Grant Agreement number 265546

TERM

Tissue Engineering and Regenerative Medicine

Deliverable: Benchmarking report
Innovation support for Tissue Engineering and Regenerative Medicine in Europe

Berlin, Milano, Pays de la Loire, Uppsala, Wallonia

Workpackage WP 3 Innovative Tools Experimentation

Task 3.3 Spin-offs, technology transfer, valorisation and market potential
Month of delivery: August 2012, M22

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Report Release Date	2012 08 27
Link (web) to the report on the project platform	N/A
Confidentiality	
Does this report contain **confidential** information?	Yes ☐ No x
Is the report **restricted** to a specific group?	Yes ☐ No x

Foreword

TERM, or Tissue Engineering and Regenerative Medicine, is a field offering interesting perspectives for new therapeutic approaches. To stimulate the development of this domain, 13 cluster organisations and regions across Europe have, with the support of the European Commission, launched a project that aims to build collaborations between regional research based clusters in the field of TERM.

The TERM consortium would like Europe to be a competitive arena for the development and implementation of advanced therapies, thus contributing to a better life for Europe's population and creating opportunities for growth in the field of life sciences in Europe.

The mapping of regional strengths by the consortium shows great potentials, but also a number of challenges that needs to be dealt with. Among the latter, the TERM project noted the difficulties to fund early projects with commercial potential, and a low number of new companies, products and services.

Thus, one part of the TERM consortium's Joint Action Plan (JAP), aims to look deeper into how innovation support, the bridge between academic research and commercialisation, can contribute to an increased flow of products and services within the field.

To that end, innovation support programs in some participating regions have been studied. The focus has been on support to very early projects, to bridge what is sometimes called the technology gap to reach e.g. a proof of mechanism or a proof of concept. Most regions present some kind of support in this phase hoping to attract commercial partners by increasing the value and decreasing the technical risks in the projects.

The result, including conclusions and some recommendations for the field, is presented in this report.

The selection of participating regions and programs has been made in collaboration with partners in the TERM consortium. All partners that volunteered to participate have been included, and thanks to their knowledge and networks in their respective regions, Uppsala BIO who has been responsible for this report, has been introduced to a vast number of programs. This is however not a full overview of all available programs in the TERM consortium.

To compile this benchmarking report, Uppsala BIO has collaborated with Dr Henrik Mattsson, researcher at Uppsala University's Department of Social and Economic Geography and senior consultant at SWECO Eurofutures AB. Dr Mattsson has extensive experience from evaluation of cluster organizations, innovation systems and innovation support, with a special interest for the life science and biotechnology sectors.

All partners that participated in the benchmarking have provided ample information and reviewed the descriptions of their programs before finalising the report. Should there still be omissions or misunderstandings in the report, they are solely attributable to the authors, who appreciate being noticed about them. The conclusions and recommendations in the report are Dr Mattsson's.

These conclusions and recommendations were discussed at the TERM consortium workshop in May 2012, as well as in the participating regions prior to the workshop. A summary of the workshop's discussions is presented in Chapter 4, as a comment to Dr Mattson's conclusions and recommendations.

Uppsala, Sweden, August 2012

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TABLE OF CONTENTS

TABLE OF CONTENTS

1 Introduction

This report presents and analyses the results from five regional case-studies of European innovation support systems for the TERM-area (Tissue Engineering and Regenerative Medicine). The study was carried out as part of the Regions of Knowledge project TERM, and the five regional organisations, which have been the basis for the studied cases, are all members of this project[1].

Regional Innovation Support System (RISS) should not be confused with Regional Innovation Systems (RIS) – the latter includes all regional actors that play a role in innovation processes (for example universities, venture capital, consultants, related industries and public institutions such as health care providers) while the former only consists of actors that have an explicit and primary mission to increase rates of innovation in the national and regional innovation system as a whole (for example incubators, technology transfer organizations and innovation-focused regional development funds). This means that a RISS-actor typically has an extrovert focus on helping others innovate, as opposed to many RIS-actors, who generally think of innovation as a means to internal profit and long-term competiveness, or who do not think about innovation at all.

Innovation is here used in a broad sense to incorporate all of the studied RISS' missions. The actual innovation support studied in this report can therefore be about anything from technology transfer and networking to proof-of-concept-programs and funding of large industry-academia research consortia. However, while there are differences between how each RISS defines innovation, there is also a common notion in all RISS that TERM-innovation is a process whereby scientific discovery is transformed into new medical technology, new cures and new hope for millions of severely ill patients in Europe and beyond. Most RISS undoubtedly see innovation as important for regional development and economic growth, but "solving the big issues" and curing the big diseases is at least equally important.

Regarding the focus on TERM, two things must be noted. First, when it comes to the technologies and scientific disciplines targeted by RISS, the scope is naturally much broader than the TERM-area. Secondly, much due to its novelty, the TERM-area is not a very common receiver of RISS-help. In fact, only a handful of cases could be identified in the case studies. Strictly speaking, what have been studied are therefore not so much actual TERM innovation support cases, but rather the RISS that would be responsible for helping TERM-projects when they come along. This is further discussed below.

The main aims of the study are to: (i) map the structure, strategies and results of each TERM-RISS case; (ii) analysing the case studies from a European perspective – answering questions about how each RISS feeds into innovation and progress of TERM in Europe; and, (iii) give recommendations on best practises as well as on future TERM – innovation support policy at the European level.

On a methodological note, the case studies rely mostly on face-to-face interviews and on-site workshops with people in leading positions in selected RISS actors. When circumstances so dictated said methods were replaced by teleconference[2].

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[1] *The selection of cases is based on a combination of availability and suitability. The aim has been to include as many cases as possible within the limited time- and resource frame of the TERM-project. Given that each included case has brought something new to the picture, it is reasonable to assume that the report has missed things by excluding some cases. However, given the large overlap of lessons learned in those cases included, it is equally likely that the relevance of this report goes well beyond the studied regions.*

[2] *This was partly the case for the Milano study.*

Following this introduction, the next chapter presents the general observations of the study and chapter 3 makes recommendations for TERM innovation support at the regional and European level. Chapter 4 summarizes the discussion at the TERM project partners' workshop in May 2012 on conclusions and recommendations from the benchmarking. Together, these chapters can be read as one summarizing documents. The five cases or regions studies are presented in more detail in chapters 5 through 9.

2 General Observations

By nature of regional differences in industrial and academic structure of the TERM-project partner-regions, the scale, scope and preconditions of the studied RISS also varies. This means that a strict benchmarking study has not been possible, rather the study gathers experiences from participating cases in an open-ended fashion. Where possible, best practices and common challenges are identified – here called *general observations* – but the report offers no explicit comparison of the relative performance of each RISS.

2.1 Few TERM-projects: due to novelty or mismatch?

As noted in the introductory chapter, only a handful or TERM-related projects are currently receiving support from any of the studied RISS. By comparison, there are hundreds of projects in other technology areas. One way of explaining this is to say that it is only natural that TERM-technologies are not as common since the technology is still very new. The study at hand, however, seems to suggest that there may also be a mismatch between TERM-technologies and traditional innovation support. One example of this is that most contemporary innovation support programs are based on trying to connect academic results with loosely defined industry needs. In the TERM-area, which is more complex in terms of technology, clinical requirements and regulation than most other areas, it is not sure that this model will work. Indeed, it is reasonable to assume that the scale of the RISS, both in terms of funding and the number and competence of regional partners, is simply too limited. The traditional innovation support model seem to work, to some extent, in the diagnostic/verifying-subareas of TERM, but in the field that has the most potential for game-changing innovation – TERM therapies – the respondents of this study are more pessimistic.[3]

Another aspect of this is that the study shows a large variance in the "market pull" of different regions. It seems that this can be partly explained by differences in the regional presence of TERM-related industry. RISS that are collocated with clusters of relevant industrial actors tend to enjoy higher degrees of sophisticated market pull and can therefore more easily find avenues for technology transfer, while RISS in less industrially endowed regions have to depend more on a technology push strategy. Assuming that the TERM-area in general, and TERM therapies in particular, is more complex and risky than current technology-areas, it is reasonable to conclude that even fewer places will enjoy sophisticated regional demand for this area. Furthermore, the challenge posed by a regional lack of sophisticated market pull tends to be even harder to overcome if there is also a lack of industrial experience among the RISS personnel.

2.2 Regional restrictions at the cost of European performance

All RISS in the study apply some sort of regional restriction on who may receive their help. For some cases the restriction is rather strict, stating that projects must not only bear fruit in the region but must also be the fruit of regional funding – i.e. you may not receive innovation support if you have not already received regional support of other kinds. In other cases, extra-regional projects are allowed if they can make the case that the project will in fact create dividends in the region. Some other cases allow regional projects to find extra-regional project partners as a "last resort" – i.e. when no regional partners are available. This study only found one actor of one RISS that allows completely free competition between regional and extra-regional projects.

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[3] *See for example the Berlin case on projects needing clinical studies and the Wallonian case discussion on time-perspectives of BIOWIN candidates from different fields.*

In effect, even though we may often sow at the European level (when a RISS receives EU-funding) we always reap at the regional level. This is not necessarily a problem in and of itself, but this study shows that it presents some particular challenges for the development of TERM in Europe.

First, there are several problems of scale. The regional research base, which is the starting point for most RISS, is often too small for anything else than incremental advances in this complex and expensive field. There is also a lack of industrial partners in most regions. As discussed above, it seems likely that these two factors explain, in part, why there are so few TERM-related projects in the RISS' portfolios. Another issue of scale is the challenges most RISS experience in finding competent evaluators and experts for the selection and coaching of projects, which seems to be a very important mechanism for success. A European pool of independent TERM-experts with the right competence from industry and business development, would arguably add much value to all RISS in Europe.

Second, there are problems of low interaction. This applies both to the European innovation support landscape but also, and this is perhaps a bigger problem, to the national level. The unused potential for exchange of ideas and learning seems endless. Not only could RISS learn from one another if higher levels of cross regional/national interaction were reality, but it is reasonable to assume that there is also potential for matching and pooling of resources, experts and networks. On top of lost potential for learning and matching, the European landscape of isolated RISS and a complex variety of regional rules increases the risk for multinational partners and probably makes Europe far less attractive to such partners than for example the much more coherent North American landscape. And it is hard to see how the promises of such complex and expensive technological areas as TERM would ever become reality without multinational partners (be they Big Pharma or from other sectors, e.g. insurance companies).

In terms of policy, doing something about this might prove difficult. The regional isolation described above is not due to explicit protectionism. Rather, it follows the logic of the European system as it is currently constructed. The problem is that TERM is one of those exceptional areas where this becomes an obstacle to progress. Where the multi-regional system would normally create a multitude of ideas that compete in healthy ways to the benefit of European innovation, in the case of TERM, it hinders the achievement of critical mass.

2.3 Competence of RISS takes long time to build

On a less dramatic, yet important, note, the study shows that the competence that makes RISS successful tends to build over time in informal ways. There is no typical education that makes a good RISS manager or a successful project coach. It is important to have a rudimental understanding of the technology at hand, but it seems even more important to understand the people in charge of the projects. Indeed, one of the respondents with the best record, in terms of receiving external project funding success rate, claims that he basically has stopped analysing project proposals and now focuses all his attention on assessing the people behind it[4]. Apart from some key rules regarding what is actually possible to do within given budget and time frames, it is so hard to predict where technology will be going that all attempts to assess a project beyond its planning and budget are futile. What seems to matter, however, is that success often depends on the motivation and creativity of the project managers and investigators, and these things can be assessed up front.

[4] *This case is not directly identifiable from the presentations of the regional innovation support systems, RISS, in chapters 5 – 9, for reasons of confidentiality.*

Also, it is important that the person in charge of the academia-industry interface understands how to combine different systems that are characterized by different logics and reward systems. University scientists and private sector developers live in different realities, composed of different sets of incentives, pressures, and time lines – and success often comes when they (thanks to a third party) manage to work in ensemble in spite of this.

