TERM PROJECT

Tissue Engineering and Regenerative Medicine

Grant Agreement number 265546

PROJECT FINAL REPORT

September 2013

FP7 - Regions of Knowledge

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Tissue Engineering and Regenerative Medicine

Deliverable D6.3 Report

Final report

Work package WP 6 – Project management

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Authors	Ghislaine DUISIT, Maud TRONCHIN (Atlanpole)
Contribution	Boo Edgar (UGOT), Delphine Nicolas (MedCoast Scandinavia), Karin Agerman and Malin Höglund (Uppsala BIO), Laurence Timmermans and Frederick Druck (Biowin), Angel Pueyo (Madrid Biocluster), Rene Tonnisson (Baltic Innovation Agency), Sigrun Szepanski (BCRT)
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PROJECT FINAL REPORT

Grant Agreement number: 265546

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Ghislaine DUISIT, Project Manager

ATLANPOLE BIOTHERAPIES

Nantes, FRANCE

Tel: +33 (0)251-136-156

Fax: +33 (0)240-251-088

E-mail: duisit@atlanpole.fr

Project website address: http://www.termproject.eu/

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1.1. EXECUTIVE SUMMARY

Regenerative Medicine: hope for future treatment

Regenerative medicine (RegMed) is an emerging disruptive therapeutic approach which aims at restoring the function of damaged cells, tissues or organs by a variety of approaches including cell-based therapies, gene-based therapies and tissue engineering (alone or in combination). These innovative therapies address a wide range of disorders including severe injuries (burns, spinal cord injury) and major chronic diseases such as heart failure, stroke, insulin-dependent diabetes and neurodegenerative diseases. Most of these chronic disorders generate increasing costs for patients care and management of an ageing population, threatening the sustainability of healthcare systems. The prospect of curing (i.e. not only treating) therapies may include successful treatment of patients and ease the financial burden on healthcare payors across Europe.

Although RegMed is still emerging, the overall world market reached about 1.5 BN€ in 2012. But it could experience explosive growth, 10 times during the next 10 to 15 years. More than 300 innovative cell- or tissue-based therapeutics products have been identified worldwide, while but only 15% of these (i.e. 55 products) are commercially-available. A vast majority of the available products (75%) are still in early-to-mild stage clinical development

Importantly, EU shows a significant innovation gap with respect to the US:

- 20% of the ongoing clinical trials take place in Europe versus 55% in the US,
- 20% of the company headquarters are located in Europe versus 65% in the US.

These findings urge the need to define a pan-European strategy in order to bring new solutions to the patients and to boost competitiveness of the European industry in the face of international competition.

The TERM project

In 2010, 13 organizations from 8 European regions launched the Tissue Engineering and Regenerative Medicine (TERM) project supported by the FP7 “Regions of Knowledge” program. The TERM consortium emphasized the importance of regenerative medicine for both the future health care development and the economical growth in Europe. To contribute to the introduction of this potentially-curing medicine as a therapy of choice for European patients, the TERM consortium promoted trans-regional cooperation in key sectors: research and development, education and innovation support.

Implementation of innovative tools

The TERM consortium has worked to foster cooperation and exchange of know-how between regional research-driven clusters implicated in the RegMed area by helping:

- Identify potential partnerships and funding for joint R&D projects responding to existing market demand (market-pull) through:
    - The organization of matchmaking events targeting researchers, companies, infrastructures, education staffs and investors,
    - The launch of a new interactive web platform (the TERM Portal) to increase visibility and exchanges.
- Set up shared educational programs targeting science and entrepreneurship (release of a proposal for educational exchange programs),

- Support early innovation (proof-of-concept) and venture creation at the European level through the publication of a proposal for a multiregional innovation program.

In particular, the consortium has developed a web Portal with the purpose to gather a large, diverse community of actors in RegMed area that encompasses individuals (i.e. researchers) and institutions (i.e. companies, clusters, infrastructures, universities, investors). The TERM portal was designed as a multi-functional tool that can be used for:

- Showcase of training/education institutions and funding resources,
- Networking,
- Project management.

As the project is now finished, it is now essential to ensure the sustainability of the tools that have been implemented, and to expand the activities outside the geographical area of the TERM consortium. Upgrading the tools at a pan-European level requires:

- Recruiting other RegMed-related clusters across the EU28 countries Members,
- Connecting related European projects *(i.e. InterREG SUDOE project),*
- Linking with already-existing, viable private initiatives to ensure the sustainability of the tools *(i.e. the Regenerative Medicine Coalition RMC),*
- Makeing use of future European funding for research and innovation *(Horizon 2020).*

Recommendations to the EC

Based on its analyses, the TERM consortium urges the European Commission to set up a Research and Innovation Strategy for Smart Specialization in the RegMed field.

Therefore the consortium recommends the EC:

- To strengthen the EU position by making **a major theme of regenerative medicine for EU funded research programs** (Innovation Union), especially those intending to:
    - Address the challenge of an ageing population (European Innovation Partnership on Active and Healthy Ageing)
    - Develop cost-benefit approaches through personalized medicine
- To strengthen the European industrial leadership on innovation for companies (specifically SMEs) related to regenerative medicine by **addressing the "valley of death" that dramatically impair the innovation path**.

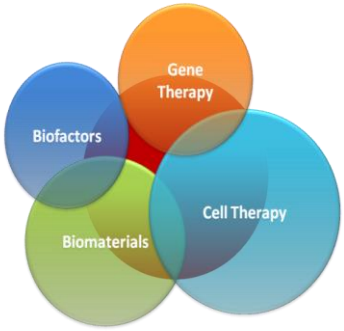
In practical, the TERM consortium recommends to:

- Strengthen conditions for pre-clinical and clinical research collaboration in Europe,
- Access, sustain and extend European expertise and infrastructures,
- Promote collaboration and experience sharing, especially public-private partnerships,
- Encourage education in entrepreneurship, in particular vocational programs, in order to train advanced entrepreneurs in RegMed area,
- Support technology transfer and venture creation by setting up an innovation support model at the EC level,
- Provide new business models to make the area more attractive to private investors and secure access to consistent public and private funding.

1.2. PROJECT CONTEXT AND OBJECTIVES

Regenerative Medicine (RegMed) is a disruptive and innovative approach aiming **to replace or regenerate human cell, tissues or organs**[1]. It intends to restore a function that has been impaired by stimulating endogenous regenerative capacities of the damaged organism and/or providing replacing cells/tissues, or to address congenital abnormalities where the normal cell function was initially absent. Hence the ultimate goal of the regenerative medicine is to cure the patients by returning them to full health rather than treat the disease.

Regenerative medicine is a complex interdisciplinary field that encompasses a variety of technologies[2]:



- Gene therapy that attempts to transfer genes into an individual's cells in order to cure certain genetic diseases (naked DNA, virus-based and synthetic nanovectors)
- Cell therapy that intends to prevent or treat a disease by the administration of cells derived from the patient (autologous cells) or from an unrelated donor (allogeneic cells). Different sources of cells are used according to the purpose of the clinical application:
  - Adult differentiated cells
  - Stem cells that are derived from embryo (hESC) or adult organism (blood SC, mesenchymal SC, adipocyte SC...)
  - Induced pluripotent stem (iPS) cells that are derived from adult cells dedifferentiated in vitro
- Bioactive factors stimulating endogenous regenerative capacities
- Tissue engineering that usually combines living cells and/or bioactive factors with scaffolding biomaterials to generate functional tissues

Expected impacts of Regenerative Medicine

Benefits for Patients

- RegMed targets life-threatening or debilitating disorders: burns, cancer, diabetes, cardiovascular, musculoskeletal, immunological and eye diseases, neurological disorders as spinal cord injuries and degenerative diseases as Alzheimer or Parkinson's diseases…
- Advanced products intend to cure and not only to treat
- Clinical research is more and more oriented towards the development of highly-personalized therapies (i.e. autologous cells and/or stratification of patient population)

Impact on Public Health

According to the United Nations Population Division, the population ageing is unprecedented (without parallel in human history), pervasive (it impacts on the whole human society), enduring and has profound implications for many facets of human life[3]. Such a rapid ageing increases the prevalence of chronic diseases that potentially require management over prolonged periods, thereby contributing to a significant higher demand for care for the elderly. Chronic diseases and severe injuries weight heavily on healthcare resources, and the sustainability of the national healthcare systems as we know them, is therefore uncertain.

[1] Mason C and Dunnill P. A brief definition of regenerative medicine. *Regen. Med.* 3(1), 1-5 (2008).

[2] Noteworthy each technology can be also used for therapeutic approaches unrelated to RegMed field, such as antiviral or anticancer treatments.

[3] Population Division, United Nations. 2002. *"World Population Ageing: 1950-2050 "*

Although it is still impossible to foresee the real benefits of future therapeutic TERM products, one can postulate that these life-changing treatments could lead to a significant reduction of the indirect costs[4] (if not of the direct costs themselves). Hence, societal challenges related to the population ageing might be addressed by improving the quality of life for patients:

- Improved management of Public Health expenses (effective overall cost / benefit ratios due to personalized treatments)
- Reduction of direct and indirect costs thanks to increase of autonomy, mobility and working capabilities for patients

Impact on European economy

- RegMed field is a new market, with only 300 innovative products identified in 2012 including 55 regenerative medicine products on the market (skin/soft tissue, wound care, cardiology and diabetes). However, overall world market is expected to grow exponentially from 1.5 B€ in 2012 to 10-15 B€ 2025.
- As a disruptive approach, regenerative medicine presents a high potential for collaborative partnerships in Europe (companies, universities, hospitals)

An emerging market

In 2012, the Alliance for Regenerative Medicine identified approximately 300 cell- or tissue-based therapeutics[5]. Only 55 of these innovative products were already commercially-available, the remaining ones being still in clinical development (mostly in early-to-mid stage clinical trials). Yet, clinical research might be accelerated compared to that of the pharmaceutical drugs, as the regulatory pathways specific to the advanced therapies guidelines[6] could still be discussed, and the regenerative medicine products might potentially follow the guidelines for orphan compound[7].

As shown in Table.1, the marketed products mainly target eye, skin, wound, and bone or cartilage repair. Interestingly, products in early development rather focus on cardiac, diabetes and oncology diseases, suggesting that the therapeutic scope should evolve in the next few years.

TABLE 1. TERM-RELATED PRODUCTS PRESENTLY IN DEVELOPMENT.

