BioCT common tools for european biotech

Public version

WP5 : Sharing Facilities

Deliverable 5.3:
Bio-CT Sharing Facility System JAP

June 2011

V. 1.0

Tables of content

1. Why a JAP

In the context of Bio-Common Tools (Bio-CT) project two deliverables have been already released:

Deliverable 5.1: From preclinical to phase 1: the bio clusters' needs for bio facilities – Experience of some European Clusters: the deliverable has been focused on the analysis of real needs for shared facilities starting from already existing experiences.

Deliverable 5.2: Bridging the gap from preclinical to phase 1: general guidelines for bioclusters' development – Report on clusters needs and selection of possible shared facilities: the deliverable has been focused on the identification of potential shared facilities in the partners cluster and in the definition of an "high level" model of collaboration in order to assure a real shared solution targeted to the companies located in each cluster. The report integrates all the outcomes of the activities performed in task 5.2, with the goal to summarize and integrate needs of different clusters in a common conceptual framework that identifies common needs and common solutions.

Now the task 5.3 – *Common JAP "Facilities" and business model proposal* has the objective to share and evaluate the clinical-development shared facilities model identified in Task 5.2., starting from the needs already identified in Task 5.1.

The clinical-development shared facilities model and guidelines (D5.2) has been distributed to the bio cluster partners 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, following the outcomes of Task 5.1 and Task 5.2, 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 the maintenance of an external “positive” environment instead of the support, after the start-up phase of facilities “in se”.

This business model will be designed 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 several “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 to be case by case 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. Of course with 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 technologies 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 identification of some key starting facilities represents the basis for the development of the Join Action Plan (JAP).

The JAP has the goal to synthetize the analyses that have been performed by the partners and to identify the practical and operational tools that need to be put in place as key elements of the proposed model. The identification and selection of some starting facilities permits the start-up of a pilot initiative and the definition of involvement through a transfer of experience to other clusters (e.g. Second circle, less developed clusters, Other clusters etc.). The scalability of the solution and its transferability to other technological sectors need to be considered, together with policy implications and recommendations.

Last but not least, 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.

1.1 Optimizing the « Knowledge Triangle »: between research capabilities and shared facilities

The JAP has to be interpreted not only as a tool to support the growth of innovative clusters and SMEs, but also also as a useful element for building a real European Research Area

(ERA). For the ERA, the realization of the European Roadmap for Research Infrastructures (RIs) is of outmost importance to reach the objectives of the 2020 Vision.

In view of the globalization of research and the emergence of new scientific and technological powers such as China and India, Europe needs to urgently speed up - and incentivize - the construction of a new European Research Area, creating virtual transnational clusters for the Research Infrastructures consolidation and growth. It is crucial to ensure, as soon as possible, a European area in which researchers, technologies and knowledge can move freely and where coordination is effective. This requires – among other things - a common vision and a set of rules.

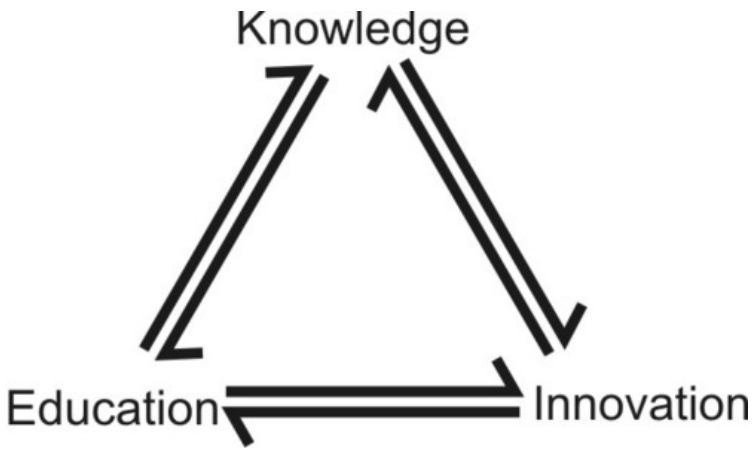
The processes of identifying, designing, constructing, funding, developing, managing and sharing Research Infrastructures (RIs) are complex and costly: no doubt that efficient and timely implementation becomes vital to the healthy development and more rapid fertilization of virtual network experience for biotech sharing facilities in Transnational Research.

Research activity involves international collaboration, either because of the need to pool knowledge and share large-scale research infrastructure or through the very nature of the research challenges being addressed. Global research challenges emanate from problems and issues that have a world-wide impact and are recognized across nations as major scientific issues. They are of a scale or complexity that goes beyond the reach of most national resources and have to be addressed on the global level.

It is not simply the global nature of research challenges that has promoted a growing international research agenda. With the rise of international trade, increased economic interdependencies between countries and the continuing development of Information and Communications Technology (ICT), organizations and individuals around the world experience and create ways to attract and capitalize on internationally mobile technology and knowledge resources.

Research infrastructures are instrumental in building long-term capacity and establishing unique regional advantages that can help attract mobile resources, for example talented

scientists. The attractiveness of research infrastructures in a particular location may be boosted by linkages between researchers, innovators, entrepreneurs, financers and other actors and institutions that matter for knowledge accumulation and use. In this new environment, the traditional focus on technology transfer has increasingly given way to a focus on knowledge sharing. The concepts of 'brain drain' and 'brain gain' have traditionally been used to signify that there may be winners and losers. With knowledge sharing, however, internationalization brings the potential for win-win through dynamic processes of 'brain circulation'. European research infrastructures, operating in the global context, are therefore set to have a crucial influence on the pan-European system by attracting a global research community and linking industry, higher education institutions and governments in the fundamental processes of knowledge creation and use for the long term.



As shown in the above picture (ERA "Knowledge Triangle" [1]), Research capacity mainly relates to the interaction between education, research and innovation.

"Research capacity building" is defined at one level as those activities which improve an organization's ability to achieve its research goals or a person's ability to accomplish specific research tasks. At a higher level, it relates to the basis for the implementation of public policies within regions or countries, beyond the interest of individual organizations. Three

1 Source: A vision for strengthening world-class research infrastructures in the ERA Report of the Expert Group on Research Infrastructures

basic categories relate to research capacity building: A) the development of research skills and knowledge in ways that contribute to human development; B) the institutional and legal framework within which research is conducted; and C) organizational performance.

The Shared facilities JAP has to take into account all the 3 dimension in order to assure the development of knowledge through a shared access to R&D and services facilities, the organisational and relational framework that permits such activity and the possibility to measure the performances of the resulting system.

2. Options considered to develop a JAP based on a common initiative to build & share a key facility in a trans-cluster environment

The development of a JAP for a common initiative to build and share key facilities and services has to be based on an analysis of possible options. Within the BioCT project, it has been established that *"..results of the activity will be the development of the common model for management and use of a trans-cluster shared facility. The JAP module has to analyse the different aspects (technical, legal, economic, etc) that will affect the life of the shared facility in order to develop both a proposal to be implemented and guidelines useful to help the implementation of similar actions in other regions"*. As it is easy to understand, several options have to be considered e.g. for governance and financing. After a long debate and discussion among the consortium partners, we agreed at the end to follow a market approach in building such model: in doing that we assumed that the facilities will have to offer their services to a market acting as parts of a virtual CRO (Contract Research Organisation) spread across different clusters and different facilities.

Successful management of research projects in a CRO can unfortunately mean different things to different people. If timelines, cost, and performance levels are not defined in advance, any outcome may be regarded as acceptable.

Moreover there are many other challenging issues associated with designing and implementing world-class shared facilities. Among these, membership, management, access mechanisms, funding and legal issues are the most crucial, as these facilities must be cost-effective and have optimal efficiency so as to facilitate the delivery of high quality services to customers.

A possible Joint Action Plan on how to share key facilities among different biotech clusters has to consider all different aspects including governance and financing schemes, together with a contract model organising access of non local operators. The ultimate goal is to summarize and integrate the needs of different clusters in a common conceptual

framework. The result could be, as stated before, the creation of something really similar to a (common) virtual CRO.

The key elements to develop a shared facilities/services common framework, which can represent the basis of the JAP can be considered the following ones:

1. Contracting
2. Organizational and managerial structure
3. Marketing
4. Financing

2.1 Contracting

Starting from the results of project discussions we decided that a "service" based approach could be useful to identify a self-sustainable model of sharing. Service delivery means relations between a provider and a user. In such context contracting is the starting step to organize, manage and maintain the service. **Service Level Agreements and Operating Level Agreements (SLA/OLA) as we defined them in Deliverable 5.2** are critical towards formalizing expectations around services with end users and customers. Without these, customers might assume assume that everything will be delivered and available at a 100% level all the time. And very little can be done about poor service when there is no definition what good service is.

In a shared facilities perspective, objectives should be set so they describe items such as response times, availability, turnaround and accuracy. Customers and each Facility should commit to mutually acceptable means of verifying compliance with service objectives and agree on actions that must take place when exceptions occur.

Type of common operational tools to be used (already identified in D5.2) could be:

- The **Service Level Agreement (SLA)** is a document that describes the 'who, what, when, where and how' of service delivery between the organization and its'

customers. A totally separate document called **Operating Level Agreement (OLA)** describes the 'who, what, when, where and how' of service delivery between/among all the groups that work together to support the customer and should be implemented. A support organization should establish an OLA that documents the availability, goals and performance expectations of the organization(s) responsible for delivering the service in conjunction with a SLA to the customers stating what services/service levels will be delivered.

- **A Balance Scorecard Approach for KPI (Key Performance Indicators) Reporting** to measure internal performances and Input-Output (OLA-SLA) quality and client satisfaction should be implemented. Mutually agreed means to measure performance and monitoring results against required levels of performance should be set, in order to give both customer and supplier an objective basis on which to assess the success of the relationship.

  The key goal is to:

  - Allow the virtual CRO to understand customer service requirements.
  - Control customer expectations for levels of service to be delivered.
  - Allow clear understanding of priorities when handling service problems.

- **Collaborative Research Agreement.** The objective of writing a collaborative research agreement is to clarify for both parties what they are trying to accomplish together and to clearly set for the rules that will govern the collaborative effort. A good partnership must be mutually beneficial. An effective collaborative research agreement will help both parties to understand and accept mutual benefit as a goal.

- **Confidentiality/non disclosure agreement.** A non-disclosure agreement (NDA), also known as a confidentiality agreement, confidential disclosure agreement (CDA), proprietary information agreement (PIA), or secrecy agreement, is a legal contract between at least two parties that outlines confidential material, knowledge or

information that the parties wish to share with one another for certain purposes, but wish to restrict access to by third parties.

The issue that should be discussed within the above mentioned contracts are related to e.g.:

- Termination Rights
- Insource/Resource Rights.
- Change Control Procedures.
- Ownership of Intellectual Property (IP).
- Termination Fees and Costs.

Standard contacts already in use in facilities identified are the starting point for the implementation. There are 2 main paths:

1) full standardization of contacts

2) maintenance of original contacts and little changes in some articles in order to assure basic access conditions

2.2 Organizational and Managerial Structure

Management of the system entails that project constraints should be managed bearing the following in mind:

- achieving the project objectives within time and cost parameters,
- doing so at the desired performance and quality level,
- utilizing the assigned resources effectively and efficiently,
- delivering high level services,
- meeting or exceeding the customer's expectations.

The project management will assure that all contractual, financial, legal, management and 'political' issues are taken into account and acted upon. The details of the procedures implemented in order to manage shared facilities in the most efficient way will be given in an Agreement between facilities and/or cluster organizations representing the facilities.

The Managing Organization, that could be completely virtual and "light", must take ownership for defining and maintaining the standards for the shared services initiative. This organization is the source of producing process documentation, providing project guidance, and establishing metrics to quantify the effectiveness of all projects. **Best practices and industry standards** should be embraced and provide the foundation for the processes adopted.