2.4 Close management and follow-up of support projects is key

Related to 2.3, another success factor identified in the study is close monitoring and management of projects. For short-term results the evidence is very clear on this point. A RISS may achieve the same result with a tenth of the budget if they select, monitor and manage the project closely.[5] The explanation seems to be that many programs in RISS are (mis)used by researchers as a means to bridge gaps in funding. For example, a researcher may apply for innovation support funding in order to finish up some on-going project that ran out of money, which means that the project is unlikely to achieve any short term results of the kind that the RISS was hoping for.

However, a note of caution for the long term effect of doing something about this is warranted. In the uncertain world of research and technology development, it is more rule than exception that things do not go according to plan. Many of the respondents talk about milestones and the like as “cosmetics” – something that has to be there for things to get going but that has no real effect on the success of the project. It is quite possible that the long term dividends of the apparent misuse of the system far outweighs any short term gains in efficiency that would be achieve by tightening the system.

2.5 Results are there but hard to measure

Related to 2.4, the study shows that it is all but impossible to isolate and measure the true impact of RISS. In part, this is due to the fact that RISS are so embedded in the RIS that we cannot know the net impact of the former. Secondly, historical study of innovation processes seem to suggest that the time perspective required to capture innovation effects goes far beyond the scope of RISS evaluation periods. Thirdly, contra-factual analysis is required to correct for all effects that would have “happened anyway”.

In sum, although it would probably be possible to assess the impact of RISS, such analyses would not be produced until decades after the fact and does therefore not lend themselves as tools for continuous RISS-evaluation. Such tools must be simple, repeatable and must measure things that are actually relevant for the evaluation process, that is, things that would inform a strategic decision process regarding the adjustment and direction of RISS tools and policies. Chapter 3 makes some suggestions about how RISS performance should be evaluated.

2.6 New financing models needed

The final general observation pertains to financing. Most current models of innovation support, and in particular models for technology transfer and commercialization, assumes that the new knowledge created by such models will be marketable (and profitable) either as a product, a service, or IP. The case of TERM therapies, however, may not take traditional forms in the market place. While costing at least as much as traditional drugs to develop, many TERM therapies would cure rather than treat the patient, which would risk making such therapies either too expensive or too unprofitable.

Yet, there are some actors that would be both willing and able to pay more than a traditional price for curing treatments – namely governments and insurance companies. Both

[5] *See for example the Walloon case study.*

stand to save considerable costs if certain diseases would suddenly be curable. The problem is that these actors are not very active as stakeholders in specific technology transfer projects at the moment. Any model of TERM innovation support for the future is likely to benefit from an early involvement of this kind of actors in particular projects with particular aims to develop treatments.

The study further shows that although additional funding for RISS activities will be necessary, there are many ways in which funding can be distributed to projects. Some RISS control the funds themselves, others do not, and there is no big difference in performance between these groups. What is important, apart from the actual presence of certain levels of innovation support capital in the region, is platform funding that allows RISS-actors to exist for extended periods of time – so that competence and networks have time to grow. Successful RISS have authority in external funding decision processes, which makes these processes local and swift. At the same time, successful RISS have a humble attitude towards their own role and value transparency and the advice of industrial and scientific experts.

3 Recommendations

Based on the general observations made in this study, the report makes two major recommendations.

3.1 Develop sound measures of impact and take lead in RISS impact debate

All RISS put significant effort into showing results of their activities. To a certain extent, this is in good order. It would not be reasonable to use extensive amounts of public funds without some sort of evaluation. On the other hand, there seems to be a clear risk that the true impact of RISS – which is long term and hard to capture in simple numbers – will disappear in the reporting of hard data such as number of spin-offs, number of patents, or number of licences – which are sometimes unfairly disappointing or farfetched in terms of causality. To manage this risk, it is important that RISS do two things.

First, RISS across Europe should collaborate in developing a strong and well-evidenced understanding of their value through in-depth studies. During the making of this report it soon became evident that there are basically no previous studies of the true impact of RISS for the TERM area. RISS taking lead in this discussion by building and distributing knowledge of this kind will reduce the risk of being unfairly judged by ill-fitting evaluation designs. For example, such studies, should focus on the extent to which RISS bridge different “gaps” in the RIS, the extent to which RISS existence and activities change the mind-sets and attitudes of regional scientists and industry with regards to technology transfer and academia-industry collaboration, and, the extent to which RISS contribute to technology transfer and collaboration by providing external networks of experts, partners and funding.

Second, simple and repeatable measures should be developed that focus on how well RISS projects are doing what they set out to do. While it is all but impossible to evaluate the true impact of projects on an annual – or even five-year basis – this study shows that it is both easy and important to assess to what extent researchers are “doing their best”. In the uncertain world of technology development, this is the only reasonable measure that can be applied in evaluating projects on a somewhat repeatable basis. All RISS programs in this study that formally or informally use this approach of project evaluation clearly outperform programs that do not, in terms of *number of projects completed* to *cost* ratio. There are many reasons for project failure, some of which are technological and scientific in nature while others are administrative or due to unrealistic project planning. Although, the former sometimes have to do with the selection skill of the RISS, the findings in this study support the notion that, overall, the former are acceptable reasons for failure and a natural part also of well performing RISS, while the latter are less acceptable and clearly manageable in short term evaluation processes.

3.2 Develop and teach a common European innovation support model

While there are many differences between the regions included in this study, the successful tools applied in the regions are surprisingly similar. No RISS program is “perfect”, but each RISS has some part that is functioning really well. Considering the similarities across regions, it is reasonable to assume that picking the best pieces from each RISS may actually result in a new model for innovation support that would improve the performance of RISS across Europe. Here, and illustrated in figure 1, follows a stylized example of how such an eclectic model would look:

- Project identification should be done by a combination of calls and scouts. Scouting tends to increase the success rate and is a good communication channel, but RISS with only scouts identify a need to grow through academia taking the initiative
- There should be a coordinating RISS actor that helps potential candidates prepare strong applications. This actor should be financed through long-term platform funding
- Projects should be selected through expert evaluation. Expert groups should have relevant industrial experience. Preferably, a European pool of experts should be created since all RISS mention a scarcity of good experts
- Industry should be brought in at an early stage and they should bring a commitment to selected applicants. Preferably, industry partners should participate in designing calls but the strategic discussion about important emerging technology areas should be independent of industry
- Milestones should be developed early on in the project selection process and should be monitored closely by the coordinating actor. However, deviations must be accepted if they are due to unforeseeable technological or scientific developments. Researchers should have leeway to develop their own strategies as long as they are arguably in line with the project objectives

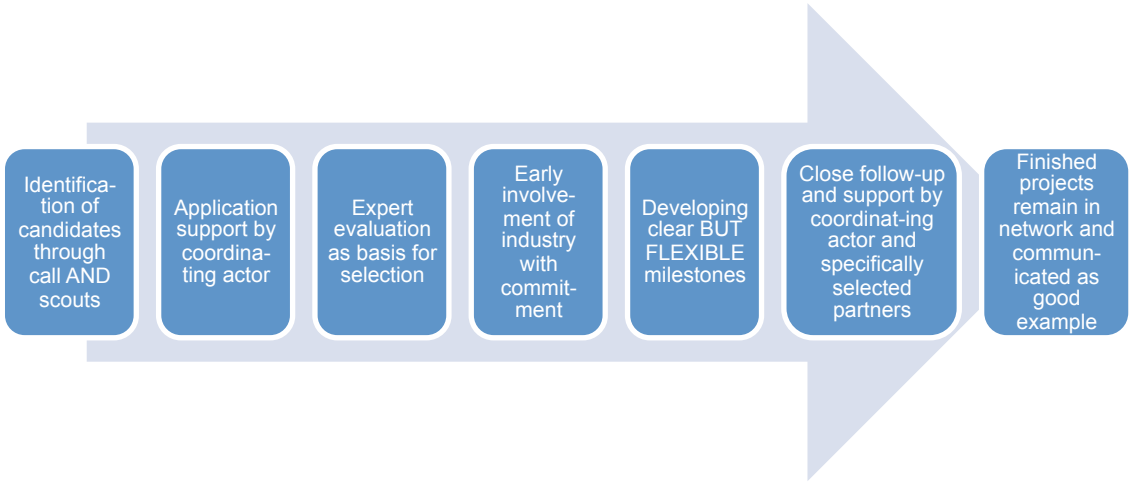

Figure 1: A European "Best Model" for TERM innovation support

- After projects are finished, they should be kept in the system and communicated as (good) examples. This is an efficient way to increase the interest in research commercialization among rsearchers, which is vital both for scale and success rates of the RISS programs.

4 Summary of project partners' remarks at Workshop May 29, 2012

An earlier version of the benchmarking report was circulated to all TERM project partners in March 2012. The intention was to provide a basis for discussion with the regional stakeholders on the report's conclusions. These regional discussions were followed by a concluding workshop May 29th for all partners in the TERM consortium.

The partners in the TERM consortium share the conclusions presented in this report. During the workshop discussions, the following conclusions and observations were added or underlined.

Close managment

- Close management is vital for projects coming from the academic research area to take off. This means that management of selected projects is best performed on the local or regional level. Groups can be financed by central, national or European sources but management in close relation to projects remains essential.
- Successful support and management of projects requires a sense of trust between all parties involved. Building trust is key, and so much easier in a regional/local context, as it needs regular meetings at close intervals.
- Related to the close management is the follow up process, and what indicators to select for project- and for program evaluation. Indicators shall be in focus at a later workshop within the TERM project. There was however a short and open-ended discussion on whether indicators such as "number of new companies" or "number of new jobs" really reflect the efficiency (or inefficiency) of programs addressing early phases of innovation bridging the technology gap.

Start from the need

- Start from the need! This was also a strong advice from the TERM project's Scientific Advisory Board when they met and discussed the TERM consortium's proposal for a vision document and the Joint Action Plan in March.
- Needs should focus on patients' and clinicians' needs. We should stimulate feedback from the clinicians and SMEs, as a means to unveil needs, and involve them as early as possible.
- Clinicians are also valuable to involve in the evaluation of project proposals, as well as for the follow up of selected projects.

Regional restrictions

- The partners meant that even if regional restrictions are understandable from a political point of view, the consequences are costly, especially for a new area such as TERM. We will never get a "critical mass" of innovations or projects moving towards innovation if we cannot make full use of research results, clinical capacities and industrial experiences in our regions. Possibility to build the "optimal" project team increases if matchmaking is not hampered by regional restrictions.
- TERM therapies are often developed to cure rare diseases, or rare variances of diseases. Collaboration on a European level is therefore crucial when projects reach phases of clinical testing and when you need to conduct multicentre studies.

- Another aspect, relating to regional red tapes, mentioned were the availability of research infrastructures, especially GMP facilities. We need to collaborate to make efficient use of these facilities, and to be able to develop the expertise needed around them.

A new model for innovation support

When discussing a new model for innovation support responding to needs in life sciences and especially in TERM, the partners favoured a mixed regional/ multi-regional/ European model.

- Defining needs could for example benefit from a European perspective on societal challenges, and from using expertise available at e.g. EMA. Restricting the use of experts to people in the own region could be detrimental, the group concluded. However, it is also valuable to have a thorough understanding of the region's or the regions' strengths when defining the scope for projects to support.
- For the Reach Out phase, the group tended however to favor a more regional approach. This is when we start building confidence and trust, someone mentioned. Still, the group saw no reason to limit a potential call only to a specific region. Openness can help build critical mass.
- The Evaluation and Selections phases would certainly gain from a process involving experts from anywhere, as in for the definition of needs. How to evaluate is however another story. Do we need one single process? A common framework allowing for regional varieties? Or should we even develop a quality seal for the process?
- Teams should be built with the competencies needed, and should not be prevented to seek them due to regional regulations. The group underlined the need to analyze the different rules and praxis concerning IP that are used in the different countries.
- The project should be linked to the innovation support process in the same region where the project's core is located, normally the region of the project's PI. This will facilitate support and reviews or follow-up during the execution phases. It is still of interest, however, to use an expert group with advisors from any part of Europe (or any part in the world) for reviewing and advising selected projects.
- Financing may be more difficult to find from regional sources, when there are no longer any restrictions on where a successful project should grow, nor on the project partners involved. The only solution is probably to seek financing from European sources.