Pathology	Early-to-mid stage trials (I, I/II, II) (%)	Late stage trials (II/III, III, pivotal) (%)	Market (%)
All pathologies	**70**	**15**	**15**
Distributed as followed*:			
Ocular	4	2	11
Cardiac	15	15	4
Diabetes	35	-	3
Oncology	26	27	3
Skin	2	-	15
Musculo-skeletal	10	34	38
Wound	8	15	26

* The numbers are presented as in % of the number in the upper

[4] Lauter FR, Ponchaut S, Bonfiglo GA, Mason C, Edgar B. "The Networking game"; European Biopharmaceutical Review pp42-47, April 2013.
[5] Alliance for Regenerative Medicine. 2012. "Annual Industry Report".
[6] The EMA guidelines for advanced therapy
[7] Orphan drug guidelines

It is noteworthy that the level of market maturity differs among the technological approaches:

- The global market for biomaterials is expected to reach €66 billion in 2017 from €20 billion in 2008 with a compound annual growth rate (CAGR) of 15% from 2010 to 2015[8]. The orthopedic biomaterial market is the most important one, with recorded revenues of €9.1 billion or 37.5% of the total global biomaterial market in 2010. However, it exhibits a slow growth because the market is relatively mature. Cardiovascular biomaterial is the second-highest market, contributing to 36.1% of the global biomaterial market in 2010.
- Regarding cell therapy, the global market seems difficult to estimate. Some reports forecast the market could reach €48.4 billion by 2015 from an estimated value of €16 billion in 2010, thus exhibiting a three fold growth rate during the period 2010-2015[9]. In contrast, other studies estimate the overall market reaches up to €1.5 to 3.2 billion in 2012[10], and should increase at a compound annual growth rate (CAGR) of 11.7% from 2011 to 2016[11]. Finally the market could experience an explosive growth to €10 to €15 billion over the next 15 years[12]. Such discrepancies may rely on the definition of the cell-based products considered in the respective studies: the definition may be restricted to advanced stem cell-based therapies, or include the highly-marketable cord blood cells for transplantation and biobanking. Moreover, the differences may also reflect the fact that cell therapy is still an emergent thus immature field.

Reinforcing EU's competitiveness

According to the US Alliance for Regenerative Medicine[13], 20% and 55% of the ongoing clinical trials take place in Europe and the US respectively. The lower number of clinical trials in Europe is in close relation with the economic development. For instance, a detailed analysis of the markets for stem cells products shows that the US and EU represent 1/3 and 1/4 of the overall market respectively[14] (Fig.1).

The difference in economic impact correlates with the number of company headquarters located in the two regions (20% in Europe, 65% in the US)[15]. Among the 60 major players in the field of Tissue Engineering, 47 were located in the United States and 10 in Europe[16].
Taken together, these results urge the need to define a pan-European strategy to bring new solutions to the patients and to boost competitiveness of the European industry in the face of international competition.

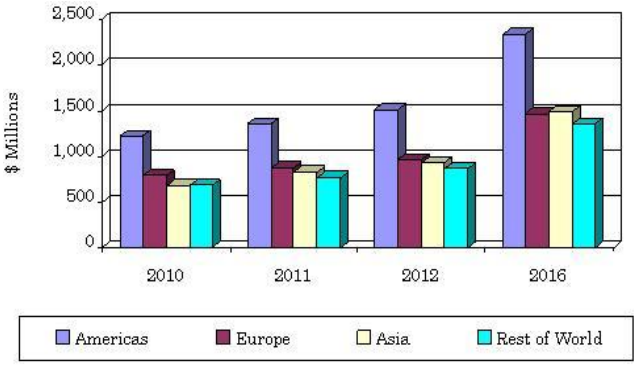


Figure 1. Markets for stem cells products
(Source: BCC Research)

[8] MarketsandMarkets (May 2011): *"Global Biomaterial Market (2010 - 2015)"*; MarketsandMarkets (March 2013): *"Biomaterials Market, Global Forecasts to 2017"*.
[9] Axis Research Mind (July 2010): *"Stem Cells Market And Technologies, 2009-2015"*.
[10] Visiongain. 2012. *"Translational Regenerative Medicine: Market Prospects 2012-2022"* p193; Bcc Research report (July 2012): "Global Markets for Stem Cells".
[11] Bcc Research report (July 2012): "Global Markets for Stem Cells".
[12] CARLSON B. 2011. *"Renewing Humans"* Biotechnol Healthc. Winter; 8(4), p17–20.
[13] Alliance for Regenerative Medicine. 2012. "Annual Industry Report".
[14] Bcc Research report (July 2012): "Global Markets for Stem Cells".
[15] Alliance for Regenerative Medicine. 2012. "Annual Industry Report".
[16] Industry Experts (February 2012): *"Tissue Engineering: The Combination of Cells & Engineering - A Global Market Overview"*.

Objectives of TERM project

To enable and strengthen the exploitation of the opportunities that are arising within the field of Tissue Engineering and Regenerative Medicine, thirteen cluster organizations and regions across Europe have launched a project, namely the **Tissue Engineering and Regenerative Medicine (TERM) project**, with the support of the European Commission.

The TERM Consortium Members

Atlanpole Biotherapies (Coordinator)
Atlanpole Biotherapies is a Western France international biocluster, Nantes.
www.atlanpolebiotherapies.eu

Baltic Innovation Agency (BIA)
BIA is providing innovation, clustering, technology and business development related services to public, private and third sector organizations, Tartu.
www.bia.ee

Berlin-Brandenburg Center for Regenerative Therapies, BCRT
BCRT is a German translational center focused on Regenerative Medicine, Berlin-Brandenburg.
www.b-crt.de

BioWin
BioWin is the health cluster of Wallonia (Belgium) that federates the innovation companies, universities and research centers in the fields of health biotechnologies and medical technologies, Wallonia.
www.biowin.org

Fondazione Centro San Raffaele del Monte Tabor
San Raffaele is made-up of three bodies within the Fondazione: the Hospital, the Research Institute and the University, Milano.
www.sanraffaele.org

Interface Europe
Interface Europe provides knowledge intensive tools and services for EU R&D strategies and projects, Brussels.
www.interfaceurope.eu

Madrid Biocluster
Madrid Biocluster aims the internal and external promotion of Madrid as an international centre for business competitiveness in the biotechnology sector and boosting the creation of new companies in the Madrid region.
www.madridnetwork.org/en/red/madrid_biocluster

MedCoast Scandinavia
MedCoast Scandinavia is a Norwegian-Swedish network organisation aiming at strengthening and developing the biomedical sector in the Gothenburg-Oslo region, Oslo.
www.medcoast.org

Région Pays de la Loire
The Région Pays de la Loire is a regional authority located in Western France, Nantes.
www.paysdelaloire.fr

Service Public de Wallonie
The legal administration in charge of funding applied research as well as of related international scientific cooperation, Wallonia.
http://recherche-technologie.wallonie.be/

Uppsala BIO
Uppsala BIO is a not-for-profit actor strengthening life science's long-term competitiveness, Stockholm-Uppsala.
www.uppsalabio.se

Uppsala Regional Council
Uppsala Regional Council is a forum for political decision-making in Uppsala County, Uppsala.
www.regionuppsala.se

VINNOVA
Vinnova is the Swedish Governmental Agency for Innovation Systems, Stockholm.
www.vinnova.se/en/

Third Parties:

Coretherapix
Coretherapix is focused on developing myocardial regeneration therapies for preventing the effects of cardiovascular disease during the acute and chronic stages of the myocardial infarction, Madrid.
www.genetrix.es

GöteborgBIO
GöteborgBIO is a life science cluster focusing on healthcare and industrial growth, Gothenburg.
www.goteborgbio.se

University of Gothenburg
University of Gothenburg has approximately 39,000 students and 5,000 employees, Gothenburg.
www.gu.se

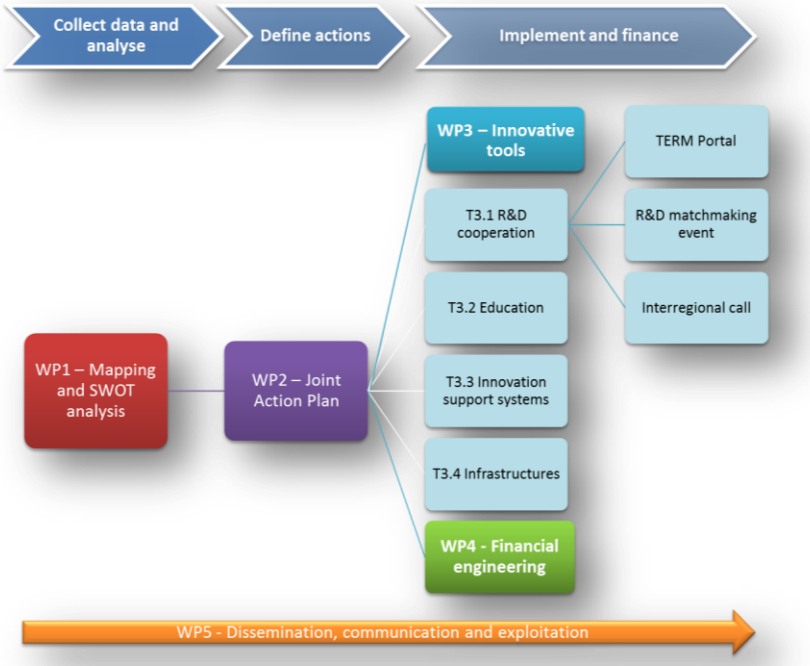
Funded in September 2010 under the framework of the FP7 "Regions of Knowledge" program, the TERM project intended to foster interregional collaborations in this biomedical area in order to:

- Address the major societal challenges identified in the EU "Horizon 2020" Strategy for Smart and Sustainable Growth
- Consolidate an emerging industry
- Ensure European technological leadership in the Regenerative Medicine arena

In accordance with the criteria presented by Europa InterCluster[17], the TERM project worked to strengthen European research-driven clusters in RegMed field by combining two approaches: **the development of regional clusters focused on translational medicine**, thereby supporting innovation from the end-users perspective, and **the cooperation of complementary clusters** to construct a value chain of productive innovation. In particular, the TERM project intended to counteract the negative impact of Europe fragmentation by encouraging collobaration and exchange of knowledge in education, research and development. The building of **a transnational community of actors** was sought to help all stakeholders within the TERM consortium to get the maximum support.

[17] Europa Interclusters white paper: « The emerging of European world-class clusters » (2010).

Figure 2. The TERM workflow.