The following key project process areas have to be defined and actively managed by the Project Management Organization:

· Service initiation

· Resource management

· Scope management

· Change management

· Cost management

· Risk Management

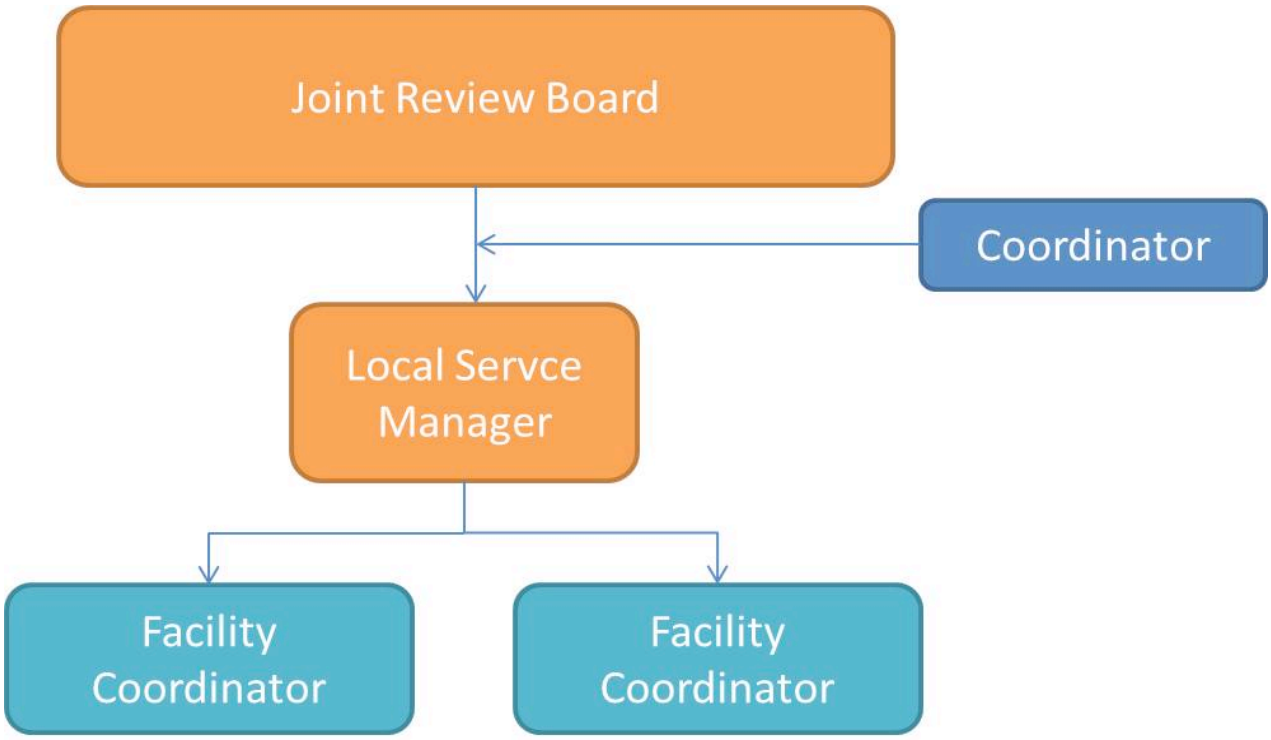
· Schedule development

· Communication Management

· Status Reporting

· Project Closure

In order to get a better separation of functions and responsibilities, the management methodology could be basically structured at two levels (*see picture 1, below*):



First level: STRATEGIC DEVELOPMENT (High level decision making): the JRB

The virtual organization will be managed by a Joint Review Board (JRB) which will consist of one delegate from each selected cluster that has involved facilities in the system. In case the cluster could decide to appoint a representative of the involved facility as member of the JRB. The JRB will be responsible for setting the strategic direction and define - if necessary - pricing, Service Level Agreements and Operating Level Agreements. The JRB will be also responsible for:

- establishing common operational procedures to be followed by the partners for carrying out their research activities;
- preparing common formats and templates to be used by the partners for reporting activity;
- Define SLA/OLA and pricing policies

- defining the proper tools and “infrastructure” for assuring links between the different multidisciplinary research teams.

The JRB will convene periodically (annually or Quarterly) or by phone conference on established dates. One Coordinator will be identified with the aim of maintaining the wider view of the Project, acting *as trait d’union* between JRB and each facility and constantly considering longer-term exploitation aspects.

If the number of involved clusters exceeds 5 it will be necessary to organize a real “assembly” that will elect the members (ideally 5) of the Joint Review Board.

A cluster could decide to appoint the facility/ies involved as its representative/s in the JRB.

Second Level: LOCAL SERVICE MANAGEMENT (Low level decision making)

This level of management will be performed by the Facility Coordinator (FC) from each facility involved. The Local Service Management (LSM) board will convene periodically (ideally every 4 months, at least twice a year) or on demand.

The local Facility Coordinator, will be responsible for ensuring that correct procedures are carried out. It will also be responsible for seeking consensus on the virtual organization steering. By clearly separating the basic functions to be performed, the management organization becomes far more flexible and is able to cope with possible changes.

The FC will be also responsible for:

- triage proposals internally and to make sure they are complete and scientifically accurate
- monitoring and reporting processes and results and service quality;
- defining the marketing and exploitation strategy for the services;
- define local SLA/OLA contracts and pricing;

- proposing corrective actions, in case of problems that might affect achievements or delay activities

2.3 Management and Business Models

A management model is the organization's core logic for creating value. Therefore a successful management model will offer unique value, is hard to imitate or recreate, can easily be altered and is grounded in reality. At the very beginning, it is crucial to choose between two different type of models, each one with its own peculiarities:

- Centralized Model
- Decentralized Model

Type of model	Description	Pros	Cons
Centralized	Single point of entry	Integration Coordination	Rigidity Cost of implementation
Decentralized	Local point of entries	Flexibility Local personalization	Lack of coordination Risk of defocalization

The real difference is between a “structured” system of different facilities that can be accessed through an unique central entry point (unique one-stop-shop approach) and a “not structured” and flexible system based on different “one stop-shops” located in each clusters involved. The first model is more efficient the second is more “open” and flexible.

The management model is linked to the identification of a possible business model that will have to be self sustainable.

2.4. Marketing

A market approach is at the basis of a self-sustainability model. It starts from an identification of customers/users typology and of their needs. It Is parallel to a top-down approach in the identification and creation of new core facilities based on state of the art technologies . The basic elements to be considered are:

Market positioning

The core strengths and the unique selling points of the virtual CRO must be identified and analysed against competition. A differentiation strategy call for the development of services that offer unique attributes that are valued by customers or that customers perceive to be better or different from competition. The value added may allow to charge for a premium price.

To pursue a differentiation strategy the skills required are:

- Access to cutting edge facilities
- Skilled people
- High reputation

Market assessment

The study will be conducted mainly in Europe with some investigation in USA and Asia.

A preliminary evaluation of the main market issues should be performed. The cluster level is the starting point for such activity and the SWOT analysis already realised is a basic input.

Marketing Delivery Vehicles

Different marketing vehicles must be used to implement the marketing strategy and marketing plan by delivering the marketing messages. The use of direct mail and email in a consistent manner, and alternating these with other vehicles such as monthly newsletters to let prospects and clients know about new solution and service offerings. Newsletters are a

perfect mean to illustrate the provider's expertise, its community, events and other relevant information that can be used to build familiarity and trust with their prospects.

Web platform

Ideally a web platform could be both a marketing tool and a collaborative tool for the system. A common web platform has the role to be:

- The positioning place of the system with the use of a common logo and "corporate image"
- A way to identify facilities and local contact points
- A way to promote the list of services offered by the facilities identified
- A place where it will be possible to access the "rules of the games" of the system

2.5 Financing

A review of local (cluster level) financing schemes and opportunities that could be activated in order to permit to SMEs to access/use shared facilities has been performed. The idea is that the starting point of the system could be the activation of already existing financing schemes. An analysis of the opportunity/possibility to use such schemes for services that are not delivered by local providers but are delivered by facilities abroad is really important and request a commitment, if such will be the strategic path, by local public authorities.

In this perspective the role new financing schemes (based ideally on a "voucher" system) is very interesting and the possibility to use in an innovative way already existing transnational financing schemes (such as Eurotransbio) could be useful.

We also have to take into account that the level of financing by public authorities will lower in the next years and that the shared facilities system will need to be self-sustainable in the medium term.

2.6 The consensus on key options

Bio-CT partners widely discussed about which of the different options would be better suitable as key element for a JAP able to propose and implement - on a pilot scale - a system capable of sharing key facilities in a trans cluster environment. The main necessary elements to be considered are:

- A selection of entry points able to provide both information on the system and support to the companies
- A set of "basic rules of the game" accepted by the players
- A self-sustainable approach, able to guarantee the survival of the system even without any public support (otherwise it cannot be considered "sustainable").

The set of identified rules should be light enough to allow the facilities to adopt them without radically changing their procedures and organizational behaviour and also allow the model to be flexible and to include, in perspective, new facilities which would like to be part of the "system".

The best model to suit these needs is represented by a **de-centralised model**, with several access points, ideally one per region. This approach allows the system to be close-to-the-companies (since the access point is local and well known) and allows the single access points to be able to tailor their offer to the specific needs of the regional companies, in particular the SMEs.

When accessing a research facility for "outsourcing" part of their research activity the companies normally look for:

- accessibility: the facility should be easy to access, no barriers (e.g. who to contact?) and no too high hurdles (e.g. contracts in the local language only) that might block their path. If the access is "tutored" or "supported" this represents a plus.
- advantages: namely in terms of cost (reduced), quality (certified or guaranteed) and time (quick and defined). Advantages should come out from the agreed rules of the game.

Within BioCT the partners do not have any power to "impose" rules to the facilities so, what is possible to do, is to provide guidelines which will have to be accepted by the facilities when deciding of being part of the system.

In more pragmatic terms there are 4 main framework elements on which we can work in order to ensure "advantages" to the companies willing to access the shared facilities through the system:

1. services are offered at a discounted rate,
2. IPR
3. quality
4. time of payments.

These aspects should be also monitored through Key Performance Indicators and some performance assessment needs to be put in place, mainly with the aim of monitoring what is happening in the system, not of controlling it. This means that at least the following aspects should be monitored:

- number of companies requesting the services (from each region and on each facility)
- customer satisfaction (via formal and informal feedback collection)
- the economic value of the activities (amount in Euro), to provide an economic dimension of the relevance of the system and to monitor the economic advantages it can deliver.

So the model that the BioCT partners decide to propose could be summarized as follows:

- Every regional cluster acts as an entry point to a decentralized system where some basic common rules are in place and are accepted by the facilities which are willing to be part of the system.
- These facilities formally agree to do this by signing, if applicable together with the

cluster involved, a framework agreement (MOU) where are stated the basic common rules about:

- Language of contracts and communications
- IPR
- Quality (GLP, GMP etc)
- Level of information and transparency to be provided
- Clear Advantages for SMEs
- Possible discounts policy
- Time of delivering (sure time for delivering and clear priority assigned)
- Quality to be assured
- Complementarity of the services offered

Some KPI (Key Performance Indicators) should also be identified in order to monitor the performances of the system and help the partners in taking further decisions.

This agreed, a prototype set of tools has been developed. The prototype – together with its business model - will be composed at the end by:

- a set of specific services coming from the different (shared) facilities
- an information package / marketing tool and marketing plan for promoting the offer towards the companies (at the beginning through the CEBR and BioCT web sites and also through the partners websites and the facilities websites).
- the set of accepted basic rules
- a coaching activity targeted to the newly developed cluster (within BioCT, Debrecen).

As previously stated, this approach could be compared to the definition of a “virtual CRO” offering a set of complementary services and will need to have a customer satisfaction tool attached to it.

It will be the duty of each cluster (through its cluster management company) to be able to channel that set of complete services towards the cluster companies. Here a “labelisation”

process (sort of “certification” and quality/reliability assurance process) could be useful and also recommended, in particular in view of an enlargement of the number of facilities being part of the “system”.

Some “labelisation” of the companies can also be useful but, in this case, it only means that they comply with some “light” conditions, for example being a SME, being part (or formal members, if this is the case) of a cluster and having accessed the “system” through the local cluster management company that acts as unique official entry point.

The result of the initial stage of this activity will be at the basis of some policy recommendations targeted both towards the EU for future trans-regional/trans-cluster policy actions and potential financing schemes (voucher schemes) and towards the local (regional) authorities, showing the benefits for the companies and for the cluster development. In such perspective the system has to be coherent with regional policies and to exploit opportunities already offered by local financing schemes.

The system, as it is proposed, is practically cost free and the self sustainability is assured both by the marketing approach and the synergies with public authorities schemes and policies, particularly for marketing costs and for the management of the process.

Advantages for the companies can be seen in having access to a set of specialised high level services at lower rate, under defined standard conditions, having a “tutored” access and a quality level guaranteed by the local cluster managing company.

3. The model proposed for the JAP

Starting from the options that are the basis of the consensus among the partner, the BioCT project developed a practical model based on tools as key components of the Joint Action Plan.

The elements of the JAP are

1) A **Marketing Plan** that defines the "market" and "strategic" approach of the sharing facilities system

2) A **Governance model** that defines the organisational issue of the sharing facilities system and also defines the basic common rules in accessing facilities and in delivering services with a self sustainable approach. It contains

- The strategic framework and the relationship model
- Contractual guidelines and basic standard contract that could be suggested
- Self sustainability and Key Performance Indicators guidelines

3) A **Memorandum of Understanding** between cluster managing companies and facilities that are interested/available to enter in the sharing facilities system: the MOU contains a first identification of facilities that are involved in such pilot phase

4) A **Financing model** that identifies the 2 extreme options for the sustainability of the system

3.1 Marketing approach

The purpose of this marketing plan for the sharing facilities proposed initiative is to set the direction to promote the business, build a customer base, meet its needs, and determine any opportunity to identify the way to implement a self-sustainability approach, both for the

system as a whole and for each single facility involved in the initiative. The marketing plan is intended to highlight:

- What the Sharing Facilities System will offer
- Who the Sharing Facilities System is selling to
- What type of Services Sharing Facilities System will offer
- Who the Sharing Facilities System competitors are
- What is the relevance to actual market of all those platforms
- How the Sharing Facilities System will promote its business at single level and as a whole
- How we the Sharing Facilities Systemand the single facilities involved will price the services

Market Study & Positioning

Competitive positioning is about defining how you "differentiate" your offering and create value for the market. It's about carving out a spot in the competitive landscape and focusing your company to deliver on that strategy. The marketing strategy for the Bio-CT Sharing Facilities System includes:

Market Segmentation: to define the overall market trend, how the Sharing Facilities System as a whole and at single level can follow it in terms of market share and profit position. The starting point will be to identify typologies of customers and different customer subtypes in order to tailor more specifically customized services.

Customers Identification: to define the customers' profiles, investigate the problems the customers might face when trying to find or purchase a scientific service and generate solutions for the identified problems, so the customers will get reasons for buying the products/services. In this step it is important to start defining possible synergies and unique

selling propositions between two or more facilities. The cluster level will be to starting point of such activity.

Competitors Identification: to list competitors both at national and European level. It is necessary to include any competitor that can solve the customers' problems, even if their solutions are much different than ours – they are still our competition.

Identify Service Offering & Pricing

The value proposition is a logical consequence of the previous phase. The aims of this new step are:

- Identifying areas where your competition is vulnerable.
- Determining whether you can focus on those vulnerable areas – they are major opportunities.
- Identifying products/services you can offer to meet the true needs of your market in a new and better way. Define customers' price expectations in terms of value, quality and service.
- Identifying the opportunities for new service development.
- Identifying a pricing strategy that is uniform between the members of the Consortium: policy, strategy and objectives should be combined in the pricing decision and aligned to all Sharing Facilities System members.

