

HAND BOOK

OF RECOMMENDATIONS
FOR INTERNATIONALISATION
AND BEST PRACTICES



bioXclusters
European Innovation Worldwide

Handbook

of recommendations
for internationalisation
and best practices

“Coming together
is a beginning;
keeping together
is progress;
working together
is success”.

Henry Ford

A common goal

bioXclusters is a European initiative, funded by the European Commission (Directorate General for Enterprise and Industry), financed under the CIP programme (Competitiveness and Innovation Framework Programme). It unites four bioregions in Europe with one single overarching aim - supporting the competitiveness of the SMEs in the four European clusters by facilitating internationalisation and by creating a single European entry point for global players in the life sciences sector. The four partners in bioXclusters are Biocat, Catalonia (Spain), BioM, Bavaria (Germany), bioPmed, Piemonte region (Italy), and Lyonbiopole, Rhône-Alpes region (France). The project also benefits from the know-how and long-standing experience of the regional development agency ERAI (Entreprise Rhône-Alpes International), which is the coordinator of the project.

Strengthening and promoting the international competitiveness of life sciences' sector SMEs beyond Europe is an essential task in an increasingly globalised environment. One main argument for this is the observed growth effects of cross-border venturing, and the "demonstrated capacity of SMEs to drive economic development at national, regional, and global levels" (European Commission, 2007). Meeting the requirements of the accelerated globalisation process that markets have experienced over the last 30 years, and designing tailor-made internationalisation strategies, are crucial goals for sectors such as the biotechnological, biomedical and medical technology sectors, which are by definition global.

With this objective in mind, the bioXclusters "Handbook of Recommendations" presents the conclusions of the two-year (2012-13) project, resulting from the work of the four leading clusters along with the agency ERAI. Pooling their knowledge, resources, skills and good practices has led to this manual, which is focused on three markets in particular: Brazil, China and the United States, although there are future plans to broaden this focus.

After analysing the specific internal value creation processes of the consortium regions, it was possible to identify meta-cluster processes and input opportunities that could increase the efficiency and efficacy of internationalisation activities for all partners and to supplement traditional go-to-market strategies.

From basic research to the production and marketing of new therapeutics or innovative medical devices, the whole life sciences sector is making waves in the international arena, and the capacity of SMEs and larger-scale businesses to act and compete in this environment is vital to the development and future viability of the European life sciences sector.

Internationalisation should influence both the field of research and scientific exchange, and of business partnering and commercial promotion.

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1

Specificities and characteristics of the life sciences sector

Key messages:

- *Sector with high societal impact (biotech, medtech and healthcare).*
- *Very different sizes of companies: high proportion of SMEs (a sizeable proportion are made up of 5 to 10 employees).*
- *Public health system is the main customer but the patient is the final target.*
- *Large amount of economic resources needed and long time-to-market, if reached at all.*
- *Health systems and regulatory frameworks vary substantially across countries.*

This handbook aims to contribute to the understanding of new venture internationalisation by first analysing how the particularities of the life sciences industry shape the internationalisation process of a company. These particular characteristics of the sector must be borne in mind when designing internationalisation strategies. Life sciences, which broadly comprise the medical technology, pharmaceuticals and biotechnology subsectors, are typically considered a high-technology industry. However, fundamental differences distinguish the life sciences industry from other high-technology industries; for example, the life sciences industry relies on science-based knowledge and aims to improve the quality of life. It is therefore a sector with an especially high societal impact through its direct influence on public health. At the same time, product development is particularly expensive and more risky than in other fields.

In addition, the life sciences industry is highly regulated, and all international business activities must comply with varying local demands for their products. Moreover, the financing of the healthcare sector differs among countries. Thus, the global development of a product is a complex endeavour, including expensive and complex clinical trials, the difficult financing of a long R&D process, variable regulatory demands, difficulties in gaining access to hospitals and doctors, and difficulties in scaling-up marketing and sales.

Importantly, a main issue setting the life sciences sector apart from other sectors is that there are several kinds of organisations integrated along the value chain: from basic research (private and public research centres, hospitals) to product development (start-ups and SMEs) and market (SMEs and larger pharmaceutical companies). These organisations and companies of varied nature require a wide range of strategies, from exploration (basic research) through examination (e.g. clinical trials) to exploitation (dedicated biotechnology firms).

IN THE SCIENCES SECTOR THERE ARE SEVERAL KINDS OF ORGANISATIONS INTEGRATED ALONG THE VALUE CHAIN: FROM BASIC RESEARCH (PRIVATE AND PUBLIC RESEARCH CENTRES) TO MARKET.

These varied organisations and enterprises work in the same fast-evolving environment of healthcare. However, close communication and the monitoring of needs among the various stakeholders can be challenging. This is an area where cluster management organisations can play an important supporting role in bringing people together and facilitating exchange. We should not lose sight of the fact that the final customer of biotech products, medical devices and other healthcare solutions is usually the public healthcare system, which pre-determines treatment options and also negotiates the price. The patient is the final target and end user, but –unlike in most other sectors– does not have a direct influence on the choice and price of the product.

The size, as well as the nature of companies in the life sciences sector, is diverse. Most companies, however, fall into the SME (Small and Medium-sized Enterprise) category and only a few are large companies (in the partner regions of bioXclusters, 5-10% of the total number). This is especially true in Europe.

