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PROJECT FINAL REPORT

Final publishable summary report

Grant Agreement number: 229984

Project acronym: BIOCT

Project title: European Biotechnologies Common Tools

Funding Scheme: CSA-SA

Period covered: from 1/09/2010 to 31/08/2011

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1 - Executive summary.

Common tools for European Biotechnology (BIOCT) was a project that brought together five bioregions across Europe to identify common challenges for the economic delivery of biotechnology and develop key tools that could be delivered in partnership across Europe.

The key regions had a diverse history and pathway of development, and included:

- Paris (represented by GENOPOLE, project Coordinator) – significant economic cluster with significant concentration of academic, biotech and pharma actors.
- Berlin (represented by BIOTOP) – maturing cluster almost at economic maturity and a one of the main clusters in Germany, with strong biotechnology development and maturation;
- Barcelona (represented by BIOCAT) – Earlier stage cluster than Berlin or France but strong development based on long term political and financial support;
- Piemonte region (represented by BIOINDUSTRY PARK Silvano Fumero SpA / bioPMed cluster) – Early stage cluster based on solid research foundations and strong cluster strategy implementation;
- Debrecen (represented by GND) – Embryonic commercial bio community, based on a strong Hungarian university and long term regional planning and support;

These clusters/bioregions were supported in the project by i) the Council of European BioRegion, a network of over 60 bio communities in Europe with the mission to defragment biotechnology, and ii) InnoTSD, a expert consultancy which undertook cross cluster analytical work.

The project started with a SWOT analysis of bio community strengths and weaknesses. This was then used to identify common needs between all bio communities and the potential tools that could be utilised by the bio communities in partnership.

Three key tools were identified for the Joint Action Plan:

Project scouting and maturation: One of the Europe's major commercialisation challenges is the development of the *right* technologies at *sufficient* maturity to be able to survive as a commercial platform. TSB Innovationsagentur Berlin (in the Berlin-Brandenburg region) and Genopole (in the Paris region) developed their respective well proven scouting and maturation tools that can be delivered on a range of budgets and which would add significant value through being delivered across clusters.

Reversing brain drain and cross-regional mobility: the primary rate-limiting factor for cluster development is experience biotechnology development skills such as CEOs, CFOs, clinical and regulatory specialists. A defining feature of mature clusters is the availability and recycling of these skills. Biocat (in the Catalonia region) developed a successful scheme that it already delivers to enable biotechnology SMEs, where they can access short-term business skills from anywhere in Europe for critical periods of company development.

Sharing facilities: Europe has a wealth of specialist research platforms but many are not open for small companies to access, making poor use of high cost public investment. Bioindustry Park Silvano Fumero SpA / bioPMed cluster (in the Turin region) developed a platform for increasing access to facilities and skills where markets do not deliver, opening up facilities for Europe-wide access and ensuring maximum value to SMEs.

These tools were combined into a Joint Action Plan for launch post-project and supported by an online cluster-mentoring platform.

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2 - Summary description of project context and objectives

2.1 - Project context

The BIOCT project was developed from a core group of biotechnology clusters in Europe that wished to develop common tools for the support of biotechnology economic delivery in clusters across Europe. The objectives of this project focussed on key platforms that underpin cluster development and continued growth, with the following topics selected as not only important for cluster development, but also reproducible across clusters in Europe.

European regions and countries have to join forces if they want to have a chance to be competitive in the new global scenario expected for the 21st century: a strong (political, economical and technological) prevalence of China; growing emerging economies and markets (Brazil, India, Russia,..) anxious to have a stronger presence worldwide; a deep crisis of the ideologies behind the political and economical powers that characterised the 20th century in the US, Latin America, the Middle East, northern Africa and the Far East. Unless European regions and countries join forces and vision and become truly aligned, Europe will have a hard time to thrive and even to survive as a competitive biotechnology region.

In the frame of such a scenario, and within the scope of biotechnology, the BIOCT project was aimed at bringing together a number of leading European bioregions to imagine, discuss and propose a pathway(s) to fostering the competitiveness and efficacy by which European early stage biotech companies (or projects) may successfully go through the so-called death valley from research to business, i.e. through the early stages of uncertain development up to the industrial validation of their technologies and businesses.

The seed ideas behind BIOCT relied on a core concept: the *sharing of assets* among European bioregions as the key way to support a growing European competitiveness and a rational, integrated and economically sustainable growth. *Shareable assets* or *shareable tools* are understood as all kinds of material or immaterial instruments, like expertise, procedures, good practices, skills, equipment, buildings, platforms... Such instruments can be grouped into three categories: (i) human resources, (ii) facilities and equipment and (iii) processes, structures and collective know-how.

The concepts supporting Bio-CT are relatively straightforward, namely the engagement of the triple helix to build sustainable cluster and regional support and interaction.

The challenges behind the triple helix engagement became evident during the project – particularly the need to engage regions through the policy levels. Political and financial

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structures have changed radically since project launch and the most effective methods of implementation and delivery often lie lower down the operation ladder.

Partners also faced the challenge of finding common ground for needs and shareable tools that can be shared realistically and productively.

BIOCT brought together, for the first time, and with a focused task, people and teams who collectively manage a budget that is 100+ times larger than the cost of the project. It has developed trust and a multi-biocluster forum that the consortium partners are now committed to keep alive and at the heart of their respective activities. It developed a strong awareness about that *sharing* (of any type) has been, and still is, rather absent in the minds and activities of most European Bio-clusters, including the consortium partners themselves.

2.1 - Project objectives

The overall project objective, is to create a **Joint Action Plan** that enables any region in Europe to pick up and deliver, within a wider network of clusters, support services that are validated as effective for economic delivery of biotechnology.

Objectives within this overall project objective include:

- To undertake a full SWOT analysis of regions involved
- To create a model for inter-regional support to support brain drain and mobility
- To create a model for inter-regional support of project scouting and maturation
- To create a model for inter-regional networking and access to facilities
- To create a Joint Action Plan to integrate each model for implementation
- To support the project with extensive dissemination and project partnerships
- To develop a cluster mentoring programme

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3 - Description of main S&T results

3.1 - SWOT analysis

The SWOT analysis was undertaken with the following actions:

- Methodology to collect information
- Analysis of the data
- Results and synthesis
- Conclusion

Main interviews within the SWOT were:

- Torino / Piedmont: 10 interviews
- Paris / Ile-de-France: 13 interviews
- Berlin / Brandenburg : 10 interviews
- Barcelona / Catalonia: 11 interviews
- Debrecen / Hajdu – Bihar: 8 interviews

SWOT content

The following factors were assessed in each cluster:

- The innovation value chain in the biomedical field and on the evolution of Biomedical clusters to give a common understanding on the concepts and vocabulary used in the analysis
- Description of the cluster, key figures for companies, key figures for research, key figures for human resources and training, description of scientific and technological field.
- Global analysis (each marked 1-5) of the different activities of the cluster, as following:
 - Research and networking : activities like attracting talents, promoting the region through conferences, fostering thematic networks, connecting research organizations
 - Policy action : activities like contributing to an improved public perception of biotechnology, its benefits and its applications, publishing informative material, organizing conferences, setting-up programs dedicated to biomedical matters
 - Cluster expansion: activities like structure of the cluster and increasing the number of members

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- Innovation and technology : activities like enhancing the exploitation and the marketing of research in life sciences, developing partnerships between enterprises and research laboratories, increasing the value of research results, leading innovation to the market
- Education and Training: activities like increasing attractiveness of jobs in the field of biotech and biomed, improving the skills at regional level, increasing the number of students and qualified people, setting-up specialized training courses
- Commercialization and cooperation: activities like fostering the consolidation of the regional biotechnology and biomedical business sector, accessing to capital (seed money, venture capital, etc...), increasing internationalization and cooperation with foreign clusters/markets.

SWOT analysis conclusions

Each cluster of the BIOCT consortium represents a significant part of the Bio-health potential in its respective country and, for 3 of them (Barcelona, Paris and Berlin), they can be ranked in the top 5 European BIO clusters. Therefore those can provide the BIOCT project with much experience and many assets. Moreover Turin which is not far from the three ones mentioned here above and Debrecen, that is under development and smaller than the others, can provide some specialities that are less developed in the others or are complementary to the existing potential. For instance, Debrecen can provide a significant potential in clinical trials and testing and certification while Turin can bring imaging competencies and the link between the mechanical field and its technologies and the medical devices.

The cooperation among the members of BIOCT will be facilitate by the fact that the strategic positioning of each cluster that has been put in evidence by the SWOT analysis is in many parts complementary to other positioning. As for example, Paris region needs a stronger biotechnology sector and therefore to increase the number of companies but also their size. The project maturation phase is well developed with plenty of actors (TTO in the research institutes and universities, incubators, seed capital, strong expertise in analysing the projects). However some problems remain in the coordination of the actors, in finding the appropriate human resources, in solving IP issues and in increasing links with the market, in fine chemistry or in animal testing. These two competencies can be found respectively in Barcelona or in Debrecen. Therefore, in this case, BIOCT actors might gather their respective efforts to develop in common a strategy to get the Paris region expertise in project maturation but also to speed up the development of their own Biotech companies. It will be an asset for their big players but also give attractiveness for skilled persons out of Europe that are thinking about coming back.

