and need more support than other partners. So the design of joint projects may continue, and cooperation in general and confidentiality agreements covering intellectual property issues are signed.

The issue of cooperation agreements is crucial, for two specific reasons: on one side the intellectual property issues have to be regulated and, secondly and more importantly, there is the need to cover - in a formal way all potentially critical points. It could be difficult, for example, to know in advance whether the planned activity is a simple service agreement or if it is (or will be) part of a broader collaboration with all the consequent implications. There is no doubt that the service providers try to be as clear as possible from the beginning, but it is often very difficult to decide when is the service and when it comes to cooperation, especially before the experiments start. As a consequence, the practical and pragmatic rule is that this is being decided on a case by case basis.

Finally is has to be mentioned that the role of the facility as a "state of the art" research provider has to be continuously confirmed and maintained, in particular through projects and R&D activities involving, as much as possible external EU or in any case international partners.

2.5 Need n.2: Organisation

Many studies state that some rules must be established for prioritizing time and access to the instruments.

In addition – and this is confirmed by the day by day practice - it is often necessary to do some kind of scientific evaluation of projects submitted by applicants and ensure their compliance with the technical specifications of the platform and scientific objectives. Moreover, issues relating to intellectual property rights need to be properly addressed, such as define clear rules for the publication (or secret) of the results obtained from the direct use of platforms, the staff must be hired and trained to operate the facility and, last but not least, some calculation on the costs of the facility and of its sustainability in the long term has to be done.

This is clear in the mind of the platforms managers but, up to now, not so much has been done and especially not in a structured and formalised way. Some adaptation to the specific condition (place, environment, existing academic and industrial networks, etc) of each single platform has been the general rule for internal standards and regulations and it is here that we can see room for the "common tools" BioCT project is developing.

We also have to keep in mind that in the biotech field (more than in other sectors) the economic potential of the sector has lead to and increased pressure from industry. And when the industry is maturing, the instrumentation becomes increasingly important and can act as a tool for technology transfer, so the access to research facilities represents a key factor for the development of the enterprises. In this scenario, shared facilities are mainly at an intermediate stage in the transition between exploration and exploitation, stimulating business growth, the instrumentation being a key issue.

It is of course of capital importance to maintain some flexibility, in order to ensure an adaptation to the needs of the two "worlds" – academic and industrial - that are trying to work together. The academic model can not be generalized: when the sector is maturing, the actors start to specialise and services around specific technologies can be developed on a commercial basis. Moreover, as a general rule, it is better to avoid the coexistence of public and private research facilities offering the same services: first of all because the first are highly subsidized and can distort the market and, secondly, because the public sector research is often a market itself, especially for some start-ups and SMEs.

2.6. Need n.3: Financing

Financing plays a vital role in industry and in science. A more efficient use of existing facilities through an higher capacity utilization and through avoiding duplication of equipment in the same region are crucial. The real challenge, however, lies in the management of daily operations and running costs with the objective of ensuring adequate funding.

In the real cases that have been analysed existing funding sources usually include service charges, university budgets, research projects and grants and other public funds. Subsidy is needed for the purchase of new equipment and also, in many cases, is needed to cover operating costs. This is particularly true due to the fact that many technology providers normally focus on providing only the services that are not - or not yet - available from the private sector. As soon as a technology is mature enough to become commercially viable, public or public-like R&D providers will generally leave the field to the industry: classical sequencing services are an example of this. Being in the field of state of the art R&D activities, it is very difficult to decide where to draw the line between what is and what is not available in the industry.

The situation at European level seems to be very "fluid" and "empirical", with no defined and standardised rules and most decisions made on a case by case basis. This stated there is room for some common tools and standards, especially taking into account the present and future trends for the sector. The number of large facilities to be shared at regional and interregional level is expected to grow, mainly because of financial reasons (nobody can

afford everything), but also because some changes are expected in the research itself. The role of smaller research groups (10 people or less), with high interdisciplinarity are expected to be more relevant, basic facilities are changing in their relevance, dynamism is fast and those that are relevant now may not be as relevant in 5 years: flexibility is (and will be) the keyword for the staff. This improvement is also expected between the facilities of the industry, because university budgets are shrinking and there is a strong need to reduce costs wherever it is possible.

Finally, the role of basic equipment in shaping regional policy and the attractiveness of a given region will also be important: specialization and consequent division of labour (through cooperation) seem to shape future scenarios.

2.7. Conclusion

According to the degree of maturity of the technology and industry strength (presence of large companies, existence of a dense network of SMEs and start-ups etc), the delivery of scientific services can be punctual, temporary or may acquire a degree of permanence. It is clear that in life sciences a single facility itself, even with the best research teams, has a limited capacity in solving complex problems on its own. Literature and specific meetings with professionals confirmed that both academic teams and the industry can benefit of a series of distributed facilities, allowing them to be more efficient in their research and their cooperation, especially when they make use of contractual research agreements. In a shrinking credit environment this is even more true and, within the industrial world, it applies both to SMEs (in particular) and to large companies: neither of them can afford to buy all the necessary up-to-date equipments and develop all the skills to run them properly within their teams. At the same time collaboration with academia can provide relevant knowledge, including access to equipment: where the investment is too high compared to the market or when employer has identified as a potential market niche, temporary facility sharing can last in the long term.

The organization of shared mechanisms for research and early production definitely requires flexibility in its design: the flexibility to move easily from public to private and vice versa,

flexibility adapt the rules of use, depending on the stage of technology development and maturity industry. This situation is in favour of hybrid solutions, where public-private initiatives seem to better answer the inputs from the industry.

3. Best Practices in Biomedical and life sciences

The next section includes some best practices that have been identified as applicable for Bio-CT project objectives, specifically for outsourcing contracting issue.