Another specificity of the life sciences sector is the time companies need to reach the market and obtain results with their products – an average of 10 years for drugs and 5 years for medical devices. A great amount of economic resources are needed and there is often no guarantee of results. Only few companies already have products on the market and many of them have a portfolio of products in development phases. Many projects are discontinued after a period of not producing positive results, and numerous expensive clinical trials do not lead to the expected outcomes, leading to failure of the candidate drug and, in some cases, of the entire enterprise.

Healthcare systems vary substantially from one country to another, and in particular their regulatory framework may differ considerably. It is an emerging global trend that national healthcare policies are going beyond the strictly clinical aspects of pharmaceuticals to the wider social

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and economic aspects. Depending on a country's political economy, regulation is exercised in varying degrees on the production and/or distribution and marketing of drugs. Regarding life sciences technology, largely non-public healthcare systems, for instance that of the U.S., are not proactive in implementing new technologies. In contrast, systems with centralised public management and large public health systems tend to have stronger links between technology assessment and technology management (PHR, 1997).

Indeed, universal healthcare systems vary according to the degree of government involvement in providing health care. For instance, in France, Spain, Italy, Australia and the Nordic countries, among others, the government is heavily involved in the commissioning or delivery of healthcare services and access is based on residence rights, not on the purchase of insurance. Other countries, like Germany, have a much more pluralistic delivery system, based on obligatory health insurance with contributory insurance rates related to salaries or income, and usually funded jointly by employers and beneficiaries. Yet other countries, such as the Netherlands and Switzerland, operate via privately-owned but heavily-regulated insurers that are not allowed to make a profit from a legally-established part of the health insurance provided, but that can profit by selling supplemental insurance.

The high level of funding needed, the comparatively long time-to-market, and the regulatory burden can hinder the ability of companies in the life sciences sector to attract venture capital, especially during times of limited fundraising and in early stage phases.

2



Internationalisation in the life sciences sector

Key messages:

- *International cooperation starts in early development stages. Most companies/projects in the life sciences are 'born global'.*
- *The manufacturing process is not the determining factor for internationalisation, while partnering, looking for synergies/complementarities, licensing and know-how are essential.*
- *Europe is considered a "domestic" market. The US is often the main target country outside of Europe, despite its relatively low accessibility.*
- *Clusters play a key role in helping companies in their internationalisation process.*

SMEs and clusters on occasion face internationalisation as an added difficulty to normal enterprise. In the life sciences sector, it is essential to grow internationally because the market as well as the competition are global in nature. However, the SMEs often do not have the internal skills and experience to reach out to international markets. They need support to define their strategy, to identify the appropriate goals and the skills and resources that are necessary, as well as entry points and partners in international markets.

Internationalisation can refer not only to companies who target other markets but also to companies who want to attract clients from other markets to Europe. Clusters play a key role in helping both, in particular for the latter, by helping to increase the attractiveness of European regions for companies based outside Europe, i.e. publicising their good infrastructures, competitive conditions, logistical and service support, soft landing options, etc. These are key concepts for increasing our visibility as a gateway for foreign companies potentially interested in Europe. The intensification of foreign trade has led many large-scale life sciences companies to expand their sales and distribution activities and clusters may help to attract investments in Europe from these companies.

On the other hand, most companies who target outside markets are already "born global", with partners in several European countries and established partners outside Europe. Some European studies have shown that starting activities abroad at a very early stage in their life cycle is the preferred internationalisation strategy of SMEs (e.g. Kilantaridis & Levantis, 2000). Many of these companies have only a young history and therefore little experience of establishing new links. Their business models are frequently based on a protected technology the development of which is associated with a high investment in R&D.

INTERNATIONALISATION IS NOT AN OPTION IN LIFE SCIENCES, THE PATIENT IS GLOBAL AND NO PRODUCT IS DEVELOPED WITH THE TRADITIONAL APPROACH OF LOCAL MARKET FIRST, FOREIGN MARKETS LATER.

Internationalisation can be viewed as an ongoing process in which 'born global' SMEs try to prevent uncertainties in their international involvement by increasing their knowledge of the market. Knowledge of the target markets often informs the companies' internationalisation process. In this context, the role of clusters becomes essential.

Our perception, after many years of working alongside life sciences companies in their internationalisation, is that the contacts and first collaborations with partners in other markets can start at the research & development stages. In most cases, what determines the approach to foreign markets in the life sciences sector is not the manufacturing or the commercialisation of the products, but, at very early stages, the search for resources (e.g. financial resources), R&D cooperations, licensing and know-how. The joint efforts of clusters within the bioXclusters project have been particularly significant in this context in terms of providing the know-how necessary to approach the international venture.

In summary, a high percentage of projects and/or companies are already born global and therefore internationalisation seen from the traditional point of view of "exportation of goods and services" is not the "one size fits all" approach best suited for all of them.

In addition, in the context of life sciences no client or potential client is exclusively local. Drugs, diagnosis kits, medical technologies and many other products are already conceived and developed by targeting the whole world population.

Outside Europe

European SMEs in clusters approach Europe as a "domestic" market. The European market is, compared to overseas markets, more accessible, both culturally and geographically. SMEs in Europe have the tools

and the channels (events, networks...) to reach partners within the EU. Cultural differences are not a big issue, thanks to a long-shared history. Thus, the need of SMEs for support/advice primarily concerns reaching markets outside Europe.