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As for another example, Barcelona can offer good expertise in chemistry and structural biology which is a weakness in Germany and France for instance while Turin can provide expertise in imaging.

Therefore, the SWOT analysis has shown that each cluster is working on its strategic positioning and that everyone is looking for something different from the others. Bio-CT project, by the choice of the tools on which it will focus the next steps of its work and by the way it will implement the cooperation, can help each cluster to reach its strategic positioning. For instance, clinical trials are a strong issue and, if a shared facility to analyze the results, to set-up a common language, has to be developed, it can be located in a cluster in which this specialty is the most developed.

86 tools have been identified as of significant importance, a majority of them can be duplicated from one region to another one, validating the concept of BIOCT : mutual exchange among the regions. The goal of the next steps of the BIOCT project were to define how those tools can be adapted to the background of each region and how the transfer of knowledge can be done, keeping in mind the necessary financing of such transfer, the intellectual property that can be attached to and the preservation of the specific interests of each region competing for competences, economic development and enterprises. In addition to those tools that can be replicated, a large number of other tools, 30 in total, exists in each cluster and therefore does not need to be shared or replicated, but to be coordinated in order to gain effectiveness through reaching a critical mass, getting more means, accessing scale effects. The next steps of BIOCT will be devoted to define the processes, regulations, governance to set up in order to implement and manage in a sustainable way this coordination.

Main components from SWOT for development:

Human resources to feed the new companies that will be set-up, the teams in charge of developing new processes and products, research laboratories that have to expand their activities. Human resources can be developed through existing training courses, but also through attracting talents located in other regions, especially outside Europe as a significant brain drain has occurred in the last twenty years. Each cluster has developed its own strategy and its own tools to fix that issue.

Project maturation that consists in facilitating the transformation of a research result into an economic product or process. It requires many actions like consultancy to design the maturation process, to protect Intellectual property, to develop prototypes at large scales, to attract seed capital and later on venture capital. To facilitate the analysis, this topic has been divided in two sections: consultancy and financing. Each cluster has developed its own tools to solve that issue and some synergies may be set-up among them.

Shared facilities as the transformation of research results into economic product or process requires many activities, testing, prototyping, clinical trials, etc... and therefore use of equipment. Some of them are expensive, rare, difficult to maintain and to use and cannot be

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duplicated in each European region. Procedures, regulations have to be set-up to enable every user in Europe to identify those equipments and to use them.

3.2 - Technology scouting and maturation

Introduction

The analysis in Work Package 4 contributed to compare project maturation instruments of the individual regions in terms of their quality and implementability in other clusters.

In the first line, the results can serve as a background to support the selection or the development of appropriate maturation instruments in the Bio-CT regions. These tools also have to promote the development of the bioregions and offer a long-term perspective for them.

The results have shown that regional instruments could be successfully implemented in other bioregions. It should be noted here that an adjustment to the single strategy of the cluster has to be done and that tools have to build on the specific needs and on existing, working institutions and programs.

It should also be sought to establish common tools at the European level. This could be a common structure for project evaluation as criteria of quality of early-stage projects and the establishment of a central pool of start-up managers who practice a systematic exchange of experience within a European network.

And finally, standardized best practice examples should be offered for central areas of the project maturation process, which can be incorporated into regions with less experience in the future. A great deal can be reached here through targeted measures.

In the course of the analysis the following key features have been identified as essential for implementing a common maturation model in Europe:

- Experts from industry are the key instrument for early stage projects
- Intensive project management is essential
- Intensive cooperation with PEAs required/ development of new common strategies for patenting

Two already existing instruments already feature these criteria: Berlin-Brandenburg's TOP 50 instrument (Version I, see below) and the Genopole Entreprises tool of Paris region (Version II, see below). These tools have been agreed to provide a basis for the formulation of a common European maturation concept. However, while serving the same need (taking early stage projects further significantly) these models vary in terms of structure, financing and organisations behind.

Therefore, it has been agreed that a European model will have to unite the strengths of both tools and will have to offer two ways to mature projects – following more the one or the other approach and depending on a region's real needs but also its capacities in terms of available funding, support infrastructure, etc.

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The Joint Action Plan for project maturation aims at giving guidelines for how to implement a common European maturation model based on the experiences and special requirements of individual clusters.

A maturation model for Europe in two versions

Version I (Berlin-Brandenburg's TOP 50)

The essence of this tool lies in systematically structuring the project maturation mechanisms already existing in different bioregions. Sharing this tool means harmonizing the project maturation efforts of the regions following this common model given above.

The following goals should be achieved with the joint project:

- Bring basic research projects, which are not in use and do not have any chance of exploitation, into industrial value creation
- Systematically close the gap between publicly funded academic basic research and industrial development
- Establish a sustainable model for the development of the PoC and for technology transfer in the Life Sciences and beyond.

The project will be composed by five main modules (details to be found in the JAP module for project maturation):

- a) Raising awareness amongst academics
- b) Identification of promising projects and findings in the scientific organizations
- c) Assessment of projects involving external experts
- d) Ensuring the Proof of Concept (PoC) by involvement of appropriate partners or by taking advantage of existing and new instruments
- e) Systematic technology transfer into SMEs, through creation of start-ups and licensing to industry or cooperation projects

Steps to follow/ "Value Chain":

- Motivation of scientists through very early networking with industry and offering a support program on its way to commercialization.
- Development and establishment of an effective communication network between science, transfer institutions and the economy. This results in a better coordination of supply and demand.
- Development of a development plan for suitable projects taking advantage of existing instruments. This allows optimal use of available funding instruments.
- Elaboration of project development plans with the participation of industry experts.
- Monitoring and controlling of project development plans by the central project management.
- Marketing is accelerated by the involvement of various multipliers.

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Success control:

A quantity- and indicator-based success control will be implemented for ongoing evaluation of the project. The controlling divides the overall process into three phases: Identification, PoC and exploitation phase. A ratio system should measure performance and provide information on the efficiency and necessary measures for optimization and control. In addition to the quantitative measurement and evaluation qualitative indicators will be used, which include a not directly measurable and mainly long-term evaluation.

Integration into the regions' infrastructure:

The project will be fully integrated into the transfer strategies of the university/ the research institutions and the Institute. The connection to the universities' transfer strategies is ensured from the beginning. As part of a successful agreement, jobs will be integrated, too, for example by the possibility of conversion of employee contracts into long-term status or other long-term commitment.

Sharing of this tool:

Not necessarily all components, actors and infrastructures of the "ideal" model described above may be at hand and work the same way in all bioregions. However, the model is sufficiently flexible to be adapted to regional differences. On the other hand, the lack of one of the stakeholders described in the ideal model is not an obstacle to the functioning of the overall mechanism. For example, in emerging bioregions "traditional" cluster management activities may not be carried out by a dedicated coordination agency but by a university department or a technology transfer office.

Therefore, as a starting point for implementation of this common maturation tool one will have to look closely at the single components of it. Starting point always is the status quo in one region: Which components are already existing, which would need a slight adjustment to fit into the structure and which would have to be newly created?

These are the factors that will have to be analyzed in terms of existence, functionality and ability to be integrated into a larger maturation concept:

- Identification of projects/ project scouting
- Expert evaluation/ assessment of projects
- Maturation support I: Application support for funding
- Maturation support II: Searching for industrial partners
- Maturation support III: Other means of support

Version II (Genopole Entreprises)

The aim of maturation model proposed from BIOCT is to make available to the project leader (whether it is a scientist willing to consider the creation of a company or a company founder already) a dedicated team who will work together with it, all along the maturation process, as needed. The **Supporting Team** is built as to being capable to walk together with the project leader from the initial idea up to the stage of the company where the project leader can move on alone.

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The supporting team may be composed of a variable number of members, according to the number of projects to be followed. Each member of the team is responsible and dedicated to follow together with 5-10 projects or companies. The supporting team is made of young professionals, in the range of 30-35 years old, with previous professional experience in science and business. A senior group leader with science and business experience manages the team as well. Collectively, the supporting team brings together a panel of crossed skills including science & technologies, intellectual property, business planning, finance, legal, negotiation, management and organization...

The starting point of the process is when a project leader spontaneously approaches the supporting team with a candidate project. After evaluation, the supporting team decides, collectively, whether the candidate project will be further supported or not. The evaluation takes into account key aspects such as the science/technology underlying the project, the supporting intellectual property and the basic business idea behind the project.

Essentially, this maturation model is characterized by the fact that there is no proactive scouting of candidate projects. The starting point of the process is the decision, by a project leader, to move on a project and potentially develop a company out of it. The maturation model is fed by the spontaneously existing flow of candidate projects.

Projects preselected by the supporting team are then submitted to evaluation by an **Expert Committee**. The expert committee makes part of the maturation model. The project leader works together with the supporting team to prepare and complete the project dossier that is submitted to the expert committee. The outcome of the evaluation by the expert committee is a *Go/No-go* decision on supporting the project. The No-go decision may include recommendations for improving or completing the dossier and resubmitting it at a later date.