There are three core types of value that an initiative can deliver: operational efficiency (the lowest price), product leadership (the best product), or customer intimacy (the best solution & service). The single facility and the Sharing Facilities System as a whole should determine which one it is best equipped to deliver.

Create Compelling Messages

This a critical step in the Marketing Plan: developing a brand strategy to help the Consortium communicate its positioning and value proposition every time the markets are touched. An Integrated Marketing Communications (IMC) program should be implemented. It will entail the coordination and integration of all marketing communication tools, functions and sources within the Sharing Facilities System into a seamless program that maximizes the impact on the customers and other end users at a minimal cost.

Marketing Delivery Vehicles & Tools

A broad range of on-line and off-line marketing vehicles should be used to deliver compelling messaging to prospects:

- Information on existing facilities
  - Platform
  - Newsletters
- Networking events
- Seminar series
  - Facilities giving presentations
  - Focused on a technology
  - Focused on how to outsource
- CRO ”liaison officers” for each cluster involved and/or for each facility involved
- Production of guidelines
- Social media
- Networking at the level of Chambers of Commerce / EEN Network if applicable
- Distinctive Bio-CT Logo

- Selected partnering events attended by a one Business Developer representing all the Sharing Facilities System

The targeted customers could be grouped in:

- Small-Medium Pharma
- Small-Medium Biotech
- Universities and Non Profit Organizations
- Medical device companies
- Other CROs

Every customer has its specific needs. The winning approach is selling what the Customers need, not what the facilities offer. Our typical customers want more than a standardized service or a product off the shelf: they want customized solutions because in general we are dealing with high added value services. So Sharing Facilities System mission is to know as much as possible about its customers' businesses so it is possible to deliver the correct solutions over time.

Matrix of Bio-CT Services vs Customers' Needs

Facility	Pharma	Biotech	No Profit	Med. Device	CRO
LIMA	++	+++	++	+	+
Genopole	+	+++	+	-	-
UTOX	++	+++	++	++	++
...	...	...	...	...	...

Bio-CT's Ideal Customers (Especially SMEs)

The matrix represents the potential of each single facility already identified to efficiently address the needs from different groups of customers.

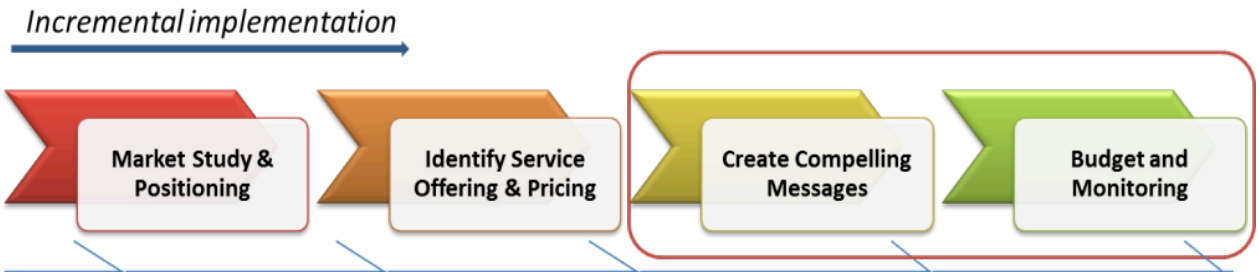
Budget and Monitoring

Once determined the Marketing Vehicles, the next step is to set sales goals, and identify KPIs for monitoring service delivery, problems, priorities and taking action to improve.

KPI monitoring: the reports should provide the members of the Consortium with summarised reports on service and product delivery. If there are KPIs for which problems have been experienced and which are important to customers (e.g. service availability), they should be highlighted. These reports should also mention any step it takes to improve customer service. The monitoring should be implemented with the final aim of:

- Continuous improvement
- Customer Oriented Performing Management System
- Identifying gaps
- Addressing gaps

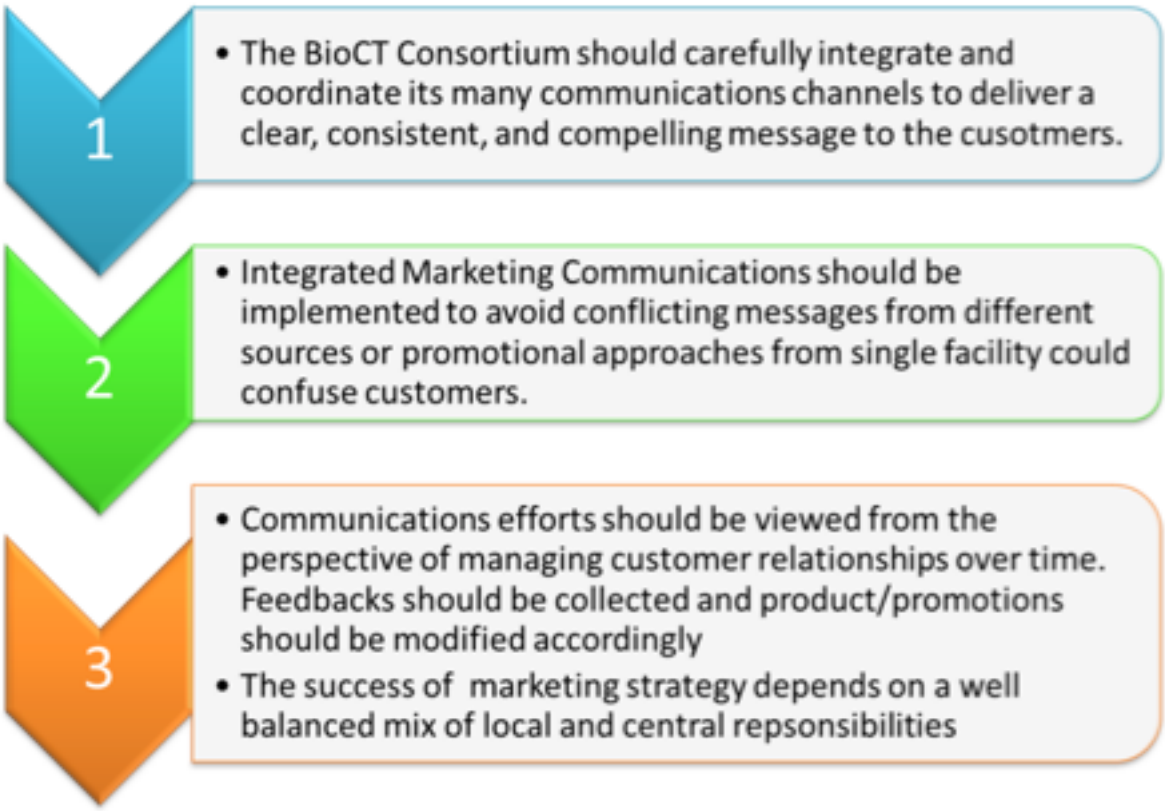
Costs for product advertising and promotion should be estimated at local and central level and the respective budget allocated. The JAP will focus only on costs related to the system as a whole and not on the costs of each single facility



Time	2 months	3 months	3 months	2 months-on
Level	• Local • Central coordination	• Local	• Local • Central coordination	• Local & • Central coordination
Output	• Shared report • Common and local marketing strategydefiniti on	• Single facility report	• Marketing campain kick -off	• Single facility • Customer report (Operational repor facultative)

Bio-CT Timeline for implementing the marketing plan

The timeline for implementing the Marketing Plan is shown in the Figure above. The implementation of each of these tasks will be monitored closely and evaluated for its performance.



The Pillars of Bio-CT Marketing Strategy

3.2 Governance Guidelines and organisational model

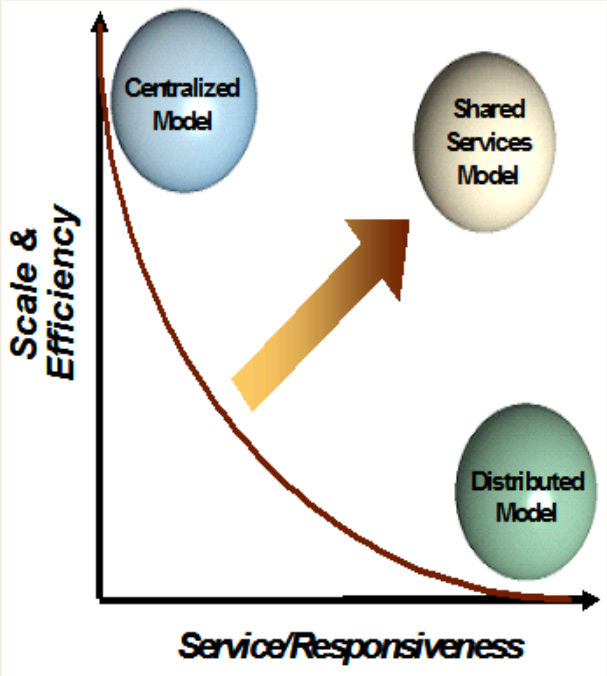
The JAP is based on discussions and decisions taken during the project development. In the following part we will try to resume the main problems related to the JAP implementation, from an organisational and governance point of view in order to introduce the JAP's main document, the Memorandum of Understanding that defines the "common basic rules" to be shared and accepted by implementation participants.

Key starting strategic elements for the JAP

One of the key elements in building the Bio-CT Sharing Facilities proposal is to ensure that the present and future research facility potential remains unlocked within the in scope

partners of the common initiative. This implies giving special attention to convergence regions and acceding countries, as well as to the efficient coordination of actions between partners. This could be achieved by increasing the integration of actions in the field of research and regional development and by adopting a wider view of the 'research infrastructure ecosystem' where many complementary activities and smaller infrastructures located in different parts contribute to the same goal.

The figure below highlights the major Bio-CT Shared Biotech Facilities critical success factors:



- **Commit to deliver unique high quality value services for each facility and define common cluster development strategy and marketing**
- **Maintain local leadership on services and apply market competitive pricing, according to local policies**
- **Address periodically performances and results and manage service continuous improvement**
- **Fairly define, at the correct detail level, the service management model (ie: tools for service definition and delivery)**
- **Manage confidentiality, publication rights, intellectual property and research failure through proper contracting:**
  - establish output expectations for optimal quality and service (SLAs)
  - optimize input for world class delivering capacity (OLAs)

Within the ERA, the development of Regional Partner Facilities (RPFs), i.e. facilities acting at regional level, is a new and important approach which assist in improving the European potential of research infrastructures. The Regional Partner Facilities would be associated with large-scale research infrastructures and through such links they could share some of the benefits.

The construction and operation of effective and timely common Sharing Facilities System is also to be seen as a key element of the process of building European Research Capacity. In our case, the Sharing Facilities System can be assimilated to a "large-scale research infrastructure" that requires efficient organization and management to achieve high standards of performance and development. The Bio-CT Sharing Facilities System will also provide the 'nucleus' for skills and knowledge formation through networked collaboration between researchers, SMEs and facilities. This could be achieved mainly through:

- Fostering human resources, which is key to the efficient operation and the long term vitality of the facility network. Tools have to be implemented to ensure and monitor continuity of accrued employment benefits for mobile researchers and experienced engineers and to promote management skills.
- Enforce the relationship between universities, partnering clusters, facilities, SMEs and local and regional authorities for an effective educational and scientific ecosystem, which can be attractive and supportive for industry. A significant increase in research funding across the EU, would require a concomitant increase in the output of trained researchers from the higher education sector. Facilities can contribute to this effort, helping by providing the multidisciplinary training needed by the industry and also to tackle the grand challenges.
- Better interaction between European and national programs, covering also the training of researchers through research infrastructures, should be encouraged: Bio-CT Sharing Facilities System should be seen and managed also as a "knowledge factory" and shown as a business and technological stimulator, encouraging, along with complementary reforms strengthening demand-led innovation and entrepreneurship (new spin-off and start up fertilization).

In order to identify resources, as first stage, we defined a specific Relationship Model that puts private and public initiatives (the so called PPP – Private Public Partnership approach) in the condition to reach common objectives. Going further through this PPP approach, we propose a proper transparent Governance System in order to maintain strategic sustainable development focus and minimise the risk of "avid opportunistic behaviours".

In such model, Public initiatives must ensure a positive ecosystem to foster innovative initiatives fertilisation and growth. Private actors involvement is necessarily linked to specific innovative opportunities identification and to performance measurement and monitoring/management tools set up and availability: cluster linked funding policies and added value services availability can be good examples (such as TT initiatives, export initiatives, quality labelling initiatives, training initiatives, etc.); territorial living labs and regional open innovation initiatives are also useful in order to build local innovative communities[2] .

On the other hand, governance issues represent a strategic and critical factor to address. In that perspective, Science and Technological Parks and in general system integrators and "interfaces" play a really important key role:

- acting as "entry point" for the local system reducing transaction costs for companies;
- leveraging on their specific asset and expertise in order to stimulate positive dynamics on territory;
- playing as promotional and common marketing engine both for public and private initiatives;
- representing a "think and acting" tank and a compensation chamber.

In some clusters a parallel organisation that involves industry associations and universities does already exist. Such organisation permits in to maintain a difference between the Science and Technological Park - that has its own mission - and the cluster managing organisation.

But in general, consolidated experience on the field has up to now demonstrated that Science and Technological Parks can be ideal cluster managing companies.

Moreover, we frequently see Science and Technological Parks building strong relations with already existing innovative clusters created and managed by different organisations, such as

2 « Living labs and open innovation policy in regions for the benefit of SMEs », Position paper to the Workshop on 27th January 2010, Brussels Date: 24.01.2010 CO-LLABS Thematic Network www.ami-communities.eu/wiki/CO-LLABS

entrepreneurial and sectorial association. When this occurs, Science and Technological Parks can synergise with those organisations providing technical and managerial skills, at negotiated market fair price.