Several key issues have been addressed during the course of the project:

- Assess the capacity of European regions in contributing to the development of Advanced Therapies through their regional research policy,
- Organize coherent and structured Regional and European support to Tissue Engineering and Regenerative Medicine research and networks,
- Develop a European knowledge of available skills and infrastructures through dedicated tools,
- Set-up a financial plan to enable the implementation of the TERM action plan and provide recommendations for the next financial instruments to policy-makers.

In practical, the work was divided into three steps: the analysis of Europe and TERM specific needs and strengths; the definition of actions and the implementation of innovative tools (Fig.2).

The TERM project sought to counteract the negative impact of the European fragmentation by promoting:

- The building of an active community of actors in RegMed field
- The sharing of knowledge and pooling of resources

The present report intends to broadly disseminate the outcomes of the actions achieved during the three-year project. A particular focus will be given on the long-term sustainability of these actions. In particular, the consortium worked to extend its network to regions from outside the present consortium. Linking existing initiatives will enable the innovative TERM tools to grow after the end of the project and continue to pave the way to a European Society that favours the introduction of this potentially-curing medicine as a therapy of choice for European patients.

1.3. MAIN S&T RESULTS/FOREGROUNDS

Workpackage WP1 – Mapping and SWOT Analysis WP Leader: ATL			
Deliverable	**Name**	**Due date**	**Actual date**
D1.1	SWOT analysis of targeted regions	05/2011	20/12/2011
D1.2	Report on synergies, complementarities and cooperation possibilities	09/2011	15/11/2011
Milestone	**Name**	**Due date**	**Actual date**
MS2	SWOT analysis and cross approach	09/2011	15/11/2011

Objectives

The promotion of cooperation within the TERM consortium first required to clearly identify the respective stakeholders in the education, research and development sectors. Mapping of the regional actors and innovation potential helped assess strengths and weaknesses of each region (D1.1 SWOT analysis). A global SWOT analysis combining and comparing the strengths, weaknesses, opportunities and threats seen in the regions of the TERM partners was released, thereby leading to the definition of common priorities (D1.2 Report on synergies, complementarities and cooperation possibilities).

Mapping

As the use of a common methodology was essential to allow cross-comparison, the TERM partners designed a consensual framework template for the mapping and the regional SWOT analyses that included 3 sets of objective criteria (field of expertise, ability to collaborate and importance of each stakeholder) and a common grid of evaluation criteria.

In a first step, the consortium performed a detailed mapping of the regional actors and capabilities regarding research, infrastructures and facilities, tech transfer and innovation support, education and training, regulatory and financing. Regional stakeholders more or less distantly related to regenerative medicine had been invited to take part in an on-line survey.

After completion of the study, up to 124 organisations such as companies, research labs, facilities/infrastructures, training institutions and innovation support systems had filled in the questionnaire[18]. As shown in Fig.3, these entities mainly consist in research laboratories (43%) and SMEs (23%). Among these entities, 58 ones were identified as directly focusing on RegMed. They were then subjected to in-depth interviews in order to better characterise their strengths and needs.

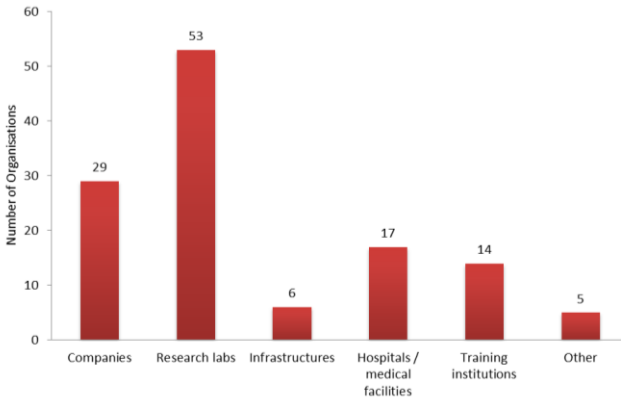


Figure 3. Types of organisations within the TERM area

The database generated from the web-survey had been further exploited in the workpackage WP3 (setting of workshops, exchange programmes and web portal).

[18] The survey included both qualitative and quantitative questions related to the typology of the organisation, the team, the activity and expertise, the assets (patents, know-how), the equipment, the collaborations (ongoing or expected), and the training. People were also questioned on the lacking skills/resources and their priorities.

Assessing regional strengths and weaknesses (SWOT)

The clusters analysed the data collected during their respective mapping, drawing the perceived strengths, weaknesses, opportunities and threats of each region while taking into account the international context.
On that basis, each partner proposed a regional research agenda presenting the priority actions to be done locally in education and training, research, development and innovation support (see WP2).

Cross-comparison and synergies

All the data from the regional SWOTs were then gathered and analysed from the consortium point of view (General SWOT analysis) to identify synergies and complementarities that could be developed in order to:

- Promote diversity and excellence of RegMed research and commercialization in European regions
- Increase performance, innovation and technology transfer through interregional cooperation and learning, between clusters, regions and projects

Hence, the General SWOT analyse was performed with the final goal that the TERM project should help increase the pace by which results in RegMed research actually reach the patients, and therefore contribute to Europe's economic growth.

Complementarities.

Interestingly the regional SWOT analyses did not show major geographical specificities, suggesting that the principle of smart specialisation might be difficult to apply in the RegMed field. As presented in Fig.4, the TERM network appears to cover a very comprehensive portfolio of research expertise in the TERM area, including basic, preclinical, clinical and applied researches. These areas of expertise are well recognized by peers and allow for leading frontline research, with a lot of international connections.
Nonetheless, as the development of RegMed products requires highly-skilled workers in science and technology, healthcare and business sectors, setting up of collaborative programs between the different types of organisations could be a way to reach critical mass and to achieve a cost-effective management of research and innovation.

Synergies.

On the other hand, several strengths, such as frontline research and clinical development capabilities for instance, have been repeatedly highlighted in the regional SWOT analyses (Fig.4). The consortium then worked to build upon its strength in order to develop the RegMed field and foster therapeutic solutions for the patients.
A detailed report on synergies and complementarities was released in 2011. It presented the different domains related to science, infrastructure, education and tech transfer areas that were likely to be particularly effective at generating collaborative programmes. That report served as a basis for the conduct of the downstream workpackages WP2-4.

Figure 4. Background for cooperation.

Strengths

1- Very complete portfolio of research expertise, including basic, preclinical, clinical and applied research
2- Frontline research in the RegMed field
3- Great possibilities for clinical trials (numerous university hospitals with easy access to patients)
4- Numerous facilities with very comprehensive equipment and skills
5- Well-functioning initiatives to support tech transfer and innovation

Needs identified

1- Increase the size of research staff involved in the RegMed area
2- Provide a larger access of facilities and infrastructures to external users
3- Encourage demand-driven rather than technology-pushed research
4- Improve training of highly-qualified personnel
5- Secure funding (in particular to bridge the growing gap between research results and proof of concept)

Workpackage WP2 – Joint Action Plan WP Leader: BW			
Deliverable	**Name**	**Due date**	**Actual date**
D2.1	List of common priorities	09/2011	25/04/2012
D2.2	Regenerative Medicine Vision Document and research agenda	12/2011	25/04/2012
D2.3	Joint Action Plan	01/2012	25/04/2012
Milestone	**Name**	**Due date**	**Actual date**
MS4	Approved Regional Research Agendas for the Advanced Therapies	07/2011	20/02/2012
MS6	Validation of the Joint Action Plan	02/2012	30/05/2012

Background

The TERM consortium has worked to build cooperation between European clusters and regional authorities to ensure that stakeholders get the maximum support to use their knowledge and resources in the most productive way. The innovative approach consists in developing a **common strategy** and **coherent action plans** to be implemented in each region.

Objectives

On the basis of a state-of-the-art analysis, the consortium was asked to draft two related documents:

- The **Regenerative Medicine Vision document**[19] outlining the needs and bottlenecks in RegMed field, and further proposing policy recommendations for the development of the whole value chain in Europe.
- The **Strategic Research Agenda**[20] enumerating all the technical bottlenecks to be specifically addressed.

In a second time, the consortium intended to address the key issues identified in the former documents while taken into account the global and regional SWOT analyses. This helped to define the **List of common priorities**[21], inherent to the consortium, specifying the topics that TERM partners see as key for the RegMed development in their regions.

Following the writing of these three different documents, a **Joint Action Plan**[22] was finally produced, detailing the concrete actions that partners should undertake within the TERM program and, after update, the ones that should be developed beyond the end of the project.

Vision document and European Scientific Research Agenda

In the Vision document, partners of the TERM consortium presented what Europe must face in order to acquire and maintain a competitive position in the area of regenerative medicine, and to make this area an efficient and affordable curative option for patients. Advanced therapies in RegMed field have the potential to deliver partly or totally curative solutions for a wide range of disorders, deeply impacting on the quality of life and life span of the patients, the treatment costs and the socio-economic burden associated with such diseases. From the European perspective, these approaches mean generating new business and economic development opportunities and sustainable growth of innovative organizations.

[19] LAMBERT D. et al. " Regenerative Medicine Vision document" TERM report (2012).
[20] LAMBERT D. et al. " European Scientific Research Agenda" TERM report (2012).
[21] LAMBERT D. et al. "List of common priorities" TERM report (2012).
[22] LAMBERT D. et al. " Joint Action Plan " TERM report (2012).

Figure 5. Key issues in RegMed that need to be faced to unleash Europe competitiveness.

Non-scientific challenges

- Tech transfer and Innovation support to foster the creation of ventures in Europe:
  - Encourage creative business models
  - Facilitate private investments and public funding for innovative SMEs and hospitals
  - Open the access to R&D infrastructures & knowledge across Europe
- Educational needs to develop skills and knowledge in Europe:
  - New European Education and training programs are needed in science, technology, innovation and entrepreneurship to train a highly-qualified workforce
  - Awareness sessions for clinicians to promote the implementation of RegenMed products in routine clinical practice
  - Public and political communication
- Harmonization of legal rules to secure the development and commercialization of innovative products
  - Address regulatory issues (embryonic stem cells for research and/or commercialization)
  - Hospital exemption
  - Reimbursement issues

Scientific and technological challenges

- Understanding the endogenous potential for regeneration of the human body
- Sharing resources
- Manufacturing:
  - Multiplicity of resources (cells, biofactors, bio/nano materials)
  - Production processes (cell culture, gene vectors, bio/nano materials)
  - Scale up
  - Methods for product characterization, quality and stability assessment
- Clinical use:
  - Cell delivery / mode of administration
  - Cell mode of action and fate in vivo
  - Regulation and monitoring of the immune response
- Animal models

Due to the novelty of that biomedical field, RegMed-related industry is mainly constituted by spin-offs and SMEs in close connection with research labs. That context has dramatic consequences in terms of non-scientific challenges that need to be addressed (Fig.5). All the research priorities and main areas of need that should be addressed in order to move the RegMed field forward were further defined in the Scientific Research Agenda. The list of scientific and technological challenges has been deliberately made generic and transversal for any indication, it is important to keep in mind that the research work required to address these challenges would often be specific to each indication or application.