3.1 The European Strategy Forum on Research Infrastructures (ESFRI)

Source: http://ec.europa.eu/research/infrastructures/index_en.cfm?pg=esfri)

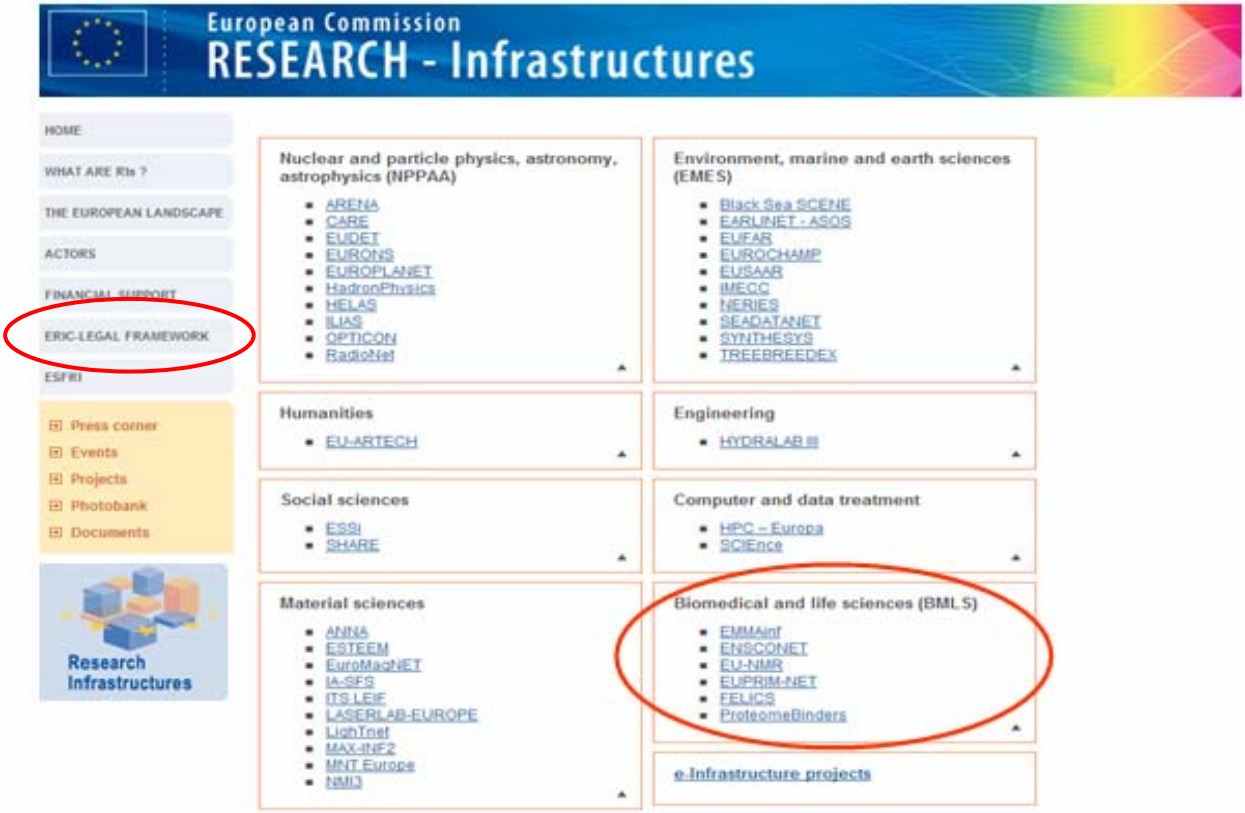
ESFRI, the European Strategy Forum on Research Infrastructures, is a strategic instrument to develop the scientific integration of Europe and to strengthen its international outreach. The competitive and open access to high quality Research Infrastructures supports and benchmarks the quality of the activities of European scientists, and attracts the best researchers from around the world.

The mission of ESFRI is to support a coherent and strategy-led approach to policy-making on research infrastructures in Europe, and to facilitate multilateral initiatives leading to the better use and development of research infrastructures, at EU and international level. ESFRI's delegates are nominated by the Research Ministers of the Member and Associate Countries, and include a representative of the Commission, working together to develop a joint vision and a common strategy. This strategy aims at overcoming the limits due to fragmentation of individual policies and provides Europe with the most up-to-date Research Infrastructures, responding to the rapidly evolving Science frontiers, advancing also the knowledge-based technologies and their extended use. Europe has a long-standing tradition of excellence in research and innovation and European teams continue to lead the progress in many fields of science and technology. However, Europe's centres of excellence often fail to reach critical mass due to the absence of adequate networking and cooperation. Therefore, there is a need to bring resources together and build a research and innovation area equivalent to the EU's common market for goods and services.

Europe should guarantee European researchers access to the infrastructures they require to conduct their research – irrespective of the location of the infrastructure – and that the European approach to the development of new research infrastructures at the regional and

transregional level, as well as the operation and enhancement of existing infrastructures, is supported.

Adequate research infrastructures are essential in promoting technological innovation, as they provide the conditions and critical mass required to carry out cutting-edge research. New scientific and technical challenges call for increased performance of research facilities and better knowledge exchange between different disciplines. This increase in capacity and performance can, in part, be achieved through better coordination of existing facilities and the development of simple operational mechanisms. In addition, funding the design and construction of new infrastructures affects the direction of research for many years afterwards. There are already several networks in Europe that allow the exchange of best practices, the organisation of training, access to and the development of new instruments. Increasingly, this is an important way of enabling Europe to engage the best scientists and optimise the use of RIs.



3.1.1 European Research Infrastructure Consortium (ERIC)

Source: http://ec.europa.eu/research/infrastructures/index_en.cfm?pg=eric

The Community legal framework for a European Research Infrastructure Consortium (ERIC) entered into force on 28 August 2009. This new legal form is designed to facilitate the joint establishment and operation of research facilities of European interest.