In such context, governance and management should be highlighted as a potential issue.

At territorial level, it is necessary to outline that in the European experience several regions and countries have created such PPP based governance systems, that can be segmented in 3 main groups, of some interest for our purposes:

1. The first group focuses on few strategic and macro topics (as infrastructures, export promotion tools, common marketing, etc.). But, from the enterprise point of view, it becomes difficult to hold a position and suggest trends and technological priorities that meet the interest of the whole local business community, especially with regards to those clusters integrating many phases of the industry value chain. Science and Technological Parks start from such group in their initial development phase.
2. The second group represents the most common interaction model, with the cluster organization playing the role of facilitator and hub to merge complementary skills of production, research and consulting. Here, when projects deal with specific technologies and trends, the number of stakeholders can decrease dramatically and the collective framework vanishes. Such clusters are based on quality instead quantity and the governance system assures fair project building tools to every member of the cluster.
3. The third group operates basically on day by day practical interactions and may pose the problem of conflicts of interest since the cluster organization - which traditionally has daily contacts with the enterprises – should have the mission to act as public funds manager and enterprise excellence selector, role which imposes a more distant, institutional approach.

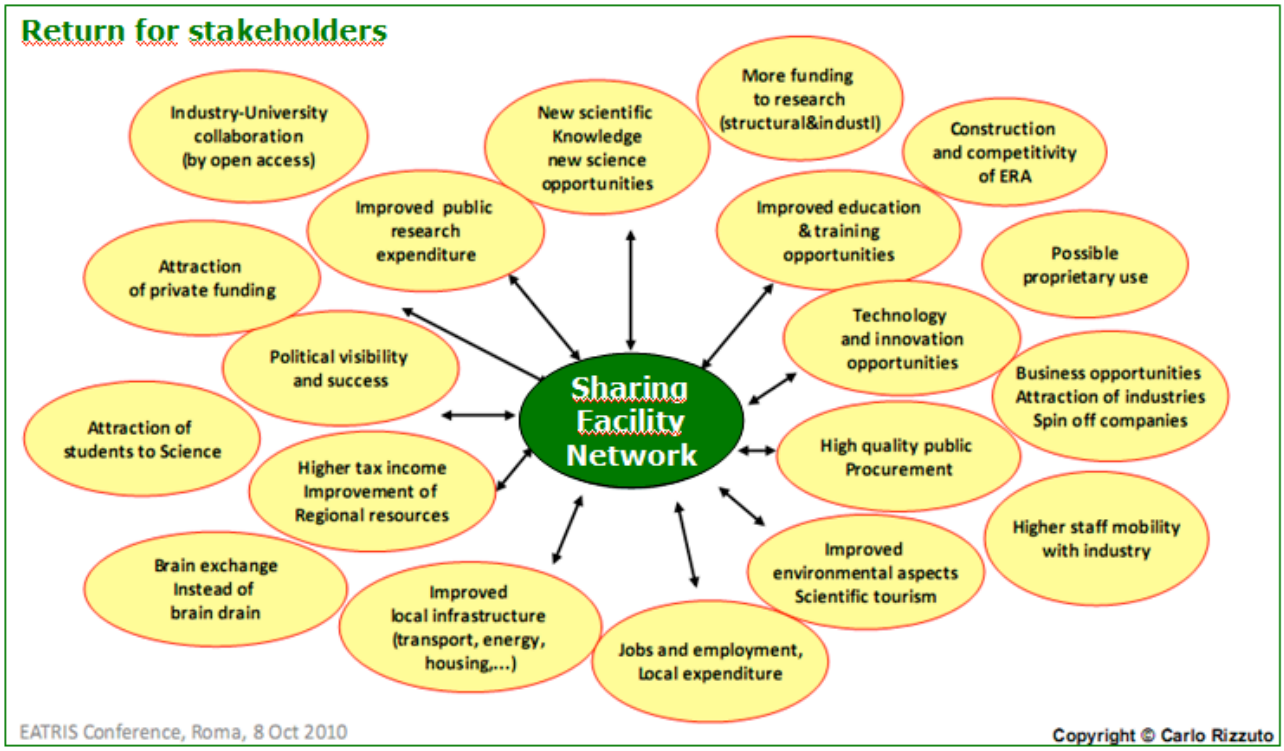
Managing stakeholders expectations

Comprehensive management methods aim to achieve a number of objectives, including high level user services, better interaction among all interested partners and future customers, productive links with industry and educational organizations, open access to scientific data, together with their use and protection.

Basically there are two options in facilities management: the vertical structure and the horizontal one.

Vertical research infrastructure management applies mostly to single sited research infrastructures: this is hierarchically organized with concomitant consultative bodies for policy making and managing processes. Spatial and horizontal oriented structure is applicable to distributed, e-infrastructure and virtual research infrastructures. This second managing model is structured around a core-hub model, supported by various specific councils with different responsibilities and competences. The basic feature of this kind of management organization is the multi layer level of governance.

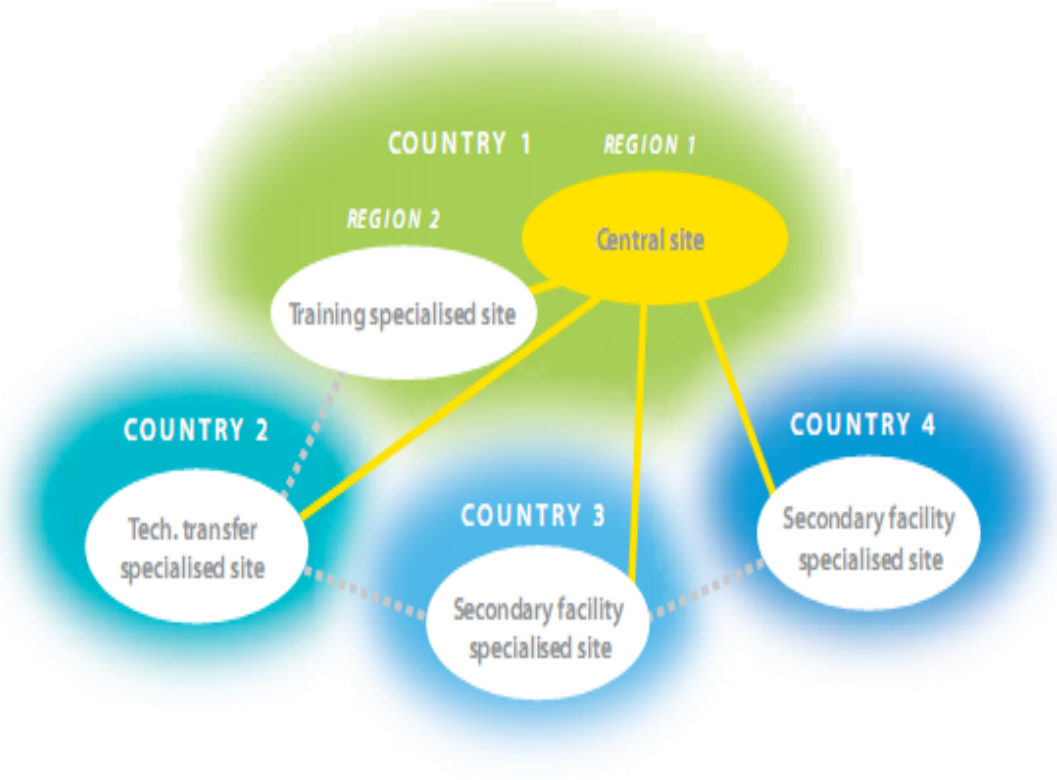
As the below picture shows, managing a Sharing Facilities System may addresses several stakeholder expectations, problems and challenges concerning not only globalization and internationalization, but also legal status, financial issues, governance, risk sharing, etc. A sound management structure depends on the implementation of the right governance structure for the virtual network and covering its effective use, maximum lifetime exploitation, maintenance and steady financial support.



Key principles guiding the governance of Bio-CT Sharing Facilities System should be:

- involving all clustering partners in the development, planning and overall monitoring of the facility;
- ensuring transparent and accountable governance and operational arrangements at least at systemic level. On issues related to management, it is recommended that further optimization of the use of research infrastructures could be achieved by enhancing cooperative and remote operation tools
- guaranteeing contemporary e-tools for communication and decision-making;
- ensuring that the research infrastructure research program is led by scientific members and a Scientific Advisory Board if necessary should be created to support this task at facility level

Figure 2: An innovative approach for addressing the site problem



According to the ERA, a possible solution is to leverage Bio-CT Sharing Facilities System to a broader approach by increasing the impact of the research infrastructure availability in Europe to combine in perspective a main site with secondary or specialized infrastructures located in other places (see figure 2 above[3]).

Common evaluation criteria for Management & Control

According to the ERA, the pan-European character of research infrastructures should normally be analysed according to "input" factors, which can be summarized under three categories, as indicated by the Community Research Programs:

- **Scientific excellence**: A research infrastructure of pan-European relevance should have the potential to bring significant improvements in the relevant scientific

3 Source: A vision for strengthening world-class research infrastructures in the ERAReport of the Expert Group on Research Infrastructures

and technological fields as compared with nationally available facilities. The facility should ensure open access to all interested researchers, based on the quality of the user proposals. Its research staff should have demonstrated a high level of appropriate research competences.

- **Capacity of management**: a research infrastructure of pan-European relevance should demonstrate appropriate management structure and procedures; quality and relevant experience of its staff; appropriate allocation of resources to be committed for its open access (budget, staff, equipment).
- **Capabilities to generate impacts:** a research infrastructure of pan-European relevance should possess appropriate capabilities (budget, staff) for the dissemination and/or exploitation of project results and knowledge, as well as for the management of intellectual property and for spreading scientific excellence in its particular domain. Such research infrastructures should prove their potential to make scientific knowledge and advances accessible to potential users, in particular for industry, in terms of direct access and/or use of the data generated by the facilities. They should also provide focal points for relevant training of researchers and engineers.

The impacts of research infrastructures relate to the impacts of the research and innovation that they facilitate and need, therefore, to be evaluated and rated consistently. According to the ERA, those impacts can be classified as direct scientific impacts, the new knowledge created and the theoretical advancement of science achieved via the research they facilitate, and indirect or technological impacts, the innovations in the production of goods and services that arise as spin-offs from the development of research infrastructures or the benefits accruing from the advances in scientific knowledge that stem from their operation.

Apart from scientific and technological impacts, other types of impacts could be summarized as follows:

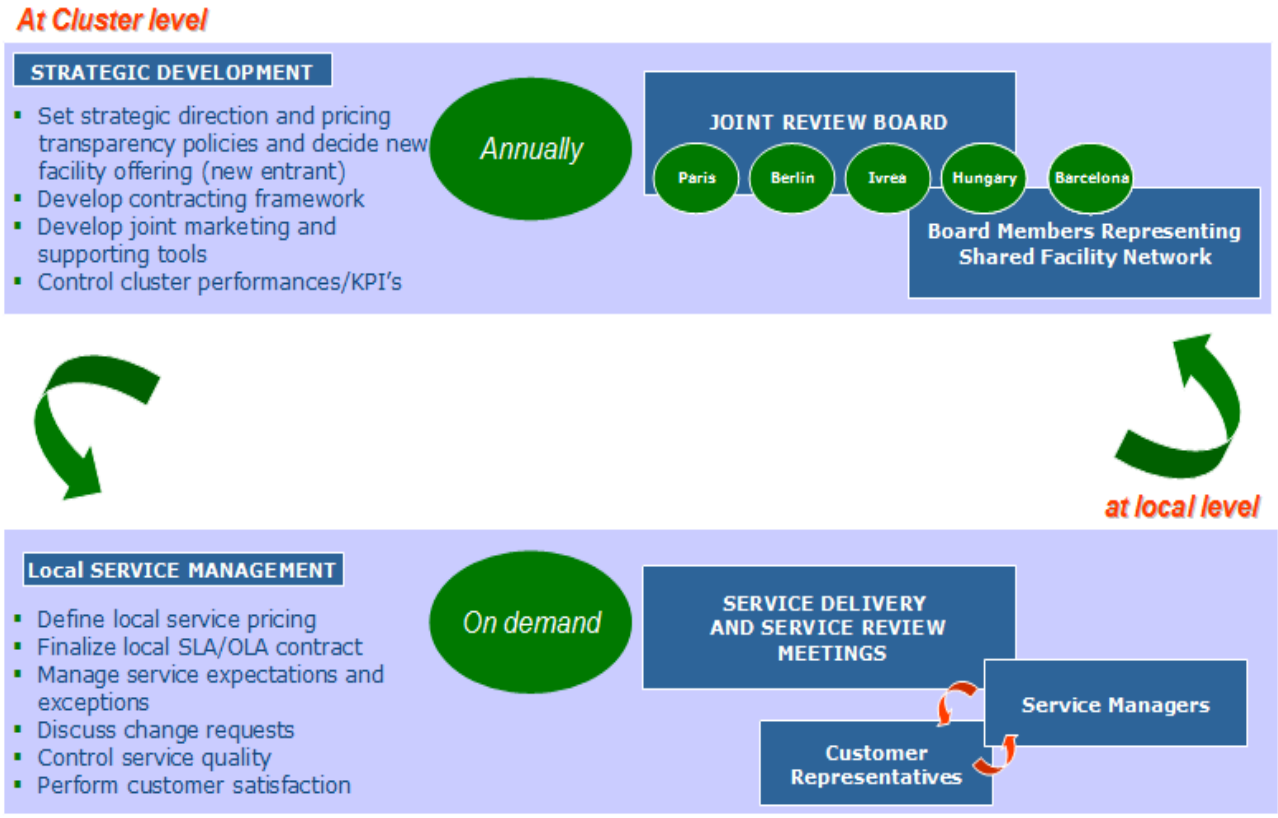
- **Economic impacts -** The short term contribution to economic growth and

employment arising from the construction and day-to-day operation of a research infrastructure. Medium to long-term effects on the economy relating to technological advances induced by the operations of an regional facility

- **Social impacts** - The contribution to general wellbeing arising from progress made in science, which stems from the research process and its contribution to improving the quality of life of citizens.
- **Political impacts** - The contribution to political stability and cohesion, resulting from the construction and operation of a research infrastructure and from the advances in science it facilitates.
- **Environmental impacts** - The direct effects relating to the construction and operation of a research infrastructure (e.g. energy consumption, CO2 footprint, water needs, other impacts on physical environment). Indirect effects such as the improvement in environmental conditions stemming from advances in science facilitated by a research infrastructure.