In a nutshell, 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. To contribute to this competitiveness, the TERM consortium recommended the overall goals in RegMed should be to:

- Strengthen conditions for pre-clinical and clinical research collaboration in Europe
- Access, sustain and extend European expertise and infrastructures in TERM
- Accelerate the development of products and services addressing healthcare needs using research results and industrial competencies and facilitate sustainable development and growth of companies within the field.
- Provide new business models to make the area more attractive to private investors and secure access to consistent public and private funding.
- Prove the commercial potential of complex TERM therapies

List of common priorities and Joint Action Plan

These priorities were the basis for the definition of actions that the consortium intended to take within TERM project. This strategy was structured around **5 themes** for which the consortium defined common challenges, priorities and actions. The concrete actions were further described in Joint Action Plan, and several innovation tools have been defined and implemented accordingly.

The five strategic themes were split into 2 workpackages, namely WP3 (innovative tools) and WP4 (financing). WP3 was subdivided into 4 tasks corresponding to different targets of stakeholders. Each task has been taken in charge by one partner of the consortium as WP or Task Leader:

- Collaborative partnerships and projects (T3.1)
- Education & Training (T3.2)
- Technology Transfer and Innovation support (T3.3)
- Infrastructures (T3.4)
- Financing (WP4)

The five strategic themes are detailed in the following parts of this document. In principal, TERM consortium aimed at facilitating cooperation and exchange of know-how between regional clusters and authorities by developing the visibility of the regional stakeholders, the development of shared programs in R&D, education, innovation support and research infrastructures, and to promote access to financial resources (interregional call, European funding, private investors…).

Future vision

As shown in the following parts of the document, important actions have been performed within each WP in the second mid-phase of TERM project (M19-M36): education programs and funding resources, integration of regional innovation support systems, databases and collaborations of research infrastructures... In addition, regions have stably benefited from interregional sharing of knowledge that has been achieved by mentoring activities during the course of TERM project (workshops, case studies). Besides, the close collaboration between the TERM partners has definitely been a key advantage with specific partnerships created in the program and a continued collaboration open to new regions with similar interests after the end of project.

Workpackage WP3 – Innovative tools experimentation WP Leader: ATL			
Deliverable	**Name**	**Due date**	**Actual date**
D3.1	A database of the existing infrastructures/services and of the possibilities to share them	05/2012	14/12/2012
D3.2	Exchange program between SMEs, universities, research centres, clusters and health care organisation	11/2012	
D3.3	Minutes of the final workshop / seminar with presentation of results	07/2013	

The WP3 objectives were to:

- Prepare the full deployment and implementation of the action plan,
- Share experience on specific tools to make value out of these priority fields,
- Analyse how to adapt these tools for developing a collaborative approach at European level,
- Enable TERM regions with a less-developed research-profile accessing validated tools and measures.

TASK 3.1 – Exchange of ideas on potential consortia in view of future research activities
[Task Leader: BCRT]

In Europe, national research systems tend to move towards a more integrated and interconnected European Research Area[23]. European research policy thus promotes international research collaborations, e.g. through the European Framework Program, with the aim of overcoming the research fragmentation along national and institutional barriers.

In RegMed area, an especially interdisciplinary field, research also tends to promote networks and collaborative studies. Key Opinion Leaders from all the consortium parts highlighted several advantages to collaborate within the regions network: pooling of regional scientific resources (e.g. knowledge and skills in various research disciplines) will lead to cross-fertilization of ideas and the generation of intellectual benefits; interregional collaborations will provide access to complex instrumentation and large infrastructures, enabling standardization of technologies and costs savings; setting up large-scale multicenter clinical studies will bypass the limiting size of each regional patient population; collaboration between regulatory and political experts will facilitate harmonization of region-specific guidelines and institutional frameworks; and finally pooling of education resources will improve the training of highly-qualified personnel. As a result, priorities for interregional cooperative approaches within the TERM consortium are:

- Use synergies and complementarities as drivers of research collaboration,
- Promote the interaction between research institutes, companies, and governmental institutions,
- Facilitate cooperation between partners in order to implement the TERM Scientific Research Agenda,
- Make use of modern communication technologies to facilitate distant communication.

In line with these priorities, the three activities have been initiated within the frame of the task T3.1:

- Organize a **European workshop for cooperation and match-making,**
- Facilitate the development of a **European interregional collaborative funding program**,
- Build the **TERM Portal** in order to facilitate collaboration by using modern communication technologies.

[23] http://ec.europa.eu/research/era/understanding/why/why_do_we_need_era_en.htm

TASK 3.1.1 – Collaborative R&D projects involving SMEs
[Task Leader: BCRT]

Background

As highlighted by the Vision document[24] and Lauter's white paper[25], the roadblocks and challenges that may impair the development of regenerative medicine in Europe urge the regions to share their talents and encourage open innovation.
In that context, the TERM consortium intended to foster exchange of ideas on potential consortia in view of future research activities on diagnostic and therapeutic products. Importantly, industrial partners were encouraged to join in these consortia from the beginning of the R&D projects to ensure strong product-orientation. New projects must be driven by market need and exhibit a strong translational focus.

Objectives

The TERM project sought to increase the development of collaborative R&D programs by setting up a workshop for cooperation and matchmaking:

- Identify region-specific skills and infrastructures that complete those of other regions
- Identify opportunities for high-potential joint research project
- Set up research consortia, if possible

TERM matchmaking event

The workshop **"Trends and challenges in Regenerative Medicine - towards interregional collaboration in Europe"** took place at the Berlin-Brandenburg Center for Regenerative Therapies on Nov 22-23, 2012. The minutes of the meeting have been released (18/12/2013).

A group of invited European renowned academic and industrial experts from the fields of preclinical and clinical research in cardiology, immunology, neurology, and orthopedics as well as leaders of academic translational research programs discussed innovative ideas in an interactive format. A total of 26 invited experts with distinguished expertise and practical insights from eight European regions discussed their views on how to move forward in the RegMed field in Europe. Within three categories, namely "Exchange of Know How", "Access to Infrastructure" and "Joint Product Development Projects", participants discussed various opportunities for international collaboration to accelerate product development in the field.

All experts agreed that collaboration will accelerate the continual delivery of new treatment options for so far difficult or untreatable diseases and will allow focusing on most promising projects. Sharing knowledge and resources will help generate innovative products a) with decreasing efforts, b) in the shortest possible timeframe, and c) with the highest possible efficacy. In this development process, it appears to be of particular importance to:

- Exchange know-how on successes and failures,
- Extend training and networking activities by pooling of resources,

[24] Vision document

[25] Frank-Roman Lauter, Sylvie Ponchaut, Greg A. Bonfiglio, Chris Mason & Boo Edgar (2013) "European regions should share their talents to catalyze open innovation in regenerative medicine and encourage economic growth: so why wait?" European Biopharmaceutical Review; Spring.

Figure 6. Possible cooperation proposed during the workshop in Berlin.

Exchange of Know-how
Training
Training of researchers & clinicians, in particular on GLP
Training on new technologies in clinical immunology
Technologies
Establishment of GMP facilities, GMP consultancy
Expertise in biomaterials, alternate biomaterial to 'peptide amphiphiles', artificial matrix for stem cells
Translation
Translation of successful phase III results in orphan disease field into clinical applications
Access to Infrastructure
Core facilities
Cooperation on animal models to improve capacities and efficiency
Exchange on standardization of assays (cytokines, flow cytometry, cell production, …)
Technologies / models
Predictive animal models of human cell engraftment
Expertise in immunotolerance for allogeneic cell therapy product
Preclinical testing of cells for safety & efficacy
Biobanking
Cooperation in bone / biobanking
Marketing
Distribution partnerships
Clinical approaches
Clinical partners for phase II and phase IIb / III studies
Improved research / clinic connection

- Enable standardization / harmonization of technical and regulatory procedures,
- Collaborate in multicenter large-scale clinical studies,
- Make use of modern communication technologies, in particular of the prospective TERM platform, to facilitate distant communication on research interests, knowledge and infrastructures.

As the mission of this workshop was to also initiate and/or extend cooperation in the RegMed field and to identify new high potential joint projects by focusing on future requirements in clinically approaching regenerative therapies, the experts presented their main approaches, technologies, and cooperation needs, learned about current European R&D focal points, discussed latest pre-clinical & clinical translational projects, and initiated collaborative relationships. Some possible domains of cooperation are illustrated in Fig.6.

Future visions

The TERM consortium suggests a follow up meeting to the workshop "TERM – Trends and challenges in Regenerative Medicine - towards interregional collaboration in Europe" in 2014. Themes would be a review on started projects since Nov 2012, identification of additional new projects; New inputs to generate an exchange platform for the Identification of Offers and Needs from the consortium members and a review of potential funding opportunities to realize the projects identified.

Initiated by the BCRT, six leading translation centers for Regenerative Medicine from Europe and North America founded the Regenerative Medicine Coalition (RMC) that aims at accelerating the translation of joint therapy development in RegMed field. RMC is working with investors to find a new financing model for cell therapies and aims at accelerating the pooling of expertise and technology[26]. With regard to the sustainability of the TERM network, the BCRT aims at better exploiting the synergies between TERM and RMC. Such a cooperation has been promoted at the Infrastructure Workshop in Nantes (Oct 2012), the Regenerative Medicine Foundation 2012 Conference in Charlotte (Oct 2012) and the 8th World Stem Cell Summit in West Palm Beach (Dec 2012).

[26] Nature Biotechnology 2012, Volume 30 (7), 573 – 574

TASK 3.1.2 – Preparation of a call for interregional projects
[Task Leader: ATL]

Background

The Regional Research Agendas defined during the WP1 were then approved by the Regional authorities (milestone MS4). To push forward the European development of innovative therapy products, the regional bodies within the TERM consortium worked to design a dedicated **trans-European funding programme.**
A pilot interregional call for research proposals was thought to:

- Encourage public/private collaboration,
- Support market-oriented and upfront science projects,
- Make use of the tools implemented during the TERM project in order to facilitate exchanges and partnerships

Objectives

The action plan of the task T3.1.2 was to:

- Share experience on the definition of an interregional or funding programme,
- Launch a common call for projects funded by the Regions and adopting the Eurostars-Eureka rules.