An ERIC is a legal personality based on EU law (Article 171 of the EC Treaty), which is reserved for the purpose of establishing and operating a research infrastructure.

Members will be states and intergovernmental organisations. Members can be represented by one or more public entities with a public service mission.

The ERIC is an easy-to-use legal instrument providing:

- the spirit of a truly European venture (also allowing the participation of non-European countries)
- a legal entity recognised in all EU Member States
- flexibility to adapt to the specific requirements of each infrastructure
- some privileges/exemptions allowed for intergovernmental organisations
- a faster and more cost-efficient process than creating an international organisation

An ERIC can benefit from exemptions from VAT and excise duty in all EU Member States and it may adopt its own procurement procedures, which have to respect the principles of transparency, non-discrimination and competition but are not subject to public procurement procedures.

Research infrastructures (RIs) play an increasingly important role in the advancement of knowledge and technology. They are a key instrument in bringing together a wide diversity of stakeholders to look for solutions to many of the problems society is facing today. RIs offer **unique research services** to users from different countries, attract young people to science, and help to shape scientific communities.

New knowledge and, by implication, innovation, can only emerge from high-quality and accessible RIs: for example, radiation sources, data banks in genomics, observatories for environmental sciences, systems of imaging or clean rooms for the study and development of new materials or nano-electronics are at the core of research and innovation processes. Moreover, RIs help to create a new research environment in which all researchers - whether working in the context of their home institutions or in national or multinational scientific initiatives - have shared access to unique or distributed scientific facilities (including data, instruments, computing and communications), regardless of their type and location in the world.

RIs are therefore at the centre of the **knowledge triangle** of research, education and innovation, producing knowledge through research, diffusing it through education, and applying it through innovation.

Community legal framework for a European Research Infrastructure Consortium (ERIC) [1,34 Mb]
Council Regulation n° 723/2009, 25 June 2009

ERIC Practical Guidelines for applicants
April 2010

- The legal framework for a European Research Infrastructure Consortium (ERIC) has been designed to facilitate the establishment and operation of research infrastructures of European interest with the involvement of several European countries.
- Complementing national and inter-governmental schemes, the ERIC Regulation provides a common legal framework based on Article 1872 of the Treaty on the Functioning of the European Union (TFEU).
- An ERIC is a legal entity with legal personality and full legal capacity recognized in all EU Member States. Its basic internal structure is very flexible, leaving the members to define
- in the statutes, case by case, membership rights and obligations, the bodies of the ERIC and their competences. The liability of the ERIC's members will generally be limited to their respective contributions.
- An ERIC is recognized by the country hosting its seat as an international body or organization for the purposes of the directives on value added tax4 (VAT) and excise duties. It also
- qualifies as international organization for the purpose of the directive on public procurement.
- An ERIC may therefore, under certain limits and conditions, benefit from exemptions from VAT and excise duties on its purchases in all EU Member States and it may adopt
- procurement procedures respecting the principles of transparency, non-discrimination and competition but not subject to the directive on public procurement as implemented in national law.
- The ERIC framework has been developed primarily for new research infrastructures but it can also be used for existing infrastructures if these, exceptionally, consider it to be useful to change their legal status and to become an ERIC.

3.1.2 Biomedical and life sciences (BMLS)

Under the umbrella of ESFRI, a variety of networks of research infrastructures projects have been funded by the EU in Fp6 and FP7: here following is a selection of those that are mostly in line with the scopes and objectives of Bio-CT.

At the address http://ec.europa.eu/research/infrastructures/projects_en.html, information can be found on these projects and on many others, even more recent.

EMMAinf: European Mouse Mutant Archive Infrastructure

Improving our understanding of multiple sclerosis, breast cancer and many other diseases that are entirely or partly inherited depends to a large extent on mutant mice that have been deliberately bred with genetic defects. European medical researchers have created hundreds of these 'mouse models,' but lack of money and space means that not many of them are preserved once their original purpose has been fulfilled. The EU-funded EMMAinf project is helping to save valuable mutant mouse strains collected by EMMA, the European Mutant Mouse Archive.

BETWEEN THE DEVIL AND THE DEEP BLACK SEA

Experiments on animals are an essential part of modern medical research and, of these animals, the most important is the mouse. After human beings, the mouse was the second mammalian genome to be fully sequenced. Thanks to recombinant DNA technology and embryonic stem cells, if a gene can be identified, scientists can now breed a strain of mutant mouse in which the gene is disabled or otherwise modified. The resulting 'mouse model' can provide valuable insight into how the same gene causes inherited disease in people.

Mouse models are so useful that scientists in European research institutions and drug companies produce hundreds of them every year. In fact, they produce so many that they do not have the resources to preserve every strain once they have served the purpose for which they were originally produced. Anyone who wants to work with the same gene in the future must recreate the relevant mouse model – a task that is costly, time-consuming, and ultimately frustrating to the researcher who thinks the strain should have been preserved for posterity.

To avoid such wasted effort, the European Mouse Mutant Archive (EMMA) was set up in 1999 to preserve useful mouse strains so that they can be used by other researchers. With partner organisations in Italy, France, Germany, Sweden, Portugal and the UK, EMMA provides a valuable service to Europe's medical and biomedical research community.

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RESEARCH - Infrastructures

http://www.emmanet.org/

FURTHER DEVELOPING EMMA

The EMMAinf project is generating a large-scale and distributed repository of mouse lines that appears to the outside world as one unique centre, and that distributes the lines to the scientific community. Hundreds of new mouse lines of high interest will be cryo-preserved as embryos or spermatozoa during the life of the project.