In case of a *Go* decision by the expert committee, the project is assigned to the supporting team for further maturation/incubation. At that point, a specific member of the supporting team is assigned to the project and will be responsible for the mentoring, follow up and maturation/incubation of the project inside the structure.

In practice, the input of the supporting team turns to be quite essential for the early steps in the development of the projects and companies. In addition to offering an external, objective, professional view on the project and on its fundamentals (science, technology, business idea, management, opportunity...), the supporting team contributes with significant amount of time (man-hours). Such time is dedicated to supporting both, the project itself (collecting and evaluating information (IP, market and other types), assistance with project/company presentations to public and private investors, assistance in the preparation of plans (business plan, product development plans...) as well as the project leader or entrepreneur (mentoring, coaching, teaming... up to kind of motivational/psychological support).

The supporting team works together with the project leader/entrepreneur and follows the project/company as long as it is needed and requested to do so; there is no time limit a priori. In some cases, the entrepreneur and the company become autonomous relatively quickly and

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continue their development independently and out of the frame of the supporting team. In other cases, they need a continued, long lasting support before they are ready to taking off. The same applies to the intensity of the need, which in some cases may be a rather circumstantial need of some support; while in other cases require a deep involvement of the member of the team involved.

As described, the model requires a basic structure made of two elements: an Expert Committee and a Supporting Team. The Expert Committee controls the entry of candidate projects to the process, based on their pertinence and eligibility on a number of aspects (science-technology, business, management, opportunity). The specific criteria used by the Expert Committee for the selection of projects can be eventually modified and adjusted to fit with specific temporal or geographical circumstances or environments. They can be made more stringent whenever the project flow increases, or the resources available by the supporting team become a limiting factor, or to adjust to the fluctuating liquidity of the financial markets (venture capital or other) expected to support the incubated projects/companies. The Supporting Team, on the other side, is in charge of moving the selected projects/companies forward through the maturation/incubation process up to a point where they become independent and can continue their development as autonomous entities. The role of the supporting team is to creating a contained environment where the project leader /entrepreneur and the project can growth, mature and develop themselves in a protected, incubated, mentored frame, while at the same time they are challenged and pushed to perform and to move forward, by the dynamic and professional members of the team.

How to share this tool?

One feature of the model is that the application of the model can be delocalized. This is of key importance when considering the *sharing* of tools between regions or countries. The process can, in principle, be applied by steps or modules, and more or less irrespective of the geographic location of the parties, and this at different levels as is explained below.

- 1 - The Expert Committee can be composed of members from different regions or countries. The expert committee itself can be either physical body, with members acting from the same location, cluster or region and holding physical meetings, or, alternatively, it can be a virtual body, with well-defined and common rules but composed by professionals acting from different places;
- 2 – The Expert Committee, whether a physical or a virtual body, can receive and assess projects/companies originated from clusters, regions or countries different from the one where the Committee is supposed to operate;
- 3 – The Supporting Team can handle projects or companies, and work with project leaders or entrepreneurs from clusters, regions or countries other than the one where the supporting team is physically present;
- 4 – The Supporting Team can eventually be, or become, either virtual or decentralized. Effectively, the supporting team can be composed by active members who will be

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operating from different clusters, regions or countries, while following common rules and a common process.

For the above, the model appears to be an ideal shareable tool. In addition, it is relatively easily convertible into a shared configuration.

The simultaneous practice of the model by different European regions would be an effective way to foster convergence within Europe. The practice of the model would favour the exchange of human resources, expertise, know-how and practices among clusters of different degree of maturity, thus helping younger organizations and less mature regions to benefit from those more mature. Expert Committees composed by the best possible skilled professionals from different regions, would be accessible by all regions involved and, thus, their candidate projects would benefit from the best possible advice. More developed and structured Supporting Teams will be able to host and train members of Supporting Teams from less mature regions. Members of Supporting Teams from less mature regions will thus benefit directly from the environment and experience of more mature regions.

In our view, the simultaneous practice of the model by different regions can be implemented with relative ease, with no major financial or operational burden for the clusters involved. To foster the exchange of staff members among Supporting Teams, we propose here the implementation of an *ad hoc* **Exchange Program** between the clusters involved. By the Exchange Program, a cluster will exchange one-to-one, one member of its respective Supporting Team by a member of the Supporting Team of the other party. The exchange would be subject to a certain number of conditions to facilitate its feasibility: (i) it will be limited to a well defined period of time, ideally in the range of 1 to 2 years time; (ii) during such period of time, the exchanged-members will be 'expatriated', i.e. they will continue being employees of their respective clusters of origin, while temporarily delocalized to a different country. This will give to the exchanged-members the security and visibility necessities for them to decide moving (with their families) to a different country. As the Exchange Program will be based on the exchange of preexisting job positions, the expected financial burden for the cluster willing to participate to the program is minimal; as the outgoing expatriated member of its staff will be simultaneously replaced by an incoming expatriated member of the staff of the partnering cluster. The practice of the Exchange Program will be of great utility to favour communication and understanding among clusters; will favour the convergence and spread of good practices; will contribute to the coming closer of different cultures; among other benefits. Clusters with higher level of resources, development or sophistication will be able to practice a higher number of simultaneous exchanges; while less resourced clusters will have a more limited number of people to exchange. Clusters with no such a thing like a preexisting Supporting Team will be able to participate to the Exchange Program by engaging one or more newly recruited, or recycled, employees into the Program. After the exchange period, expatriated members would come back to their countries of origin, and will be able to implement their learning and novel skills in their original clusters. In the eventuality some expatriated members did not return to their

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clusters of origin, their novel expertise would have in all cases contributed to the convergence of skills throughout Europe. Eventually, the Exchange Program may include a ‘come-back clause’ in order to minimize the leakiness of the system and the staying of the expatriated members in the hosting country.

The sharing model for project maturation and company incubation described above, together with the exchange program, are the perfect frame for the implementation of what we can call ‘project co-incubation’. We understand by ‘co-incubation’ the simultaneous existence and development of the same project (or company) in two different countries. Co-incubation may be an attractive option for early stage companies (or projects) that can benefit from their double existence in two separate environments, whether it is to access skilled staff, investors, grants, or other. The existence of fluid, dynamic and mixed supporting teams which would integrate members from different regions or countries would definitely increase the number of cases of co-incubation.

In spite of the simplicity of the concept behind the idea, the sharing of human resources, expert committees or maturation/incubation processes represents, in practice, a huge and demanding challenge. Clusters and regions are confronted to strong barriers that, first of all, need to be overcome; none of them is a real obstacle provided the willingness to collaborate and share is present. Such barriers are, for instance, culture diversity (different ways of doing things), language (sharing project/company information among clusters, staff members and expert committees from different countries presupposes that all oral and written exchanges are in a common language), the sense of self-sufficiency (specially present in more mature clusters and regions), as well as restrictions, in many regions, to invest or spend money in other regions and, specially, in other countries.

A fundamental question behind the sharing of a maturation model is the source of financing. As a principle, the activity got to be financed by that or those parties that may find a benefit in such activity. In the sharing of a maturation model across Europe, there are at least three parties that can be identified: the cluster or region that ‘provides’, the cluster or region that ‘receives’ and Europe as an entity in itself. As a general case, it may be defended that the contribution of the ‘receiving’ cluster/region to the financing of the sharing activity should be more important than the contribution of the ‘providing’ cluster/region. The relative contribution of each of those two parties will be variable on a scale where on one extreme there is the notion of a pure service; where there is a net provider and a net receiver, and in which case the financing is expected to be made by the receiver. On the other extreme of the scale, the sharing may be equal-to-equal, in which both clusters or regions provide and receive at the same time, and somehow, each of them finds a benefit in such an exchange. In this case, both parties could be expected to equally co-finance the sharing activity. In all cases, however, the supra-entity called Europe is present and participates as a third party involved. Without Europe in between, the sharing would become a mere self-fishing activity between the clusters or regions. It is in the prime interest of Europe to promote and foster such things like convergence, co-development, transfer, joint and integrative strategies,

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etc...all they being concepts that would not necessarily be a part of the equation if the activity involved regional interests only. As Europe, itself, is a unquestionable, and likely the first, beneficiary of the sharing activity, it can legitimately be expected that Europe should heavily contribute to the co-financing of any sharing activities; and that Europe would likely have to take over the biggest financing contribution out of the three parties. Without the interests of Europe, the sharing between regions would most likely not spontaneously occur.

3.3 - Harnessing talent

The main objective of this section is to identify a compendium of recommended good practices in fostering reverse brain drain across Europe, and improving inter-sectorial and cross-regional mobility. After the analysis of different instruments to achieve the goals of this WP, the conclusion was the proposal of the creation of a “Pool of Biomanagers” as an effective tool to foster a reverse brain drain.

General description

Pool of Biomanagers is a platform containing a database of high experienced specialists that will allow the entities from biopharmaceutical sector, identified as target client in this document (see below), to access to these high skilled professionals in order to enhance their competitiveness and, on the other hand, to enable these professionals to open up the possibilities of career.