The USA is still the main target country. Almost all companies will think of entering the US at some point in their development. However, the North American market is mature, crowded and self-sufficient. The United States is the life sciences market par excellence. This leadership is based on a system that simultaneously grows and consolidates the market: strong intellectual property protection, a regulatory framework that has consolidated the Food and Drug Administration (FDA) and their rules as the gold standard, and significant public and private funds for biomedical research, among other factors. The United States has a strong research system and a biopharmaceutical sector that stands out for its innovation. For years now, the US biopharmaceutical industry has been an important factor contributing to the country's economic growth, creating more than 650,000 jobs directly and around 4 million indirectly. However, moving into this market is not an easy process. For instance, obtaining FDA approval can take between 18 and 50 months and be quite costly.

According to the EU Commission (EU, 2007), the most important barriers for SMEs doing business in markets outside Europe are: knowledge of foreign languages, lack of adequate market information and local contacts, complexity of paperwork, bureaucratic procedures (administrative costs) and the different business cultures existing in foreign markets. Other issues that are often addressed by non-financial business support measures score slightly lower but are also important: laws and regulations in foreign markets and different national technical standards.

LIFE SCIENCES
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3



Different typologies of “going international”

Key messages:

- *Life sciences companies approach internationalisation from different needs: they may seek co-development partnerships, funding, international distribution channels or licensing.*
- *In life sciences, the manufacturing process is not a determining factor in “going international”; cost is not the only determinant, and access to technology is always decisive.*

European companies have followed a process of rapid growth in international trade in both goods and services, particularly since World War II, leading to increased commerce across national borders and expansion of firms into foreign countries. Initially, a company is purely domestic in terms of both production and markets but then it reaches domestic saturation and must look into foreign markets to maintain growth (Dicken, 2007). However, companies in the newly-emerging life sciences sector are following a different course.

Different kinds of companies follow different internationalisation processes. Born-global companies should not be analysed as a homogeneous group. For instance, they can commit resources to foreign markets at different speeds (Melén & Nordman, 2009). The different kinds of experiential knowledge (i.e. knowledge gained through experience) of the key employees of SMEs influence the levels of resource commitment of the companies in their interactions in foreign business relationships and foreign markets. Thus, the SMEs with key employees who have high levels of international knowledge are generally fast investors in reaching foreign markets (“high-committers”). On the other hand, companies whose key employees have less experiential knowledge generally invest more slowly in their internationalisation efforts.

New forms of internationalisation must be considered, including the type of cooperation initiated by clusters. In both medical and industrial biotechnology, the lack of financial power slows down production and export-oriented internationalisation. Industrial biotech companies are making a virtue of necessity (i.e. limited resources): they supply small, highly-specialised niche markets with either just one or a limited number of products. This enables them to avoid time-consuming and costly marketing activities as well as expensive logistics. The same is the case for service suppliers in the field of medical biotechnology (Arndt et al., 2012).

Life sciences companies can approach internationalisation from any among the different perspectives of their different needs: primarily, access to technology and knowledge, partnerships for development, funding, distribution channels, and the licensing and manufacturing capability in the foreign market(s).

An increasingly utilized way for helping innovation in the international arena are co-development partnerships across companies in different countries, in which two or more companies or R&D institutions with the same goal (i.e. delivering a new product or service) combine their different resources and capabilities, thus reducing expenses in R&D and time to market. Partnerships may involve a local company with the knowledge of the necessary administrative procedures and cultural practices in a country in combination with a foreign company that has the technological know-how. In the pharmaceutical industry, large firms such as Pfizer, with strong R&D budgets and capabilities have often used the "market for know-how" strategy for developing their R&D agenda, i.e. contracting access to new technologies from smaller stakeholders (e.g. SMEs), while the small companies for instance have sought alliances with large ones to obtain the resources to take their projects forward.

IN LIFE SCIENCES,
INTERNATIONALISATION
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FACTORS LIKE ACCESS
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PARTNERS MAY IGNITE
THE PROCESS EVEN
BEFORE THE PRODUCT
IS ON THE MARKET.

The scarcity of economic resources in local markets is what, in most cases, ignites or even forces the internationalisation processes. Access to finance is vital in order to start or expand a business and the need to obtain funding often leads European SMEs to explore different options in other continents.

When companies already have products on the market, they may also be in the right frame of mind to embark on their international expansion. In this case, distribution is the driving factor. The company does not operate its own international channels but works through intermediaries for physical distribution in the foreign market.

In other cases, the company wanting to go international either sells technology or does business in the form of a contractual agreement, involving patents, trademarks and copyrights, adopting the form of licensing, franchising or other types of contracts. In licensing, the licensee buys the right to exploit technology and products from the licensor, which is protected by intellectual property rights such as patents, trademarks or copyrights. The licensor benefits from the licensee's local knowledge and distribution channels or from their R&D capacities; it is a low-cost strategy for internationalisation since the foreign entrant makes little or no resource commitment. Licensing is frequent in the pharmaceutical industry because it helps to avoid the usually high R&D investments needed. Licensing can play an important role as a stepping stone to other international marketing strategies.