The archived strains will be supplied to users on request, as frozen material, for a nominal charge. For highly-demanded strains, a stock of living mice will be constantly renewed according to the needs of the users. These strains will be distributed as live breeding pairs. Germ-free lines, required particularly for immunological studies, will also be generated and maintained.

The database of available mouse mutants is being improved, and the web interface for choosing and ordering mice is being made easier to use. The overall management and coordination of EMMA, including dissemination of information and biological material, is also being upgraded with the help of the EU funding in EMMAinf.

ENSCONET: European Native Seed Conservation Network

It is estimated that up to 60 000 plants, more than one-fifth of the world's plant species, are currently threatened or face extinction in the wild. As part of the "Global Strategy for Plant Conservtion" to halt the ongoing loss of plant diversity, ENSCONET will establish a network of European Seed Banks to ensure better coordination of European seed conservation efforts. The EU-funded network will provide a vital framework for establishing common methodologies for seed collecting, curation and data management, and offer an important central resource for conservationists and the wider plant research community.

SOWING THE SEEDS OF THE FUTURE

Plants are a vital part of the world's biological diversity and an essential resource. Besides crop plants, which provide our basic food and fibres, many thousands of wild plants have great economic and cultural importance, providing food, medicine, fuel, clothing and shelter for vast numbers of people throughout the world. Plants also play a key role in maintaining basic ecosystem functions and are essential for the survival of the world's animal life. For all these reasons, it is essential that we protect our biological heritage.

Seed collections play a key role in ex situ plant conservation and are an important source of research material and data for plant conservationists. There are several major collections in Europe, but such research infrastructures are usually part of independent institutions, often working at a local or national scale. ENSCONET brings together 19 of these institutions from 12 EU Member States, covering 6 of Europe's 10 biogeographical regions.

European Commission
RESEARCH - Infrastructures

EU-NMR European Network of Research Infrastructures for providing Access and Technological Advancements in bio-NMR

EU-NMR: European Network of Research Infrastructures for providing Access and Technological Advancements in bio-NMR

http://www.eu-nmr.eu/

Magnetic resonance imaging (MRI), a technique that enables medical scientists to create a visual representation of layers of tissue and bone lying beneath the skin of the patient, is probably one of the best known applications of the study of Nuclear Magnetic Resonance (NMR). In the past, NMR could only image larger features, but progress has now been made that enables mapping the shape of molecules and examining atomic-scale features. The EU-NMR project supports research in Life Sciences using NMR techniques by mobilising much-needed tools and expertise. Five leading Research Infrastructures providing essential services to the research community and 21 of the largest European national laboratories operating in the field of Nuclear Magnetic Resonance Spectroscopy have joined forces to provide researchers across Europe with access to the most advanced magnetic resonance instruments, support networking activities and promote joint research efforts.

European Commission
RESEARCH - Infrastructures

EU PRIM-NET [dstl] CNRS NIBSC DPZ

EUPRIM-NET: European Primate Network Specialised infrastructures and procedures for biological and biomedical research

http://www.euprim-net.eu/

Scientists say monkeys' DNA is so close to humans' genetic make-up that they are classed in the wrong order of species. Indeed, the monkey is so close to man that non-human primates are suitable models for biological and biomedical research. They are essential for the successful development of new strategies against human diseases, whether infectious viruses like HIV/AIDS, hepatitis and malaria, or neurological disorders such as Alzheimer's or Parkinson's, as well as for cancer research; finding new vaccines and gene therapy; and organ transplants. They may be essential for man, but the high ethical demands of research on primates and the complexity of the research mean they must be handled with care. That is where the European primate centres come in. Eight specialised centres in Germany, the Netherlands, Sweden, France, Italy and the UK are working together in an EU-funded Integrated Infrastructure Initiative aimed at advancing knowledge and competence in the areas of primate-based research, animal keeping and breeding. EUPRIM-NET, a project that kicked off in April 2006, seeks to provide top-quality service to support the best science meeting the highest ethical and welfare standards.

3.2 Ephoran

EPHORAN

EPHORAN is a Multi-Imaging Service Company focused on preclinical research and development.

EPHORAN's founders and shareholders are Bracco Imaging Spa, Advanced Accelerator Applications (AAA) and Bioindustry Park Canavese (Bi.P.Ca.).

EPHORAN

EPHORAN MULTI-IMAGING SOLUTIONS

POSITIONING

➲ As a provider of multi imaging solutions, EPHORAN is uniquely positioned in pre-clinical and clinical imaging allowing serial/longitudinal imaging experiments during pharmacology and toxicology animal studies. This will allow a reduction of the number of animals used for drug efficacy testing and consequently reduction of associated costs of drug development.

➲Biopharmaceutical SMEs will take advantage from our pre-clinical imaging technologies to carry on effectively their research and development projects in different therapeutic areas.

3.3 Arizona Research Laboratories (ARL) – division of biotechnology imaging facility

ARL – Division of Biotechnology Imaging Facilities

Facility short description and general policy

The Imaging Facilities (IF), administered by the Arizona Research Laboratories, Division of Biotechnology, are open to all faculty, staff and students who can make effective use of electron microscopy. The IF are dedicated to providing the equipment, knowledge and skills that are necessary to assist researchers in meeting their needs, from routine confirmatory procedures through state of the art electron microscopy.

The IF are equipped for scanning and transmission electron microscopy of most biological material. The equipment available for routine specimen preparation includes ultramicrotomes, vacuum evaporators, critical point driers, magnetron sputtering devices, and miscellaneous ancillary equipment..

Equipment is also available for advanced techniques of specimen preparation and analysis, such as ultra rapid freezing and observation of frozen hydrated samples, freeze substitution, freeze fracture, scanning transmission electron microscopy and energy dispersive X-ray microanalysis. The Facilities also have fully equipped darkrooms for processing negatives with formats from 35mm to 4x5 into prints and slides.