Experts Profiles

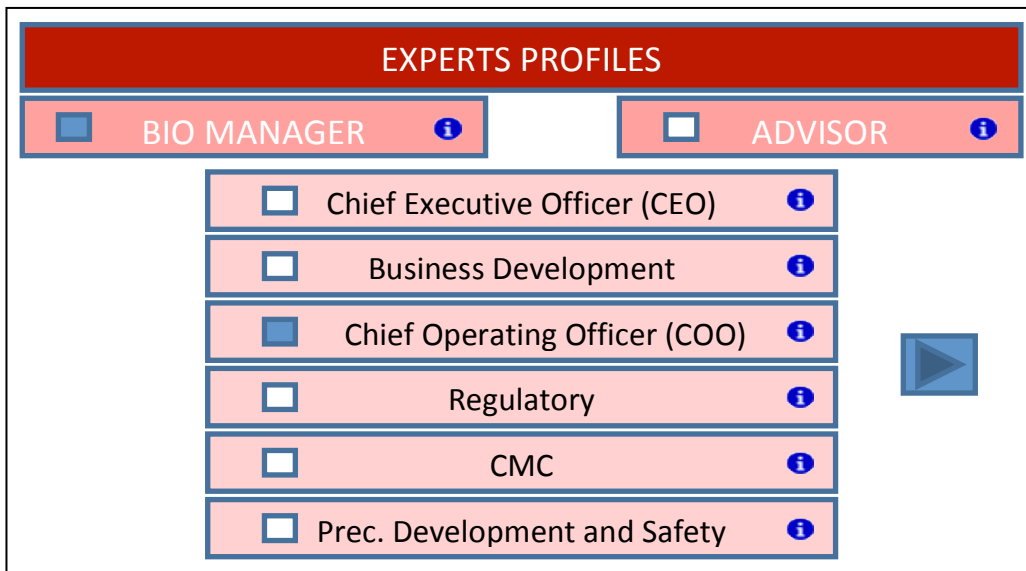
It has been identified six **Expert Profiles** considered **key positions** for the optimal plan and execution of projects in such fields as drug development, diagnostic and biomedical technologies, in their early stages:


- Chief Executive Officer (CEO)
- Business Development
- Chief Operating Officer (COO)
- Regulatory Affaires
- Preclinical Development
- Chemistry, Manufacturing, and controls (CMC)

In the deliverable D3.2 the detailed description of these profiles can be found, including skill and duties of each job position.

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Fig. 1. The search form (illustrative figure)



EXPERTS PROFILES	
<input checked="" type="checkbox"/> BIO MANAGER <i>i</i>	<input type="checkbox"/> ADVISOR <i>i</i>
<input type="checkbox"/> Chief Executive Officer (CEO) <i>i</i>	
<input type="checkbox"/> Business Development <i>i</i>	
<input checked="" type="checkbox"/> Chief Operating Officer (COO) <i>i</i>	
<input type="checkbox"/> Regulatory <i>i</i>	
<input type="checkbox"/> CMC <i>i</i>	
<input type="checkbox"/> Prec. Development and Safety <i>i</i>	

Importantly, all profiles must meet common requirements:

- Senior experts with minimum five years of international experience (recommendable ten years) in Biotech, Big Pharmaceuticals, Technology or Diagnostic companies, directly involved in the development, licensing or marketing authorization of drugs or medical devices.
- Strong technical and professional skills.
- Flexibility to switch into entities in different countries (mobility commitment will be compulsory).
- “Entrepreneurial spirit”: leadership, team management skills, etc.

Target Clients

The tool is aimed at helping the entities that work on **Early Stage Development** in biopharmaceutical sector. These are usually **Young Innovative Companies (YIC)**, **Incubators**, and **Technical Transfer Offices (TTO)**. The Pool will be restricted only for these types of the entities. Therefore, big pharmaceutical and head hunters companies will not be allowed to register as a tool user.

Location

CEBR, as the European Council of Bioregions, will host the Pool of Biomangers database on its Website. CEBR is the most appropriate institution for this task because of its multiplier feature. Due to its close relation with different clusters and bioregions can act as a perfect communication channel and then facilitate the flow of information and accessibility to the

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Pool. This will result in the dissemination of the tool much far away that among the Project partners.

Operability

Log In and selecting experts

To avoid a non appropriate use of the 'Pool of Biomangers' by such companies as big pharmaceuticals or human resource companies, a previous registration of the client (YIC, Incubators and Technical Transfer Offices) is required in order to verify its data.

The client, once logged, accesses to a search form where defines the kind of experts looked for. When defined them, the client accesses to the list of experts that match the selecting criteria, classified by categories if more than one have been selected. The list will be anonymous and only the information from CV defined as public will be displayed: work experience, educational Background and comments of the professional

Contacting experts

The user does not contact the experts directly. The system sends automatically an e-mail to the expert selected by the client with the information about which company is interested in acceding to his full CV. This mail will contain live links to answer yes or not depending on the expert decision. If positive, the client will receive the following information: Contact information such as telephone or e-mail, and full CV of the employee. If the answer is "not" the additional explanation will be required on why the expert denies this access.

Simultaneously, the system will send an alert to the tool administrator that the contact with the expert has been established and will inform him if the response was positive or not.

Job interviews

Database Manager's work will be limited to contacting job offers with professionals without any further responsibility on the selection process. However, in order to evaluate the success of the Platform, the information on the results of the selection process will be collected.

Two months after sending the full CV of the selected expert the client will get an e-mail with live link to the evaluation questionnaire and will be invited to answer it.

Others

Dissemination actions are planned to ensure the project success and to incorporate new users from outside of the initial clusters.

During the implementation of the tool all legal aspect of the terms and conditions of use will be defined.

Dissemination actions are planned to ensure the project success and to incorporate new users from outside of the initial clusters

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Conclusions

It is noteworthy that the objective of this platform is not the professional recruitment. The Pool aims only at facilitating a contact between the clients and the experts, so any legal responsibility of the selection process will be of its users.

It is expected that the availability of the pool of Biomanagers across European Regions will provide the following benefits for all involved parties; Biomanagers, Regions and Target Clients:

- Availability of a European centralized pool of Biomanagers which includes key expert profiles for an optimal development of drug projects in early stages.
- Availability of standardized professional profiles across European Regions.
- Integrated system of European pool of Biomanagers linked to job vacancies.

The proposed design and functionalities of the Pool should be attractive for the potential target users. In fact, the initial feedback received demonstrates that there is a great interest of European and US clusters in implementation of such kind of tool.

3.4 - Shared facilities

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 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.

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

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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. When a technology is mature enough to be exploited without further investigation, it is often outsourced to private companies. Some technology platforms are highly stabilized, fully operational tools which run on a routine basis (e.g. 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 it is possible to expect routine work (e.g. proteomics platforms). These elements clearly emerged also during the meetings that have been organised in the first phase of Bio CT project and in the SWOT analysis.

Those considerations have represented a starting point for further developments on the topic. What happens in real life is that, for each technology platform, the user is not the same. When a research facility 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. All those problems are affecting the real possibility to offer “access” to SMEs for something that is more similar to a scientific service than to an R&D project. 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. When platforms are run on a commercial basis, the propensity to pay is a key criteria to select customers, while when the platforms are still in development, scientific and technological criteria prevail for prioritizing. So, to summarize, the results of initial analysis, culminated in a focused BIOCT workshop held in Torino (Italy) on February 2010, is that research in life sciences increasingly depends on different expensive equipment and on the highly trained team of specialists present in different facilities required for their operation.¹

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This implies the need for a new strategy for the entire infrastructure of transnational research: an approach that will develop a new model to offer to the international community, particularly SMEs, the possibility to access shared facilities and the technology platforms that are necessary for the progress of companies R&D activities. The trend towards shared research infrastructure is recommended not only by economic pressures and general reason of efficiency, 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 premises 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.

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 equipment 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.

It is natural that such general approach has to be matched with specific local territorial conditions (i.e availability of facilities), with the typology of the considered facility and with the degree of maturity of the specific bio-cluster where such strategy will be implemented. According to the degree of maturity of the technology, cluster and industry strength (presence of large companies, existence of a dense network of SMEs and start-ups etc.), the delivery of scientific services by a facility can be punctual, temporary or may acquire a degree of permanence.

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The development of a “new” model of sharing

In coherence with the analysis and to develop and propose a new way to solve the facility problem, the BIOCT partners decided to identify in parallel through a review of critical facilities needed, at regional level, then at a set of complementary and synergistic facilities present in different clusters that, together are covering the value from preclinical to clinical phase 1. BIO-CT main focus is on sharing platforms/facilities that are accessible and which offer a service-like type of relation and not are research collaboration. The SWOT analysis, that has been carried out at the beginning of Bio-CT, served as a background to support the selection of tools, and shown that each cluster is working on its strategic positioning and that everyone is looking for something different from the others. The SWOT analysis too has showed what is strong and what is weak in each cluster, but also the existing tools that they have developed and the tools/needs that remain to be set up or covered. The basic idea was to build on a solid basis and, by a collective and shared action plan, a common model to reinforce each cluster and its complementarities with the other, without avoiding the necessary competition that has to remain among them. In such perspective the cooperation among the members of Bio-CT has been facilitated by the fact that the strategic positioning of each cluster (as it emerged from the SWOT analysis) is in many parts complementary to other positioning. In order to identify the facilities to be considered for the development of the shared model some key variables have been considered:

- The **Consistency of the facility** with Maturation process;
- The **Excellence of the facility** (Qualified, Labelled etc.);
- The **Accessibility of the facility** (i.e. the structure/platform is not dedicated to a specific (restricted) group of users)
- The **Lacking of the facility** in one of the other cluster;
- The fact that the facility **Meet Needs** of Projects/Companies in the death valley
- The facility **Positioning** along the value chain of the biotech industry (specifically from discovery to early clinical development).