From a scientific perspective, economic and environmental impacts may appear irrelevant – the value of a research infrastructure to the process of scientific discovery may be regarded as the single most important aspect of its potential impact. But consideration of the economic impact of research infrastructures becomes particularly relevant in times of economic recession.

Starting from all the above mentioned elements, the picture below suggest a possible **relationship model** between strategic facility management development (at head of cluster level) and local service management level:



In order to reach this result it is necessary to outline a need that is not discussed here as an element of the JAP: a new generation of professional, full-time managers of research infrastructures is needed in order to ensure efficient and cost-effective exploitation of the available resources, as well as ensuring that top level science is carried out at all times.

Also, policy-makers need to get a basic understanding of the role and rules by which research infrastructures can make an effective contribution to their R&D programs, as well as to the economy through innovation and education, as real “knowledge triangles”.

It is essential that existing managerial expertise is made available in the most effective way and that as much hands-on experience as possible should be encouraged.

Contracting guidelines

As we outlined before, the relationship model that stands at the basis of the Bio-CT Sharing Facilities System is based on a contractual framework. World-class service contracting guidelines are the starting point to correctly design and then manage the system: the interactions between the parts are impacted by various factors that have to be addressed within the contractual framework. A major issue in the contracting phase, which is the starting step to organise, manage and maintain the system will be the failure to adequately address the needs of other dependent services in the contracts that govern a shared facility service and could seriously undermine the benefits of the two sets of arrangements. To some degree outsourcing arrangements are only just starting to tackle this issue. Flexibility, in terms of being able to change or terminate service arrangements, is key to tackling these issues. Adding special framework provisions that require suppliers to cooperate and coordinate with other third party suppliers are also useful. Probably the most important thing for the customer/SME is to envisage an overall strategy for their outsourcing, so that to the greatest possible extent they can identify areas of common dependency between suppliers and address those points in the established contract.

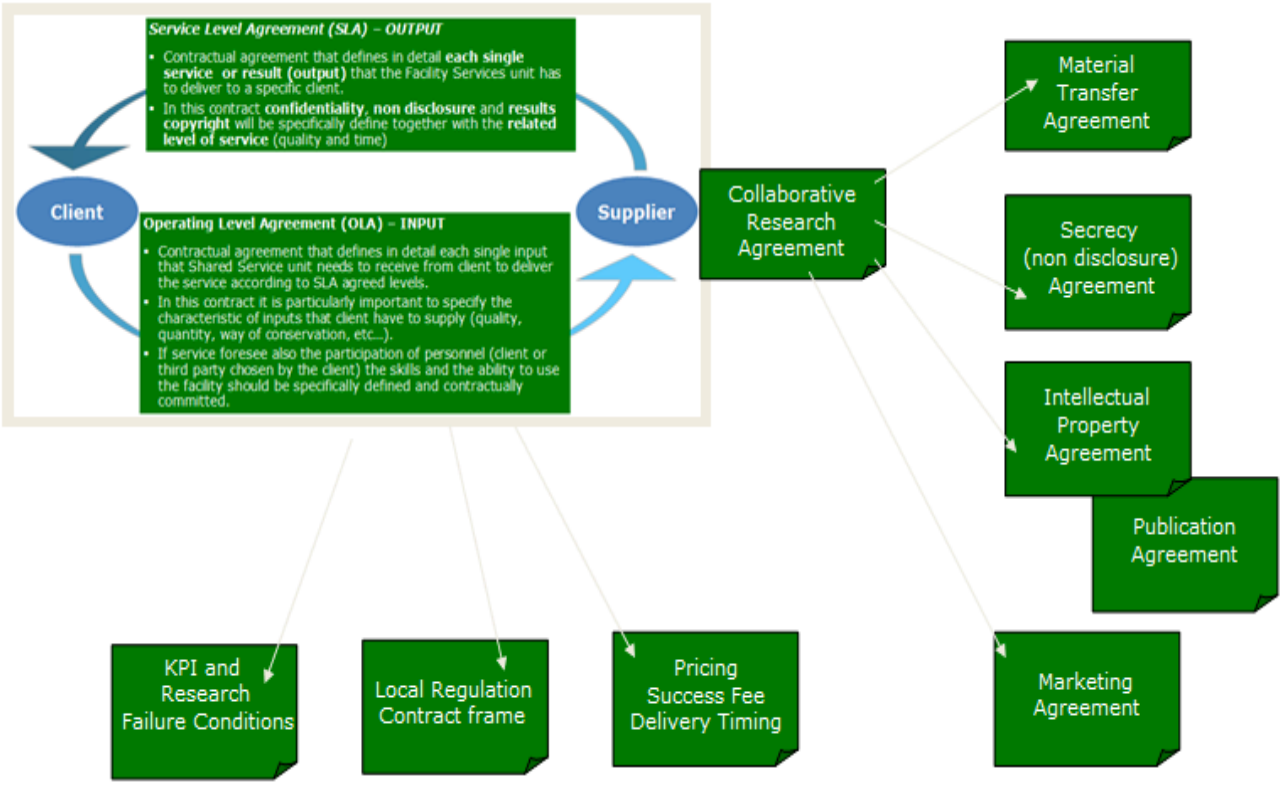
Service Level and Operating Level Agreements (SLA/OLA) guidelines

The Service Level and Operating Level Agreements (SLA/OLA) are a formal agreement signed-off between facility supplier and Client (SMEs) in order to define responsibilities and to motivate both parts to a continuous focus on end-to-end process improvement at the proper negotiated price. Every outsourcing agreement contains service level agreement (SLA) and operating level agreement (OLA), against which the service provider will be measured also if SLA and OLA are not explicitly identified.

For other areas of outsourcing, particularly those where there is less standardization in processes, the establishment of performance levels may be more difficult: this is an area where the biotech industry could use more planning because the industry's current

outsourcing arrangements tend to have relatively few performance measurement provisions.

Generally speaking, the Bio-CT Sharing Facilities System contacting framework can be summarized as follows:



The objective of writing a collaborative research agreement (that in our case can be represented by the SLA/OLA contracting frame) is to clarify, for both parties, what they are trying to accomplish together and to clearly set forth the rules that will govern the collaborative effort. A good partnership must be mutually beneficial and an effective collaborative research agreement will help both parties to understand and accept the mutual benefit as a goal. An effective agreement must be based on a real win-win relationship, one that is truly mutually beneficial. So to start with, the concept of the collaborative research project must involve a research project through which both parties benefit from the work that will be done. A poorly written agreement can tear apart an otherwise harmonious relationship. On the other hand, a well-written agreement, in which

all parties understand their responsibilities, will build and strengthen a productive scientific relationship. An effective agreement will be clear both to the researchers doing the research work and to the managers of both parties. And a well-written collaborative research agreement can lay the groundwork for moving the results of research toward commercialization.

Most collaborative research agreements have in general different general parts. They can also be somewhat flexible in the terminology they use, so the names assigned to the subparts are not terribly important.

Collaborative Research Agreements may include terms governing the following:

- The parties (2 or more)
- Field of use / Scope of work to be conducted
- Applicable law and compliance with export control and other laws and regulations
- Management and staffing of the research project, Project leaders (1 person identified for each party)
- Schedules and deliverables
- Publication of the research results
- Options to license the intellectual property arising from the research collaboration
- Confidentiality: care of data and confidential information exchanged during the research
- Transfer of materials among the collaborating organizations
- Use of Client name (and the collaborator's name) and use of facility suppliers name
- Rights and procedures to terminate the project
- Taxes, insurance, warranties, liability, governing law, and other items necessary for contracts
- Subject (possibly with annex to give details)

- Payment: amount, VAT, timetable, bank details
- Liability
- Dispute settlement
- Quality management

The Sharing Facilities System will not impose a standard contact to the facilities involved but it will suggest the above described guidelines as tool to align different contractual schemes

Licence agreement and Field of Use guidelines

As the name suggests, a field of use provision in a license agreement limits the licensee's rights in the licensed technology to specified applications.

Typically, the field of use restriction first pops up in the definition section of the license agreement, and is usually called the "Field". It will then appear in the grant of rights or actual license provision, where it serves as a limitation on those rights. For example, a grant clause with a field of use restriction may state that "Licensor hereby grants to Licensee a non-exclusive license of and under the Licensed Patents in the Territory to make, have made, use, sell and import Products for use in the Field".

Field of use restrictions deserve special consideration in biotechnology. Consider a Compound that might have potential preventive, diagnostic or therapeutic uses for several disease indications in both humans and animals. In the absence of field of use restrictions, the licensee would have rights to exploit the Compound in all of those fields, and if the license were exclusive, no one else would. If the license does have field of use restrictions, but they are not carefully considered and drafted, the licensee might not have rights to do what it wants to do. The goal in drafting field of use restrictions is clear and unambiguous language so each party (and a court, if it ever came to that) knows what is included and what isn't.

From the licensor's perspective, it wants the most narrow field of use that gives the licensee what it wants/needs, but also gives the licensor the opportunity to exploit the other potential uses of the Compound.

From the licensee's perspective, on the other hand, it wants as broad as possible a field of use (for example, therapeutic use in humans or cancer in general) or, ideally, no field of use restriction. Much will depend, of course, on the stage of development of the Compound.

Such element could be important in the finalisation of R&D agreement and service contracts and they have to be considered by the facility.

Biotechnology and Intellectual Property Rights (IPR) & Intellectual Property Protection (IPP) guidelines

One of the most important issues, which has been raised due to the emergence of modern biotechnology, is the legal characterization and treatment of trade related biotechnological processes and products, popularly described as Intellectual Property its protection (Intellectual Property Protection = IPP) and the Rights (Intellectual Property Rights = IPR), available to protect this property have been the subject of discussion in recent years.

In this connection, one may like to compare biotechnology with other technologies, the advances in which are covered by the patent system and are, therefore, routinely licensed and marketed.

The term property, is often found associated with physical objects only, such as household goods or land, for which ownership and associated rights are guaranteed and protected by law prevalent in a country. This property is described as tangible. Intellectual property, on the other hand, is intangible and includes 'patents', 'trade secrets', 'copyrights' and 'trademarks'. The rights to protect this property prohibits others from making, copying, using or selling the proprietary subject matter. Under biotechnology, one of the most important examples of intellectual property is the processes and products, which result from the development of genetic engineering techniques through the use of restriction enzymes to create recombinant DNA. The characterization of these research results as intellectual properties encourages industries to allocate labour, research and development (R&D) units and funding to facilitate the production of commercially marketable items.

Due to these intellectual properties, many legal and public policies, which are impediments to biotechnological research are also being challenged and are, therefore, undergoing changes. This is understandable, because if public policies do not allow the development and commercial use of an intellectual property, no industry would like to invest funds in this research.

The impact of IPR on the availability of genetic diversity will also be witnessed. There are also arguments against patenting life forms like transgenic animals and plants, because these patents will work as impediments in free exchange of genetic materials for improvement of crops and livestock.

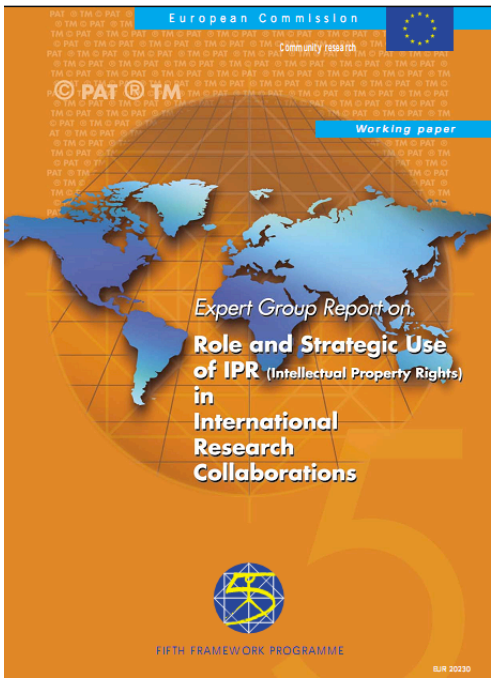
The Expert Working Group 'Role and Strategic Use of Intellectual Property Rights in International Research Collaborations' developed a broad strategic view of the various IPR and International Research Collaboration issues from a Research policy perspective: what are the issues, their importance, and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

To sum up the purpose of the report[4] is to develop a broad strategic view of various IPR issues from a Research policy perspective.

Key issues covered include:

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

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



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

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

It is common to assume that IPR frameworks are important in settling how the results of research collaborations are distributed between the various individual members or categories of members involved in collaborations. But IPRs are far more important than that. It is the IPRs and the conditions regarding their ownership and utilisation that determine the nature, scale and participation in such research. The increasingly important role of IPRs at all stages of the research and innovation process will have a determining effect upon the nature of collaborative research, its focus, and its success. The reason for this is that IPR philosophy is intricately bound up with, and controls, knowledge flow, creation, use and exploitation before, during and after a project.

Intellectual outputs from research collaborations include formally protected knowledge, tacit knowledge and other results such as commercial knowledge of markets, consumers and other 'non-scientific and technological' knowledge, as well as contributions to the pool of

public knowledge. Policies and strategies must therefore take account of this broad range of results.