Results

Regions parts of the TERM consortium were asked to do their best to define ex-ante budget in order to support the interregional call for projects. Unfortunately, the concept of a top-down approach for funding was well-accepted by only two regional Authorities within the consortium: Service Public de Wallonie (Belgium) and Pays de la Loire (France). In the other regions, the ex-ante definition of a budget for that kind of call was not possible.

The two regions, Service Public de Wallonie and Pays de Loire, drafted the specifications and application procedure of the pilot call for joint projects:

- Consortia should involve at least one SME (or firm under incubation) and one Research and Technology Organisation from each region.
- Participants from Wallonia and Pays de Loire could be funded according to the rules of their respective regional funding programme[27].
- The projects should address innovation issues in RegMed, including gene transfer, cell therapy and biomaterials regardless of the pathology scope.
- The project duration was of 24 months.

Unfortunately, the pilot project was eventually canceled as the bilateral pilot call seemed to be redundant with already-existing funding: the bilateral agreement for innovation support signed by Bpi-France and the Wallonia DGO6, and the ERA Net Euronanomed programme that can support RegMed related projects.

In conclusion the regional Authorities within the TERM consortium were not able to set up of an interregional call for innovation. The main reason for this failure is that the number of funding agencies parts of the TERM project was insufficient. However, a rapid survey of regions from outside the consortium showed that, apart from a few exceptions, European regions are not capable of financing ex-ante calls. Taken altogether, these observations highlight **the crucial importance of EC funding programmes**.

[27] Participants from other regions within the TERM consortium were welcome to join in the projects, but were not eligible for funding from Wallonia or Pays de Loire.

TASK 3.1.3 – Creation of the TERM web portal
[Task Leader: IE]

Most of the data generated by the different WP were intended to be integrated as building bricks into **an interactive web platform**, named the TERM Portal.

The TERM portal was designed as a multi-functional tool that can be used for:

- Showcase for training/education institutions and funding resources
- Networking
- Project management

The platform has been launched in May 2013. As the Portal is considered to be essential to ensure the cohesion of active community in the field of the regenerative medicine, the questions of its development and sustainability after the end of the project are the primary focus of the business plan.

Vision

The TERM project worked towards the initiation of an active society in regenerative medicine. With the objective to provide actors, of the knowledge triangle, wide access to supporting services for the development of advanced therapy products.

In a nutshell, the Portal helps to:

- Find news and events
- Ask and answer questions
- Find collaborators and manage joint projects
- Identify potential resources (funding, infrastructure, training)

Yet, fostering cooperation between the eight regions of the TERM consortium is not sufficient to achieve the level of excellence that is necessary for the penetration of highly-competitive international markets. Boost the global competitiveness in Europe requires extending the TERM network to, at least, a pan-European level.

Purpose

Overcome fragmentation. In contrast to the existing web platforms that target specific networks of SMEs, researchers, innovation supports, infrastructures or training institutions[28], the Portal intends to gather all together the actors implicated in the development of the regenerative medicine. The transnational cooperation will build the critical mass to create an innovative and competitive position for Europe in the global biomedical research arena.

Knowledge exchange and standardization. The web platform promotes open innovation by encouraging the sharing of raw data, failed experiment results as well as successes in order to avoid repeating cost-effective mistakes.

Training. The Portal intends to support the two levels of educational actions that are absolutely required to ensure that advanced therapy products will be available to patients across the globe[29]:

[28] See the detailed list in the Appendix
[29] EDGAR B. "The need for entrepreneurial culture to implement Regenerative Medicine in Europe.", Report from TERM 2013

- Promote and disseminate the new Regenerative Medicine knowledge as standard method of care.
- Increase the availability of qualified personnel on the market in basic science, biotechnology and entrepreneurship by facilitating the visibility and internationalization of Science and Business curricula.

Improved performance and access to infrastructure. The development of advanced therapy products in Europe urges the need to convert research-driven infrastructures into innovation-driven ones[30]. Hence, the Portal encourages the market-pulled management of facilities by:

- Increasing the visibility of the research infrastructures
- Promoting open access to the SMEs
- Improving the understanding of the innovation process

Financial resources. The Portal has been designed to provide information of public and private funding resources capable of supporting collaborative projects and/or mobility programs in Europe.

Public-private cooperation. Working as a meta-cluster, the Portal helps to connect stakeholders from academic and private sectors with the aim to bridge the so-called "valley of death" of the innovation process[31]. Taken altogether, its functionalities intend to:

- Limit the negative impact of the early innovation gap
- Lower the financial risk for late-stage ATMPs development
- Improve the entrepreneurial culture in Life Science
- Accelerate development and commercialization of clinically-available products

Scope

Every actor working in field the Regenerative Medicine is a potential end-user of the Portal. Importantly, the web platform admits both individual and institutional membership:

- Research organizations (and related researchers, clinicians, students, engineers, technicians…)
- Companies (spin-offs, SMEs, large companies…)
- Training institutions
- Research infrastructures (and managers, technicians…)
- Funding organizations
- Public authorities

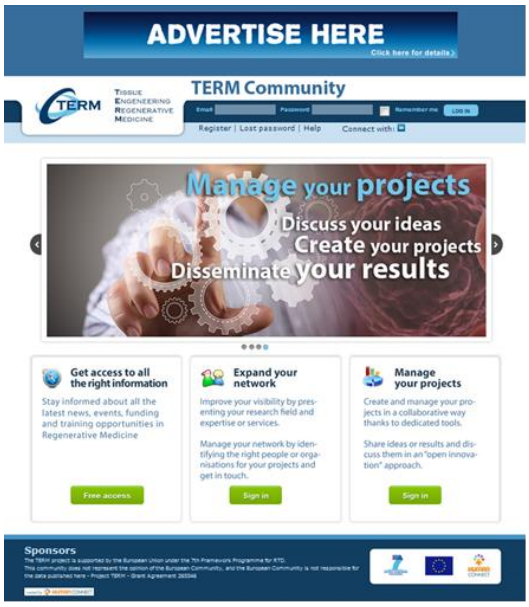
Advanced functionalities

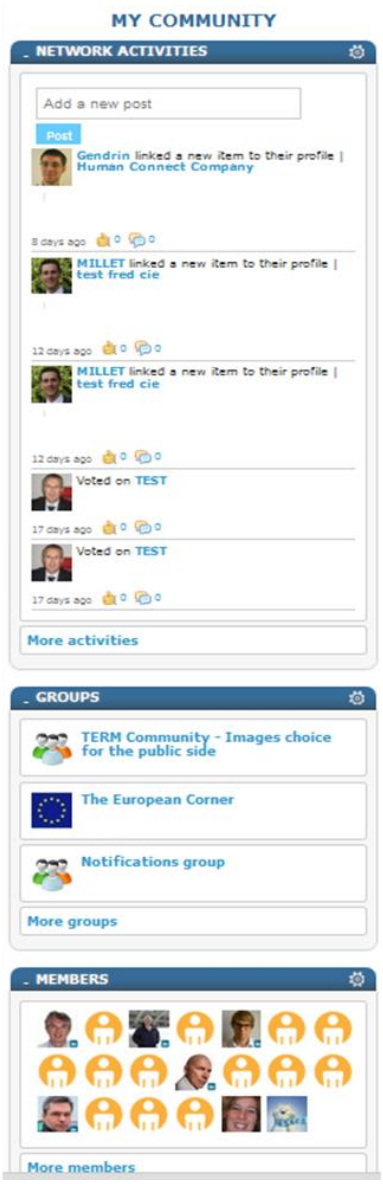
The Portal is a multi-function platform that offers more than just simple content. It provides many other services including discussion, highly customizable sorting and searching, targeted news and matchmaking. Designed to provide a personalized and integrated view of information in the European TERM area, every stakeholder will:

- Get access to scientific, industrial and financial information (including news and events)
- Expand its network (improved visibility)
- Manage its projects (access to partnership and funding opportunities, dissemination of results)

A dynamic "social-network", where the users can post messages and discuss on topics related to the field. Gathering a community of actors will contribute to the cohesion between the European regions by encouraging exchanges of know-how and best practices.

[30] DUISIT G, "Workshop on Research Infrastructures Towards Translational Research Infrastructures in Tissue Engineering and Regenerative Medicine", Report from TERM 2013
[31] AGERMAN K. "Framework for a multiregional innovation support program", Report from TERM 2013


ADVERTISE HERE
TERM Community
Manage your projects
Discuss your ideas
Create your projects
Disseminate your results
Get access to all the right information
Expand your network
Manage your projects
Sponsors


MY COMMUNITY
NETWORK ACTIVITIES
Add a new post
Post
Gendrin linked a new item to their profile | Human Connect Company
8 days ago
MILLET linked a new item to their profile | test fred cie
12 days ago
MILLET linked a new item to their profile | test fred cie
12 days ago
Voted on TEST
17 days ago
Voted on TEST
17 days ago
More activities
GROUPS
TERM Community - Images choice for the public side
The European Corner
Notifications group
More groups
MEMBERS
More members


MY PROJECTS
LAST IDEAS
TEST
by Pierre Fuhrer
Status : Open idea
Votes : 2 - Score : 83 %
Comments : 0
LAST PROJECTS
Project ABC
Group dedicated to the design and writing of the project ABC
More projects
RESULTS
Marie Curie movie (published by : Loher)
Other
Keywords : youtube marie curie scientific communication
96 days ago
More results
SUGGESTIONS
There are no people to suggest
More suggestions

TASK 3.2 – Education and training
[Task Leader: UGOT]

Background

Regenerative medicine may be seen as several disruptive products, innovations and therapies being introduced to a market that is quite unprepared for how to implement new ideas. Furthermore the introduction of new products and new treatment modalities in health care is painfully slow. In addition these new products are submitted to new ways of verification, yet other ways for evidence based medicine, regulatory pathways and spiced with procurement rules common for Europe but widely interpreted.

There is therefore a huge need for capable individuals able to handle science, the clinic, regulatory issues and commercialisation of these new products. A solid huge educational effort to increase the capability of the individuals managing and handling regenerative therapies as well as the patients receiving them is needed. The communicative request for knowledge exists on several levels (Fig.7). This section of the document is a summary of information based on TERM project work to increase the ability meet the need to educate the individuals for the future in this field.

Figure 7. Potential courses following the innovation chain.