Professional assistance is available for consultation, for service needs, for adaptation of techniques of others, and for developing or teaching new techniques. Individual users who are qualified and wish to prepare and analyze their own specimens and interpret the results are encouraged to do their own work.

Use of the IF is available to individuals who have received instruction by an IF staff member and/or have demonstrated to the staff's satisfaction that they can operate the equipment safely and effectively. The staff is prepared to assist during difficulties. Alternatively, sample preparation and operation of the microscopes can be performed by the IF staff as a service to the investigator.

A list of charges for services and use of the equipment is attached. Anyone needing to use the IF should contact either of the IF Managers to make an appointment for discussing research plans, procedures and costs.

ARL – Division of Biotechnology Imaging Facilities

Confidentiality and Intellectual property

- All information in a research project is considered privileged and will not be reveled to individuals not employed by the Imaging Facility by Facility personnel.
- Communication about a project and its specifics may be necessary between the staff of the Imaging Facilities, with members of the EM committee and the administrators of the Division of Biotechnology.
- *Acknowledgements:* For the purposes of funding and Facility justification, it is requested that if you use IF services for any aspect of your research, teaching or publication, you acknowledge those services as having been provided by the: Biotechnology Imaging Facilities, University of Arizona. Please provide one copy of any publication for our files.
- *Collaboration and co-authorship:* In some cases it will become obvious that the staff is contributing more than just technical advice to a project. In these cases it may be appropriate that the investigators include the IF staff member as a co-author. The distinction would be that the staff member is doing work on the project to an extent that is not usually provided to other clients of the Facilities, and that he/she is helping interpret and give direction to the portion of the study that deals with electron microscopy. Co-authorship with IF personnel will not excuse the investigator from cost recovery for supplies or use of the equipment

ARL – Division of Biotechnology Imaging Facilities

Regulation and procedures to use the facility

- *Proposed research questionnaire*: All who want to use the IF are required to complete a brief questionnaire outlining their proposed research involving electron microscopy. From this questionnaire and from consultation with the investigator, the IF staff will advise the investigator on the feasibility of the proposal and prepare an estimate of costs involved, to assist in the establishment of funding prior to the initiation of the work. The contents of these questionnaires are confidential, and will be used to advise the client and to compile administrative reports, justify
- *funding of the operating budget*, document use of equipment purchased on hared instrumentation grants, and support future shared instrumentation grants.
- The research proposal and the initial consultation must be completed before the EM-related work is begun. Graduate students must have the proposal, the cost estimate, and statement of biohazard approved and signed by their research advisor, confirming the validity of the project, the safety of the project, and the availability of funds.
- Items of concern for the consultation will include the type of sample, the proposed EM methods, previous EM work on similar material, the feasibility of the anticipated project, specialized techniques that may be necessary, the type of equipment needed and the availability of such equipment.
- *Literature references* to previous protocols, provided by the investigator, will facilitate the discussion. Time frame, deadlines and possible interruptions will be addressed.
- Anticipated costs and the availability of funding will be a necessary part of the discussion.
- *Safety concerns* also must be addressed.
- *Pilot studies or trials* of experimental methods maybe required to determine potential problems and assist in establishing a suitable protocol.

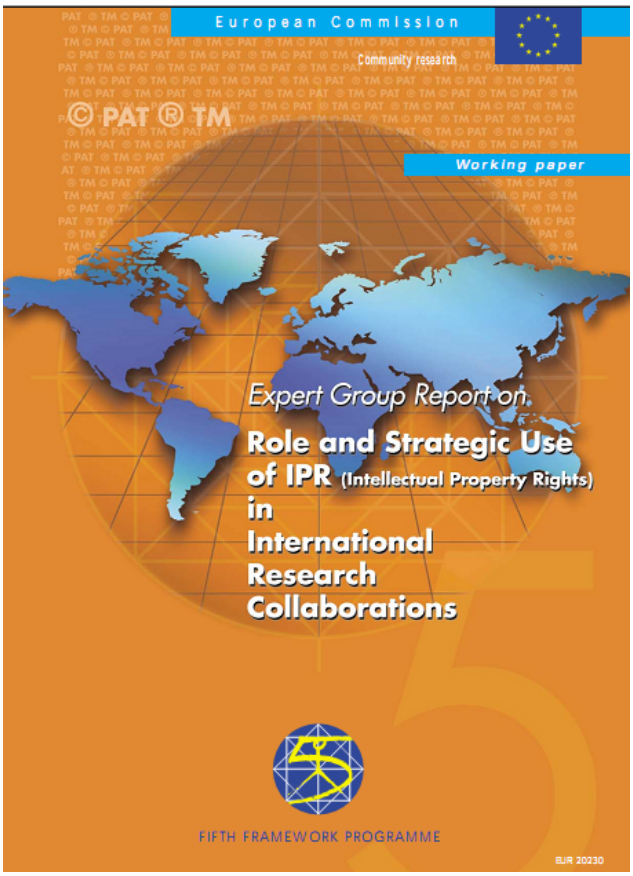
Pricing issue

- *Charges:* By University policy, the IF must charge for use of its facilities and for the services of its staff. These charges are levied only to the extent of recovery of the IF's costs. Cost recovery will assist inensuring the availability of up-to-date and operational equipment and technical services.
- Under federal guidelines, no investigator can receive goods and services for less than the posted rates. There are, however, special circumstances in which funding might not be readily available; the staff of the IF will suggest possible sources of funds in these special cases.
- *Supplies:* The IF must require reimbursement or replacement of all supplies not included in the cost of a procedure. The IF assumes no responsibility for material defective due to manufacturing error, and recovery will rest with the user.
- *Availability and charges:* Charges for service work include costs for a technologist's time and therefore are substantially higher than for equipment use rate alone. Also, there are no exclusions possible for cost recovery on service work. Service work cannot be done for graduate students, unless the work is of a minor, supportive nature, and the student's advisor deems that service necessary and agrees to provide full funding for it. All requests generally are handled on a first come, first served basis; exceptions to this can be made at the discretion of the Facility Manager. Please remember, however, that due to the limited personnel available to the Facilities, during certain times, unscheduled service work may be impossible, and at other times delays may be expected. Two days notice is required before samples are brought in, so that required materials can be prepared.