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4

The clusters' role and the contribution of bioXclusters

Key messages:

- *Clusters collect information and knowledge of the ecosystem and use it to facilitate access to target markets (missions, agreements with other organisations, etc.)*
- *Understanding the foreign terrain and the culture paves the way to success.*
- *Acting as facilitators and business accelerators is the main mission.*
- *Coordinating efforts from governmental economic development organisations and clusters will help SMEs succeed on international markets.*

European SMEs know that internationalisation in life sciences is not an option but a need. Nevertheless, sometimes they need support to identify the internationalisation strategy that will work for them, to identify the appropriate goals, to identify the necessary skills, find resources, entry points and partners, especially when targeting distant markets. The Chinese market, with its big companies and complex regulations, is an example of large opportunities entailing big challenges. A main objective of the bioXclusters project has been the achievement of critical mass to foster internationalisation of the clusters' members' activities while providing better support to companies through offering a full range of competences and services, such as specialised market knowledge, training sessions, organisation of missions, signature of MoUs (Memoranda of Understanding), acquisition of competencies and intermediation with target-market partners.

The actions undertaken by the four partner clusters as part of the European bioXclusters project have promoted the internationalisation of the life sciences sector for European SMEs, and continues to do so. This has involved organising and playing a role in business match-making events, thus allowing the enterprises to access overseas markets and establish technology or business partnerships and therefore increase their innovation capacity and make them more competitive globally. bioXclusters' initiatives have also contributed to prepare the ground for practical cluster cooperation across borders and to make a more strategic use of transnational cluster cooperation on markets outside Europe in areas of strategic interest.

The Brazilian, Chinese and US-American markets offer big development opportunities. Companies have to face big challenges to enter these markets. What is the role of clusters in this scenario?

CLUSTERS ACT AS FACILITATORS FOR SMES TARGETING FOREIGN MARKETS, PROVIDING SECTORAL KNOWLEDGE, CONTACTS, ENTRY POINTS AND KNOW-HOW.

Clusters have had a proactive approach in terms of internationalisation. Clusters have learnt to work together in order to support the growth of their respective companies and to assure sustainability and prosperity. Clusters have jointly identified strategic paths to offer the best opportunities to their companies. As a consequence, a relationship based on trust, transparency and mutual understanding has been a key factor. Brazilian, Chinese, European and US-American clusters (and similar organisations) are aware of these factors and are committed to set up long-term relations in order to exploit all the opportunities and to maximise their benefits.

Thus, clusters are valuable organisations whose actions are boosting the internationalisation of companies in their region from different perspectives. Generally, strong cluster organisations can help reduce the uncertainty in a distant and unfamiliar market, and enable connections that otherwise would have been difficult to establish, thus becoming a gateway through agreements with parallel entities in the target countries. Clusters have already reached agreements with similar organisations in target markets for the benefit of a wide network of stakeholders both in Europe and in the target countries, so they have acted as facilitators, this becoming their main mission.

For example, during the trade mission to China in May 2013, the bioXclusters partners signed MoU with the two main biotechnology parks in Shanghai: Shanghai Juke Biotech Park and Zhangjiang Hi-Tech Park. These agreements will help to boost collaboration between European and Chinese SMEs, and facilitate the exchange of information on markets, processes and technical aspects of landing in China and in the European bioregions. The mission also included two partnering conferences. The Sino-European BioPartnering event, which gathered 150+ players from both regions (China and Europe), aimed to facilitate contact to people and institutions that could help European companies with their strategy for entering the Chinese market.

Also, the role of clusters in internationalisation is crucial for attracting foreign direct investments (FDIs). Although the focus of the bioXclusters project has been supporting internationalisation of European SMEs, we are aware that clusters, together with territorial internationalisation agencies, could serve as an entry point to Europe for non-European organisations. Therefore, clusters can also play a key role in building “win-win” relationships with non-European counterparts by facilitating in this way the establishment of long-term strategic relationships.

Information & knowledge

The idea that information is power is a cornerstone of any business venture. The joint work of the bioXclusters partners has brought together the knowledge generated during the project (missions, conferences, studies, etc.) with valuable information from the previous activities of each of the partners. The clusters and ERAI have also connected the different resources available for the benefit of all the stakeholders in the ecosystem. Thus, we have created an information hub (i.e. providing bi-directional knowledge (to/from the system)), gathering valuable, first-hand information that is made available to companies and stakeholders in the ecosystem.

The joint work of over two years of the project has created highly useful information and knowledge that has provided impetus towards the internationalisation of the companies in the region. In addition, the exchange of best practices and experiences, also with clusters from other sectors, has enriched the opportunities and information available for SMEs and strengthened their capabilities to grow through international alliances/partnerships. These actions have often spontaneously led to other effects, such as new relationships emerging between companies of the same sector during missions to faraway markets, which have created highly advantageous synergies for all parties involved.

Providing opportunities, contacts and entry points in target markets (incubators, science parks, etc.) represents one of the most significant undertakings of the clusters. Entry barriers are lowered through recommendations based on first-hand knowledge of the field, also providing tailor-made support services. A case in point during the two-year bioXclusters project has been the mobilisation of a series of experts, who have helped us prepare the missions abroad into their countries of origin, providing advice to the clusters on which types of organisations to approach for exploring collaboration opportunities.

Cooperation

Cluster organisations can be a key success factor for success for SMEs' internationalisation. Indeed they have the experience and expertise of the field. They are familiar with the issues faced by the companies, in particular regarding the life sciences and health sectors. Life sciences clusters, such as those united in the bioXclusters project, might be considered as the most adapted organisations to address SMEs issues on foreign markets because they are able to act as a one-stop shop for tailor-made support services for the SMEs of their specific sector. In addition, during the project lifetime the cluster partners have also benefited of ERAI's experiences as an internationalisation agency, implementing some of their tools, such as the Cluster Mobility Programme (financed by the Rhône-Alpes Region) and relying on their world-wide offices for organisational support.