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

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

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

The role of IPR, starting from element previously discussed is a key element in relations between a facility and a customer and from a contractual point of view they have to be treated with the right attention and with a full respect of IPR already existing and IPR that could be derived from the R&D and/or service activity.

Confidentiality/non disclosure agreement guidelines

This is one of the most important parts of the contracting frame in biotech facilities service modelling. As previously briefly stated, a non-disclosure agreement (NDA), also known as a confidentiality agreement, confidential disclosure agreement (CDA), proprietary information agreement (PIA), or secrecy agreement, is a legal contract between at least two parties that outlines confidential material, knowledge, or information that the parties wish to share with one another for certain purposes, but wish to restrict access to by third parties. It is a contract (or a specific part of it) through which the parties agree not to disclose information covered by the agreement. An NDA creates a confidential relationship between the parties

to protect any type of confidential and proprietary information or trade secrets. As such, an NDA protects non-public business information. NDAs can be "mutual", meaning both parties are restricted in their use of the materials provided, or they can restrict the use of material by a single party. It is common to assume that IPR frameworks are important in settling how the results of research collaborations are distributed between the various individual members or categories of members involved in collaborations. But IPRs are far more important than that. It is the IPRs and the conditions regarding their ownership and utilization that determine the nature, scale and participation in such research. The increasingly important role of IPRs at all stages of the research and innovation process will have a determining effect upon the nature of collaborative research, its focus, and its success. The reason for this is that IPR philosophy is intricately bound up with, and controls, knowledge flow, creation, use and exploitation before, during and after a project.

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

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

NDAs are an integral part of the contractual package that a facility have to offer to their clients/users particularly SMEs

The issue of Exclusivity/Requirements/Minimums: guidelines

Customers should not enter into an exclusive relationship, requirements contract or minimum purchase commitment with a supplier unless faced by some compelling need to use just one specific supplier or the customer receives such huge price concessions that it

justifies the loss in flexibility. While certain arrangements may by their very nature necessitate that the customer commit to purchase a certain minimum volume from a supplier, a customer should always maintain the flexibility to buy services elsewhere if at all possible (see discussion above).

The issue of Termination Fees and Costs: guidelines

Another barrier that a supplier can establish lower the risk of termination by the customer is represented by termination fees and costs clauses. If the supplier can either establish high termination fees or create enough uncertainty as to how they are to be calculated, it can achieve a chilling effect on the customer's termination plans. If termination fees have to be accepted, then they should be set forth in terms of actual payment amount by service and by year in a schedule to the contract.

Termination rights and cost of termination have to be in an explicit way inserted in the contractual relation in order to be fair and transparent.

Standard Basic contract suggested

Our model includes 3 standard basic contract that could be suggested to clusters and/or facilities interested and involved. Suggested but not imposed: each facility, following the guidelines could use its own contractual scheme

The suggested model covers:

1. The Material Transfer Agreement issue
2. The Non disclosure agreement issue
3. The service/R&D contract issue

Self sustainability and KPIs guidelines

The Sharing Facilities System have to be self sustainable i.e. it is necessary to identify the way to be - in perspective - not "public funding dependant". The resulting model is assuming

that only the service component of facilities have to be considered and evaluated in this perspective and only the relationship model has to be analysed. Facilities in such way could have other sources of resources for R&D and/or project realisation.

Sharing Facilities System model is a really flexible model where services are self sustainable because costs are re-paid by revenues.

Some public support could be anyway useful from this point of view, mote from the demand side than from the offer side. In order to stimulate companies, particularly SME, to use state of the art technologies and services a supporting scheme (e.g through vouchers such as in the FASILIS project - www.fasilis.eu) can be envisaged. The objective could be that of stimulating the demand, so favouring the "start-up" of the process.

In order to assess the self sustainability of the resulting system it is necessary to identify KPI (Key performances indicators) that are both a way to monitor activity but also a way to monitor the self-sustainability. The Bio-CT Sharing Facilities System model proposes in the following table a basic set of KPI that have to be used at facility level but also at system level.

Objectives	KPIs	Owner
Financial		
❑ Revenue Growth	❑ % Change in revenue	❑ CFOs
Customer		
❑ Acquire new customers (local/global) ❑ Customer satisfaction (local/global) ❑ Collaboration between facilities ❑ Networking events	❑ New customers/year ❑ Survey rating ❑ Number of collaborations between facilities in delivering services ❑ Number of networking events (local/global)	❑ CRO liaison officers ❑ CRO liaison officers ❑ CRO liaison officers ❑ CRO liaison officers
Internal Business Processes		
❑ New service introductions ❑ Cross-selling	❑ % New services ❑ % Cross-sell/tot up-sell in a year	❑ Business developers ❑ Business developer
Learning and growth		
❑ Customer database	❑ Project milestones	❑ Business developers

Notes:

- *CFO: Chief Financial Officer or any person in charge of monitoring Financials*
- *CRO Liaison Officer: is the person in charge of liaise with BD, scientific staff and the CRO Liaison Officers from other facilities*
- *Business developer: sale person in charge of promoting/selling/presenting services/attending networking events*

Such KPIs are suggested to each single facility part of the system and have to be assessed periodically as KPIs of the whole Sharing Facilities System. The data collection has to be performed at facility level and submitted to the the central platform/Joint review board for assessment.

3.3 The founding document: Memorandum Of Understanding

Starting from all the assumptions discussed, from the contractual guidelines and from the relationship model proposed and after reaching a consensus among the partners, an approach based on the creation of a Memorandum of Understanding that defines common basic rules that have to be accepted and shared between partners has been developed. Topics that are covered as strategic goals of the MOU are:

- Assure the access to shared R&D facilities and scientific services delivered by such facilities to companies, particularly SMEs present in all territories involved in the agreement.
- assure to such companies, particularly SMEs, parity of treatment irrespective of the territories where they are located.
- Develop a catalogue of scientific services delivered by single R&D facilities.
- Share information on technological platforms available in the involved R&D facilities.
- Promote the system of shared access to scientific services delivered by R&D centres involved resulting from this agreement in territories involved.
- Respect confidentiality and IPR rights of companies that will access the services.
- Assure transparency and communications to the cluster managing companies involved about the name of the companies, the number of services and the typology of services and related prices delivered, in order to assess the performances of the system.
- Agree and subscribe the Sharing Biotech Facilities Management & Control Basic Guidelines.
- Meet once a year in order to re-discuss the agreement, assess the performances of

the agreement, involve more R&D centres, enlarging the number of services offered in a shared way.

All cooperative activities that will be developed under the MOU will be conducted on the basis of the following principles:

- Mutual benefit, based on an overall balance of advantages.
- Mutual opportunities to engage in cooperative activities.
- Equitable and fair treatment for the participants.
- Timely exchange of information that may affect cooperative activities.
- Respect of the goals of the agreement.

Basic common rules, that will be the basic rules shared and accepted by all facilities and cluster involved will be:

A) Costs: cost sharing approach

As a principle, each party shall bear their own expenses related to the activities performed in each involved territory during the term of the agreement. The expenses for other activities shall be decided with mutual agreement.

B) Duration, Termination, Modification: based on flexibility and adaptability

- The proposed cooperation under this MOU will be non-exclusive and will have duration of an initial period of one year, unless terminated earlier by either party upon three months' notice in writing to the other party. The Parties may agree to extend this MOU for subsequent periods of one year or more.
- In the event of termination of the MOU, the cost-sharing agreements and project documents concluded pursuant to this MOU may also be terminated in accordance

with the termination provision contained in such agreements. In such case, the Parties shall take the necessary steps to ensure that the activities carried out under the MOU, the cost-sharing agreements, and project documents are brought to a prompt and orderly conclusion.

- Membership levels: all parties that will sign the agreement will be considered as "full members" unless they are not explicitely requesting an "Observer status" that will be valid at maximum of 12 months.

- This MOU may be amended by mutual agreement of the Parties reflected in writing

C) Treatment of information and intellectual property: respect of IPRs

The Scientific and technological information of a non-proprietary nature resulting from cooperation under this agreement shall be made available, unless otherwise agreed by the Parties.

In the event that proprietary information identified in a timely fashion as business-confidential is furnished or created under this agreement, each party and its concerned participants shall protect such information in accordance with applicable national laws and administrative practice. Information may be designated as "business-confidential" if a person having the information may derive an economic benefit from it or may obtain a competitive advantage over those who do not have it, and the information is not generally known or publicly available from other sources, and the owner has not previously made the information available without imposing in a timely manner an obligation to keep it confidential.

Information designated as business-confidential by a party or participant that has been forwarded as such to the other party or one of its Participants shall be used solely for the purpose of carrying out cooperative activities under this agreement, unless otherwise agreed by the participant(s) who furnished or created the confidential information.

D) Governance : transparent, light and adaptable

Parties recognise the need to meet at least once a year in order to discuss of the agreement, assess results, involve new partners and improve activities.

A "Common Central Platform/Joint Review Board" will organize an annual coordination meeting, where the participants will be:

- One representative for each territory/cluster involved and /or
- One representative for each R&D facility involved.

All decision will be taken following a simple majority rule (50%+1 rule)

A technical secretariat will be established in order to collect information and prepare the yearly meeting. The technical secretariat will be in charge for one year and during the yearly meeting a new technical secretariat will be identified**.**

The Common Central Platform have, as majors objectives, to guarantee the Sharing Facilities System efficient and effective and to ensure a world-class service governance – as starting point to correctly design and then manage the service the interactions between the customer and the supplier of the scientific services at systemic level. To reach this targets, the Common Central Platform could define in perspective a set of specific and basic ***Sharing Biotech Facilities Management & Control Guidelines*** including e.g.:

- ***Stakeholders Relationship Model:*** addressing major communication flows between different actors involved, clear major responsibilities and majors activities allocation.
- ***Basic Service Level Agreement (SLA) and Operating Level Agreement (OLA) Guidelines***: formal guidelines defined and agreed by "Common Shared Platform" that will contain the basic contracting condition that all Parties have to include in the detail local SLA per single shared facility. Those basic condition define the common service standard that will be signed-off between facility supplier and Client al local

level and aim to define responsibilities and to motivate both parts to a continuous focus on end-to-end process improvement at the proper negotiated price.

- ***Common Pricing Policy***: addressing common service charging policies per category of service in order to guarantee maximum price transparency, alignment and competitiveness between services locations.

E) Service Quality and Performance Control: based on high quality levels and their assessment

The Parties have to view quality and reliability as a basic tool for the success of the Sharing Facilities System.

Determining the quality policy is one of the main Party's task, and it shall be implemented by all the Parties at various levels. Criteria, at facility level, shall be determined to guarantee a professional service and the adherence to international quality standards (e.g. GLP, GMP, etc.) as agreed with the customer. Each Party will determine measurable objectives and targets and shall follow its achievement as a mean for examining the quality system with the aid of periodic reviews and quality measures. Collection of data will be implemented in every possible field, for follow-up, examination and implementation of the aim to constantly improve the service quality.

Facilities have to be transparent respecting their internal quality level.

To ensure proper service quality, the Common Central Platform will define, if necessary, ***Performance Reporting Model Guidelines*** that will include:

- Service Category Key Performance Indicators.
- Service Change Request Management.
- Customer satisfaction periodical surveys, at least once a year.

F) Communication & documents in order to assure a real information flow

The Parties agree not to use the names and logos of the other Parties in any communication intended for the public domain – written, verbal or electronic – without prior written permission of the other Parties. The signature of the MOU represents such permission.

All formal communications and contracts will be in in English. In order to facilitate the access to facilities to regional customers/SMEs, each Party has the right to create all the necessary support, translations and adaptations to the local language.

G) Transparency

The Parties shall have a high regard for the transparency of their activities and the need for including and informing all relevant stakeholders of the operations of research facilities. The Parties shall make every effort to consult all relevant stakeholders on documents under preparation that have a general interest. All documents relevant to the multilateral initiative shall be made available to the other Parties**.**

H) Advantages for SMEs

The Sharing Facilities System goal is to ensure “advantages” to the companies, particularly SMEs, which are going to access the shared facilities through the system. Advantages could be defined as: A) services offered at a discounted rate, B) quality and C) time of payments. The system is flexible respecting such advantages.

I) Ethics

All Parties must comply with relevant ethical guidelines and policies in force in their respective countries, sub-national jurisdictions, and institutions. All Parties also recognize the additional requirements for research on animals and will adhere to the relevant ethical principles.

H) Limitation of Liability

No Party shall be liable for any direct, indirect, consequential or other damages suffered or incurred by any other Party in connection with this agreement including, but not limited to, loss of revenues, profits or savings by a Party, or for any demands, claims, actions or proceedings against any other Party by any person that is not a Party to this agreement.

No Party will be liable for the actions of any other Party.

L) Arbitration

If a dispute arises out of, or in connection with this agreement, the Parties agree to meet to pursue resolution through negotiation or other appropriate dispute resolution process.