Finally, the group discussed the specific case that TERM presents – the need for a new business model. There was a general concern about the low interest from big pharma for the possibilities to develop therapies that actually cure. The fear that such therapies will never be sufficiently reimbursed with current systems is one explanatory factor. With no harmonization of reimbursement systems, there is a clear risk that Europe will continue to be a fragmented market. The group agreed that this issue is probably too big to deal with inside the TERM project, but when identifying interested partners to innovative project, the issue is still important to keep in mind. Maybe these projects will not find their partners among big pharma, but rather among actors involved in health insurance?

Several times during the discussions, the participants underlined that competition is mainly non-European. We need to collaborate and focus resources to be competitive in this area.

Experiences from this workshop will be used to continue the development of a proposal aiming such cooperation within TERM in the phase between research and commercialization. A second workshop will focus on the components IP-protection and IP-portfolios as well as the choice of indicators for innovation support programs in early phases.

A final proposal, taking into account experiences from the benchmarking and all workshops, in the regions with regional stakeholders as well as workshops with the TERM consortium, will be presented as part of the TERM project's final external delivery.

5 Wallonia

Several companies that specialize in cell therapy and/or regenerative medicine are emerging in Wallonia: Bone Therapeutics (repair and regeneration of bone tissues), Cardio3 BioSciences (cell-transplant solution for curing cardiovascular diseases) and Promethera Biosciences (treatment of metabolic deficiencies and congenital functional liver insufficiencies). These companies are part of a network of about 50 regional operators that includes tissue and cell banks, highly specialized support services and university research laboratories. Recently, the region of Wallonia supported the creation of a collective platform for the production of commercial lots for cell therapy companies, and the launch of an inter-universities pre-clinical platform for technology transfer of cell therapy discoveries to industry.

During the benchmarking in June 2011, the team met with and interviewed representatives from the AST, representatives from the three academies including persons working at the TTO offices, and BioWin.

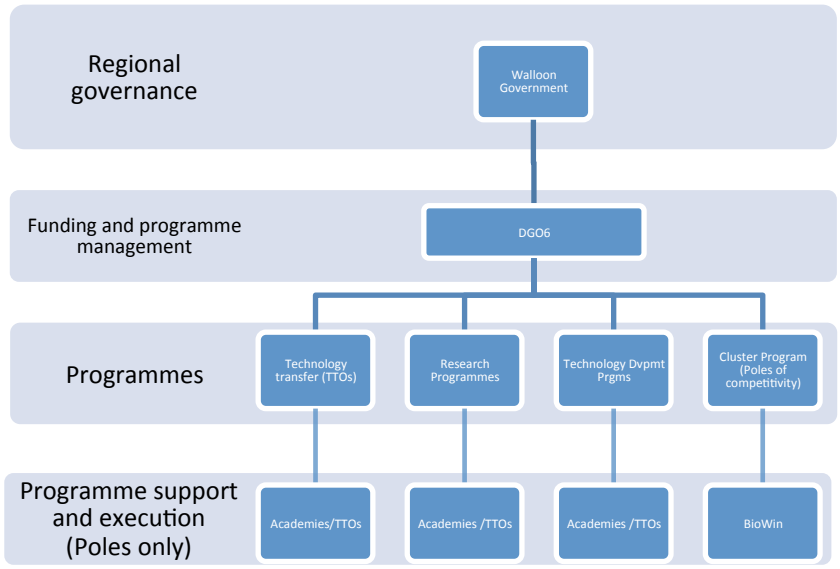

Figure 2: The structure of the Walloon innovation support system

3.1 The Wallonia innovation support system in short

By and large, the innovation support system for TERM in Wallonia has three levels (see figure 2). Apart from co-funding provided by firms, all funding comes from DGO6, the operational Directorate General for the Economy, Employment and Research. It supports and manages a range of programmes for applied research, commercialization and technology transfer, which in turn are handled by mainly three types of organisations (academies, TTO and BioWin). First of all, there are three “academies” in Wallonia, which transfer funds to different projects. Most research projects financed by the region must include partnership between companies and research. There is also an organisation called Biowin, which is a “pôle de compétitivité” – or cluster organization – that manages its own R&D program in concertation with the DGO6.

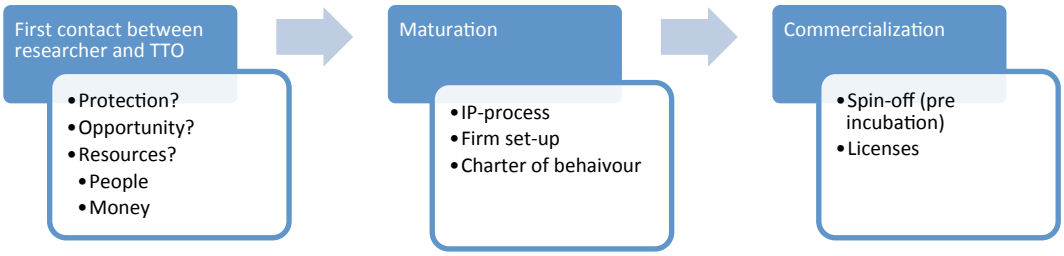

Figure 3: Innovation support process

IP and business set-up processes are typically parallel. The technology transfer process is governed by follow-up meetings and a “Charte de droits et devoirs” which is a common code for behaviour. The charter is not legally binding but still considered an efficient instrument.

5.2 Organisations

5.2.1 Academies

There are three Academies in Wallonia: the Académie Universitaire Louvain (AUL) comprising the Université Catholique de Louvain (UCL, Louvain) and the Facultés Universitaires Notre-Dame de la Paix (FUNDP, Namur) et St Louis à Bruxelles; the Académie Universitaire Wallonie–Bruxelles (AUWB) comprising the Université Libre de Bruxelles (ULB, Brussels), the Université de Mons (UMons, Mons); and the Académie Universitaire Wallonie–Europe (AUWE) comprising the University of Liège (ULg, Liège) and the Faculté Universitaire des Sciences Agronomiques de Gembloux (FUSAGx, Gembloux). These academies have a broad mission relating to the intellectual, social and economic development of their respective regions and since they are academic institutions in their own right, they can also fully assume, upon request, all roles of their member universities: teaching, research and service to the community. With regards to the benchmarking of innovation support, however, they are mainly relevant in terms of their function as support program managers and promoters of research commercialization.

5.2.2 TTOs

The Technology Transfer Offices - TTO aims to facilitate collaboration between Universities and external partners (public and businesses) in terms of scientific services, research and development, utilizing the results of research and participation in local and regional development. The following TTOs are included in the benchmarking: Université Libre de Bruxelles TTO (ULB-TTO), Université de Liège TTO (ULg), and Université catholique de Louvain TTO (LTTO/ULC).

The TTOs are commonly situated together with other organisations that in a wider range are engaged with innovation support. Since variations in the composition of such local setups are not deemed significant for the issues under study here, only TTOs are covered. This is not to say that TTOs are the only relevant on-the-ground player for innovation support. However, as is the case in most EU-states, research commercialization and technology transfer can go through the TTO, which means that these are often a first point of contact for researchers and should be involved in one way or another. There is however a parallel support process that is worth mentioning – this is handled by the cluster organisation BioWin.

5.2.3 BioWin

BioWin is a health competitiveness cluster created in 2006. Its mission is to coordinate all stakeholders in the region participating in innovation and training in the field of biotechnology and health. The objective is to create a new culture of openness and partnership favourable to innovation in Wallonia, to train, attract and retain in Wallonia a human capital of excellence, to help build collective infrastructure and technological platforms, and to internationally promote the strengths of the Walloon region in the area of Health biotechnology and medical technologies.

5.2.4 Other organisations

PICARRÉ offers assistance relating to the development of intellectual assets management.

INNOVATECH offers innovation project services and coaching.

ACCORD WALLONIE coordinates Walloon research centres (some, set up after WW II are financed mainly by industry, but the more recent are publicly financed), promote their technological resources and aims to strengthen synergies between the centres. The focus is primarily on industrial research and prototyping. *Accord Wallonie* is currently in the process of setting up collaboration agreements with the Academies so that all research prototyping will be done by *Accord Wallonie*.

SPOW is the Walloon network for regional science parks.

AST – the technology stimulation agency (under the regional government) – was founded five years ago The core mission of the AST is to organize and to network intermediation professionals in science and technology; AST does not work directly with companies but coordinates the existing networks like Accord-Wallonie, SPOW, PiCarré, etc.

There are also a number of incubators and investors, as well as several other organisations that are not of clear relevance to the purposes of this report.

5.3 Programs

The total regional budget for applied research (all areas) is approximately 200 million EUR. Representatives working with some of the programmes described below sometimes ventilated the need for indicators following both programmes and selected projects.

5.3.1. Support to technology transfer

During the 1980s, alongside their traditional missions of education and research, universities and higher education schools have gradually developed a third type of activity: industrial and commercial development of research conducted within them.

This trend has accelerated in recent years: when conducting research downstream of basic research, universities and colleges are increasingly attentive to the industrial and commercial markets, and the protection of intellectual property; they participate more actively in international research programmes, in partnership with other laboratories, with research centres and enterprises; they create an increasing number of spin-off companies; some of them have set up venture capital companies that invest primarily in the spin-off and other startups.

To support and encourage this movement, it was first decided in 1998 that the administration would no longer own the results of sponsored research conducted by universities and colleges. The second step was then to implement research programmes with calls for proposals and evaluation criteria of which the potential industrial and commercial development.

At the same time, two accompanying measures were also implemented:

Support of actors, called "valuators", that universities and colleges specifically affect the valuation of research results;

Support of patent fees of financed projects.

The valuators usually work in a "business interface" of their institution. They strive to develop patterns of utilization of the results of research with economic potential and determine the strategy of patent protection or otherwise.

Support to patent fees for universities and higher education institutes

Besides funding valuators, the DGO6 supports patent applications when the patentability and the potential economic outcomes are demonstrated. In recent years, the support has been expanded to other research institutions.

5.3.2. Research programmes

Mobilizing programmes

Through mobilizing programmes, Wallonia has set two objectives: to strengthen the scientific potential of its universities and colleges as well as developing the expertise of recognized research centres and developing them with the Walloon industries. These programs are usually based and focused on areas that are of great interest for the Walloon industry.

“FIRST” programmes

Exchanges between academia and industry are a major objective of the Walloon Government in research and technological innovation.

FIRST programmes enable researchers to learn from industry while maintaining their academic anchor. Each project supports, for two years or more, salary costs of a young researcher responsible for conducting, in the university or higher education colleges, a research project that could have a long term impact on the Walloon economic and social development.

FIRST Programmes have three key objectives:

- Increasing the scientific and technological potential in universities or higher educational colleges and recognized research centres;
- Valuation and transfer of this potential to Walloon companies;
- Training future business executives to emerging technologies, in order to disseminate them among Walloon companies in which they are expected to pursue their professional activities.

"FIRST spin-off" aims to support the creation of spin-off and training to entrepreneurship for researchers through the development and validation of products, processes or services that could create value in industry in the short term.

“FIRST international” aims to support and develop partnerships between Walloon companies and research units of universities or higher educational colleges through the development and validation of products, processes or services.

“FIRST Higher Educational Colleges” and “FIRST Enterprises” aims to support the transfer of technology and know-how to Walloon companies by increasing the scientific and technological research units associated with universities, through the development and validation of products, processes or services that create value in industry in the short

term. In the first scheme the researcher is hired by a University or Higher educational College, in the second one, by the Enterprise.

“FIRST DOCA”: aims to develop a new technology that can be valuated by the research centre to Walloon companies. The project is part of a doctoral thesis conducted by a researcher in a recognized research centre in collaboration with an academic unit of the French Community. The student is supervised by a university sponsor designated by the academic unit.

CWALity

This program aims to support the development and validation of products, processes or services essentially new for industrial development in the short term by SMEs carrying the projects submitted.

CWALity has two objectives.

- Conducting research in an industrial SMEs in order to develop a new product, process or service that meets a market demand (new needs) ;
- Strengthen collaboration between the research world and the business world.

Technological guidance

The Walloon Region has a large number of recognized research centres that can contribute to the dissemination and integration of emerging technologies in the industrial sector and can assist companies wishing to improve their processes or to develop a new product.