A last element was the consideration of the “**service**” **dimension** i.e. the capability of the facility to be able to manage a “service” relation with a company. The exercise has been concluded with the identification of 12 different facilities in the 4 cluster involved that respected all the criteria identified. Starting from such 12 facilities a sub group of 5 has been identified as basic core of the analysis².

It was natural in meantime to try to forget the “scientific interest” of the selected facilities and to concentrate our efforts in understanding which are the organisational, marketing economic and regulatory problems behind a shared model of access taking in account the explicit need for a self sustainable model. We tried in such perspective to consider also what could be the specific advantages for each single facility to be involved in such approach.

After a common work, the main answers can be summarised as follows:

AA.VV “WP5 : Sharing Facilities Deliverable 5.2: Bridging the gap from preclinical to phase 1: general guidelines for biocluster’s development – Report on clusters needs and selection of possible shared facilities”, August 2010

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- A bigger “market” for services: usually facilities are conceived to offer service to a local market or even to a very limited “captive” market. The only exceptions are those facilities that, from the very beginning of their life, are conceived to be “international”. In any case, also for those facilities, a better “marketing proposal” could be a plus.
- Better synergies with other complementary facilities, so they could be able to follow the development of a product through many different steps and to work with complementary actors
- Standardization of internal documents and a boost to quality level assurance: facilities with more difficulties in contact with the market could learn from more advanced facilities
- Better understanding of market needs: the BIOCT activities and tools will help them to move from fundamental research facilities to more market oriented services platforms
- Better technological integration between facilities: solutions are more and more the result of different technologies/services linked to each other. And of course integrated alongside the product value chain.
- Possibility to leverage their internal asset through a pan-European offer. This will also provide more visibility out of the local territory (and, why not, also on the local stage).
- If they are integrated in an international system of services, more visibility means more clients, more clients mean more money, more money means more resources to invest in R&D and new technologies.

Starting from such possible advantages we analysed the different variables that a shared model has to consider in term of efficiency and efficacy and with a focus mainly on 3 different dimension:

- Contracting
- Management
- Control

in order to develop both an organisational and a service delivery “ideal” model to be implemented in a possible pilot action at trans-cluster level³.

All those activities has been realized collecting information from the facilities themselves but also from companies and stakeholders (i.e. regional authorities through their local R-SACs). The basic idea was to develop a “win-win” model where all actors would have advantages from a full implementation of the solution.

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The “ideal” model of collaboration has been developed and shared with all the cluster involved and with the selected facilities in order to allow the positioning of each territory within the model. The positioning has been done considering the stage of development of each cluster (position relative to the development timeline of a biotech cluster) and the typology of facilities already existing and that have to be built. Concretely, this has meant for a cluster to compare the facilities it has with those that the model has identified as critical for the transition of the entire system into a preclinical phase 1. After the identification of facilities that can be considered as “lacking” or “not enough developed” in each partner cluster during the stage of the product life cycle, it has been necessary to evaluate the real systemic impact. That has meant that, depending on the strategic vision of development of the cluster, it has been finally decided what typology of facilities had to be inserted in the pilot actions and, in a more strategic way, what could be the priorities for the strategic and logical development of the whole biotech cluster system.

A “make or buy” option has been analysed in this phase, together with financing and self-sustainability issues. The systemic approach leads to an overall definition of a common relational business model and a focus on services more than on facilities “in se”. This approach allows to tackle from a more interesting perspective the self-sustainability issue that, in this way, is interpreted from a real “market” point of view. This is due to the fact that the starting assumption is that if there is a “market failure” that justifies huge public investments in building new facilities that have to be shared, the self sustainability model will have to be “market based”. So the role of the public sector will remain focused on maintaining an external “positive” environment instead of the support, after the start-up phase of facilities “in se”. This business model that has been developed as a consequence of such considerations, has been analysed on the basis of the regional policies and on the inputs provided by the different partners. Indeed, several good/best practices for the self-sustainability of biotech facilities have been shared by the partners, in order to handle different “Business model propositions” which can be potentially applicable to every partner cluster but also, in general, to every biotech cluster. The different business model propositions have been analysed following a trans-cluster perspective, i.e. as if they are part of a trans-cluster initiative that follows the practical option to adopt a “sharing facilities” model among the clusters involved. This is based on the idea that using synergies and managing key facilities in different territories in a complementary way, it will be possible to avoid duplications and generate economies of scale. This of course generates positive impacts on the regions, the cluster members and the facilities. Such approach also allows to simplify the financial issues related to the sharing facilities proposal: if the Sharing Facilities/Services model is self sustainable, it has to coordinate its activities with public policies and schemes but, at the same time, it has to follow a market approach.

The resulting model is conceived as practical tool to offer a shared access to SMEs to facilities that are able (and ready) to open their platforms and services to multiple users, regardless their geographical localisation, within or outside the local cluster. The model based on a business approach, the procedures for use, the commercialisation strategies and the

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identification of some key starting facilities represents the basis for the proposed Joint Action Plan (JAP) that contains the description of the collaborative model and of the basic strategic tools (i.e. marketing plan, standard contract, cooperative agreements, business plans, different scenarios, etc.). The identification and selection of some starting facilities permits in an immediate perspective the start-up of a pilot initiative and the definition of involvement through a transfer of experience to other clusters and to other industrial sectors. The scalability of the solution and its transferability to other technological sectors has been considered, together with policy implications and recommendations.

Recommendations on implementing Shared Facilities

In such last perspectives a basic set of recommendations have been developed:

1. Use of vouchering schemes for SME to access sharing facilities schemes (some good examples are already on-going)
2. Inclusion of the possibility of trans-cluster sharing services schemes in public financing schemes
3. Support the creation of state of the art facilities in complementarity with other clusters
4. require self-sustainability plans to facilities financed by public financing schemes

The JAP is not only a passive activity based on a sharing policy respecting what is already existing: the JAP starts from what is already existing and through an innovative way, permits a shared access to already existing facilities, for the benefit of all the players.

3.5 - Mentoring activities

Mentoring between clusters is a key activity that Europe can deliver, as a result of its objectives to build partnerships. The network of biotechnology clusters provided by the Council of European BioRegions is an ideal platform through which to launch a mentoring programme and the BIOCT project has provided this opportunity.

All clusters in Europe have knowledge to share, no matter what their size or maturity.

Needs and capability within clusters

Emerging cluster needs:

- Commercial biotechnology experience
- Services of maximum benefit to early stage start ups
- Cluster integration activities

Emerging cluster knowledge:

- Designing comprehensive cluster strategy
- Understanding economic development needs within the regions
- Creation of infrastructure

Mature cluster needs:

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- Cluster assessment within a larger cluster

Mature cluster knowledge:

- Effective company support
- Experienced business expertise
- Understanding of long term cluster development

A mentoring programme does not need to be expensive or time intensive – it smooths the flow of information between clusters around specific topics and enables trusted information to be shared within a confidential environment. Any programme developed should be designed for long-term operation and will be a source of information for wider non-confidential publication and education.

Cluster Managers are constrained for time and finance – extensive travel is not viable within a mentoring programme. As public budgets are cut for clusters both large and small, mentoring must fit resources available. Too many ambitious EC funded programmes provide short term benefit, only to end as soon as funding is complete.

The work undertaken within BIOCT started with an understanding of:

- How clusters need to benefit through mentoring
- The most effective method of cluster mentoring

Initial planning with consortium

Mission: to mentor different elements of cluster development within a triple helix context – enabling complete and fully integrated development of biotechnology support

Potential participants: Primary targets are regions newer to biotechnology as an economic driver but it does not exclude those regions that have existing economic production from biotechnology with key areas which they would like to improve or introduce.

Activity targets for BIOCT: To design and test the concept of mentoring, with the intention to roll out the programme beyond project close.

Activities: There are two main potential routes, online and face to face:

Face to face: The critical element here is for all elements of the triple helix to be involved – BIOCT consortium members gained benefit through project meetings and the project itself but they are often not in a position to implement activities in their biocommunities without wider support.

The Council of European BioRegions already delivers Special Interest Groups which provide face to face flow of information between clusters and the Emerging Regions Group has been very active within the BIOCT project.

It was agreed within the consortium that additional face to face mentoring was not required or feasible beyond work already undertaken by the Council of European BioRegions.

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Online: This was the preferred option for the BIOCT consortium – it reinforces existing physical activities for the clusters and can be a destination for information and knowledge generated from face to face meetings.

The simplest option is LinkedIn – using the CEBR group and creating specific discussions – seeded by the consortium and then introduced to wider CEBR Membership and contacts from the rest of the consortium. The discussion topics reflect the core project topics and should also bring in all elements of the triple helix, not just consortium members.