3.4 Intellectual property rights in international research collaborations

Source: http://ec.europa.eu/research/era/pdf/ipr-eur-20230_en.pdf

The Expert Working Group 'Role and Strategic Use of Intellectual Property Rights in International Research Collaborations' met five times in 2000-2001 to develop a broad strategic view of the various IPR and International Research Collaboration issues from a Research policy perspective: what are the issues, their importance, and the best approach in addressing them. Experts also submitted individual contributions to be discussed at the meetings. The group then made its own recommendations concerning the objectives, scope and content of appropriate guidelines and policies, and a final report was prepared by the Rapporteur in conjunction with the Chairman. The meetings were attended by Commission staff, who contributed information on EU policies and programmes.



The purpose of the report is to develop a broad strategic view of various IPR issues from a Research policy perspective.

Key issues covered include:

1. The Role of IPR and Public Policies in International Research Collaborations
2. Purpose and Structure of R&D Collaborations
3. IPR and Knowledge Management in R&D Collaborations
4. International Legal Aspects of IPR in R&D Collaborations

Background

The purpose of the report is to highlight the importance of intellectual property rights (IPRs) in international collaborations, to recommend good practices in relation to the use of IPRs in international collaborations, and to suggest policy responses to problems arising. Problems are generated by the diversity of international practice regarding IPRs, including patenting regimes, rights of privately or publicly employed researchers, as well as social and cultural norms. The Report focuses on the interaction between three developments affecting intellectual property in research collaborations:

- Increasing research collaboration between various entities involved with research;
- Changes in the global economy during the past couple of decades , and
- Changes in the use of national and international IPR systems.

It is common to assume that IPR frameworks are important in settling how the results of research collaborations are distributed between the various individual members or categories of members involved in collaborations. But IPRs are far more important than that. It is the IPRs and the conditions regarding their ownership and utilization that determine the nature, scale and participation in such research. The increasingly important role of IPRs at all stages of the research and innovation process will have a determining effect upon the nature of collaborative research, its focus, and its success. The reason for

this is that IPR philosophy is intricately bound up with, and controls, knowledge flow, creation, use and exploitation before, during and after a project.

Intellectual outputs from research collaborations include formally protected knowledge, tacit knowledge and other results such as commercial knowledge of markets, consumers and other 'non-scientific and technological' knowledge, as well as contributions to the pool of public knowledge. Policies and strategies must therefore take account of this broad range of results.

The importance of formal collaboration agreements is that they force the participants at the outset to identify their own interests, rights and responsibilities, and to recognise those of others within the project, and to codify these within a legally binding document which can be consulted during and after the project's lifetime.

An important, if not central part of these agreements deals with the allocation and utilization of IPRs.

We conclude that collaborative research is growing in importance both in Europe and around the world. Its success depends upon the existence of a set of IPR rules ensuring both that economic returns are available to participants and that there is reasonable access for third parties to the knowledge generated. Such rules should facilitate trade between the various participants in research and must be designed in the context of an overall system taking account of all interests.