Technology guidance is designed for businesses seeking a scientific or technical expertise from a research centre, the profit of technology audits of problems with processes or products. It aims the promotion of technological innovation in enterprises.

Collective research programme

This programme aims to strengthen the expertise and know-how of approved “collective research centres” in areas relevant to the activities of a group of companies or a Walloon industry. It involves the selection of research projects that could contribute to social and economic development of Wallonia.

To ensure the opening of interdisciplinary and comprehensive coverage of projects, the association of at least two centres is mandatory.

5.3.4 Cluster projects

"Competitiveness clusters" in R & D focus on innovative and collaborative projects that bring together multiple partners (companies, universities, colleges, research centres, public research organisations).

Wallonia has decided to strengthen regional competitiveness in sectors where it already had potential. After an academic study identifying the most promising areas, the Walloon government has identified five areas of economic importance and, in 2006, five Walloon competitiveness clusters were labelled, one of them being in life sciences, Biowin

5.3.4.1 BioWin R&D portfolio

BioWin runs one of the research programs, funded by the DGO6, that aims to bring research results towards applications in projects set up by Walloon companies and academic researchers. The programme is guided by a portfolio philosophy, and issues regular calls for proposals.

The team behind the programme works closely with the project teams from cradle to grave.

As of March 2012, BioWin has just above 20 R&D projects in their portfolio. The projects are distributed in technological and time-to-market dimensions as shown in table 1.

Time to market	< 3 years	3 - 8 years	> 8 years
Biomarkers	0	4	1
Tools and instrumentation	3	1	0
Drug delivery systems	0	4	1
Novel therapies	0	1	1
Human health IT	0	1	0
Medical devices	0	2	0
Drug discovery	0	0	2

Table 1: BioWin R&D-project according to technological and time-to-market dimensions

To be eligible for funding applicants have to:

- Be a consortium of at least two firms and two academic institutions based in Wallonia (the consortium may include partners from outside the region but these are not funded)
- Be a consortium managed by a firm
- Fit with themes defined by BioWin (see table 1) and must be innovative
- Be a true partnership (no subcontractors)
- Provide at least 20 % co-funding for firms, depending on the size of the firm

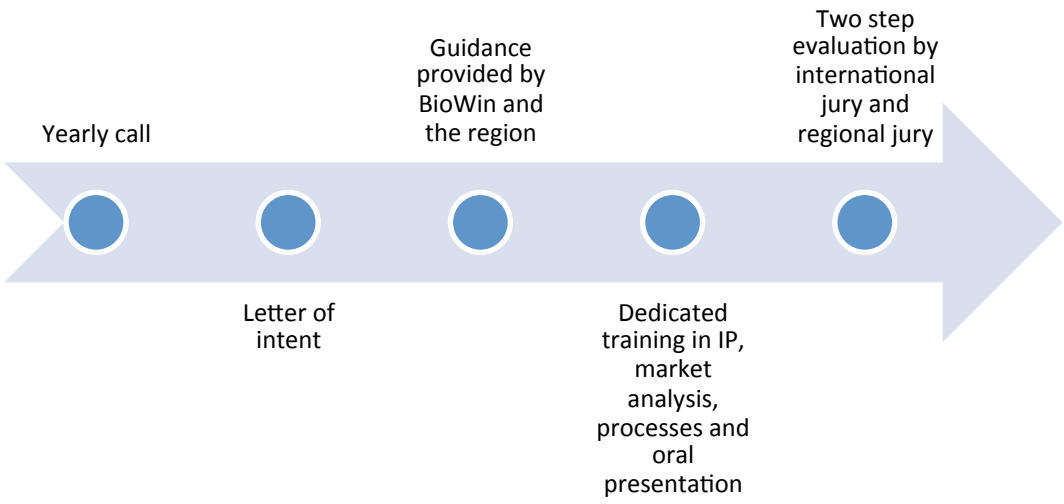

Figure 4: The BioWin call R&D-project selection process

Once a project has been approved by the Walloon Government it enters a follow-up process that involves:

- For each project, biannual contact between BioWin and the consortium
- Mid-term evaluation by international jury with a focus on deliverables and schedule for commercialization

- Regular reporting to the Walloon Administration
- Exit meeting at the end of the project

BioWin has possibilities to stop projects that do not meet expectations but only at the mid-term evaluation. Both the selection and evaluation processes offer a strong quality value to the projects – especially as a result of the world class competence that is making up the international juries. TTOs are sometimes negative to the BioWin project since it is parallel and in some ways in competition with their own projects.

5.3.5 Technological development programmes

Fonds de maturation

Fonds de maturation (Maturation funds/FdM) was set up in order to provide more funds for proof-of-concept projects. An international benchmarking had identified that there was a missing link in the Walloon system and that firms were created too early – before proof-of-concept had been established. The programme has been running for two years with two calls per year.

Candidates are selected by a committee composed of academies, TTOs, funders and other actors in the region. DGO6 then has to approve the list of candidates – which they usually do unless there is some formal error in the application. Two significant formal requirements are that the project is based on research that has already been funded by applied research funding from the region and that it has a potential to be commercialized within the region.

In some cases projects are encouraged to find industrial partners or at least a letter of intent. There is, however, no limitation to licensing and the university cannot claim its normal overhead. Each project receives 50 000 – 100 000 EUR.

Some academies make a general call while others actively scout candidates through TTOs – or combine the two strategies. There seems to be a preference for the general call as scouting is too limited and the call also fills a pedagogical and marketing function.

A clear limitation is that the FdM are only open to regionally funded research.

Funding to Companies and refundable loans

They are granted to a company wishing to carry out an experimental development project.

The granting of the refundable loan is subject to several criteria like the innovative nature of the project including its contribution to scientific progress in terms of acquisition of new knowledge, the project's technical feasibility and its relevance to the technical and economic needs of the Region, etc.

As part of this assistance, the company owns the research results in compliance with the agreement with the Walloon Region.

5.4 General observations from the Walloon innovation support system

Close management and follow up of selected projects, as well as which phase of the commercialization process that is targeted seem to be very important success factors.

This was mentioned in relation to The Fonds de maturation and the Biowin programmes, for example.

However, the Fonds de Maturation programme is limited to already regionally-funded projects.

One interviewee mentioned the risk that researchers take the step towards commercialisation too early. Badly timed support could be counterproductive. The lack of common clear definition of proof-of-concept (even at European level) could lead to such timing problems.

The rules of financing are defined by a decree and depend on the status of the research organisation categories (Universities, SMEs, Research centres or large companies).

Regarding the time to contract, there is still room for improvement in some programmes: The objectives of DGO6 regarding all 2012 calls are eight months from publication of the call to contract signature (six months form deadline to contract).

6 Pays de la Loire

In the case of France, the national and regional innovation support structures are quite intertwined. Far from being a remote source of funding (which is also the case), the national support structure is represented “on the ground” in the form of regional innovation support offices that play an active role in the regional landscape. Some functions of regional programs are at the moment, or are becoming increasingly, parallel to national functions. This is briefly illustrated in figure 5.

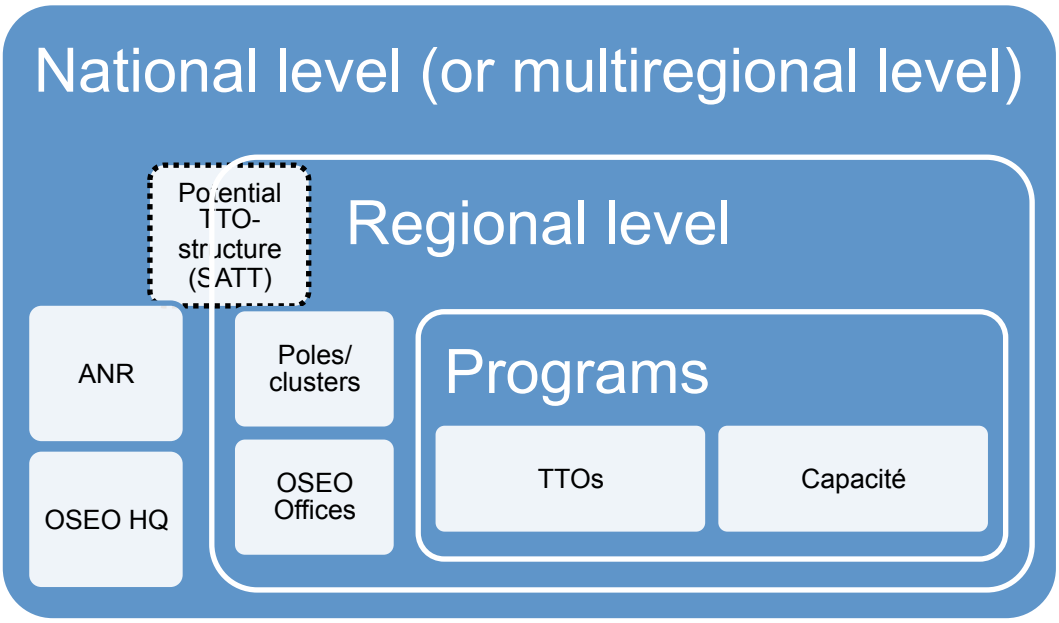

Figure 4: A brief overview of the innovation support structures present in Pays de la Loire

The national level offers various sources of funding, like OSEO, a national agency supporting companies. OSEO is also regionally present and has an executive function in the innovation support programs. At the regional level the Competitiveness poles (or clusters) are important actors along with the Région Pays de la Loire itself. Finally there are a number of organizations that work specifically with certain aspects of innovation support. The following describes this in more detail.

6.1 Région Pays de la Loire

The regional government of Pays de la Loire (RPL) is a significant financier of both basic research and of commercialization projects. The French state allocates a research budget of approximately 55 million EUR to the region out of which 10 million EUR go to specific research projects and the rest to larger infrastructural and competence development programs.

For the period 2007-2013, RPL distributes the funding according to a scheme of seven main priorities that are based on the regions academic strengths – for example the health area. Health alone receives about 40 % of the regional research funding. The aim of the regional funding is to fund research which is not yet ready to apply for regular state funding but which has the potential to be developed into a successful candidate for state or EU funding. One of the overarching aims for the region is regional economic growth through innovation.

RPL has several tools for stimulating innovation. For example, the “transfer engineer” program supports projects towards achieving proof-of-concept by dedicating an expert full time to the project for a period of one year. The funding for this program comes from various sources, mainly from the Fonds Pays de la Loire Territoires d’Innovation, managed by OSEO (see 6.5) and funded by both the Region and the State.

Another tool is the “innovation detection” service, or scouting, in which approximately ten experts scan for potential project and present interesting findings to a funding committee. The “Regional Gate to Innovation”-tool focuses on putting academic researchers to use as consultants to industry. A final example of the kind of innovation support that is provided by RPL is the effort to attract strong academic researchers to the region. Regarding proof-of-concept project funding, RPL makes selections in part on a strategic basis, assessing candidates on how much the region would benefit from the project and if similar work has already been funded, and in part on the characteristics of the project as such, for example by assessing if it is mature enough to reach proof-of-concept if funded.

Approximately one in five applications is successful in receiving funding. So far, funded projects have mainly been evaluated on (i) how well they have achieved goals and milestones; and, (ii) their impact on their respective thematic area in the region. The RPL is currently looking at developing new ways of evaluating projects.

Currently, work is underway to make innovation supporting tools and programs more efficient with the state financed innovation organization SATT (Societé d’Accélération du Transfert des Technologies, or Organization for Acceleration of Technology Transfer). What this change will mean for regions like Pays de la Loire and their future role is yet unclear.

6.2 ATLANPOLE

One of Atlanpole’s missions is to stimulate innovation-based economic development, in particular by stimulating the creation of new firms with growth potential. The cluster works with several growth industries – one of which is biotherapies.

Atlanpole may support the entire life cycle from project selection to firm growth. The first step commonly involves scouting of potential candidates. A committee composed of people from academia, industry and other expert groups meet on a monthly basis to select which projects that should be supported. The selection is made from a regional pool of candidates that may represent more or less any technological area.