On the basis of ERAI's tools, the partners have also implemented successful pilot actions, such as inviting high-level experts to Europe based on the Cluster Mobility Programme, and organising missions with the help of ERAI's foreign offices in the Brazil, China and US.

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One of the successes of these pilot actions relies on the combination of the clusters' sector-specific expertise and the tools that economic and international agencies have developed. Thanks to the cooperation between both types of entities, i.e. clusters and governmental organisations, the bioXclusters partners have been able to provide tailor-made services such as the co-organisation of missions abroad with adapted programmes for SMEs and the arrangement of individual meetings in the target countries.

In order to provide SMEs with efficient dedicated services, it is important to combine clusters' sectoral expertise and the tools that economic and international agencies make available on their respective territories. Cluster organisations have a deep knowledge of the sector (the "ecosystem") and are familiar with the issues faced by companies in the life sciences and health sectors, while governmental economic development organisations are the stakeholders managing public funds. Ideally, if we succeed in matching these two complementary resources, the benefit for the SMEs will increase exponentially.

Although it is a constant bi-directional process, it can be concluded that the role of the clusters is based on two main functions: 1. providing sectoral knowledge of the target markets and 2. paving the way for companies in the region with an aim to kick-starting their international venture. The mission based on these two key functions is to play a facilitating role in enabling access to the target markets.



5

Requirements when facing international markets: SMEs vs large-scale companies

Key messages:

- *Different needs for different-sized companies.*
- *SMEs: need advice and knowledge, reliable contacts, funding, distribution channels and co-development partners.*
- *Large-scale enterprises: search for advantages when landing and investing, mergers & acquisitions, in-licensing from local partners, scouting for research projects.*

The bioXclusters regions bring together over 1,700 companies developing their activity mainly in the fields of oncology, personalised medicine, and the therapies for cardiovascular, neurological, infectious, inflammatory and autoimmune diseases. These companies are characterised by their frequent adoption of innovative approaches.

The landscape is mainly formed by a large number of SMEs and a small number of large-scale enterprises. In the bioXclusters partner regions, around 90% of the companies are SMEs.

Differences stem from the greater flexibility, responsiveness, and even expertise of the SMEs, set against their poorer resource base -in terms of finance- in comparison to larger businesses. SMEs are confronted with greater difficulties in accessing international markets than their larger-scale counterparts. Limitations in finance and related physical resources have continued to be highlighted as a main barrier to the internationalisation of SMEs. Lack of capital and other company resources and limited access to key infrastructure have been reported by SMEs recently investigated in Europe (Kilantaridis & Levanti 2000).

Financial restrictions can take two forms: lack of finance impeding the company's ability to identify opportunities arising from the opening-up of other national markets than their own original market, and inadequate financial resources restricting the exploitation of opportunities already identified.

Other constraints derive from the limited management time available in SMEs, in part because of the small number of managers with specialist expertise. Acquisition of market information is also problematic for SMEs. On the other hand, SMEs enjoy advantages in the process of developing an international orientation, such as greater flexibility and responsiveness to changes in the marketplace, and "advantage-seeking behaviour" (Fiegenbaum & Karnani 1991).

THE APPROACH TO FOREIGN MARKETS USUALLY DIFFERS DEPENDING ON THE SIZE AND MATURITY OF THE COMPANY.

SMEs and the clusters

Clusters acknowledge and work with the realisation that the challenges during the internationalisation process faced by SMEs and large-scale companies are substantially different. Inadequate knowledge of overseas markets also emerges as an important barrier. This suggests that information gaps remain a critical challenge to SMEs even in the current era of extensive information availability. SMEs generally need further advice on the internationalisation process, as well as valuable (and sometimes difficult to obtain) knowledge about target markets that clusters can provide them with. Furthermore, identifying reliable entry points and contacts in target markets will definitely help SMEs to face the internationalisation process, especially at the beginning, when there is greater uncertainty.

Recent surveys also reinforce the importance of finding an appropriate foreign market partner as a key factor for the internationalisation of the SMEs. Missions such as the venture undertaken by bioXclusters in China in May 2013, for instance, which saw the participation of 13 European companies coming from the different clusters involved, has helped to foster collaboration between local and visiting companies for funding and co-development.

'Large-scale companies'

The needs of large-scale companies when approaching an international activity are focused on factors such as the search for economic advantages for landing and investment in foreign markets. They need to be familiar with the conditions they will face in target markets and what advantageous circumstances are going to boost their business venture. Here, clusters may facilitate access to local policy- and decision-makers and thereby support this process, in particular for large companies from outside that are looking to expand to Europe and invest there.

SMEs
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"Open innovation" ("firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as the firms look to advance their technology", in the words of Chesbrough, 2003) is an important factor for large-scale enterprises today. It is recognized as a critical tool for accelerating growth, and the rapid pace of change in emerging technology markets underlines the importance of searching ("scouting") for and incorporating technologies from potentially all stakeholders in the innovation ecosystem. Thus, having knowledge of the research projects and licensing opportunities in a region is also a valuable consideration for large-scale enterprises when mapping out an internationalisation plan, and clusters can help in this area.

Cross-border mergers and acquisitions (M&As) have become more frequent over the past decade as a mode of entry in a foreign market and the institutional setting and national culture of the new market can be challenging and the main obstacle to successful internationalisation (Denison et al., 2011). The cluster, through its own contacts and links with government-led foreign trade offices of the country of origin, can be key in supporting the successful internationalisation for these large companies.