IPR's report index

CHAPTER 3: IPR and Knowledge Management in R&D Collaborations

CHAPTER 4: International Legal Aspects of IPR in R&D Collaborations

4. Examples of EU initiatives of trans-regional collaboration on sharing facilities in biotech

4.1 NetBioClue – Networking Biotech Clusters in Europe

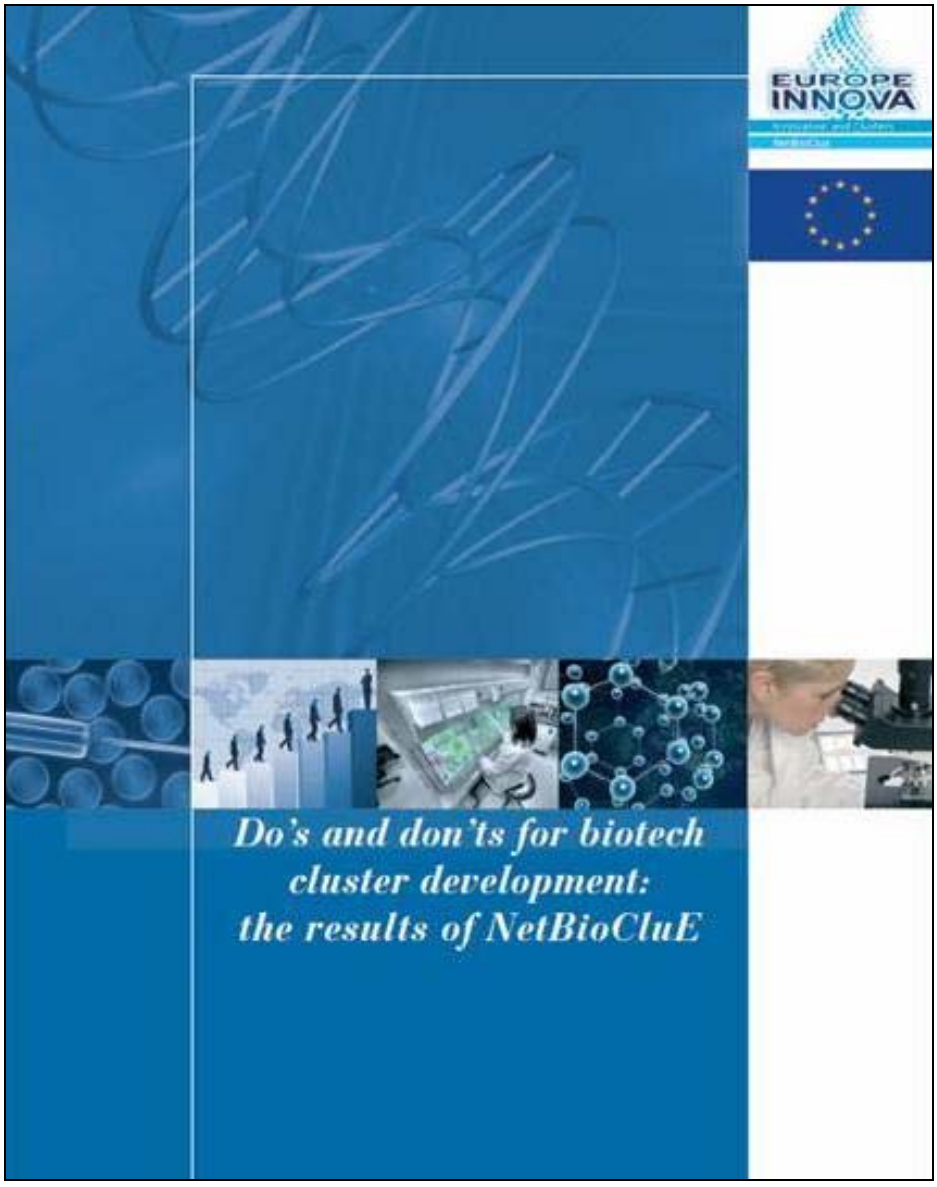
NetBioClue (FP6 – 2006-2008) aimed to support networking, collaboration and the transfer of knowledge among innovation clusters in the biotechnology for health sector in Europe. The project addressed all types of innovation including technological and organisational innovation.

NetBioClue promoted the development of the innovation system at EU, networking different players, promoting co-operation, and encouraging transnational learning and global competitiveness. It addressed the specific needs of the biotech sector at different stages of development, through transnational learning and increased global competitiveness.

The project had 8 main objectives:

- To study the evolution of the clusters
- To identify factors that contribute to successful cluster development
- To identify best practice within clusters in relation to specific innovation issues relevant to the biotech sector
- To analyse transnational factors in cluster development that contribute to excellence and increased competitiveness
- To develop a scientific methodology for testing pilot-scale projects within clusters, and to assess the excellence of innovation related activities
- To design joint programmes and pilot projects which will conducted in an extended form at a later stage
- To foster the creation of transnational mega-clusters and international co-operation
- To provide policy recommendations to local, national and European authorities involved in cluster development in the sector.

The project was greatly successful and led to the now running ABC Europe Project. All the results of the project and the lessons learnt were collected in the final publication "*Dos and Don'ts in Biotech cluster development – The results of NetBioClue*".