A majority of accepted candidates will enter a five year program which aims to result in a successful firm start-up. Those candidates not suitable for firm creation will follow a specially adapted parallel program. Unsuccessful candidates may be aided by Atlanpole in finding ways forward. Each project has a budget of approximately 100 000 EUR, of which 15 % goes to external services and the rest is in kind contributions by Atlanpole. To some extent, external partners also contribute in kind. All in all, the program costs about 1,2-1,8 million EURO per year.

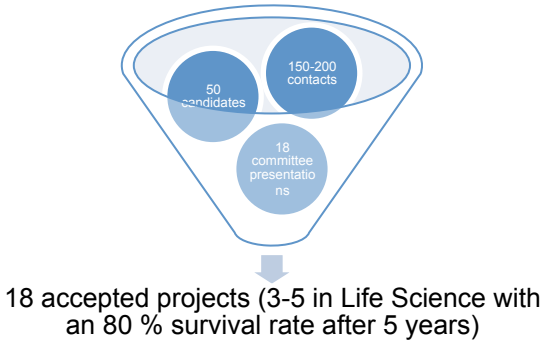

Figure 5: Illustration of the Atlanpole project selection process on a yearly basis

Atlanpole's support starts before the candidates meet the selection committee in the form of summary market studies, short education for the candidate research team and the development of a "pre-business plan". After a project has been selected and a firm structure has been set- up, a more comprehensive support process picks up.

Throughout the process, a consultant follows the firm closely. Each consultant typically manages a portfolio of 12-15 firms, which are supported in several ways: (i) to develop strategic market plans; (ii) to target the right market segments; and, (iii) to develop business models.

Firms also have access to a "talent pool" of lawyers, IP experts and accountants – some for free, others for a fee. Education is also provided for project managers, mainly in human resources, marketing, sales and negotiation.

Projects are selected on both a "technology push" and "market pull" basis – that is, both projects that meet the markets need to solve existing problems and those that create new market segments, are of interest. Most projects, however, are relatively mature from a technological point of view. Occasionally, and if motivated by market studies, projects that does not yet have proof-of-concept are selected in order to support the finding of such proof.

In the life science area, drug development projects are rarely selected since such projects are too far from market. These may instead enter the collaborative project route. However, start-ups within the pharmaceutical area are common, there is even some within the sub area of regenerative medicine, but these have often started out as knowledge intensive service companies. These companies are entitled to the same support as those starting with a product focus. In fact, this route towards commercialisation is even encouraged, as it gives the company a certain financial strength before starting costly r&d efforts or discussion with external investors.

In terms of the regional connection of the project, the important factor is not whether a project already has strong links to the regional economy but rather its potential for future impact on for example job creation in the region. There is, however, probably some natural bias towards favouring projects, which are familiar in the sense that they are in line with the regional experience in terms of sectors and technology areas.

In terms of indicators and other type of follow up, Atlanpole measures the number of successfully created firms while maintaining a humble perspective. As Atlanpole would be the first to point out, they are often but the first of many actors that contribute towards successful firm creation and development, and it is difficult to assess the exact importance of each of these actors' contribution – including that of Atlanpole. This is of course a general problem when it comes to attributing success to various component of a complex innovation support system.

6.3 Atlanpole Biothérapies

Atlanpole Biothérapies (Atlanpole Bio) is a competitiveness cluster driven by Atlanpole that specializes in three areas of biotherapy:

- Immunobiotherapy
- Regenerative medicine (cell- and gene therapy and biomaterial)
- Radiotherapy

Constellations of three or more partners (at the moment at least one laboratory and two SMEs) may receive support for developing innovative ideas within the listed areas. Atlanpole Bio helps selected projects with feasibility studies, to find additional partners, administration and applications, market studies and finding funding. Being labelled as an Atlanpole project also brings certain benefits when applying for funding from the Fonds Unique Interministériels, FUI.

Financing may come from regional as well as national sources and comes in different sizes depending of the regional attachment and the partners. Regional projects may be financed up to 45 % while exterior projects may be covered to 30 %. Foreign partners are welcome but are not eligible for funding.

Both technology push and market pull projects are accepted. There used to be an imbalance caused by a general lack of interest among researcher, but this has started to change recently. Approximately 10 % of presenting project candidates are accepted.

6.4 TTOs

Two TTOs have been studied: The TTO at the University of Nantes (TTO-UN) and the TTO at the university hospital (TTO-CHU).

TTO-CHU is mainly an interface between researchers at the university hospital and external technology transfer actors, such as patenting offices. TTO-CHU also supports researchers by allowing them to use university facilities, to help them find clinics for clinical trials, and with regulatory and biostatistical issues. The hospital also supports clinical trials connected to the TTO. TTO-UN offer more support in terms of regional, technological and competitive intelligence reports. Both TTOs also perform a general project feasibility assessment.

The TTOs receive an annual budget for handling patent applications and are in a sense limited in their capacity to offer additional services. If the IP fails to catch interest in the market after targeted and general marketing, the TTO is generally out of options even if the researcher is motivated to continue the project.

TTO-CHU has about fourteen patents of which eight have been licensed. TTO-UN has about fifty patents of which twenty are licensed. Currently the system is undergoing change as the SATT-project is being introduced. SATT stands for Societé d'Accélération du Transfer des Technologies, or Organization for Acceleration of Technology Transfer and is an initiative to integrate all TTOs and their staff. The initiative will be built on a multi-regional basis, using the regions' skills, experiences and specificities.

As is commonly the case in Europe, the TTOs in Pays de la Loire suffer from a lack of resources, mainly in terms of staff. The TTO model of co-owned patents and patent marketing takes time to carry out and therefore there is a lack of time to do the necessary market intelligence work. Another problem, which Pays de la Loire also shares with most other places is a lack of coordination between regional innovation support actors and the TTOs.

6.5 OSEO

OSEO is a national agency and is present throughout France. Its mission is to support innovation, to guarantee bank loans and funders and to provide mainly investment funding for companies. OSEO is a national organisation with a centralised program for all of France, but it has several regional offices and also collaborates with the Pôles de Compétitivité (Competitiveness poles or cluster organizations). The main target group is SMEs and these are supported in a number of ways.
The foundation for OSEO operations is that the organization has its own budget for innovation support. The support offered to firms may pertain to any step of the firm's development and the size of the support will depend on the needs and potential of each particular project.

The main innovation support programs provided by OSEO are:

(i) "Aide à l'Innovation", which is a soft loan (interest free) which is only reimbursed if the project is a technical success.

(ii) Cluster program financing innovation, which biannually supports regional cluster calls for collaborative projects typically involving SMEs, large companies and public laboratories.

(iii) Strategic industrial innovation program, which focuses on breakthrough innovation. This program awards grants or loans, depending on how close to the market the funded tasks of the project are, in order to find R&D-based solutions to gaps in industrial value chains.

(iv) Zero interest loans, which aim to improve cash flow. Comes with the same support methodology as other OSEO programs.

(v) "Loans for pre-equity phase", for very young companies with exceptional innovation potential. The aim of the seed financing is primarily to help early stage projects into better positions for negotiating with potential financiers. This loan can be combined with Aide à l'Innovation.

In the case of the Pays de la Loire region OSEO supports about 200 projects per year, distributed on five business advisors. The national OSEO office in turn to a large extent supports the regional office in Pays de la Loire with IP-issues, legal aid and technical support. The geographical setup of OSEO is therefore a combination of the national and regional structure. The national level offers support in certain areas but the regional presence is important for OSEO's ability to efficiently support the projects.

Only French partners are eligible to OSEO funding but foreign partners can be part of the project as far as they do not require French funding.

The main contributions of the OSEO structures described above are: (i) access to the OSEO business development methodology; (ii) an increased access to funding for the project, and; (iii) an increased access to external competence. In addition to this OSEO also offers information about and access to European collaboration and other international openings.

The main target group for OSEO is innovative firms but the organization may also support a research group that wish to commercialize research results. The latter, however, often requires an active interest from a firm in the research group.

The OSEO method and focus is currently undergoing some changes. First of all there is a shift in focus from technology to financing, as OSEO observes that even technologically successful project will fail if there is no funding. In general, there are more good ideas than there is funding. In this sense it makes more sense to work with efficient financing

via loans and guaranties instead of grants. Another change in focus is from helping to start firms to helping firms develop and grow in a sustainable way.

6.6 Capacité

CAPACITÉS is an organization within the University of Nantes in the Pays de la Loire. Its mission is to professionalize the interface between industry and academic research. CAPACITÉS was created in order to increase the university-internal impact of technology transfer projects. Previous experiences showed that most of the beneficial impact land in industry and that most transferred technology do not reenter the university to form a base for further research.

Therefore, CAPACITÉS is owned by the university and it does not sell patents or knowledge, but rather methods and products. Also it does not create spin-off companies but rather aim to create new activities around university based projects.

Otherwise the approach is for the most part similar to that used in classical research based business development. One difference worth noting is that there is a clear ambition to let researchers be researchers and not to try to force them into business. Instead, engineers are involved to commercialize the project or to develop it toward a proof-of concept. They are also in charge of the exploitation of the knowledges and the skills and of their transformation into services for the companies to provide source of innovation.

CAPACITÉS is a fairly young organization and it is hard to say anything about the results. The envisioned results is to create licensable IP, products, firms or service sales in a form that will allow the competence to remain within the university. Today, CAPACITÉS has ten teams located in 10 different laboratories (out of a total of 75 labs). Financing is currently provided by ordered research and by sales of services.

The main idea behind CAPACITÉS is that commercialization should develop within the university, indeed in the very laboratory where the research is being carried out. The argument is that commercialization entails so much more than creating a patent – it is also about know-how and competence creation. While a patent may be sold and exit the lab, the other knowledge that has been created in the project should be used to, for example, increase the capacity and attractiveness of the laboratory. CAPACITÉS allows linking the university at the economic world within a long-lasting relation both demand-oriented and supply-oriented (inbound and outbound open innovation). It gives the university, the capability to follow the needs of the market and to companies, a support in their process of innovation. The ambition is to extend CAPACITÉS activities and to further link them with other regional innovation support functions.

7 Milano

Unlike the preceding case-studies, the Milano study focuses on just one actor in the RISS – the TTO of the San Raffaele Hospital. The hospital has a strong research agenda and is a "private Scientific Institute, belonging to the San Raffaele del Monte Tabor Foundation, recognised by the Italian Ministry of Health as a Scientific Institute carrying out biomedical research and clinical activities of relevant national interest (IRCCS)."[6] There are approximately 700 basic research scientists working at the hospital in different fields and there is a medical school that offers a broad array of training programs.

The aim of the TTO is to help basic and clinical research results to reach the market and the TTO reports directly to the scientific director of San Raffaele. There are several ways in which technology developed at the hospital can be transferred to the market.

7.1 Forms of tech transfer

The primary goal is to find a way to develop products and services in collaboration with industrial partners. In some cases, however, the TTO develops ways to continue the project internally. This is common for cell- and gene therapies, since the potential of such therapies is often better understood by the hospital-based TTO than by an industry who mostly focuses on the fact that the technologies are often far from market at the time of transfer and also typically require years of expensive and clinical trials before they are marketable.

In a majority of cases the technology transfer takes place within a pre-existing company structure but some transfer processes have resulted in spin-off companies, e.g. in cancer treatment, telemedicine services and diagnostics services, to mention a few.

A third form of technology transfer is strategic alliances with large multinational companies, for example GlaxoSmithKline (GSK) and Merck Serono. GSK and San Raffaele have a partnership in gene therapies, focusing on six rare disease areas. The partnership dates back to 1994 when San Raffaele and GSK started working on gene therapies for treatment of Severe combined immunodeficiency (SCID). Today, three treatments developed within this partnership are in phase III clinical trials. The advanced treatments developed by GSK and San Raffaele are not always patented. In the case of the SCID-therapies, this is protected by an orphan drug status, which gives similar or even better protection than a patent.

One very important contribution of GSK in this partnership is that they are able to develop cures into actual treatments that can also benefit patients outside of the San Raffaele hospital, something that San Raffaele does not have the capacity to do on their own. On the financial side of the technology transfer project in strategic partnerships, the industrial partner receives exclusive rights to the technology platform in exchange for an initial down-payment and following milestone-payments. San Raffaele then invests this money in the development of therapies and will, at the end of a successful project, receive royalties from the industrial partner's sales.