Implementation

This includes the following:

- LinkedIn Group as part of the Council of European BioRegions existing Group – called ‘Life Science Cluster Mentoring in Europe’
- The group is invitation only, with all members approved by the Group Manager (Claire Skentelbery, CEBR)
- It is currently open to BIOCT members but will be expanded to CEBR Members before the close of 2011 – bringing in almost 50 biocommunities and associated expert members
- The groups will be strictly non-commercial, already a pre-requisite of CEBR member activities. All posts will be approved by the Group Manager, with a code of conduct in place for all Members. No advertising of services will be permitted and no soliciting for work will be posted.
- Communication will be maintained through the group, rather than Member to Member contact in the first scale up of the Group, with the intention of avoiding unwanted direct mail.
- As the Group expands and requests for assistance may evolve beyond group postings, the intention is to develop a more consultancy-based structure. Should a skill of a group Member be useful in a more intensive fashion, away from group postings – the Member will arrange a consultancy-style agreement with the beneficiary. This was agreed as important within the group to avoid over burden of skilled Members and to add measured value to services given within the mentoring group. This will be a private matter between the parties involved and not-regulated by the Group Manager.

The Group has clear subsections as follows:

- Discussions: here are posted the key topics for mentoring discussion – based on real life requirements of emerging clusters and often generated from face to face meetings hosted by CEBR, from BIOCT and other project meetings
- Members: This will list the full profiles of each Group Member, their experience, skills and ability to contribute to the group
- Promotions: This includes requests for assistance from clusters e.g. a specific skill required for the cluster managers or one of their companies/actors. This is an opportunity for members to promote well regarded experts from their own clusters

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(freelance specialists are an excellent resource for small companies). Posts will be requests only and not sales pitches

- Jobs: This can be used for job adverts available within the Group Member clusters – CEBR has several Recruitment agency Members and they will be permitted to post jobs under a strict code of conduct, including maximum number of jobs at any one time.

Promotion and monitoring

- Upon launch to the full CEBR Network – the Group will have a dedicated website area on the CEBR website and become an integral part of CEBR operation.
- It will support its Special Interest Groups, which target all areas of cluster operation. Information will flow from meetings into the group and out of the group into face to face meetings, ensuring sustainable use of the group and active participation by all Members.
- Updates will be included in all CEBR Newsletters and SIG meetings – the Network already draws upon multiple sources for its members and this will become an important tool for member communication and discussion as budget/time pressure constraints grow.

The Cluster mentoring platform is a strong tool to support clusters across Europe (and beyond), particularly emerging regions, often geographically remote and with small cluster teams and limited infrastructure.

This tool supports the Joint Action Plan from the BIOCT project and can provide a platform post-project for each element of the JAP as it is activated.

It is low cost to operate and flexible – at present it makes use of all free tools with LinkedIn, and can be lined with other tools currently used by CEBR, such as DropBox, Skype and SurveyMonkey. Scale up to fee-paying elements of LinkedIn is the logical next step but an additional custom-built platform is unlikely to be necessary, the expense and additional benefit is unlikely to deliver value for money compared to platforms such as LinkedIn.

3.6 - Joint Action Plan

In the last years, there has been an increasing exposure and networking activity and collaboration between research groups and companies from different European countries. This phenomenon has been mainly driven by the successive EC Framework Programmes. However, bioclusters, as such, have not really developed or nurture relations with clusters in other regions, whether in their same countries or in other European countries.

In addition to the challenges intrinsically linked to building any new tools, the development of sharing programs or shareable tools between bioclusters or bioregions faces a number of fundamental and additional barriers at the cluster/region level; such as the sense of self-sufficiency, of competition, the presence of rigid strategies, among others...

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Given the situation above, we have searched to minimize the burden (whether it is operational, financial or strategic) associated to collaborating/sharing between bioclusters and regions, which are not used to such sort of activities. While building the JAP, we have therefore privileged an approach aimed at bringing bioclusters together around a common goal and interest (collaborating/sharing) in the softest possible way, while minimizing the potential risks for the parties. In that sense we believe that the proposed Model Contract (see annex) is a perfect tool to creating a primary link between signing bioclusters, with a minimum level of exposure. Such Model Contract is extremely flexible in its contents, which allows the signing parties to adapt it to any specific subjects of collaborative sharing. Moreover, the Model Contract is written using a legal wording and, more important, its structure is largely comprehensive as it covers all the items needed to close and usually included in a legally binding agreement. The signature of the Model Contract by any two signing parties would create a light obligation only. Such obligation is reduced to work together (through the Steering Committee, see below) in identifying and materializing suitable opportunities for collaborating and sharing. Once concrete opportunities for collaborating and sharing will have been identified, they will be included into specific annexes to be signed by the parties and joint to the Model Contract. Such ad hoc annexes will rule the terms and conditions for the execution of the specific actions.

Bio-CT project was granted by the European Commission in order to provide different bioregions in Europe with the necessary resources to explore how single regional efforts and tools can be shared in the future and/or jointly be developed further. The project itself ends with an agreed Joint Action Plan ready to be implemented in the Bio-CT regions. It is clearly stated in documents and by EC officials that the “real” implementation will be up to the regions after the end of the project. Having this in mind the following points are of vital importance for all project partners:

- The JAP and the fact that several European regions collaborated in finding the best way to share their tools is not by itself an order or directive for regions to implement automatically the recommendations. Therefore, still after the end of the project an effort has to be made by the project partners. They will have to continue working on integrating their competent regional administrations, thus convincing them about the value of taking measures to implement all or partially the Joint Action Plan. This means not handing over the JAP as a stand-alone document but actively explaining and suggesting steps for best implementation. Of course, further communication between Bio-CT partners will be crucial for implementation since the JAP cannot include every single detail of implementation and cannot give an answer to every single problem which might arise when implementation actually starts in different regions. Therefore, the establishment of a Steering Group where former Bio-CT partners actively communicate, meet and exchange their experience on implementation would be very useful.

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- Through Bio-CT the regions have agreed on working together, sharing experience, exchanging best-practice and commit themselves to actively influence and advise the course of the project (through participation in R-SAC and C-SAC, etc.). However, no region can actually be forced to take the opportunity of implementing the JAP if they do not want to. Nor can a region be judged by how much of the proposed actions in the JAP will be actually implemented. Since it is the regions which will have to fund the joint activities the last decision will be up to them. Moreover, high-level political elections have taken place in several Bio-CT regions in the course of the project which could result in a stronger/lower commitment to Bio-CT's goals by regions

Since reality in the partner regions is very different, a highly flexible approach towards implementation will be needed. The JAP must have this requirement in mind. Therefore, the idea of structuring the JAP as a **General Contract** or a **Memorandum of Understanding** between the partners including variable annexes with the precise activities and tools to be implemented (and showing how to do this) is a suitable format to let regions choose what exactly should be implemented according to their regional priorities and capabilities. The real “deals” can then be done bilaterally between single partners following the principle of offer and demand of regions. Starting from this model, the JAP has to be further developed and made accessible for other partners step by step to finally become an attractive offer for all Europe.

3.7 - Financial commitments and recommendation

As mentioned and explained earlier and considering the Recommendation brought to the Commission the implementation of the general Contract or MOU, will be taken on the partners current budgets in time and travel expenses.

Based on the experience that could be derived from this first step, and with the creation of new funding schemes, the same Partners, alongside with others, will be in an excellent position to access to the second step, and eventually launch new, more ambitious common tools.

Special recommendation about the Funding of projects derived from the RoK calls.

The General objective of the Bio-CT project was made very clear by its precise wording in the Call – there was expected to be a precise and narrow set of deliverables from the project. At the end of the project, we came to this simple observation: once our conclusions were driven and a set of tools selected, we had no real financial scheme to follow.

The starting point for BIOCT was to convince our Regional Authorities to co-invest in a Common Tool, and then to apply to the different EU funding booths to find the missing part of the funding, if any.

This process is not practical for many reasons:

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- The traditional reasons: “Arrogance” (we have everything, why should we care?). “Dignity (Why shouldn’t we have our own tool?), “Fear” (We’ll never have enough return for our investment) and/or (Our IP might be stolen from us), etc.
- The seasonal reasons: The Crisis is here. The Kitty is empty, etc.

Therefore, there is an alternative that may work:

We bring, as a result of our effort, a number of tools that we, as Officers responsible for the Development of our Bioregions, consider as of high value to our Projects/Companies. Say: Tools A,B,C,D.

We recommend that the European Commission engage a thorough assessment of such tools, which could end up on this possible outcome:

- 1st Set: Tools A, C are considered as interesting but not urgent and will have to find local funding. In case such funding is proved insufficient, and need complementary EU funding, the Commission creates a **Funding Information Taskforce** in charge of orienting the project leaders towards the existing funding structures available in the EU. (Structural Funds, EIB, FP, etc.)
- 2nd Set: Tools B, D are considered by the Commission as outstanding and should be implemented urgently.
 - They are immediately granted with a **label** (The same kind of the “Eurostars”, maybe: “EuroTools” ?),
 - And **above all**, their Business Plan should be granted a pre-financing that could be at the minimum of 10%, and more desirably at the level of 20 to 33%.