The pilot phase: facilities identified as starting elements

The Bio-CT project in the previous activities has identified some facilities that, following the service delivery model, has been used to prototype the system-

From each facility a standard description form has been filled. The basic elements of this form are:

- Scientific contact details
- Service description
- Methodology/technology that are available at the facility description
- Quality level assured
- Pricing Model

The starting facilities that has been used to develop the model are the following ones:

Lima Facility at Bioindustry Park Silvano Fumero (Cell and molecular biology and Bioanalytics)

Biomanufacturing facility at Genopole (Biomanufacturing)

UTOX facility at PCB Barcelona (Toxicology)

1) LIMA FACILITY AND SERVICES

0. Contact details

Bioindustry Park Silvano Fumero – Laboratorio Integrato Metodologie Avanzate

Via Ribes, 5 – 10010 Colleretto Giacosa (TO) – ITALY

Ph. +39 0125 561311 – Fax +39 0125 538350

Contact person Dr. Stefano Porzio - porzio@bioindustrypark.it

1. Services

Bioanalytics

- Quantitative analysis of small molecules, peptides, proteins, including protein biomarkers
- PK, TK and PK/PD data analysis
- Protein analysis: protein identification, peptide mass fingerprinting and MALDI imaging

Cell and Molecular Biology

- Molecular Biology: method setup, validation and application of quantitative RT-PCR and qualitative assays (SDS-PAGE, Western-Blot, Dot-Blot)
- Two dimensional electrophoresis, including Image analysis
- Cell Biology: setup of standard and costumer-dedicated cellular assays
- Cellular and Sub-cellular protein localization and protein-protein co-localization
- Recombinant protein production in bacteria (Lab-scale)

2. Techniques

Bioanalytics

- LC/MS/MS for analysis of small molecules and peptides (method setup, validation and application)
- ELISA for quantitative analysis of therapeutic proteins and protein biomarkers in clinical and preclinical studies (method setup, validation and application).
- In vitro Early ADME (intrinsic Clearance , CYPs inhibition, Protein Binding, etc.)
- Mass spectrometry analysis (MALDI TOF-TOF or LC-ESI-Ion Trap) of both low and high molecular weight compounds from synthesis or purification processes.

Proteomics

- Peptide mass fingerprinting by protease digestion and mass spectrometry (LC-ESI-Ion Trap)
- MALDI imaging of unlabeled compounds (endogenous and exogenous), including in situ peptide fingerprinting
- Two dimensional electrophoresis (2-DE) and 2-D western blotting

- Proteome and phospho-proteome analysis: qualitative and semi-quantitative by image analysis

Cell and Molecular Biology

- Seup, Validation and Application of:

i. Quantitative assays (qPCR and ELISA)

ii. Qualitative and semi-quantitative assays (RT-PCR, SDS-PAGE, Western-Blot, Dot-Blot)

- Setup of Pharmaco-Toxicological cell based assays:

i. Standardized assays (LDH/MTT cititotoxicity, apoptosis, etc.)

ii. Costumer-dedicated assays

- Cellular and sub-cellular protein localization and protein-protein co-localization by confocal microscopy
- Lab-scale recombinant protein production in bacteria, purification and testing (product qualification by activity/structure check)

3. Quality

L.I.M.A. activities are conducted according to a Quality Management System (QMS) highly inspired to principles of Good Laboratory Practices (GLP) and approved by the C.E.O. Bi.P.Ca.

This QMS is based on a Quality Policy defining the rules for managing activities in the following macro-areas:

- Personnel training and recording
- Activities planning, executing, monitoring, recording, reporting
- Equipment maintenance and recording
- Facilities management
- Documentation archiving

An internal Quality Assurance Unit monitor the accordance of activities and facilities to QMS requirements by implementation of a Quality Assurance Program based on audits to activities, facilities, procedures.

The goal of continuously improving the quality of data released by L.I.M.A. is achieved throughout the implementation of corrective and preventive actions following QA audits and a constant attention to personnel training on Quality System requirements.

4. Pricing

Standard price + methodology to calculate customized prices

2. GENOPOLE BIOMANUFACTURING CENTER

0. Contact details

Genopole – Centre de Bioproduction

Genopole Campus 1

5, rue Henri Desbruères – F-91030 EVRY CEDEX

Ph. +33 1 69 90 74 00 – Fax +33 1 69 90 74 01

Contact person: Mr Naceur Tounekti - naceur.tounekti@genopole.fr

Ph +33 1 60 87 83 00

1. Current Services

- Preclinical production of monoclonal antibodies and therapeutic proteins by mammalian cell culture
- Master & Working Cell Bank production
- Upstream and Downstream process development
- Preclinical batches production up to 200L capacity
- Consultancy : mammalian cell culture processes, scale up to manufacturing scale, quality controls,..

2. Techniques

The Center features a 1,300 m2 multipurpose production facility including 650 m2 of biosafety level 2 clean rooms (air classes ISO 8 to ISO 5).

Upstream processing – master and working cell bank preparation and storage, inoculum preparation, cell culture, clarification and concentration.

The three USP cell culture rooms are completely independent and enable the simultaneous production of different biologics.

USP room 1 is dedicated to the production of small batches. In this case, the culture is performed in flasks, roller bottles, wave system or disposable bioreactor systems.

USP room 2 houses a series of three bioreactors (working volumes 20, 200 and 1250 L) that can be used in a cascade configuration, according to the required manufacturing quantities. A third room is available for other cell culture technologies, such as multi-liter bag-based systems.

Downstream processing – purification, concentration (TFF), viral inactivation, nanofiltration.

The most innovative USP and DSP technologies (single-use material and connectors, aseptic transfer ports and modular equipment, etc.) are used to increase production flexibility.

Pharmaceutical utilities (purified water, clean steam, medical gases, etc.) are supplied to all production rooms and are monitored by a Building Management and Alarm System, as well as HVAC and premises parameters and operations, and alarm reporting.

Air treatment has been running with 10 air handling units which allows segregation and a very high level of independence and pressure control flexibility.

3. Quality

The Biomanufacturing Center's premises and utilities have been designed and built in compliance with European and North American Good Manufacturing Practices (GMP) requirements. The project has been monitored with design qualification from the design phase through to delivery of the installations. From delivery to commissioning, the Biomanufacturing Center's quality management system (QMS) has been running in accordance with ICH Q10 guidelines. The QMS is flexible and appropriately dimensioned for a contract development and manufacturing organization of this size. The objective is to obtain a EU GMP agreement for the manufacturing of API for clinical trials in 2013.

In the mean, the production Unit is open for services related to:

- Pre-GMP (research, preclinical grade) process development and optimisation for mammalian cells
- Process scale-up for mammalian cells (pre-GMP)

4. Pricing

On request – customized prices

3) Unit of Experimental Toxicology and Ecotoxicology (UTOX)

0. Contact details

Unit of Experimental Toxicology and Ecotoxicology

PCB – Edifici Cluster

C/Baldiri Reixac, 10-12

08028 Barcelona
SPAIN

Contact person:
Dr. Miquel Borràs (director):
Ph. +34 934037193
mborras@pcb.ub.cat

Alce Coloma (sales manager):
Ph. +34 934039710 – Fax +34 934037104
acoloma@pcb.ub.cat

Dr. Jesús Purroy

Director Científic
Parc Científic Barcelona
Baldiri Reixac 4, Torre R
08028 Barcelona

T +34 93 403 49 96
jpurroy@pcb.ub.cat

1. Services

- in vivo experimental toxicology
- in vitro experimental toxicology
- preliminary toxicological screening of bioactive molecules adapted to industrial needs
- risk analisys and expert reports
- nanotoxicology research
- ecotoxicology
- food safety quality and research

2. Techniques

In vivo experimental toxicology

- Systemic toxicity: histopathology, hematology and clinical biochemistry.
- Acute toxicity
- Repeated-dose toxicity
- Local tolerance / Sensitization:
- Irritation (skin, eye and mucous membranes)
- LLNA (Local Lymph Node Assay)
- Genotoxicity:
- In vivo MNT (Micronucleus Test)
- Comet Assay
- Toxicology of Reproduction and Development: Teratogeny and Reprotoxicity
- Prenatal Developmental Toxicity Study
- Reproduction/Developmental Toxicity Screening Test

In vitro experimental toxicology

- Systemic Toxicity: Citotoxicity
- Toxicology of Reproduction
- EST (Embryonic Stem cells Test)
- MM (MicroMass test)
- FETAX (Frog Embryo Teratogenesis Assay - Xenopus)
- WEC (Whole Embryo Culture)
- FET (Zebrafish Embryo Teratogenesis assay)
- Genotoxicity
- In vitro MNT (Micronucleus Test)
- Comet Assay
- MLA (Mouse Lymphoma Assay)
- Local tolerance
- Hemolysis
- RBC
- Carcinogenesis
- CTA (Cell Transformation Assay)

Ecotoxicology

- Field studies: sentinel species + exposure and effect biomarkers.

- Laboratory studies: battery of regulatory ecotoxicity assays (REACH, veterinary drugs and pharmaceutical /cosmetic/ food products).

Water environment (fresh and marine water):

- Acute toxicity in fish
- Algal growth inhibition test
- Daphnia magna acute immobilization test

Terrestrial environment:

- Plant germination and growth test
- Eisenia foetida reproduction test
- Nitrogen Transformation Test

Preliminary toxicological screening of bioactive molecules adapted to industrial needs

Customized battery of in vivo/in vitro toxicological assays for the screening and/or valuation phases of drugs, chemical, cosmetic and veterinary products.

Food safety, quality and research

Nanotoxicology research

3. Quality

UTOX activities are conducted according to two different type of Quality Management Systems (QMS):

1) The TECNIO one, highly inspired to principles of The ISO 9001:2000 and approved by ACC1Ó (Generalitat de Catalunya).

This QMS defines the different type of working process in the laboratory and the rules for the managing of the specific quality documents.

2) GLP: Good Laboratory Practices

The UTOX is in process of certification for Ecotoxicology assays (for veterinary drugs).

However, it is already able to perform other assays under the principals of GLP.

4. Pricing

Custom made according to the protocol.

3.4. Financial issues and public financing

The implementation of the MOU has been analysed from a financial point of view following two extreme working options:

1 - a market option: self sustainability has to be reached acting without a specific public support

2 - a vouchering scheme option, where a specific financial scheme has to be implemented to support the request of services by SMEs

The financial scenarios are based on the assumption that only the relationship model has to be analysed so no financial analysis has been realised to understand the self sustainability of each single facility involved. The analysis has the goal to understand if the Sharing facility system could be sustainable from a financial point of view and not if the facilities inside the system are sustainable from the same point of view.

1 - Market option

In such option no public financing scheme to stimulate request will be implemented. Each partner that will be involved will contribute to the overall system with:

A coverage of costs (maximum 1000 euro/year for partner) to cover general and common marketing activities will be mandatory for all involved partners.

In kind/in people contribution to cover the management of relations between facilities and SMEs will cover the rest of costs. In this scenario coverage of relationship and marketing costs will be the results of the success of activities (services delivered to companies) through a percentage of the overall value of services delivered through the system to the cluster managing organisations that will be competent (i.e. the cluster managing organisation and/or the facility itself that will be competent for territory and/or for the delivering of services).

Costs that are considered are:

- Personnel
- Marketing material and web site
- A Monitoring system (third party)
- Travel for the organisation of event that will be hosted free of charge by cluster managing organisation involved

No formal organizations will be built. Each facility has to cover its internal costs: as we stated before, we are proposing a relationship model and not a model of self-sustainability of single R&D facilities. Such data are based on the following assumption of costs at system level starting with 3 partner involved. Personnel costs are offered in-kind by the organisations involved. The considered scenario analyses also a possible growth in the use of services offered by the system and consequently calculates the costs related to such delivery (relationship costs).

Starting from those assumptions the scenario consider that a certain % of revenues is used to cover the relationship costs not already covered by the in kind contribution and the direct contribution by the facilities involved. The option implies that the involved cluster managing organisations will invoice the involved facilities in order to recover such costs.

Starting from those assumptions a development scenario has been considered: it starts from 3 facilities involved in the system at the beginning (year 1) and will reach 15 facilities after 10 years.

Costs that are considered are the following ones:

Year	Revenues from services (%)	Personnel	WEB + marketing material	consumables	Monitoring system	Travel
1		1500	0		0.00	0
2	15,000	11786	11,000		6000.00	4000.00
3	30,000	16971	11,330		6180.00	4120.00
4	42,000	25080	11,670		6365.40	4243.60
5	57,000	33566	12,020		6556.36	4370.91
6	67,500	41486	12,381		6753.05	4502.04
7	75,000	45729	12,752		6955.64	4637.10
8	78,000	49406	13,135		7164.31	4776.21
9	87,000	53837	13,529		7379.24	4919.50
10	97,500	58457	13,934		7600.62	5067.08

The final results from a revenue point of view is summarized in the table below:

Payment in

	Year	0	1	2	3	4	5	6	7	8	9	10
Partners contributions (Money)	Payment in	0	3000	4000	6000	8000	10000	11000	12000	13000	14000	15000
Partners contribution (in personnel)	Payment in	1500	9,900	13,200	19,800	26,400	33,000	36,300	39,600	42,900	46,200	49,500
Revenues from services	Payment in	0	15,000	30,000	42,000	57,000	67,500	75,000	78,000	87,000	97,500	105,000
B Other from financed activities	Payment in	0										
	A Total in(EURO)	**1,500**	**27,900**	**42,900**	**59,200**	**82,800**	**101,900**	**118,000**	**125,300**	**138,600**	**153,400**	**165,200**
	B Total in(EURO)	0	0	0	0	0	0	0	0	0	0	0
	A+B Total in (EURO)	1,500	27,900	42,900	59,200	82,800	101,900	118,000	125,300	138,600	153,400	165,200
		0	1	2	3	4	5	6	7	8	9	10

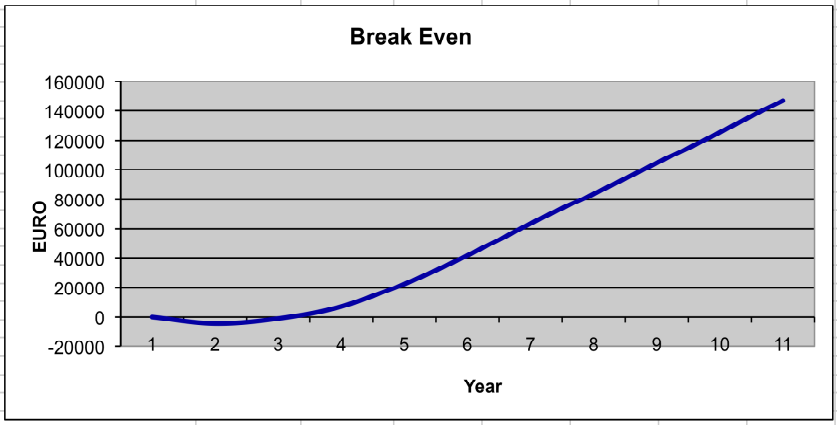
In such scenario the break-even point is reached at the 5th year of activity.