San Raffaele also has a multifaceted strategic partnership with Merck Serono in neuroscience. Merck Serono provides support for a neuroscience institute at San Raffaele, including a PhD-program. Furthermore, the company invests in specific neuroscience research project, the resulting IP of which will stay with the San Raffaele hospital. In exchange Merck Serono gets molecules validated by San Raffaele and also some clinical trial work carried out by the hospital on Merck Serono molecules and clinical methods. Strategic alliances are not restricted to agreements with global pharma companies. The

[6] *http://www.sanraffaele.org/EN_home/Care/Introduction_to_the_Hospital/index.html*

business model is, on the contrary, available for any company in search for cooperation with pre-clinical and clinical research groups.

7.2 TTO methods for finding, selecting and transferring technology

Like many other TTOs, the TTO at San Raffaele has very limited resources to do anything else than to be the interface between research and business. All in all three people work at the TTO, two of which have a research background and manage the interface with scientists at San Raffaele.

The interface with researchers is mainly managed through personal monthly meetings where the TTO visit groups of researcher. The aim of the meeting is at the one hand to try to understand what the researchers are doing and what of this that may be relevant for the future and for industry. On the other hand, they also serve to help the researcher understand the value of commercializing their research, not the least in terms of the economical benefits this could bring to the lab and to the researcher personally. Good examples play an important function in this context and also spread through word of mouth. Successful technology transfer project therefore have a value also in that they tend to generate further interest and ambition among researcher for patenting and commercialising their research results.

This open ended approach, however, only seems to work at the TTO-researcher part of the interface. The San Raffaele TTO previously tried to make IP, research results and good examples visible to industry but it proved difficult to expose such things in a meaningful way. The reason seems to be that results are still in a very early phase of developing a new treatment, and often represent only small pieces of a larger puzzle. Unless the industrial unit is really initiated in the particular piece at hand, they risk ending up with only parts of early data, related to pipelines affected by high attrition rates before approaching the FDA or similar.

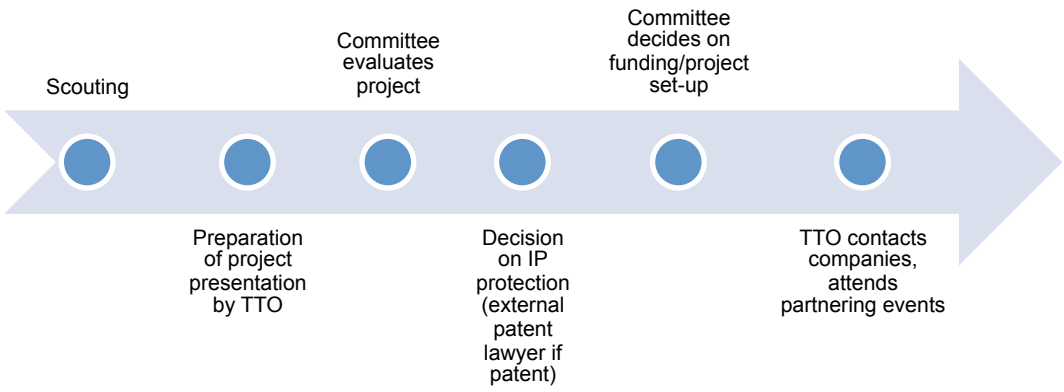

Figure 6: Overview of the San Raffaele process for finding, selecting and setting up technology transfer projects

Once the TTO has identified relevant results, a committee of senior experts evaluates these. The TTO writes a summary on the result, which discusses, among other things, its novelty, usefulness and market applicability. The scientist behind the result then makes a short presentation of the project and there is a discussion about whether to patent or to

use other forms of IP protection. If a decision is made to patent, an external patent lawyer is engaged to prepare the application (commonly a US provisional patent application).

Once a project is approved the TTO bring the presentation material to identified companies that might be interested and to the matchmaking sessions at partnering events. The single most important aspect of the project marketing process, however, is that the scientist behind the project goes to these events and makes a good impression on potential industry partners.

It is the committee that makes all major decisions in the above-described process. However, they are guided by another committee, the Scientific Advisory Board. This group consists of internationally renowned scientists – all members are currently non-Italians – who come once a year for a 3-4 days session where they meet with the heads of divisions from the San Raffaele hospital. The Scientific Advisory Board evaluates the scientific content of the research carried out at San Raffaele and also the TTO. The evaluation results in a report which serves to help San Raffaele and the TTO to decide which areas to develop and which to drop. This is an important tool for freeing up unfruitful investments. While the industrial partners of the TTO are often relevant in making decisions on which IP to keep, they are insufficient for this discussion on strategic areas for the future and the Scientific Advisory Board therefore fills an important gap.

7.3 Results and room for improvement

As of 2011, the TTO at San Raffaele had 45 patent families and 53 licences. Whether technology transfer projects end up in a patent or in a licence depends on the case and also on the collaborating partners. In some cases, it is important to patent in order to be able to cooperate with industrial partners. In other cases, for example involving antibodies, expertise or animal models, the result are often not patentable, but still possible to license to companies. Licenses may be an important way to speed up the research, but if licenses to not have continuous support from the inventor they will quickly fail. In the end it is the committee that decide which form to choose.

The TTO is principally evaluated on whether it brings enough profit to cover costs. To break even it needs to make about 3,5 million EUR per year, which is about 5 % of the total research budget, and by these measures the TTO is doing well.

In order to further strengthen its contribution, however, the TTO identifies the following needs:

- A platform budget that would allow the TTO to invest about 50 -100 000 EUR in each project. This would significantly help developing the technology, validation and arriving at proof-of-concept. There are many projects (25-30 % of all dropped projects) that almost make it to a point where companies would be interested to invest but that have to stop when they hit the gap between technology transfer funding and validation/proof-of-concept funding.
- Lowered regional restrictions by funders so that the TTO would be able to broaden the matching search outside of the region of Lombardy. There is not enough critical mass in the region, and sometimes not even in Europe, to find partners for projects.

8 Berlin

The actors in Berlin's Regional Innovation Support System (RISS) of particular interest in this study are situated in and around the *Charité - Universitätsmedizin Berlin*[7]. The *Charité - Universitätsmedizin Berlin* is a joint institution of the *Freie Universität Berlin* and the *Humboldt-Universität zu Berlin*. It is a renowned clinic with 300 years of tradition in health care and research. Being one of the largest research hospitals in Europe, the Charité has four campuses with more than 100 clinics and institutes. With 15 000 employees, out of which almost one third are doctors and scientists, the Charité is one of the largest employers in Berlin. The scientific mission of the hospital is mixed with excellent healthcare and internationally renowned training of clinicians and researchers. More than half of the German Nobel Prize winners in Medicine come from the hospital[1].

In the following, the most interesting actors and programs, from the perspective of the TERM-project, are exemplified.

8.1 Regional Structures

8.1.1 Charité – Universitätsmedizin Berlin

Several intermediates acting as interface between economy and academia offer innovation support at the Charité. Among these are the patent exploitation office ipal GmbH, the Charité Technology Transfer Office (TTO), the Business and Clinical Development units of Charité, BCRT and universities, the Berlin-Brandenburg School of Regenerative Therapies (BSRT), the Charité Stiftung Berlin, the central biotechnology coordination office BioTOP, and several centers for clinical studies. Services include scouting / coaching activities up to the assessment of patentability and market capability of new technologies and their comprehensive patent protection and technology development all the way down to successful commercialization and clinical application. Moreover, start-ups are supported by various regional and national public funding programs.

8.1.2 Ipal GmbH

The ipal GmbH[8], a company of IBB Berlin and Berlin´s universities, is a technology marketer in the Berlin region. Ranging from the assessment of patentability and market capability of technologies to their comprehensive patent protection and technology development all the way to successful commercialization and administration of property right portfolios, and strategic IP-consultancy, the company provides an extensive catalogue of services in support of innovations, patents and licenses. Apart from academics, ipal also operates for non-academic research institutes, small and medium-sized enterprises, start-ups as well as for patent and technology funds, thereby bridging the gap between science and industry.

8.1.3 Charité Technology Transfer Office

The Charité TTO[9] started as one of Germany's first university TTOs in 2002. At this time, German TTOs were in reality functioning as patent agency units within the universities. Following efforts to better implement the Lisbon Strategy 2000, however, technology transfer services have been further expanded, now focusing more on revenue opportunities for universities. Along these lines, cooperation with industry became more important. Today, the Charité TTO functions as what could be described as a broker between re-

[7] http://www.charite.de/en/charite/
[8] http://www.ipal.de/en
[9] http://technologietransfer.charite.de/

search and commercialization funding / programs. In short, the TTO scouts technology emerging in Charité research and helps identified projects to apply for and win grants for the commercialization of their research results.

The key competence of the TTO is to know the grants market and to be able to identify those emerging technologies, and the people behind them, that have the potential to succeed. As of 2011, the success rate of the TTO in terms of successful grant application was 120 successful applications in 150 tries, which by most comparisons must be considered quite impressive.

The TTO targets different funding programs at the EU, federal and regional level depending on the type of project that they are helping. For example, the PROFIT program[10], which is a regionally administered EU funding program; the ZIM program[11], which is a federal program awarding a total of 2 billion EUR for three-year periods, and; another GOBIO[12] which awards about 5-6 million EUR per project over two - three years. Another important program, which is described in further detail below, is the TOP 50 program.

Projects are identified solely through scouting, there are no open calls. The scout also manages accepted projects in terms of advice and coaching. The process by which projects are selected starts with a feasibility assessment in order to determine if the project is possible to carry out within the given budget and time frames. In the past, this step had often excluded drug development projects involving early stage clinical trials, based on a simple calculation of how much money is needed to get the project into phase IIa (which is here considered proof-of-concept). Getting such a project from the end of the preclinical phase to proof-of-concept costs about 10-15 million EUR, which exceeds the maximum budget of most grants. To overcome this 'valley of death' the German Federal Ministry of Education and Research (*Bundesministerium für Bildung und Forschung, BMBF*) has implemented the GOBIO program. Within the recent four GoBIO evaluation rounds, 34 projects were accepted for funding. Out of these projects, 15 companies were founded[13].

8.1.4 Berlin-Brandenburg Center for Regenerative Therapies

The Berlin-Brandenburg Center for Regenerative Therapies[14] (BCRT) is an interdisciplinary translation center in the field of Regenerative Medicine. With its bundled expertise and state-of-the-art infrastructure situated in numerous research facilities, clinics, small companies, and in particular with its tight research / clinical linkage, it offers excellent preconditions for translating the promises of scientific advances into clinical applications. The development of regenerative therapies is supported by the departments "Business Development" and "Clinical Development / Regulatory Affairs", as further elucidated below.

Business Development at BCRT

Currently, over 100 projects are being developed at the BCRT. The Business Development unit[15] (BD) supports these projects by providing opportunity analysis service to the investigators on the one hand and on the other by establishing the dialog with industrial partners at an early stage. BD's goal is to quantify project-specific translational risks as well as value potentials for prospective commercialization partners.

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[10] http://www.ibb.de/profit
[11] http://www.zim-bmwi.de/
[12] http://www.go-bio.de/
[13] http://www.go-bio.de/projects
[14] http://www.b-crt.de
[15] http://bcrt.charite.de/BD

Traditionally, new academic ideas are checked for their market potential by the technology transfer offices of the universities after patents have been filed and significant R&D resources have been invested (Fig. 1). BCRT scientists and clinicians check their concepts early on; at the stage of idea development. All information is used to develop an optimized target product profile with an increased likelihood for effective technology transfer.

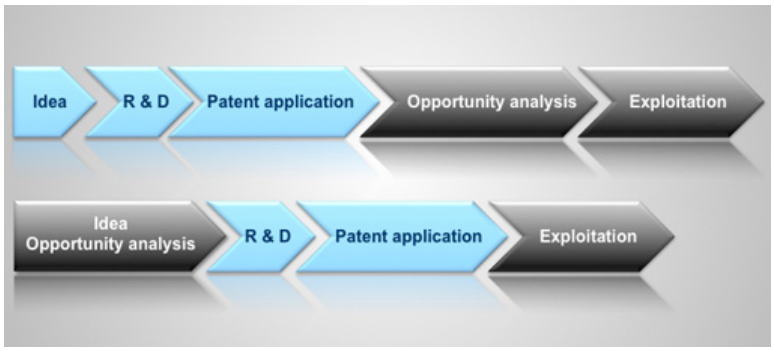

Fig. 1: *Early opportunity check infrastructure.* Traditional opportunity analysis after patent application versus early opportunity check of project ideas.