Last but not least, in-licensing with local, generally small partners in the foreign markets is an often-used strategy for market entry with large companies.

LARGE COMPANIES
NEED CLUSTERS
TO ACCESS
POLICY-MAKERS
AND IDENTIFY
RELEVANT
RESEARCH
PROJECTS IN
A TARGET REGION.

6



Standardised approach to markets learnt from the project

Key messages:

- **Three-step approach:**

1. invitation of foreign experts and delivery of workshops
2. missions to target markets
3. becoming an information and support hub

- **A set of tools has been developed to maintain the communication within the system and with stakeholders, in Europe and abroad.**

- **A shared strategy in order to assure coherence, impact and sustainability.**

All good projects must be accompanied by a suitable methodology for achieving their targets. After defining the parameters of a project, its main goals, and the environment it shall be implemented in, a work structure is required to create a dynamic ecosystem. To effectively and productively approach each of the target markets, we suggest a three-step procedure:

- 1) *Invitation of foreign experts and delivery of workshops with them in Europe.*
- 2) *Missions to the target markets co-organised with internationalisation agency support.*
- 3) *Becoming an information and support hub.*

1) After choosing the target market, two lines of action were followed by bioXclusters: inviting foreign experts to visit the European regions and delivering country-specific internationalisation workshops with companies from each cluster. These meetings were always been extremely productive. A case in point is the visit of the expert consultant for SMEs and life sciences arena from Silicon Valley, Karin Hollerbach, CEO of Taku Group (California-USA), who visited the bioXclusters regions in April 2013. During her stay in Europe she held meetings with companies, regional agencies and different support organisations that play an active role in the internationalisation of SMEs. During her trip to Europe she was in Lyon, Barcelona, Turin and Munich. The approach was double-sided, i.e. aimed at supporting the internationalisation of SMEs and also fostering the attractiveness of the bioXclusters regions to an outside partner.

2) Missions were organised to the target markets to meet and understand the contacts and the environment there first-hand, with the support of ERAI's offices, which have dedicated teams working closely with the

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RESULTS IN
EFFICIENCY, EFFICACY
AND IMPACT.

target countries' players. bioXclusters offered the clusters' companies (mainly SMEs) a unique chance to explore and understand the life sciences sector and market in the target countries – Brazil (São Paulo and Rio de Janeiro), China (Shanghai) and the United States (Boston)–. There companies had the opportunity to meet with the right people and obtain the advice they need to prepare for doing business in the respective market. Thus, bioXclusters was able to offer the companies and organisations that participated in these missions an approach that is different from that of a traditional trade mission.

Brazil: In September 2012, the bioXclusters partners visited Brazil for the first time. Eduardo Soares, the expert who visited Europe in April 2012, helped us design the mission and identify the right partners to visit. Different institutions in Sao Paulo and Rio de Janeiro were visited and valuable contacts were identified. A public bioXclusters report was issued.¹ We finally signed different partnership agreements with three relevant Brazilian life sciences partners in different cities.

In September 2013, the European Commission travelled to Brazil with a selection of nine European life sciences clusters alongside four SMEs. The mission had the objective of fostering bilateral exchanges at different levels between European and Brazilian partners and was organised around the BioPartnering Latin America event. There are a lot of opportunities in Brazil thanks to of the strong growth of their market, and their fast-growing middle class, with an increasing purchasing power and demand for high-quality healthcare.

China: The bioXclusters partners, along with 13 European SMEs, were in Shanghai in May 2013. The main objective of the mission to China was to discover and detect key entry points into the life sciences market in this country. bioXclusters participated in a unique Sino-European BioPartnering event, stimulating exchanges between Chinese and European researchers and entrepreneurs and

¹ <http://bioxclusters.files.wordpress.com/2012/11/report-brazil-missiondef.pdf>

² http://bioxclusters.files.wordpress.com/2012/11/report-china-mission_bioxclusters_may_2013_def.pdf

attracting more than 150 companies from both Europe and China. This event was organised by Gao Rong-Hui, the invited Chinese expert with the support of the Lyonbiopole's representative in Shanghai, as explained in the report issued.² The Chinese market offers huge opportunities in the healthcare sector: it has shown yearly growth rates above 20% over, not during the last 10 years. However, bridging the cultural gap and handling the complex IP situation in China, among other factors, need to be taken into account when establishing commercial and technological relations with local Chinese partners. One of the main questions that the bioXclusters partners tried to answer through their activities was how to help the European SMEs penetrate this very fast-growing market and keep a long-lasting position in it.

United States: A mission to Boston in October 2013 was mainly targeted to small companies working in the “Personalised Healthcare” field.³ The delegation did not only visit institutions and companies in Boston, but also met personally with selected experts and received training on a series of specific topics that European companies should know about when planning to enter the US market. Several topics were discussed with experienced US experts and sector specialists, such as “the main rules to be acquainted with in terms of regulatory affairs, reimbursement and patents” and “how to attract investors”.

3) Becoming an information and support hub is essential to foster the internationalisation of the wide and innovative network of SMEs in the participating regions. bioXclusters has worked to collect and provide information from all flanks of the internationalisation process by providing country reports of the three target markets. As set forth in previous chapters, information is power and the partner clusters dedicated a large proportion of their efforts to collecting, processing, organising, sifting, spreading and internalising all this information. Information has been disseminated in two ways: by providing

³ <http://bioxclusters.files.wordpress.com/2013/10/131002-program-usa-mission.pdf>

information to the clusters' ecosystems and by acting as a source of information about the EU market for the target markets' players. Thanks to these efforts the partners were able to sign several cooperation agreements.