There are also other strong reasons for the introduction of education is this field, as there is a need for a renewal of the entrepreneurial culture. Europe recently launched an entrepreneurial action plan that stresses the importance of more entrepreneurs and entrepreneurial thinking to bring Europe back to growth and higher levels of employment**.** Without an innovative and disruptive entrepreneurial education this will only be hopes and no reality.

Objectives

The objectives of the Task 3.2 were to:

- Address the existing gaps in education and training,
- Propose European solutions.

Data and discussions on the available education and the visible needs have been gathered in the Joint action plan[32] and underlined by the TERM Scientific Advisory Board[33]. A proposal[34] for exchange programmes between SMEs, universities, research centres, clusters and health care organizations to increase the potentials for regenerative medicine has been released by the end of the TERM project *(deliverable D3.2).*

Identification of critical issues

During the autumn 2012, a workshop on education was held in Gothenburg and the potential areas for joint activities were highlighted. [35] As shown in Fig.8, critical issues encompass dissemination of RegMed-related information as well as scientific and tech transfer challenges.

[32] LAMBERT D. et al. "Implementation plan: joint actions", TERM report (2012).

[33] The scientific board are composed by of Profs Mason, (UK) Menasché (France), Figalio (Italy) Culme-Seymore (UK) Dr Vallier (UK) Ms Martinez (Belgium) and Mr Luria (Spain).

[34] EDGAR B. "The Need for Entrepreneurial Culture to Implement Regenerative Medicine in Europe", TERM report (2013)

[35] Five Meetings in the TERM projects, Gothenburg sep 2012, Berlin November 2012, Madrid, Nantes and Charleroi December 2012

Figure 8. Critical issues to be addressed by educational efforts.

- The understanding of regenerative medicine; a communication/information issue to the general public, patients and other stakeholders on the potentials for regenerative medicine to understand and accept the potential for the therapy
- The interest for science and life science matters among European pupils and students:
- The number of potential talents and the number of life science students knowable in regenerative medicine, including the need for translational and transplantation techniques and unmet competence need.
- The relative few scientific ideas that transfer to innovations and clinical use.
- The entrepreneurial culture across Europe inside academia, health care and industry
- The clinical knowledge of evidence verification in regenerative medicine
- The management capabilities in regenerative medicine
- The health care capability in managing and implementing the knowledge transfer, licensing agreements, production and implementation of regenerative medicine

Key issues related to education and training in science and management were further discussed during a scientific meeting held in Berlin (end of November 2012)[36], and three additional meetings with the respective research-driven clusters in Madrid, Nantes and Charleroi (December 2012 - February 2013). On the basis of these meetings, the TERM consortium urged the need to:

- Increase the visibility and accessibility of existing educations in the TERM area and develop training and courses corresponding to the remaining needs in order to increase the availability of qualified personnel on the market (both for industries and academia): bio-production in GMP environment, regulatory and reimbursement (procurement) aspects of advanced therapies
- Increase the entrepreneurial culture and develop the managerial and entrepreneurial skills among the scientific community and students.
- Improve the mobility among researchers and students both between different sectors (e.g. industry and academia) and regions (through exchange programs).

Yet, although cooperation between European training institutions is essential for the global increase of competences, it often encounters regional barriers. After quite extensive study time to understand the reasons, it appears that political, pedagogical, religious, ownership or commercial potentials are sometimes too significant to be overcome.

Potential levels of action

Four main actions are proposed to address the educational needs[37]:

- Initiate collaboration between different educational initiatives to the process of filling in knowledge and competence gaps, including knowledge in clinical studies and regulatory performance
- Make use of the available education/courses already developed regionally to reach the visions for, within and after TERM for all Europe
- Build dedicated entrepreneurial courses and programmes to increase the number of available managers and innovations and to meet unmet competence needs
- Evaluate and developing parts of available portals to link educational and mobility initiatives in the TERM area as well as linking available web based lectures/courses in specific fields. The Erasmus and Move On are available.

[36] WEINHOLD M., "Trends and challenges in Regenerative Medicine - towards interregional collaboration in Europe", TERM report (2012).

[37] See details in EDGAR B., "The Need for Entrepreneurial Culture to Implement Regenerative Medicine in Europe", TERM report (2013).

Future visions

Discussion on educational needs have been held during the two-year project. On that basis, several levels of actions have been identified. Now, there is a need to move from vague proposals to firmer ones with clear accountabilities based on incentives but also a need to widen the project to EU28 or to the 900 million inhabitants of the whole Europe.

The understanding of the entrepreneurial culture for the implementation of new therapies such as regenerative medicine is crucial and highlighted by the European Commission while also health care personnel; managers and paying stakeholders have to be educated. Again the need is fully stressed by the European Commission and some countries are focusing of the need for such life-long learning that includes entrepreneurship and also taking care of the gender issue.

The action proposals are far stretched and underline the importance of the mixed education, also vocational, in innovation and entrepreneurship. They point out areas of new technology as of special significance and high importance for Europe. The success in the future will depend on how:

- Universities can and may collaborate to open up and allow for exchange for students, teachers, programmes and courses
- Soft skills in innovation and entrepreneurship is introduced in universities and universities become entrepreneurial
- A dedicated master in advanced therapy may be set up and run with local benefit
- Management capacity could be built with the existing cluster driven courses and universities may drive available courses for life long learning
- Available ideas and venture capital will be spread over Europe based on an exchange of knowledge and open innovation platforms.

Ongoing discussions between three institutions internal to the TERM consortium (namely Audencia in Nantes, Universidad Autónoma de Madrid (UAM) and University of Gothenburg) will demonstrate the feasibility for such joint education.

TASK 3.3 – Spin-offs, technology transfer, valorisation and market potential
[Task Leader: UPPBIO]

Background

Within the RegMed area, new types of definite cures for e.g. degenerative diseases are likely to be developed. Such therapies will address age-related diseases, create new innovative products and be a base for a growing life science sector. Europe is extremely active in the area of TERM, or as it can also be named; advanced therapies, both from the patenting side, as well as from the point of view of clinical development of new products. Nevertheless, there are still few products that have reached the market and it is therefore not yet clear which will be the preferred business model that will grant economical growth and return on investment for the many companies interested in investing in these new therapies. Thus, further scientific, clinical and business proofs are required before a wider implementation in healthcare can be seen.

Simultaneously, large parts of the Pharmaceutical industry in Europe have seen its pipeline of new products shrinking for years, and an industrial restructuring is ongoing where industries search more frequently to find early projects externally. The gap between academic research and industrial development therefore more than ever needs to be addressed.

The path from the lab to the market is a winding road with many potential pitfalls and obstacles on the way forward. The first valley of death on the path is called the technology discovery gap; this gap separates the cutting-edge scientific discoveries from the evaluation of their commercial feasibility. Looking on the financial landscape there is a similar gap between the funding of basic research in the academic setting and the funding of product development in the industrial setting. These two gaps are overlapping, and in order to secure safe passing for potential new commercial projects, the process of securing that needs expressed within clinics and within industries can be solved by high-class basic research, wherever they are obtained, by whom and when, can be funded and supported by a well-functioning program in Europe.

In order to make projects, coming from academic or basic research, more attractive for the funding available for product development, they need to be made investable. The funding and support process should thus bring the projects to a proof of concept, making them attractive and investable for European companies, incubators and investors who can efficiently bring them to market. It should also be a process that works toward market pull rather than technology push to secure need of potential product outcome.

Objectives

The Task 3.3 of the TERM project aimed at developing **a framework program for multiregional innovation support**, in order to increase the value of investments made in research and of individual projects by reducing technology risks involved and connecting the projects with industrial knowledge and healthcare needs:

- To share experience among regional clusters and authorities on specific tools to make value out of these priority fields.
- Support to spin-offs from research to innovation by developing a process that bridges the fist valley of death, from research results o proof of concept.
- To develop an efficient concept for evaluating and coaching TERM projects having research results with potential to be developed into commercially viable proof of concept, ready for commercial development and financing with a well functioning network of innovation support adapted to TERM related need.
- Stimulate cross-disciplinary and cross-functional projects.
- To prepare the full deployment and implementation of the action plan.
- To analyse and adapt these tools for developing a collaborative approach at European level.

Figure 9. Benchmarking of five Regional Innovation Support Systems.

General observations:

- There are few TERM projects supported today by RISS actors
- Regional restrictions hamper efficient development
- Close management by regional organizations is important
- Funding can come from any source
- New business models required

Needs expressed:

- Funding: There is a financial need for execution of defined proof of concept projects.
- Europe: There is a need for a multiregional coordination and thus less regional restrictions.
- Regions: There is a need for close management of projects.
- Coordination: A pool of European experts should be engaged and RISS organizations should be organized in a certified network.

Benchmarking report on Innovation support for TERM in Europe

The global SWOT analysis carried out during WP2 showed that Europe has a great potential to develop a competitive position within this domain. All participating regions in the TERM project offer different type of support to bridge needs in industry and healthcare with academic research results. As an extension to the SWOT analyses, the consortium has carried out a benchmarking study of innovation support programs in some of the regions.

The benchmarking covered five European countries, partners of the TERM project (Pays de la Loire in France, Berlin Brandenburg in Germany, Wallonia in Belgium, Uppsala in Sweden and OSR in Italy), and their respective regional innovation support systems were analysed. As the task leader Uppsala BIO together with Dr Henrik Mattsson, Uppsala University and Sweco AB, who has a long background in the evaluation of cluster organizations, innovation support systems and innovation support with a special interest for life science and the biotechnology sector, visited and interviewed the five regions different innovation support actors.

Both the SWOT and the benchmarking[38] reveal challenges to be addressed (Fig.9). These may be lack of funding to new projects and start-ups, or challenges in connecting clinical and industrial needs with academic research, i.e. bridging the so called technology gap.

Framework for a multiregional innovation support program

The benchmarking report points out interesting examples with related success factors. Some issues stand out, however, where Europe needs to improve for a better outcome of investments made in research and a more efficient use of competencies developed for innovation support. Some issues are general, while others are more specific to RegMed.

Building on the experiences, results and conclusions from the benchmarking, the development of a framework for a multiregional innovation support ("**Innovation Management 2020**") was initiated. In order to suggest a framework that builds on existing experiences, a first workshop discussing the benchmark report and a first draft of a framework was carried out in May 2012. As the European Commission is an important financial structure and have access to experiences regarding different programs to promote innovation, members of the EC were also invited to the workshop. A second workshop was held in November 2012, the focus of the workshop was on how to show results from early innovation support programs.

[38] MATTSSON H. and NEIL M. "Benchmarking report Innovation support for Tissue Engineering and Regenerative Medicine in Europe", TERM Report (2012).