The BCRT needs partners from pharmaceutical industry as well as from academia for joint programs on early-stage candidates. At the regional level, the Regenerative Medicine Initiative Berlin-Brandenburg (RMIB, further described below) is an excellent platform for exchange between scientists and companies. At the international level, BD initiated the establishment of a German-Californian RegMed Initiative[16] for funding of joint projects, i.e. a cooperation of the Federal Ministry of Education and Research (*BMBF*) and the California Institute for Regenerative Medicine (CIRM). In order to further accelerate the translation of joint therapy development, BD recently initiated the formation of the Regenerative Medicine Coalition[17] (RMC) as a transatlantic consortium of six leading Translation Centers for Regenerative Medicine from Europe and North America.

Clinical Development and Regulatory Affairs at BCRT

The department Clinical Development and Regulatory Affairs[18] (CD) is supporting all projects of the BCRT selected for the development as medicinal product, medical device, or as a combination of both (mostly defined as Advanced Therapy Medicinal Product, ATMP). CD supports the development process from first proof of concept throughout to regulatory approval. Moreover, CD is a competence center and contact point for industrial partners seeking for expertise in the clinical development and regulatory affairs field of Regenerative Medicine.

Moreover, the Competence Center for Advanced Therapy Medicinal Products[19] (CCATMP), established in 2010 with support from the BMBF, cares for the early translation of ATMP-projects from basic research to clinical application (phase I / II clinical studies) and commercialization. By means of chosen case studies, regulatory and early health technology assessment processes are developed.

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[16] http://www.bmbf.de/en/6845.php?hilite=cirm
[17] http://www.the-rmc.org/
[18] http://bcrt.charite.de/CD
[19] http://www.ccatmp.de/

Berlin-Brandenburg School of Regenerative Therapies

The Berlin-Brandenburg School of Regenerative Therapies[20] (BSRT) offers an interdisciplinary and international education programs for graduate and post-graduate students with specific focus on education of biologists / biochemists, physicians / chemical engineers, and clinical scientists in the field of Regenerative Therapies. This graduate school is of particular interest to those wishing to look beyond pure research and who are aiming at translating their scientific discoveries in the field of Regenerative Medicine into clinical applications. At BSRT a new type of scientist is educated to have not only a profound understanding of their own field, but also a substantial understanding of the associated translational needs.

8.1.5 Stiftung Charité

Stiftung Charité[21] (Charité Foundation) promotes entrepreneurship and innovation at the Charité Medical School and supports it in its transformation into an entrepreneurial organisation. The Stiftung Charité was established in 2005 as an independent, private foundation by the entrepreneur and philanthropist Johanna Quandt, with the aim to support the innovative energy and excellence of the distinguished university hospital and medical school in Berlin. The Stiftung Charité supports application-oriented research and entrepreneurial projects, spin-offs and start-ups by its funding programmes and operational projects. Moreover, the Stiftung awards an annual innovation prize to the trailblazers in the Charité. A platform for inventive doctors and researchers from the Charité und other national and international medical schools in provided by the organisation of the “Charité Entrepreneurship Summit” that is a major event in the field of technology transfer. The foundation also organizes workshops for inventors in the life sciences and in medical technology.

8.1.6 BioTOP

BioTOP[22] was created by the two federal states Berlin and Brandenburg in order to coordinate all issues concerning biotechnology in the German capital region. The organization works with universities, research institutes, small- and medium sized businesses, investors and politicians in order to initiate specific projects and in other ways help develop Berlin-Brandenburg as an internationally strong center for Life Science. BioTOP is funded from a variety of sources, including regional government, the Berlin Investment Bank and the EU, and formally sorts under the *TSB - Innovationsagentur Berlin GmbH*. An advisory board of experts from industry and academia provides strategic support.

BioTOP offers a range of specific services to the various target groups mentioned above. Among other things:

- Initiation and management of networks
- Support for technology-oriented start-ups
- Support for innovative project concepts to access funding
- Building and coordination of scientific and interdisciplinary networks
- Establishing contacts between experts from all disciplines

[20] http://www.bsrt.de/
[21] http://www.stiftung-charite.de/
[22] http://www.biotop.de/

Another important part of BioTOPs mission is to support technology transfer from academia to industry, for instance by means of the TOP 50 program, as described below.

8.1.6 Top 50

TOP 50 is a program funded by the Federal Ministry of the Interior that aims at bridging the gap between basic research and market-orientated development. The program was created as a response to the ascertainment that there was a mismatch between, on the one hand, a high commercial relevance of many scientific findings and research results within the life sciences and, on the other, the low number of technology transfer projects that reached commercial exploitation. Several causes were identified to explain this mismatch, almost exclusively related to technology transfer rarely reaching proof-of-concept, which is more or less a requirement for the project to be attractive to further exploitation by industrial actors[23]:

- Scientists lack knowledge about commercialization or do not prioritize commercial utilization, since they have low incentives to do so
- Lack of validated data
- The value of research results for marketable services and products is not being recognized
- Lack of contact points between academia and industry which impedes access to development expertise and also limits the number of scientist in commercial networks
- Scarcity of resources in the region

In particular, this was seen as detrimental to the innovative potential of SMEs in the Berlin-Brandenburg region.

The TOP 50 program aims at helping projects bridge this gap by providing a broad range of support measures, such as IP-consulting, market analysis, partner searches, coaching, project development, business plan development and application support for additional funding (overlapping function with TTO as described above). All in all the TOP 50 projects receive support from a vast landscape of actors in the Berlin-Brandenburg regions, as illustrated in figure 2.

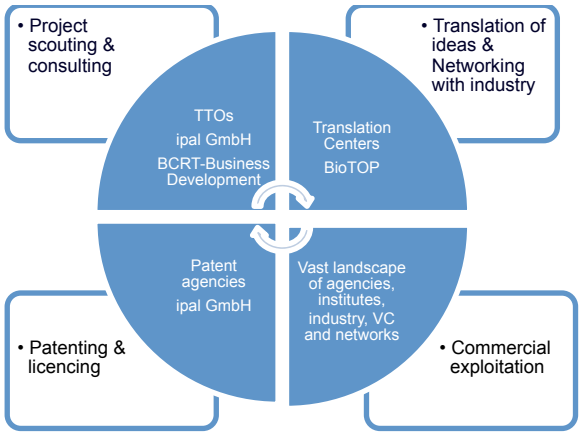

Fig. 2: *The context of the TOP 50 program*

[23] *Powerpoint presentation "TOP 50 A new approach to improve technology transfer in Life Sciences: From qualified projects to successful technology transfer" Bio-CT Workshop/ CEBR Special Interest Group Emerging Regions Debrecen, 2-3 March 2011*

The selection and support process starts when scouts identify potential candidates and helps them prepare initial project plans and descriptions. Candidates should be based in the Berlin-Brandenburg area, or at least in Germany. In the next step, BioTOP examines the consistency of the projects and selects appropriate experts together with their network of partners in industry and academina. For those projects that pass this pre-evaluation, the next steps involve an expert evaluation of the commercial value of the project and the development of measures and milestones by which the project will be managed and implemented. In the project implementation phase of the TOP 50 program, BioTOP and selected experts and partners continously give support and input to the researchers. TOP 50 projects may unfold in different ways depending on among other things the form of the project and the constellation of project partners. Both purely academic constellations and industry academia partnerships are allowed. Figure 3 offers a stylized overview of the TOP 50 process.

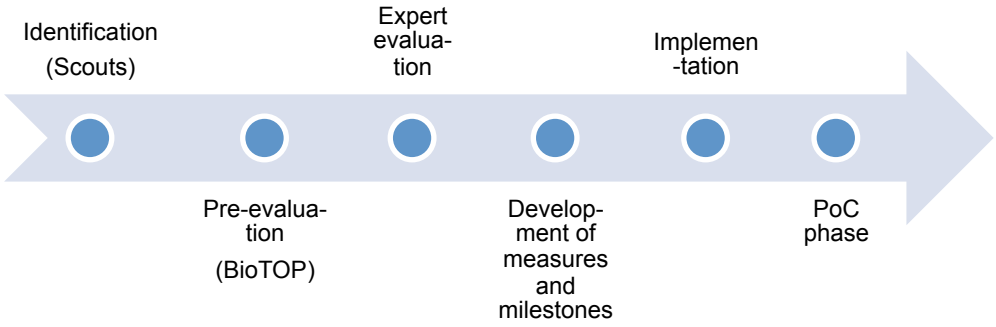

Figure 3: *The TOP 50 process*[24]

There are three key experiences made in the TOP 50 program. First, it is important to find competent experts from industry, especially for early stage projects. Second, intensive project management is essential. Third, there is a strong need to further stress the importance of technology transfer in academia and in the administration of public research institutions, so that these may better align their efforts with the RISS activities.

8.1.7 Regenerative Medicine Initiative Berlin-Brandenburg

Based on early initiatives to promote networking between working groups in the field of Regenerative Medicine, the "Regenerative Medicine Initiative Berlin"[25] (RMIB) was founded in 2003. Initially focused primarily on science, the network opened out to the corporate sector in 2007 and has concentrated since then on networking between scientists and industry as well as between companies. RMIB establishes joint working groups between scientists and users, develops communication structures between the players in Regenerative Medicine, as well as to adjacent fields and regional political institutions, and supports location marketing for this regional competence centre.

The RMIB's most important communication tool is the "Treffpunkt Regenerative Medizin" as a discussion and event platform covering current developments. In addition, the RMIB organises other specialised and interdisciplinary meetings and conferences.

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[24] *Powerpoint presentation "TOP 50 A new approach to improve technology transfer in Life Sciences: From qualified projects to successful technology transfer" Bio-CT Workshop/ CEBR Special Interest Group Emerging Regions Debrecen, 2-3 March 2011*

[25] http://www.rmib.de/

RMIB is a project of the *TSB Innovationsagentur Berlin* and funded by the federal state of Berlin, the federal state of Brandenburg and the Investitionsbank Berlin, and cofunded by the European Union (European Fund for Regional Development).

8.2 Results

Any project that relies so heavily on public funding at some point will have to show the public why they deserved the funds and what it has led to. Hence, RISS actors of the region are currently discussing how to measure the impact of their innovation support activities that are mainly funded by public money. As for the strengths of the programs and activities so far, the RISS identify the networking and learning processes initiated by the interaction between researchers, experts, coaches and industry as the major positive impact. The long term regional effect of both, an increased knowledge and connectivity of locally based individuals, must be considered significant, even though it is hard to capture in a project-, or program evaluation perspective.

Increased knowledge and connectivity of the kind created here has several practical applications which are beneficial to the region's innovative capacity. Solutions to practical problems are often found in the intersection of competences but making the connections requires knowledge about which nodes need to be connected, which is why RISS play an important function.

Finally, it seems clear that the high success rate of the studied RISS is a result of experience. RISS officers are often the interface between academia and industry and this requires a competence that is mainly built through "learning-by-doing". To be successful, it is instrumental that RISS officers can rely on a network of seasoned regional industry and academic leaders. The creation of such competence, by RISS programs and units must therefore also be considered an important output. Within the recent years, in particular repeated and successful interaction between the different parties has allowed the generation of trust and affinity.

8.3 Room for improvement

Over the last two decades, Berlin-Brandenburg has established an elaborate infrastructure for technology transfer and exploitation in the field of Medicine and especially Regenerative Medicine. This infrastructure facilitates the translation of ideas into new therapies and products. Berlin-Brandenburg RISS see room to improve its infrastructure in the following areas:

- Plan projects according to medical need. Implement opportunity check and risk score tools at all levels of the translation value chain (see BD BCRT).
- Recognize patents (not only publications) as output criteria of academia. Avoid patenting of immature results.
- Prepare scientists for the conversion of their R&D project into a business project early on. Provide further education programs in entrepreneurship, project development, financing and IP management.
- Enable fast track POC in clinical trials. Establish efficient procedures and standards. Sufficiently fund first development steps / clinical studies. Establish models of public funding of clinical studies (e.g. through country and health insurances)26. Currently, clinical studies only, if profitable for pharma industry (e.g. not for unpatentable substances and principles, orphan drugs). High costs for efficacy studies – investigator initiated or driven clinical trials hardly possible.