Communication tools

The standardised approach to markets has been enhanced with a set of communication tools that have allowed us to maintain an efficient communication within the system and with stakeholders. This communication strategy has created, reinforced and sustained the knowledge about the project and activities, not only in the bioXclusters regions but also in other European regions and abroad.

These communication tools have proved to be very valuable.

The strategy we put in place in terms of communication was structured as follows:

- Development of a strong marketing strategy through the creation of a common bioXclusters image, presented as a brand towards markets outside Europe. The common image was supported by marketing messages and a common strategic approach was defined in order to create sustainable activities.
- Corporate website of the project (www.bioXclusters.eu), where all the information about the project has been made available to the public.
- Use of the ECCP European platform as a tool to spread the knowledge of the project to other projects/organisations within Europe and as a platform to increase the visits to the corporate website.

A SET OF
COMMUNICATION
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BETWEEN
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- Twitter and LinkedIn: we have put in place a double strategy: spreading the knowledge as widely as possible and providing updated news of the project's activities. In addition, we have been redistributing relevant information about the three target markets (i.e. Brazil, China and the U.S.) to our followers on Twitter. We have common pages on all partners' websites, with a common presentation.
 - Publishing press releases and specific communication messages through networks and websites.
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Recommendations



Internationalising your cluster

- Plan a medium-/long-term strategy using defined impact indicators/ performance indicators.
- First, identify the needs of the companies in your region in detail. Then, adapt the recommendations for a target market to the needs and capabilities of the companies.
- Cluster companies should be supported to identify their most appropriate target markets, which are not necessarily the most mature and developed ones (e.g. the US).
- Limit the number of target markets for which you want to provide value-added support.

- Bear in mind cultural differences across international markets. Approach each market according to its specificities.
- Keep in contact with persons and institutions in the target country, to ensure long-term collaboration options.
- Exploit already existing network links and work with local representatives to create a trusting and close relationship. Relations with international partners are based on trust and common experience and can take a long time to establish and consolidate.
- Provide your stakeholders with regular information about the target markets.
- Build a strong network of potential entry points in each target market.
- When facing new and faraway markets, it is convenient to do so step by step and with the assistance of skilled support services.
- The more precise you are, the more chances you will have to find suitable partners: Choose a set of subsectors of activity for each target market and align your strategy correspondingly.
- Set up options for “on-demand” services, or contacts in a target country, that are available to individual companies travelling on their own.

Working with other clusters to reach international markets

In addition to the previous recommendations, when working in consortium with other clusters, you should take into account:

- Work with a unique collaboration methodology and align all activities with a defined joint strategy. Appear as one unique meta-cluster.
 - Appreciate the value and impact of good communication, marketing and branding. Create a common brand to go international, for example using common marketing leaflets, a common website, common e-mail addresses or coordinated business cards.
 - Define your added-value as a meta-cluster from the beginning.
 - Define your support platform exploiting the meta-cluster approach.
 - Identify one person representing the meta-cluster to the outside. This can be taken in turns and can be linked to specific markets.
 - Build links with synergistic and complementary initiatives inside a single territory and at the meta-cluster level.
 - Try to represent and market the meta-cluster with all its assets and companies, providing opportunities along the entire value chain of your sector.
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References

Arndt O. et al., 2012. The cultural and creative industries in the macroeconomic value added chain. Impact chains, innovation, potentials. Summary of an expert report compiled on behalf of the German Federal Ministry of Economics and Technology. Fraunhofer ISI, 2012.

Chesbrough, Henry William (1 March 2003). Open Innovation: The new imperative for creating and profiting from technology. Boston: Harvard Business School Press.

Denison D.R., Adkins B. & Guidroz A.M., 2011. Managing cultural integration in cross-border mergers and acquisitions, *Advances in Global Leadership* 6:95-115

Dicken P., 2007. "Global Shift: Mapping the changing contours of the world economy", 5th Edition, London: Sage.

European Commission, 2007. Supporting the internationalisation of SMEs: Final Report of the Expert Group, Brussels: European Commission Enterprise and Industry Directorate-General

Fiegenbaum A.V. & Karnani A., 1991. Output flexibility - A Competitive Advantage For Small Firms, *Strategic Management Journal* 12:101-114.

Kilantaridis C. & Levanti A., 2000. Internationalisation and the size of the firm, paper presented in Association for Small Business Enterprises (ASBE) conference, www.sbaer.uca.edu/research/asbe/2000/11.pdf.



Passeig de Gràcia 103, 3rd Floor
08008 Barcelona - Spain
www.biocat.cat

Biocat is the organization that promotes life sciences in Catalonia through the implementation of specific programs and initiatives, facilitating access to financing and talent, and internationalisation. It is fostered by the Government of Catalonia, the City Council, companies, hospitals and research institutions. Catalonia bioregion is made of 520 companies, 54 research institutes, 20 science & technology parks, 15 hospitals with research activity and 12 universities with studies in life sciences, that altogether have in operation more than 400 research groups working on life sciences.



Am Klopferspitz 19 a
82152 Martinsried - Germany
www.bio-m.org

BioM is the coordinating agency of the Bavarian & Munich Biotech Clusters, and the network hub for all biotechnology companies and start-ups in the region, one of the top biotech hotspots in Europe. BioM is government-funded and provides services to biotech SMEs, including marketing, BD, consulting, training, trade missions, and an information portal at www.bio-m.org. A recent focus area is the "m4 Initiative for Personalized Medicine", a large industry-academia collaboration program.