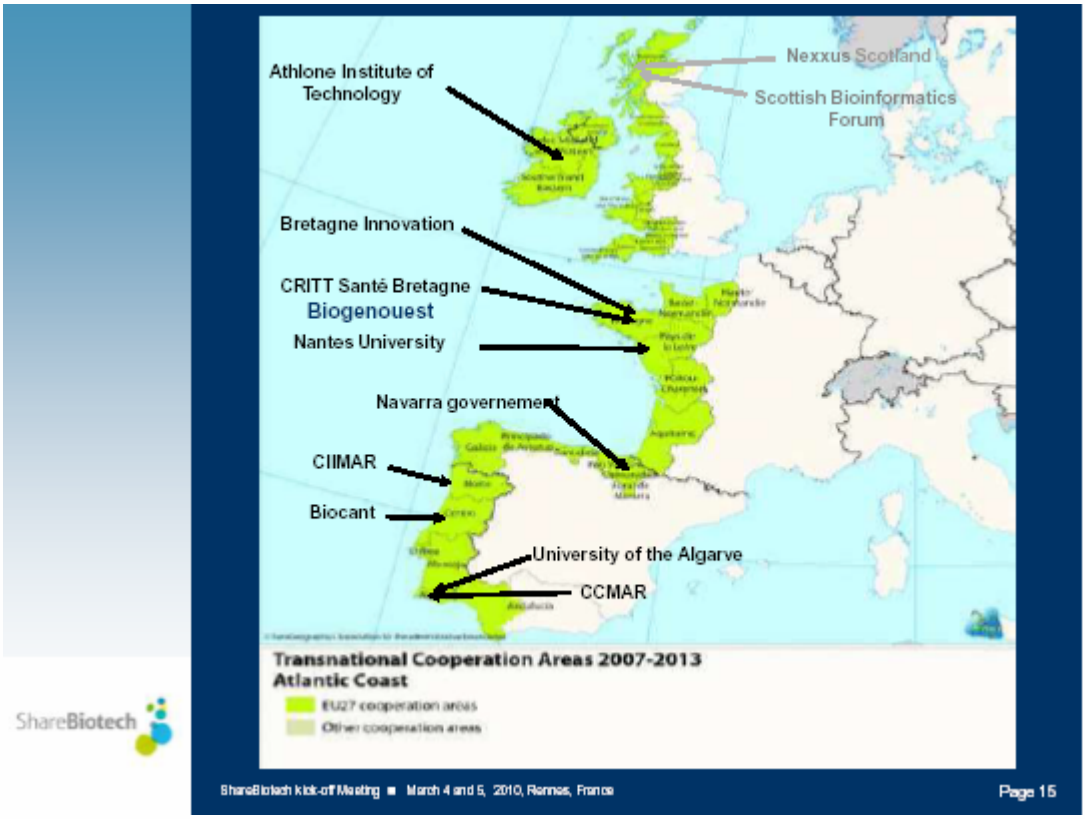
Netbioclue final report

4.2 SHARE

SHARE (Supporting and structuring HealthGrid Activities & Research in Europe: developing a roadmap) project ended up in 2008 concluding 27 months of a EC funded project under the FP6 framework. The SHARE project was originally built on the conclusions of the HealthGrid "White Paper", which suggested the development and deployment of health grids technology within 10-15 years. Part of the new Information and Communication Technologies (ICT), Grids are computing networks which shall benefit a large number of application in healthcare in the coming future by sharing and analyzing data in medical research area. The project is now finished and has evolved into recommendations through the SHARE Road Map that will benefit the entire user's communities onto health application to the grid technologies.

This project involved the participation of universities and laboratories from several European countries (Spain, Belgium, UK, Germany and France) as well as three other participants from America (Chicago) and Asia-Pacific (Taïwan). All these partners gathered all their knowledge and their know-how in order to reach just one goal: develop the Grid's initiative for a better healthcare of mankind.

Project website: www.eu-share.org



The Share partnership

4.3 Alma in Silico

The Alma in Silico project, financed by the Interreg IV Program, is a running collaboration within the Euregio Meuse-Rhine between the GIGA-Research (University of Liège) and the Universities of Hasselt (BIOMED), UMC+ Maastricht (GCM) and RWTH Aachen (IMB). The aim of this 3 year-project is to build an integration, dissemination and knowledge management platform in the field of "systems biology".

This project will link industries, research programs and academic education, through funding allocated by the Interreg IV European Funds and the committed Regions (The Walloon Region, the North Rhine Westphalia, the Flemish Community, the Belgian and Dutch Provinces of Limburg).

The project consists in 3 main actions including the development of a euregional bioinformatics platform, the establishment of a technology platform for systems biology and validation projects (inducing efficient collaborations in research against cancer, multiple sclerosis, pharmacological an toxicological studies, …) which will use the 2 previous platforms.

An additional action will concern the knowledge sharing in order to establish a training program in bioinformatics for researchers and life sciences technicians, and also in new methodological, technological and informatics tools.

The Alma in Silico project is built up on top of the virtual laboratory Alma-grid which was previously supported within the framework of Interreg III.

Project website: www.alma-in-silico.com

4.4 Fasilis - Facility Sharing in Life Sciences

FASILIS is a transnational pilot project (Interreg IVB) that aims to give Small and Medium sized Enterprises (SMEs) in the human health sector, such as biotechnology, pharmaceuticals and medical technology, easy access to a wide range of public and private research facilities in six human health clusters.

- The Health Technology cluster in South East England
- Health Valley in the Eastern Netherlands
- Medicon Valley in the Øresund Region
- The North-Brabant LifetecZONe cluster
- Bioregion STERN around Stuttgart
- The BioLiege cluster in Wallonia

Through FASILIS, SMEs will be able to work with providers of knowledge and equipment beyond those that are currently available at the regional level, broadening their competence networks and stimulating innovation and new business development.

FASILIS offers:

- Regional contact points for personal and quick advice.
- A FASILIS catalogue with an overview of participating facilities.
- A voucher scheme to stimulate transnational innovation. All FASILIS vouchers have been distributed. It is no longer possible to apply for a voucher.
- With the experiences and conclusions from this pilot project, FASILIS aims to create a framework for durable long-term cooperation between SMEs and facilities in Northwest-Europe.

FASILIS will open up public and private research infrastructures in the field of human health (biotech, pharmaceutical and medical technology) to SMEs from other regions in North West Europe. The aim is to give SMEs access to a far wider range of research facilities than is currently available at a regional level, broadening the competence networks of both SMEs and research infrastructures and so contributing strongly to increasing regional innovation capacity in the field of human health.

Project website: www.fasilis.eu

4.5 Episode – Exploiting the Potential of Structural Biology through NMR and Associated Technologies

EPISODE is a project financed by the European Commission's Framework Programme 7 (FP7) that will allow regional governments, research institutes, and businesses in the regions of Tuscany, Berlin-Brandenburg and Campania to interact and create a strategy for new routes between scientific research and economic growth. The project will create a common plan to ensure that the first-class resources of the two regions are exploited and sustained.

In an era in which research, financing, and the economy are always in the daily headlines, it is becoming increasingly clearer that science, government, and industry must unite in

common goals and maximize existing resources in order to remain competitive at an international level. It is also clear that the output of publicly-funded research institutions must be tangible for the improvement of the quality of life in the regions in which they are located.

The regions involved in this project have many of the elements necessary for first-class biotechnology industries, but a strong support system is lacking. EPISODE will endeavour to correct this situation and create new opportunities for synergistic growth.

Objectives

1. To create research-driven clusters of regional authorities, research entities, and business/industry.
2. To identify ways that the components of these research-driven clusters can benefit from one another.
3. To foster transnational and interregional cooperation and learning.
4. To mentor regions that are less-developed in EPISODE's subject area.
5. To develop Joint Action Plans to increase regional economic competitiveness through R&D activities.

Project website: www.episodeproject.net

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Web links

- Infrastructures
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- ESFRI - European Strategy Forum on Research Infrastructures
  http://ec.europa.eu/research/infrastructures/index_en.cfm?pg=esfri)

- Funded projects on infrastructures
  http://ec.europa.eu/research/infrastructures/projects_en.html

- Alma in Silico project
  www.alma-in-silico.com

- Episode project
  www.episodeproject.net

- Share project
  www.eu-share.org

- Fasilis project
  www.fasilis.eu