[26] *Patents - Curse or Blessing of High School Medicine* (talk by Prof. Dr. Ulrich Dirnagl)

- Found spin-offs as late as possible and keep R&D as long a possible at translation centers.

- Establish joint instruments at the European level[27], e.g. shared structures / experts for consistent project evaluations as a quality criterion for early-stage projects; the systematic exchange of experiences within a central pool of start-up managers; establish standardized best practice models; combine the strength of different regional models in one European technology transfer instrument.
- General lack of venture capital is main barrier to successful technology transfer and a major difference compared to the biotechnology scene in the USA[22].

[27] Corresponding with *BioTOPics, Technology Transfer, Issue 41, December 2010*

9 Uppsala

Since the 1960's, Uppsala has been an important center for pharmaceutical, biotechnological and medical research and business in Sweden. The city is part of the larger Stockholm capital region and the home of over 200 companies in primarily biotech tools, diagnostics and pharmaceuticals, including several multinational life science companies. Industry aside, Uppsala hosts two universities with a strong record in biotechnological research, Uppsala University (UU) and the Swedish University of Agricultural Science, (SLU), one of Sweden's strongest research hospitals – Uppsala University Hospital (UAS) - and government agencies such as the Medical Products Agency and the National Food Administration Agency. Recent reports estimate that almost one in five jobs in Uppsala are in life science.[28]

9.1 Uppsala BIO

A central RISS actor for life science in Uppsala is Uppsala BIO, which runs several programs and activities with the aim to help Uppsala's life science sector to long term growth. Technically, Uppsala BIO is the life science branch of STUNS, the *Foundation for collaboration between the universities of Uppsala, business and society*. STUNS was founded in 1985 by different regional government bodies, the two universities in Uppsala and the Uppsala Chamber of Commerce.

Uppsala BIO is funded to a large part by the national agency for innovation systems, VINNOVA, but is also like a member based organization with about 30 members, including companies, the two universities, Uppsala University Hospital, and local government.

Uppsala BIO has several parallel strategies in place for supporting life science development. The most important ones related to innovation support are labeled verify, commercialize, and network.

The *verify* strategy is about taking ideas into proof-of-concept. Uppsala BIO has developed two methods for doing this. One is BIO-X, described in chapter 9.4. The other one is called Innovation Akademiska and is today a service within the Uppsala University Hospital (UAS). One idea in Innovation Akademiska is to identify ideas in the everyday health care activities and turn them into new product and solutions.

The *commercialize* strategy aims as supporting the company creation phase of innovation processes. Uppsala BIO is one of the partners in what is sometimes called Uppsala Innovation Arena, which gathers experiences and networks for the benefit of entrepreneurs. The arena is a collaboration between the RISS partners to make sure that projects, start-ups and entrepreneurs get the right support when needed. Support includes issues ranging from IP and financing to business development and legal matters. Several RISS actors and national innovation support actors collaborate, also involving experienced industrialists and entrepreneurs.

Uppsala BIOs ongoing role, in collaboration with the incubator Uppsala Innovation Centre (UIC), which is described in more detail in chapter 9.3, is to make sure that Uppsala Innovation Centre focuses sufficient and right resources on the needs of life science companies and projects towards the building of competitive new companies.

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[28] *Stockholm-Uppsala. Företag i regionen 2010. (Mapping of Life Science Companies in Stockholm-Uppsala in 2010. In Swedish) Indicators for Stockholm-Uppsala Life Science 2011:1, Lindquist, P. and Hallencreutz, D.*

The *network* strategy aims at broadening the professional networks of different actors in the life science landscape. This can be about strengthening inter-company ties and connecting entrepreneurs to capital, but also about creating and nurturing new contact surfaces between different segments of the regional and national innovation system – such as government agencies, public authorities, business and universities. Uppsala BIO has several reoccurring events and arenas for meetings and networking – for example the conference BIO Ångström where university researchers and companies gather to discuss technical solutions for life science applications and the more informal after work BIO-PUBs where life science professionals, entrepreneurs, policymakers, students and others listen to short thematic talks and mingle.

9.2 Uppsala University Innovation

Uppsala University Innovation (UUI), another partner in the Innovation Arena, is a Swedish equivalent of a TTO. In Sweden, researchers at public research organizations, such as universities, have exclusive rights to the IP of their research results. Universities therefore do not have any inherent claims on technology transfer processes. However, since the state and most universities recognize the importance of supporting the use and commercialization of research results, most universities have some sort of organization attached to it that works towards this end.

UUI has a quite broad array of tools and activities for supporting research commercialization – for example, they offer expertise on project management, commercial development, business consulting, patenting and other legal issues. UUI can also help researcher find funding for commercialization projects, or fund them directly through the Uppsala University holding company – UUAB.

A novel development of interest is the creation of so called AIM days. AIMday® is a thematic event where academia and industry gathers to discuss industry needs and academic solutions. The thematic focus is decided by UUI but it is the participating companies that formulate the specific questions that are being discussed in the AIMday workshops. As of march 2012, seven AIMdays have been organised focusing on different subjects, for example, in the summer of 2011, more than 100 life science researchers and industry representatives gathered to discuss future cancer treatments.[29] Uppsala BIO considers the AIMday to be a tool, which could provide a starting point for some BIO-X processes (see 89.4).

9.3 Uppsala Innovation Centre

Uppsala Innovation Centre (UIC) is an incubator, collocated with Uppsala BIO and UUI in the Uppsala Science Park. UIC collaborates with Uppsala BIO. The latter contribute significant funds to UIC to have an incubation program that is able to care for life science companies. For example, life science companies are allowed more time before having to be commercially viable than companies within other technology areas. This collaboration was preferred to Uppsala BIO building a specific life science incubator from scratch.

UIC welcomes entrepreneurs and start-ups from universities, from the private sector and from public sector, regardless of their geographic location.

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[29] *For more information on the function and impact of AIMdays as a proactive tool for research commercialization see: Baraldi, E., Lindahl, M., & Severinsson, K., 2011, Entrepreneurial Universities Seeking New Ways to Commercialize Science: The case of Uppsala University's AIMday, paper presented at the Nordic Academy of Management, Stockholm, 22-24 August, 2011*

The UIC process has five steps: (i) UIC Business Start; (ii) UIC Business Lab; (iii) UIC Business Prep (iv) UIC Business Accelerator, and; (v) UIC Alumni.

In *Business Start*, potential entrepreneurs are supported in developing their ideas and trained in business management. UIC has a broad collaboration with experts from industry and financing that participate in the program. This phase culminates in a project presentation in front of external experts that evaluate the project and the entrepreneur.

In *Business Lab*, projects and young companies in early development stages are supported in the creation of business plans and contacts with potential business partners. This step contains meetings with other entrepreneurs, as well as with business counselors, marketing experts and other coaches. At the end of the business lab step, the business plan of each project is presented to experts, which is seen as a way to practice for meetings with future investors and partners.

Business Prep is a recently added step, coming from the fact that many companies leaving the Lab were not ready for the next phase. It is also a gate for companies that have started without any RISS support, but reached a phase where they need some input to go further.

In *Business Accelerator*, the focus is on turning the idea into a commercially viable business, that is, a business that is able to get financed by sales or external investors. Only companies with a business plan, a defined market need and international market potential may enter this step. IP issues should also be resolved or at least thoroughly assessed. Accepted companies are assigned one or more business coaches, who follow and advice the company for up to one full workday per week for two years (3 years for life science companies).

UIC Alumni, offers continued support to previous participants in the Lab and Accelerator steps. This support includes things like follow up by coaches, participation in seminar series and networking events.

9.4 BIO-X™

Uppsala BIO's verify strategy contains a process for helping ideas that correspond to needs in the market place to bridge the "technology gap", that is the gap between basic research funding and proof-of-concept. This process is called BIO-X and is illustrated in figure 10.

BIO-X recruits projects by thematic calls aimed at academic researchers/research groups. Themes are selected with a point of departure in customer or market needs – for example in health care. Successful candidates will receive funding of up to two million SEK (or approximately 230 000 EUR) for a maximum period of two years. Unless there are very special circumstances, all candidates must have a company partner and a clinical partner before the project can start, and this partner is expected to contribute financially or in kind to the project.

Candidates are assessed by external experts from science (one clinical and one preclinical expert) and industry who look at: (i) the presence of customer or market need; (ii) the presence of product potential; and, (iii) the scientific standard of the project. In a second step, the project plan and the project team are assessed. The three first selection criteria are strict, in the sense that they may directly disqualify weak applications. For the project plan and team composition, however, Uppsala BIO may help weak projects to improve if they are strong for the first three criteria.

Successful candidates are financed (after the fact) for up to two years by dedicated funds from the national innovation systems agency VINNOVA and from the European Regional

Development Fund. The funds cover approximately 50 % of the project budget and the rest must be contributed by the researcher/research group and industrial partners. If projects deviate from the plan for scientific or technical reasons, they may stay in the process, but if they deviate due to lack of ambition or similar reasons, Uppsala BIO may stop the process and cease payments. Uppsala BIO may equally stop projects that clearly will not reach its goal for technical reasons.

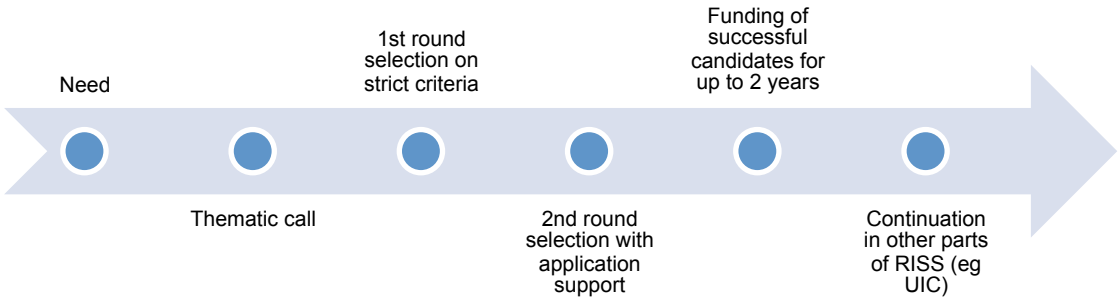

Figure 7: The BIO-X process in short

9.5 Results and room for improvement

In terms of results, BIO-X has processed over 200 applications since its first call in the year 2004 (approximately 100 applications since the market need criterion was introduced). Of these, fourteen projects received support and funding. Five projects have gone through the entire BIO-X process and of these, four projects continue to create value in companies. Other outputs include Nature publications and the attraction of external capital.

In 2011, Roche Ltd and Roche plc decided to conclude a collaboration agreement with Uppsala BIO on the BIO-X program, granting them status as “strategic partner”.

In general, the most significant impact of the Uppsala BIO centered life science RISS in Uppsala is a radical increase in interaction between various actors of the regional innovation system. This has allowed for strong synergy effects to be created in a landscape that is traditionally rich in both industry and academic life science, but where improved cooperation between academia and industry has been in demand by both partners in the wake of important big pharma companies leaving the city.

The challenges ahead pertain mainly to two things: (i) Finding a long term platform funding model for sustaining the key RISS actors – preferably one that builds on a stronger financial commitment from the regional government; and, (ii) managing the risk that key multinational companies (MNCs) leave the region. The latter should focus on the competences that such companies represent and (re)create. The RISS depends on experts and experienced individuals with a background in MNCs, both for its strategic work and for its programs, as described above. Although it is likely that this competence is “sticky” in the sense that MNC flight does not necessarily equal people flight, MNCs constitute important training infrastructure that is hard to replace. While RISS actors can only marginally influence the decision-making processes of MNCs, much can be done internally in terms of lowering RISS dependence on MNC resources of this kind.