Via Ribes 5
10010 Colletterto Giacosa (To) - Italy
www.biopmed.eu

bioPmed is the Italian innovation cluster dedicated to health care created in 2009 thanks to the intervention of Piemonte Region in the framework of ERDF - POR Piemonte 2007-2013 - Innovation clusters action. bioPmed is based on a community of around 390 companies and different universities and research centres involving more of 3900 scientists, foundations and associations active in Life Sciences fields. The initiative is led by Bioindustry Park Silvano Fumero (www.bioindustrypark.eu), the local science & technology park.



Bâtiment Domilyon
321 avenue Jean Jaurès, 69007 Lyon - France
www.lyonbiopole.com

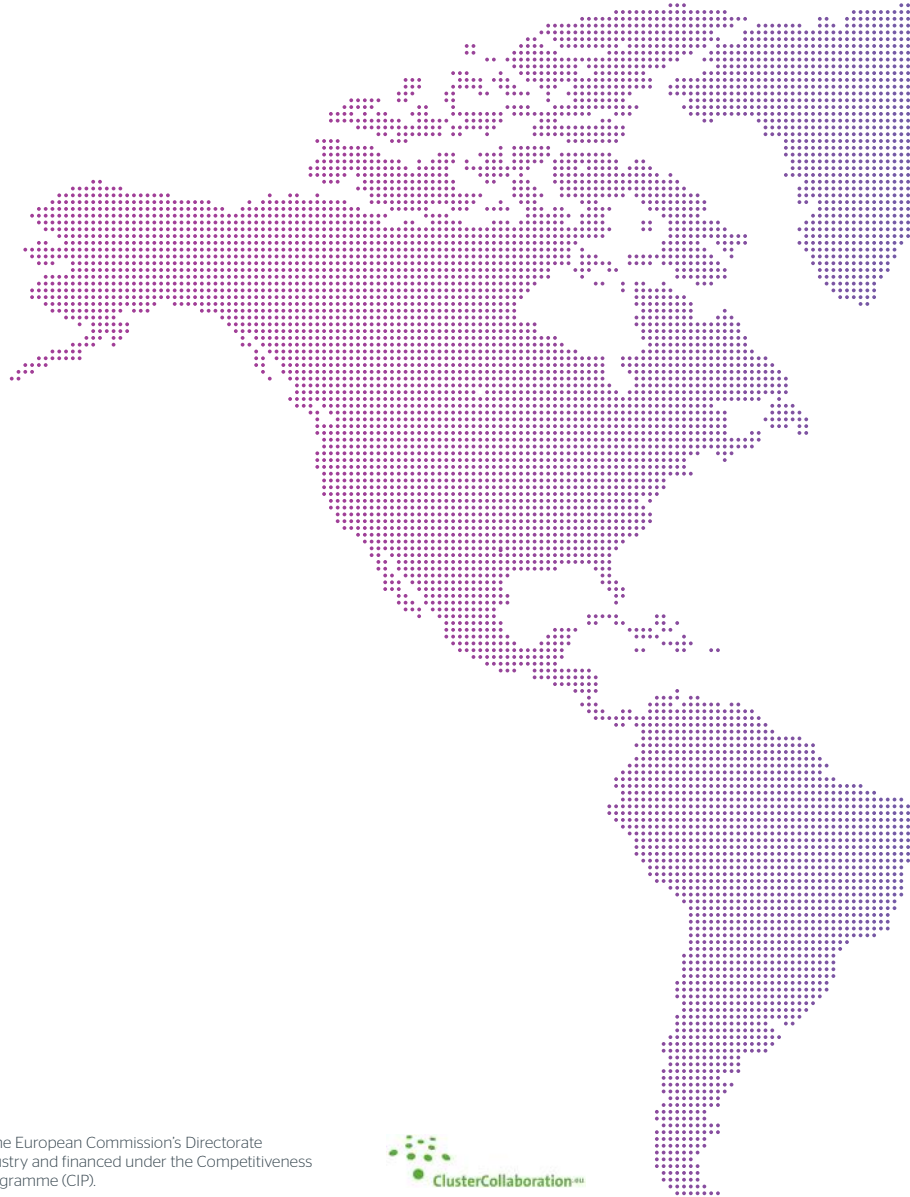
Accredited as a world competitiveness cluster in 2005, Lyonbiopole is focused on the fight against human and animal infectious diseases and cancers. Centre of excellence in vaccines and diagnostics, it aims to strengthen the competitiveness of Rhône-Alpes health companies. Designed as an interface tool between public and private research, it implements actions to foster collaborative R&D, to support projects and to increase strategic and financial partnerships for companies' economic and international development. It also provides access to shared facilities and platforms.



30, quai Perrache
69002 LYON France
www.eraï.com

ERAï (Entreprise Rhône-Alpes International) is the agency for the international economic development of the Rhône-Alpes region. ERAï is an international network of 27 offices in 21 countries. It is mobilised to act in Rhône-Alpes and abroad to provide assistance to companies and clusters from the region in their international development, and to guide foreign companies to set up their business in Rhône-Alpes.

In 2012, ERAï has been supported more than 820 companies individually in their export business through ERAï offices abroad and this, in various industries, technologies and niches to develop their international presence.



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