Figure 10. Benchmarking of five Regional Innovation Support Systems.

The proposed framework is aimed at increasing the stream of projects in Europe over the technology discovery gap which after a defined time period (usually 2 years), and if deemed successful, will be "investable". I.e. projects should, during the two years, be taken to such level that other investors (mainly private but also public) will invest and drive the projects over the commercialization and venture gaps and thus turn them into innovations. The suggestion is that through Innovation Management 2020, a multiregional Innovation Support Program, regional project management organizations will work in a coordinated programme supported by EU funding to the projects selected in the regions. The coordinated programme will apply a proven project management process in a coordinated action through Europe in order to increase the flow of projects that investors can take further to innovations.

The framework for a multiregional innovation support program[39] suggests a cost effective and efficient innovation support program – Innovation Management 2020 – strongly in line with Horizon 2020's industrial leadership and societal challenges programs. It is based on years of experiences and implementation of management support for clinical-academic-industrial collaboration projects in different European regions. These experiences are taken further towards a European coordination of the regional project management support, to increase benefit for the European society. The proposed Innovation program is suggested to be tested 2015-2017 in the TERM area, but long-term implementation from 2017 will cover all areas of life sciences.

Key features:

- Defined, goal oriented and cost effective projects
- Origin from all sources of European research
- The goal is "Investable" projects
- Regional trust and networks combined with a program open for Europe
- Budget

Proposed framework (Fig.10)

- Needs: Start each campaign/call in the programme by defining societal or market needs.
- Reach out: Find projects having solutions to such defined needs.
- Regional selection: Use common selection criteria.
- Team and matchmaking: Put extra focus on the Team, securing that the team composition in relation to what they want to achieve, after exit from Innovation Management 2020, is appropriate.
- Multiregional selection: After the above phases, invite selected project teams for oral presentations. Regional Boards thereafter make preliminary decisions which projects to fund.
- Execution: 150 – 200 kEUROs for up to two years is the financial support to develop the project to a proof of concept.

[39] AGERMAN K., HÖGLUND M. and FORSBERG E. "A framework for a multiregional innovation support program", TERM report (2013).

- Exit: Partners already taking part in the project or connected to the project by other means during the execution phase decide whether they will make further investments in the project taking it over the commercialization- and venture gaps.

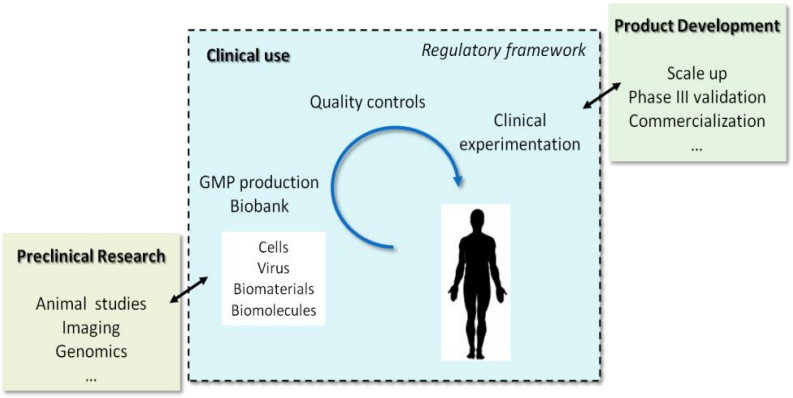
Future visions

Due to lack of financial resources the proposed experimentation of a common program for innovation support has not been carried out during the TERM project. No participating region was able to confirm the availability of these funds. Regional or national funding is available, but only for individual projects according to already more or less decided schemes, and not for a program where decision (or recommendation for decision) is to be taken by the consortium following lines of approval not defined. This roadblock clearly urges the need to sustain a joint innovation support model at the EC level.

As part of the Framework for a multiregional innovation support program a work plan for implementation of Innovation Management 2020 in Europe is outlined. The start of the pilot project is scheduled for January 2015 when Horizon 2020 is available. The owner for WP 3.3 (Spin offs, technology transfer, valorisation and market potential) of the RoK project TERM (Uppsala BIO) within WP 3 “Experimenting innovative tools” will act as project leader and coordinator for this extension. Uppsala BIO will invite in total three or four willing regions to participate in a common multiregional call using project management processes currently used in the regions taken part in the benchmarking study. Two or three of these regions are preferably partners in the TERM consortia and having project management processes in place that can be well adapted to a multiregional call. Consequently one or two external regions can, in addition, be invited to take part. As part of such pilot project, a work package (WP 5 in the Proposal of a Multiregional Innovation Program) will be dedicated to follow-up research. From this work package a long-term implementation throughout Europe will be suggested.

TASK 3.4 – Infrastructures [Task Leader: ATL]			
Deliverable	**Name**	**Due date**	**Actual date**
D3.1	A database of the existing infrastructures/services and of the possibilities to share them	May 2012	14/10/2012
Internal deliverables	*- Workshop on Research Infrastructures, Nantes, FRANCE* *- Minutes of the workshop ("Towards translational RIs in Regenerative Medicine")*		*24/10/2012* *April 2013*

Background



Developing innovative products in Tissue Engineering and Regenerative Medicine requires highly-specialized facilities dedicated to the production and storage of clinical-grade samples. In addition, preclinical and clinical researches also rely on the support of numerous wide-scope Research Infrastructures (RIs)[40]. As exemplified by the WP1 mapping, public and private infrastructures have been implemented in most of the European regions, in order to support early proof-of-concepts (phase I clinical trials). Nevertheless, the development of new therapies capable of reaching the patients requires the major research institutions to:

- Establish specialized translational centres that provide a coordinated "bench to bedside" approach, mostly relying on the integration of cutting-edge RIs.
- Open the access to research facilities to private users such as spin-off ventures, in order to reduce the direct investment costs of the companies, thereby lowering the risks associated to the development of new products.

Importantly, two remarkable international initiatives work to foster the emergence of RegMed products by integrating state-of-the-art RIs and facilitating the access to private users:

- The European Advanced Translational Research Infrastructure (EATRIS) launched in 2008 in the framework of the EU support to research and innovation [41], that provides one-stop access to a network of top-class RIs.
- The Regenerative Medicine Coalition (RMC), a global consortium of 7 translation centers[42] in advanced therapies that has been launched in 2012.

In that context, the TERM project intended to encourage the facilities from the consortium to exchange and take benefit from these international initiatives.

Objectives

To encourage cooperation between translational infrastructures, the TERM consortium specifically worked at increasing the visibility of the RIs and promoting the sharing of know-how and best practices.

[40] Such as facilities dedicated to omics, animal models, imaging, quality controls, regulatory affairs, clinical exploration, etc.
[41] For details on Europe initiatives, see the white paper "Towards translational RIs in Regenerative Medicine". TERM project (2012).
[42] The founding institutions are: Wake Forest Institute for Regenerative Medicine, USA; CABIMER Andalusian Center for Molecular Biology and Regenerative Medicine, Sevilla, Spain; the Advanced Centre for Biochemical Engineering, University College London, London, UK; the Centre for Commercialisation of Regenerative Medicine (CCRM), Toronto, Canada ; the Institute for Biomedical Technology and Technical Medicine (MIRA) University of Twente Enschede, Netherlands; McGowan Institute for Regenerative Medicine Pittsburgh, USA ; Berlin-Brandenburg Center for Regenerative Therapies (BCRT), Germany.

The action plan was divided into two parts:

- The delivery of a public list of RIs to be available online,
- The organization of a workshop gathering RI representatives from the TERM consortium.

A public database of 83 Research Infrastructures

On the basis of the survey achieved in the course of WP1, a database of state-of-the-art infrastructures has been generated in respect with two objective criteria: the RIs should be active in the TERM scope and accessible to external projects. Importantly, since addressing the complex range of activities needed to translate research results into clinical use also requires numerous supportive technologies and expertise, the selection of facilities was not restricted to the sole organizations directly related to RegMed field (i.e. specialised GMP facilities and biobanks). The scope was broadened in order to include facilities such as those dedicated to imaging, animal models generation, preclinical and clinical assessment and regulatory issues.

At the end of the study, the catalogue had a total of 83 organizations, distributed within the geographical TERM area as follow: ATL (39), UPPBIO-MCS (7), BIOWIN (13), MADBIO (3), BIA (13), BCRT (8). It has been released to the Commission as an Excel file in October 2012 *(Deliverable D3.1 "Database of the existing infrastructures/services and of the possibilities to share them").*

The exhaustive database will be uploaded onto the TERM Portal in order to facilitate its access. It will provide additional information related to the equipment and service offers in order to facilitate the identification of prospective partners for collaborative programs.

Towards translational Research Infrastructures in Regenerative Medicine

The TERM project then intended to encourage exchanges of best practices and know-how between RIs. A multidisciplinary meeting was held in Nantes on the 24th of October 2012. It gathered more than 30 RI representatives within the consortium in order to:

- Introduce transnational integrating initiatives (EATRIS and RMC)
- Shed light on infrastructures of excellence that could join these international organizations
- Define challenges in facility management and share insights and experiences

The discussion centred on the role of the RIs in the innovation process. A particular focus was given on the development of public private partnership and the opportunity to convert discovery platforms into translational ones. The minutes of the meeting were released in April 2013 as a white paper[43], that includes recommendations on the most appropriate means to target unmet needs.

Conclusion of the workshop

The workshop offered the opportunity to share experience and best practices in RI management. Optimising the use of effective RIs and the access to external users (remote or foreign researchers, industry) is a key factor for research competitiveness in Europe, and efforts made to this end were clearly illustrated during the meeting. However, ensure that all these types of users can have access to cutting-edge facilities, gives rise to challenging managerial issues such as how to sustain a well-trained workforce and how to set up a clear business plan.

Strategies to strengthen research infrastructures should then focus on:

- The long-term stabilisation of funding
- The training of skilled technicians and managers
- The prioritisation of research areas

[43] White paper: "Towards translational Research Infrastructures in Regenerative Medicine". The TERM Project (2013).

The latter point was highly debated during the workshop, highlighting the fact that most of the RIs actually operate in a discovery orientation rather than a translational one. Whereas a vast majority of facilities located within research or clinical institutions aims at supporting local science-driven research, Europe strongly emphasises on innovation-driven projects. According to the EATRIS representative, choosing to do either basic or translational research determines the services provided and RI management. A clear positioning should facilitate the setting up of business plans as everyone recognises it is very hard to manage mixed business models.