This double sign of recognition (Labeling AND Money) would make the further discussion with local funders and political decision makers, much easier, for the project holders. Those could use this argument:

“This project has been recognized as useful by our Peers **AND** by the Commission. And this second recognition is acknowledged by a first EU financing. Can **we** stay aside?”

This procedure will reduce considerably the risk for the EU finances (If the operators and Regions cannot find the missing 90% or so, nothing happens.) and, most probably accelerates the implementation of the desired common tools.

3.8 - The expected impact was both technical and strategic

The Strategic impact lied mainly in the Convergence process between mature and young Bio-Regions.

The proposal represents a unique opportunity to create optimal linkage between mature and younger EU Bio-Regions. The collaboration with highly developed

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regions will allow the development of efficient Regional Innovation Strategy that will be endorsed by all stakeholders.

Other technical impacts where projected at the regional level

Improving links between regional authorities, research entities and the local business community across Europe within research-driven clusters

The project will contribute to this impact by Fostering trans-national, including cross-border, cooperations between regional partners (research entities, enterprises, local and regional authorities) in areas or topics of common interest, either related to challenges from the globalisation of markets or the evolution of normative frames in the European context.

3.9 - List of Beneficiaries

Beneficiary Number *	Beneficiary name	Beneficiary short name	Country	In charge of Work Package
1 (Coordinator)	Genopole	Genopole	F	1 - Coordination and Management
2	Fundacio Privada BioRegio de Catalunya	Biocat	E	3 - Fostering reverse brain drain inter-sectorial and cross-regional mobility
3	TSB Innovationsagentur Berlin GmbH	BioTop	D	4 - Project Maturation
4	Bioindustry Park Silvano Fumero SpA / bioPMed cluster	BioPark	I	5 - Development of sharing Facilities
5	Debreceni Egyetem	GND RKC	H	-
6	InnoTSD	Inno	F	2 - SWOT analysis
7	ERBI Ltd	CEBR	UK	6 - Mentoring and Dissemination

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3.10 - Description of work performed and main results

The **SWOT analysis** was the first major activity undertaken of the project included all regional cluster representatives. Questionnaires were designed to suit each audience; SMEs, scientific laboratories, interface organisations and finally, policy makers.

52 interviews were undertaken in Piedmont, Paris, Berlin, Barcelona and Debrecen and final SWOT report delivered.

Following the SWOT delivery, each of the main activity areas of BIOCT were launched as defined above, **reverse brain drain, technology scouting and maturation** and **shared facilities**. Much of the work in the first 18 months focussed around results of the SWOT analysis, combined with further Europe-wide analysis of cluster needs, through Special Interest Groups hosted with the Council of European BioRegions (CEBR).

The R-SAC and C-SAC committees met centrally and within each region to help drive decision making from each cluster.

BIOCT activities were expanded to European level through the launch and expansion of Council of European BioRegions Special Interest Groups for all topics, with the additional launch of a Group for 'Emerging Regions', to underpin mentoring programme development and launch.

During the 30 months of the project, Partners have completed the internal discussions and debate on how to build a collaborative common plan of action (or Joint Action Plan, JAP) that can be applied in reality, and which would answer to the expectations and possibilities not only of the Partners themselves but most important to the expectations and possibilities of the clusters and regions they represent. Defining, aligning and agreeing on a suitable profile and contents for the JAP has taken a significant amount of work, debate and exchanges among the Partners as well as with all parties involved.

The objectives that guided the partners throughout the entire project have been to find ways and tools that, realistically, would allow the regions involved to establish collaborations in the real life (collaborations ideally aimed at potentiating convergence among regions and maximizing the exchanges and the sharing of tools and assets, in a large sense) and to set Joint Action Plan to describe how to proceed to achieving such goals.

The JAP, whatever its contents and internal mechanics, had to take into consideration the fundamentals of the current political and financial environment, such as the current financial crisis, the uncertainties about Europe, the lack of history (and hence of experience, trust...) of real life collaborations among bio-clusters and regions, the existing administrative burden and barriers inside regions which create obstacles to collaborations among regions, and finally, the quite divergent views from region to region on how to proceed further.

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3.11 - Main results achieved to date

All consortium partners are highly experienced cluster support actors and had an excellent grasp of cluster needs and development. The changes behind European cluster development, have long been driven by declining early stage investment and changing company models and the gap between established and maturing regions is more evident, despite significant efforts in building new biotechnology regions. The key learning point that emerged from the SWOT and Special Interest Groups was that *experience* of both the SMEs and their support actors was probably the most important influence on effective support.

The groups associated with technology scouting and maturation, reversing brain drain and emerging regions (as preparation for cluster mentoring), defined exposure to experienced professionals as the key factor, regardless of the desired end point.

The other major learning point has been the rapid change in policy development at regional level in Europe. While EC-level policy and funding has developed gradually, National and regional mechanisms for the development of support for clusters and the funding for such support is changing rapidly with significant reduction in funding and changes in political systems sweeping across Europe. The learning point here is that no concrete funding plan that includes regional commitment can be agreed. The best route forward for this element of the plan is understanding of funding and international collaboration ready for rapid uptake when funding becomes available.

The key results from the 30 months of the project include:

- Completed SWOT analysis
- Cluster groups launched in Reversing brain drain, Technology scouting and maturation, Shared facilities and Emerging regions
- Joint Action Plan (JAP)

3.12 - Final results

In the last years, there has been an increasing exposure and networking activity and collaboration between research groups and companies from different European countries. This phenomenon has been mainly driven by the successive EC Framework Programmes. However, bioclusters, as such, have not really developed or nurture relations with clusters in other regions, whether in their same countries or in other European countries.

In addition to the challenges intrinsically linked to building any new tools, the development of sharing programs or shareable tools between bioclusters or bioregions faces a number of fundamental and additional barriers at the cluster/region level; such as the sense of self-sufficiency, of competition, the presence of rigid strategies, among others...

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Given the situation above, we have searched to minimize the burden (whether it is operational, financial or strategic) associated to collaborating/sharing between bioclusters and regions, which are not used to such sort of activities. While building the JAP, we have therefore privileged an approach aimed at bringing bioclusters together around a common goal and interest (collaborating/sharing) in the softest possible way, while minimizing the potential risks for the parties. In that sense we believe that the proposed Model Contract (see annex) is a perfect tool to creating a primary link between signing bioclusters, with a minimum level of exposure. Such Model Contract is extremely flexible in its contents, which allows the signing parties to adapt it to any specific subjects of collaborative sharing. Moreover, the Model Contract is written using a legal wording and, more important, its structure is largely comprehensive as it covers all the items needed to close and usually included in a legally binding agreement. The signature of the Model Contract by any two signing parties would create a light obligation only. Such obligation is reduced to work together (through the Steering Committee, see below) in identifying and materializing suitable opportunities for collaborating and sharing. Once concrete opportunities for collaborating and sharing will have been identified, they will be included into specific annexes to be signed by the parties and joint to the Model Contract. Such ad hoc annexes will rule the terms and conditions for the execution of the specific actions.

The Joint Action Plan that we propose is composed of 4 elements:

- 1 Model Contract
- 3 shareable Tools: one on human resources (See WP3 here below), one on facilities & platforms (See WP4 here below), one on project maturation (See WP4 here below),,

All four elements are applicable as such. Each of them represents a reduced Joint Action Plan in itself. They can be implemented by any two (or more) parties interested. They represent actions that can be jointly performed between different Bio-clusters or Bio-Regions for their mutual benefit. They are based on the sharing of assets between different bioregions in order to converge their level expertise and access to resources.

3.13 - Brief summary of BIOCT outcomes

- **First, the JAP.** The JAP includes the Model Contract plus three proposed action plans for selected shareable tools: one for expert human resources (D3.4), one for platforms & facilities (D4.4) and one for project maturation (D5.3). This outcome includes the package of deliverables that are formally due to the EC.
- The **second outcome**, although it is to a large extent an intangible, is the fact that partners got definitively **aware that ‘sharing’ among bioregions is currently totally absent; and that**

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specific actions on *sharing* must be integrated from now in the strategic agendas of the involved bioclusters. We think that this outcome will have an appreciable impact in all the partner regions involved, and hopefully across Europe.

The sustainability of the outcomes (of both outcomes) remains, however, unsure and relies on strategic decisions from the individual clusters, on suitable sources of financing and on strategic directions from regional and European authorities.

4 - Potential impact, main dissemination and exploitation of results

The Bio-CT project results are being developed and implemented within a far wider context of support for biotechnology in Europe and this will be reflected in the impact of project results. In the original proposal, partners were brought together from their desire for practical support for biotechnology development and all partners are intent on introducing results, not only into their own clusters, but also through a networked European effort. The networking on a European level is particularly important, when considering that the key value to cluster is the availability of expert knowledge and that this will not be delivered by working in isolation.