MOU bio-ct cash-flow -- (no VAT-no taxes): current cost + Investment + revenues + incentives + self-financing

	Rate of return:	14	Is the rate of return whichactors involved alternatively can get from other similar investments									
	Year	0	1	2	3	4	5	6	7	8	9	10
	Investment time periods	0	1	2	3	4	5	6	7	8	9	10
	In Payments	1,500	27,900	42,900	59,200	82,800	101,900	118,000	125,300	138,600	153,400	165,200
	Out Payments	1,500	32,786	38,601	47,359	56,513	65,121	70,073	74,481	79,664	85,059	85,059
	Δ	0	-4,886	4,299	11,841	26,287	36,779	47,927	50,819	58,936	68,341	80,141
	Net payments	0	-4885.714	4,299	11,841	26,287	36,779	47,927	50,819	58,936	68,341	80,141
	NPV a year	0	-4286	3,308	7,992	15,564	19,102	21,835	20,309	20,660	21,015	21,617
	Accumulated NPV a year	0	-4286	-978	7,014	22,578	41,680	63,515	83,824	104,484	125,500	147,117

Expected NPV and Break Even:

	NPV (Euro):	147,117	If the Net Present value is 0 or positive value in the last time period stick to investment
	Break Even:		Break Even is found in the first year where the Rate of Return is achieved (where the line hits 0 EURO mark)



To sum up:

The technical solution to transfer the 5% of revenues to cluster managing companies has to be defined according legal status and regulations. It could be a yearly clearing solutions between clusters or realised case by case.

2 - Vouchering scheme

In the second option a Public financing demand side stimulus will be put in place in order to boost the system.

Each partner that will be involved will contribute to the overall system with:

- In kind/in people contribution to cover management of relations between facilities and SME. In this scenario coverage of costs will be the results of the success of the vouchering scheme that will lead to services delivered to companies.

A percentage of the overall value of services delivered through the system will be assigned directly by the public bodies to the cluster managing organisation that will be competent (i.e. the cluster managing organisation and/or the facility itself that will be competent for territory and/or for the delivering of services). Each time a service is sold, a percentage of the revenue is assigned to the cluster managing company that represents the facility at local level as a "transaction fee". This will be paid by the public authority or by the central platform (through an agreement among public authorities). The financial transaction will take place once a year.

Costs that have been considered are:

- Personnel
- Marketing material and web site
- A Monitoring system (third party)
- Travel for the organisation of event that will be hosted free of charge by cluster managing organisation involved

No formal organizations will be built, except in case of interregional agreements to manage the inter-cluster vouchering scheme. Each facility has to cover internal costs (we are proposing – we remind it - a relationship model and not a model of self sustainability for the single R&D facilities).

Starting from those assumptions a development scenario has been analysed: it starts from 3 facilities involved in the system at the beginning (year 1) and it will reach 15 facilities after 10 years.

The considered scenario also analyses the possible growth in the use of services offered by the system, this time boosted by the vouchering scheme and calculates the costs related to such delivery (relationship costs).

Starting from those assumption a certain % of amount of services offered through the vouchering scheme is used to cover relationship costs not covered by the in kind contribution and direct contribution by facilities involved as anticipated below.

Analysing a 10 years scenario we could have the following data for costs:

Year	Personnel	WEB + marketing material	Monitoring system	Travel	TOT
0	1500	0	0.00	0	1,500
1	14614	11,000	6000.00	0.00	31,614
2	22629	11,330	6180.00	0.00	40,139
3	34886	11,670	6365.40	0.00	52,921
4	49029	12,020	6556.36	0.00	67,605
5	61286	12,381	6753.05	0.00	80,419
6	70243	12,752	6955.64	0.00	89,951
7	77314	13,135	7164.31	0.00	97,613
8	84386	13,529	7379.24	0.00	105,294
9	93343	13,934	7600.62	0.00	114,878

The final results from a revenue point of view is summarized in the table below

Payment in

	Year	0	1	2	3	4	5	6	7	8	9	10
Partners contributions (Money)	Payment in	0										
Partners contribution (in personnel)	Payment in	1500	9,900	13,200	19,800	26,400	33,000	36,300	39,600	42,900	46,200	49,500
Revenues from services	Payment in	0	15,000	30,000	48,000	72,000	90,000	108,000	120,000	132,000	150,000	450,000
	Payment in	0										
B Other from financed activities												
	A Total in(EURO)	**1,500**	**24,900**	**39,900**	**61,200**	**91,800**	**116,400**	**141,000**	**156,300**	**171,600**	**192,900**	**496,200**
	B Total in(EURO)	0	0	0	0	0	0	0	0	0	0	0
	A+B Total in (EURO)	1,500	24,900	39,900	61,200	91,800	116,400	141,000	156,300	171,600	192,900	496,200

0	1	2	3	4	5	6	7	8	9	10

Following this scenario the sharing facility system will reach the Break—even point after 5 years.

MOU bio-ct cash-flow -- (no VAT-no taxes): current cost + Investment + revenues + incentives + self-financing

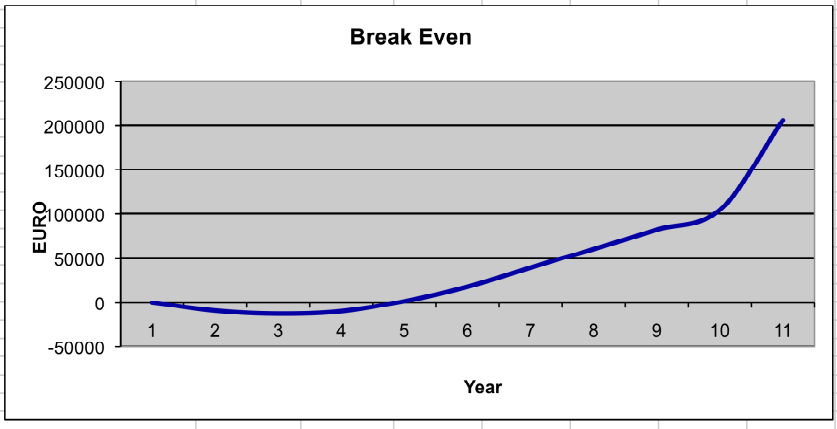
Rate of return: 14 Is the rate of return which actors involved alternatively can get from other similar investments

Year	0	1	2	3	4	5	6	7	8	9	10
Investment time periods	0	1	2	3	4	5	6	7	8	9	10
In Payments	1,500	24,900	39,900	61,200	91,800	116,400	141,000	156,300	171,600	192,900	496,200
Out Payments	1,500	35,614	44,259	57,165	71,976	84,921	94,588	102,389	110,213	119,945	119,945
Δ	0	-10,714	-4,359	4,035	19,824	31,479	46,412	53,911	61,387	72,955	376,255
Net payments	0	-10714.29	-4,359	4,035	19,824	31,479	46,412	53,911	61,387	72,955	376,255
NPV a year	0	-9398	-3,354	2,724	11,737	16,349	21,145	21,545	21,520	22,434	101,492
Accumulated NPV a year	0	-9398	-12,752	-10,029	1,709	18,058	39,203	60,748	82,267	104,702	206,194

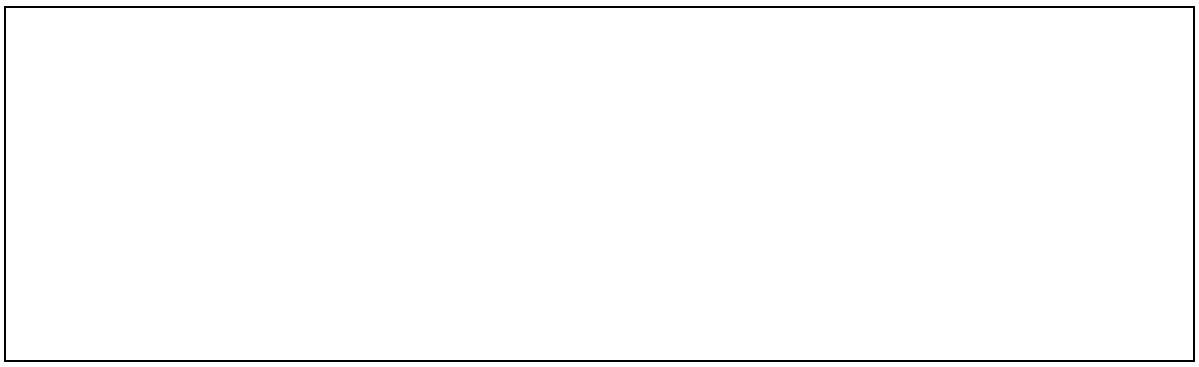
Expected NPV and Break Even:

NPV (Euro): 206,194 If the Net Present value is 0 or positive value in the last time period stick to investment

Break Even: Break Even is found in the first year where the Rate of Return is achieved (where the line hits 0 EURO mark)



To sum up:



The technical solution to transfer the 2% of revenues to cluster managing companies has to be defined according to each legal status and regulations. It could be a yearly clearing solutions between clusters or realised case by case.

4. Transferability and scalability of the model

The model proposed in the framework of the JAP is sector independent, i.e it will be possible to implement a similar tool in any different industrial sector with few adjustments (i.e. the average value of a service). The complexity of the model will probably require a few adjustments according to the different sectors and sectorial specific initiatives have to be implemented. The model is anyway flexible and could be adapted to different external conditions.

Following the vouchering scheme options probably the model is easily scalable and transferable to other sectors and could be used as an element of industrial policy and/or cluster policy.

5. Policy implications and recommendations

Starting from what we previously discussed we can identify 5 policy recommendations related to the implementation of sharing facilities schemes:

1. Use of vouchering schemes for SME to access sharing facilities schemes: Regional authorities have to support demand of scientific services as a tool also to increase the use of local facilities

2. Inclusion of the possibility of trans-cluster sharing services schemes in public financing schemes: a complementarity approach allows the regional authorities to reach a critical mass at local level and, at the same time, to offer to local companies the access to services/facilities that they need in other European regions.

3. Support the creation of state of the art facilities: as a consequence of the complementarity approach at regional level, it will be possible to have state of the art world class facilities that could be integrated in pan European and transregional networks.

4. require self sustainability plans to facilities financed by public financing schemes: regional authorities have to keep in mind self sustainability as a prerequisite of such state of the art facilities

6. Conclusions

We are in a global world and this means that competition is global. Particularly in innovative sectors, such as life sciences, it is necessary to cope excellent science with the ability to transform it in innovations. Cluster competitiveness passes through local pre-requisites but also through the ability to survive this global competition by assuring to local actors (companies, research institutions, foundations, citizens) the best condition for growth. This process is based on a really simple concept: the smartest will survive. Quantitative dimension alone is not enough to assure growth and prosperity. Quantitative dimension in a cluster requires endogen growth and in a global world where resources are more and more scarce, this is a real challenge. At the opposite, the smartest cluster are characterized by the ability to learn, adapt and innovate "vis a vis" external challenges. They are able to offer to local actors, in a specific territory, the best conditions through the creation of support processes and growth dynamics that are the results of the creation of a value network i.e the creation of an innovative ecosystem that trespass the physical boundaries of a specific cluster.

The value network approach is based on simple concepts: the ability to interact with other clusters, the capability to adapt local conditions reacting to external dynamics, the capability to anticipate changes in the external environment, the flexibility in changing the typology of links with other clusters part of an overall trans-cluster value creation network and an high degree of innovation in science, but also in the capability to transform science in innovation and in the capability to share in a smart way such innovations with other clusters.

The availability of key facilities and services able to support the development of products of internal actors of a cluster, particularly SMEs are one of the “processes” that in a value network environment have to be supported by clusters. Particularly start-ups and SMEs have difficulties in identifying opportunities, managing relations with facilities and identify solutions. They require support at different levels:

- identification of the best solutions
- managing of a relations
- transformation of a plan in activities
- assessing results

Usually companies have tactical goals and they miss the real point: the identification of key facilities and services as a tool for the development is a strategic process that will affect the potential success of a company. It is a process that requires critical mass in knowledge and the ability to do it. Such approach requires a strategic vision based on the concept of partnership and community where clusters - and facilities inside clusters - are able to interact with each other in order to reach a win-win condition and to build “flexible alliances” focused on the support of product development within companies. They are able to face the dimension/quantitative issue through a smart approach to development.

In such context clusters are usually able - as a system - to offer to local companies a set of support tools. But, at the same time, many European cluster are competing to support local companies “against” companies located in other European clusters. This is not a smart approach to development. If we agree that all clusters are facing the same international competition problem and that markets are global, clusters have to work together to offer to local companies the best opportunities as a direct consequence.

Such partnership based vision linked to the value network approach leads to a new strategy to support the product development of companies. Competitive clusters are able to create a

wider community of clusters that are able to interact each other and to build together support path for all their local organizations. They are able to interact with clusters representing different technological domains (i.e converging technologies), their are able to share knowledge and tools in an open innovation context, they are able to create trans-cluster offers activating local organization in different and focused support processes. It is no more necessary that all the elements of a development process are managed locally: the processes that support a company will be the result of the interaction of skills and competencies that are available in different clusters. This will be the future: smart clusters working together.

Annexes

1. Marketing plan presentation
2. MOU model
3. Standard contacts to be used as reference
    - The Material Transfer Agreement issue
    - The Non disclosure agreement issue
    - The service/R&D contract issue
4. Financial scenarios