4.1 Key expected impacts

The consortium proposes the following as the key expected impacts:

- Collaborative activities within the Joint Action Plan that will be implemented by the Partners soon after project close
- Activities within the Joint Action Plan that will be implemented within individual regional clusters and delivered into the international framework
- The Joint Action Plan, as a whole, promoted and championed to clusters across Europe
- The individual elements of the Joint Action Plan have already been used to support other projects, such as ABCEurope and significant synergy has been found with projects such as ShareBiotech and Facilis.

4.2 Significant project results

- Through Bio-CT the first comprehensive mapping of tools in 3 areas within the region has been carried out successfully as a part of the SWOT analysis. This mapping will be further exploited by each cluster for its own strategy development and implementation.
- The SWOT and the process of shortlisting of tools have contributed to a profound understanding of how (even less common) tools work in different bioregions.

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- An understanding of how technology transfer is managed and carried out in regions across Europe has been generated through the project, particularly on integrated industry/academia collaboration.
- The comparison with other bioregions has shown areas of excellence and areas for stronger efforts for all.
- The regional workshops or “R-SACs” have proven to be a good experience and validated advice was drafted out of them and transported to the C-SACs.
- The main workshops in Turin, Barcelona and Berlin were very fruitful and have shown similar major needs in all regions as well as similar underlying challenges in addressing such needs
- Small-scale working meetings were highly efficient and immediate recommendations could be derived from them. In Berlin two of these meetings have been organized with involvement of local project maturation experts.
- The already (before Bio-CT) existing good contacts to other bioregions in Europe have been extended, an invaluable and continuous exchange of opinions, ideas and concepts has been initiated within the consortium and will be strengthened in the future.
- Promising final deliverables have been produced. The flexible format of the JAP prepares the ground for deeper cooperation in the future.
- The integration of BIOCT into wider European activities has been invaluable – the Special Interest Groups within the Council of European BioRegions (CEBR) have provided a double benefit:
 - o Dissemination of BIOCT activities into other bioregions in Europe – from day 1 of BIOCT, activities have been communicated into more than 60 biocommunities
 - o Integration of Europe-wide feedback into BIOCT planning – it has been invaluable to understand how proposed BIOCT activities would fit into other cluster development strategies. Developing the most practical and flexible structures from the Joint Action Plan has been influenced by regular feedback from clusters across Europe, enabling the creation of a JAO most likely to be implemented elsewhere.
- BIOCT has been closely aligned with other projects, notably ABCEurope, Facilis and ShareBiotech. This has enabled the creation of critical mass and exploitation of synergy between projects – something often lacking in the many projects funded across Europe. A major benefit is the creation of a path to exploitation of BIOCT activities including Shared facilities and Harnessing Talent, where there is a strong association with ABCEurope objectives and the ability to launch services from the Joint Action Plan.

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4.3 Potential impact of BIOCT

The potential impact of BIOCT has two key facets;

- Joint, formal working between bioregions in Europe to develop and implement common services for commercial biotechnology exploitation: This has a major impact for joint cluster planning and development and has been a key bonus for the partners. Until now, it has been a challenge to bring clusters formally together – they are networked through the Council of European BioRegions (CEBR) with great success, bringing together cluster managers. However this does not engage policy makers and the long term planning for cluster development. The SWOT and subsequent Joint Action Plan has forced policy makers and cluster funders to look beyond their own horizon in cluster development – the key learning experience for the policy/funder strand of the triple helix has been that Europe has often tried to launch similar activities and that they must research this before they start something locally. There are learning points from other clusters for every aspect of a cluster strategy.
- Development of a JAP for future delivery: The rapid changes in European economic and political situations have meant that the objectives, teams and financing that lay behind BIOCT planning and original objectives have changed substantially. The impact of the project here has been interesting as it has demonstrated the challenges of taking ideas and work approved by a regional authority different from the start of the project. It has demonstrated the need for Europe to be much more cohesive between political regimes, if the long term economic benefits of biotechnology are to be felt.

4.4 Project challenges

- The preparation of the SWOT analysis has taken a substantial amount of time which could not be foreseen. Therefore, other activities started later and deliverables had to be delayed. The JAP could be finished in time but more flexibility towards the end of project would have been helpful.
- The fact that Bio-CT brought together 5 regions meant that in the beginning 5 ideas of the JAP and 5 ambitions had to be overcome and harmonized in a process to finally come to a common idea. Even though basic framework of the JAP is clearly described in the Description of Work it proved that there was still harmonization and negotiation necessary to agree on details of the structure.
- Another challenge was the heterogeneous nature/ structure/ organization of the project members (consisting of technology parks, cluster management organizations without members, technology transfer network, etc.) leading to different flexibility for actions to be taken, different needs and obligations, thus sometimes creating misunderstandings.

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- Sometimes regional stakeholders had to be motivated to contribute to the project's aims and time was invested to explain the project's scope, objectives and impact to them.
- In the course of the project some deliverables proved to have not the desired added value for the creation of the JAP and/or proved to not having a clear link to the JAP itself.
- Reporting duties are essential and of highest importance for such project. However, the many reworking and specifying requirements related to reporting made it a workload heavier than scheduled. The procedure and requirements should be analysed in detail and/or revised for future projects. Furthermore, a clear communication on requirements of reporting from the beginning would be helpful.

4.5 Dissemination of BIOCT

BIOCT was integrated in to the heart of the Council of European BioRegions activities making dissemination a central part of the project. As a direct result, BIOCT was presented as a project or as its key working elements at a formal total of 12 events in the 30 month project. Discounting holiday periods such as Christmas and summer, BIOCT was formally presented once every 2 months, maintaining its presence in European cluster development planning.

The project is confident that all active bioregions in Europe are informed of BIOCT activities and progress and have been engaged in developing ideas for common tools.

This is in addition to all the informal reporting undertaken as part of CEBR Newsletters, Special Interest Groups, website updates etc.

Key dissemination events included:

CEBR Special Interest groups: These run on major topics to support cluster development and bring together working groups of clusters to share experiences, develop new tools and undertake common activities. BIOCT was represented at all relevant meetings, with Shared facilities, Harnessing talent and Emerging regions as core platforms for discussion and development of BIOCT activities

Biocluster Cooperation across Europe: July 13th 2011, Evry. This brought together almost 90 actors active in cluster development and was an interactive, discussion-led day on BIOCT and wider elements of cluster cooperation.

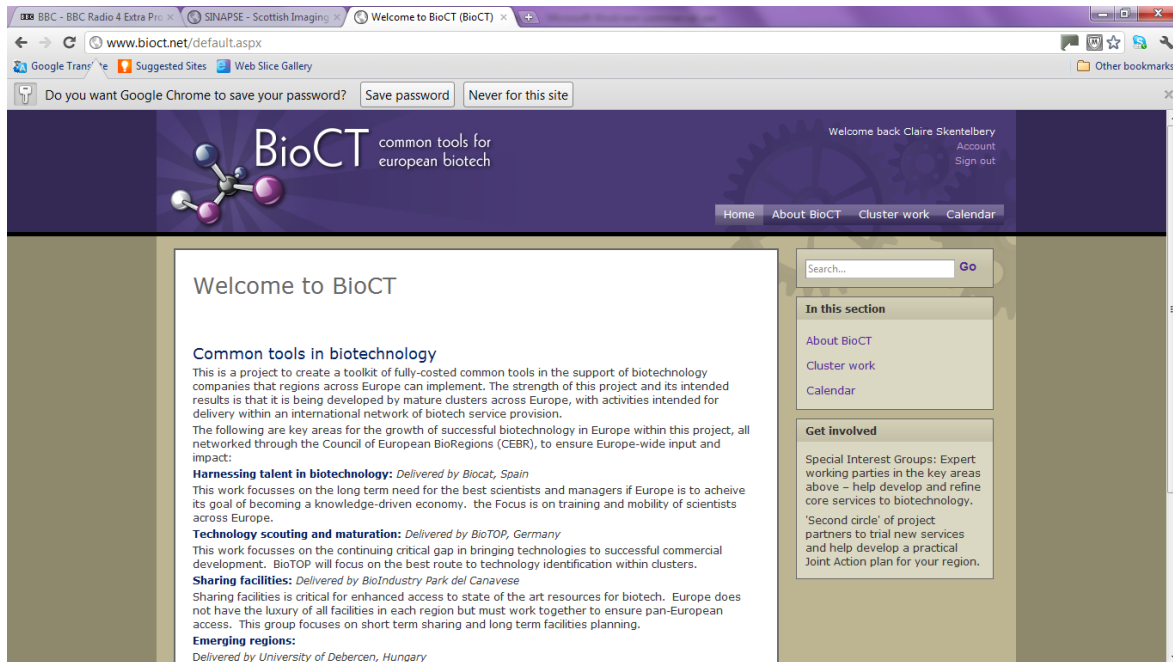
5 – Project website

The objective to launch and maintain a project support website www.BIOCT.net has been met.

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Full website development and launch was achieved at the start of the project and has been fully maintained until project closed.

Post-project updates will also be added to the website as part of its continued maintenance by the Council of European BioRegions (CEBR).



The website reported:

- News
- Calendar
- Consortium partners
- Final Joint Action Plan publication
- Links from BIOCT to external projects and activities such as ABC-Europe

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6 - Project partners

	Name	Country	Responsibility for activity	Contact
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