How to convert discovery facilities into translational facilities? Actually, the idea underlying the debate on research- versus innovation-driven RIs is the definition of the added-value. What is really sold by the RIs? According to the EATRIS representative, in the absence of very large infrastructures, the main value of the European regions is defined by patient samples and know-how. Access to specific patients and biobanks should be taken into account for the upgrading of existing RIs in the regenerative medicine field. Are these criteria sufficient to support centres of excellence?

Taken altogether, the workshop highlighted the importance to integrate existing RIs into pan-European networks in order to foster the development of innovative regenerative medicine products.

Recommendations to the European Commission

The European Commission has already invested considerable amount of resources for research infrastructures in the biotechnology field. Yet, on the basis of the exchanges of experience made during the workshop, we further recommend the EC to consider the following priorities in the definition of the next Horizon 2020 framework program:

- To support the RIs as part of the whole value chain of the regenerative medicine in Europe,
- To support the implementation of new facilities (especially those dedicated to the large-scale manufacturing for late-phase clinical trials) and the integration of national RIs of pan-European and regional interest,
- To promote the market-pulled management of research infrastructures (prioritizing the end-users perspective) by improving the understanding of the innovation process (training of RI managers) and encouraging public private partnership,
- To promote collaboration and experience sharing between the RIs.

Future vision

Standardized preparation processes and long-term storage are essential pre-requisites to the commercial and clinical application of stem cells[44]. Yet, the fragmentation of the stem cell research and the absence of consensual regulatory framework have leaded to the building of scattered cell banks. To counteract the negative impact of that dispersion on research and industry development, recent national or transnational initiatives have been compiling the available resources in databases and biobanks. But so far, all these initiatives seem to be poorly interconnected. A weak connection is also observed with the BBMRI, a pan-European network of biobanks and biomolecular resources built in the framework of the European Strategy Forum on Research Infrastructures (ESFRI).

Promoting cooperation between storage organizations in Europe will help harmonize databases and define/transfer standards for stem cell banking. But that task is so complex that is required to be developed in the framework of a dedicated EU-funded project. The European Commission is thus highly recommended to foster the integration of stem cells collections into standardized banking systems and networks with the aim to:

- For research: get better access to stem cell banks for labs and industry; harmonize legal framework for hESC collection and research
- For patients: increase safety (samples characterization, traceability and reproducibility thanks to validated SOPs with quality assurance); promote personalized medicine (patient profile)
- For the economy: increase employment, venture creation and source of income (licensing, patents…)

[44] LAMBERT D. et al. " Regenerative Medicine Vision document" TERM report (2012).

Workpackage WP4 – Financing engineering WP Leader: MadBIO			
Deliverable	**Name**	**Due date**	**Actual date**
D4.1	Detailed catalogue of financing resources and programs	M24	14/12/2012
D4.2	Agreement from Regions to set-up specific action	M26	
D4.3	Roadmap for financing (needs and suitable resources)	M32	
Milestone	**Name**	**Due date**	**Actual date**
MS11	Mapping of all funding sources (European, national, regional)	M12	

Previous considerations

Workpackage 4 has provided the participating clusters an opportunity to identify, contact and disseminate TERM concepts among a wide range of stakeholders, including entities, companies, regional authorities and specifically financial entities.

Objectives

- To define how the different measures foreseen will be **funded** by using possibilities available at the **national and local levels**, including from the private sector, or at the Community level.
- To work with financial bodies for developing **private funding**.
- To set-up a **financial plan** to enable the implementation of the TERM action plan.
- To propose **recommendations** for use of next-generation European instruments.

Detailed catalogue of financing resources and programs

A comprehensive database has been created using Excel spreadsheet including funding entities both, public and private, in regional, national and Community level. The DB structure has been sent and filled in by the Consortium Members. Information structure is:

ENTITY	Entity full name	Text
CHECKED	If the entity was checked back by the local partner	0=No, 1=Yes
VALIDATED	If the entity has been validated as financing related sectors	0=No, 1=Yes
SECTORS	Sector (Biotechnology, Life Sciences, Association)	Text
TYPE	Subsector (Public, Private, Venture Capital, Business Angel)	Text
ADDRESS	Entity address	Text
ZIP CODE	Entity zip code	Text
CITY	Entity city	Text
COUNTRY	Entity country	Text
CONTACT	Contact person or responsible	Text
CONTACT PHONE	Contact phone	Text
e-MAIL	Contact e-mail	Text
WEBSITE	Web URL	Text
COMMENTS	Comments or specifications	Text
REGIONAL	Regional particularities	Text

- With a previous screening among 776 entities collected, 275 of them have been identified in Healthcare, Biomed or Life Sciences fields and 67 clustered in Biotechnology. Checking processes have confirmed 171 validated entities as potential financers for future TERM projects type.
- Database with public entities was exported to Interface Europe on February 2012 in order to share the effort of identifying cross-country and European programs. Periodical updates and validation-filtered releases were periodically sent.
- The database can be considered updated by September 2012. It has to be understood that this database is alive and evolves continuously, both in number of registered entities and field contents. It is designed to be on-line.
- All the data have been integrated to build a DB following the specifications and criteria defined in WP4. The database should be used in a future online TERM web portal tool that permits to clusterize the information following the different variables.

D4.2.- Agreement from Regions

The **TERM Joint Action Plan (JAP)** released in March 2012 presented the collective actions to be implemented within and outside of the **TERM** project based on the strategic vision of the **TERM** partners. These collective actions were foreseen to be implemented trans-regionally by at least two clusters / regions of the **TERM** consortium.

The **JAP** described briefly the collective actions to be implemented "outside of the project". Based on the experience gained within the project, the Partners decided to reaffirm their engagement regarding these actions and to update them. Strategy is structured around 5 themes for which we have defined common challenges, priorities and actions.

Themes are:

- Collaborative partnerships and projects
- Education and training
- Technology transfer and Innovation support
- Infrastructures
- Financing

Financing Priorities:

- To foster the funding of research projects on common priorities through European funding agencies (framework program, IMI, ERA-net, etc.), private foundations or scientific societies, and by developing interregional financing schemes.
- To increase venture / private capital for research linked to the **TERM**-area
- To develop new financing models that include creative mix of public-private investments in **TERM**-companies and/or in specific **TERM**-areas

At the end time of **TERM** there are actions planned about business, financing, research and education.

The **Financial Roadmap** objective is to complement and define the implementation steps[45] of the collective actions to be implemented "outside of the project" set out in the **JAP**.

D4.3 Roadmap for financing

1. Collaborative partnerships and projects

Action 1.1: Joint actions to pitch for funding for the RegenMed field

[45] Detailed in FUHRER et al. "Deliverable D4.3: Roadmap for Financing. - Needs and suitable resources", TERM report (2013).

Leader: **BCRT**

2. Education & Training

Action 2.1: Enable mobility of students and researchers in TERM regions by increasing collaborations between universities.
Action 2.2: Define and share a curriculum for increasing "soft skills" in science students
Action 2.3: Develop a European Master in Innovation and Entrepreneurship in the TERM area
Action 2.4: Improve the management capacity for life science companies.
Leader: **UGOT**

3. Innovation support

Action 3.1: Launch European Innovation Support Program
Leader: **UppBIO**

4. Infrastructure

Action 4.1: Development of normalised stem cell banks (iPS, MSC, ESC, etc), in particular to maximize the opportunity of collaboration
Leader: **ATL – MadBio**

5. Financing Tools

Action 5.1: Meeting with private and public investors
Leader **MadBIO**

Future vision

Recommended tools as next generation financing instruments:

- Pitch meetings and Biotechnology and Risk Capital Forums: as TERM B2B meeting or the Forum Biotech and Capital Risk in Bio-Spain.

- Networking continuous effort: as our new created TERM Group (512 members by now, its first year) or Biotech Investment Group (8.901 members by now).

- Projects and Programs synergies: as BioREG Program or Regions of Knowledge Program (Trying to share RoK projects results with related Project Officers (7 projects participating from RoK 2010 call: AMI-4EUROPE, TERM, NEURORESCUE, HEALTH TIES, AFRESH, RICHARD, JADE).

It should be desirable to dispose the funding entities DB, the programs and calls documents, the research infrastructures DB, a directory of companies, job opportunities, etc., in an on-line web interactive format in a really marketplace portal tool.

1.4. THE POTENTIAL IMPACT

1.4.1. Socio-economic impact and wider societal implications of the project

Regenerative medicine is a disruptive approach that will shape tomorrow's healthcare. Considered as the ultimate prolongation of the personalized medicine that consists in stratifying the patient population to select the most-responding one, RegMed will develop highly-individualised therapies with high response rates and effective overall cost:benefit ratios (Fig.11).

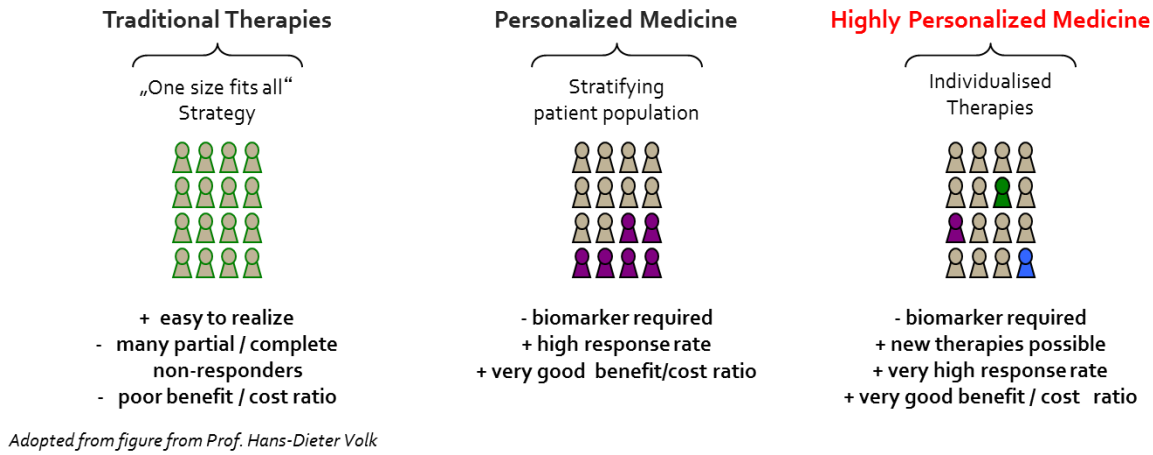
Societal and economic impacts of RegMed are expected to be of main importance. Based on its work, the TERM consortium highlighted that regenerative medicine will:

- Propose treatments for life-threatening or debilitating disorders,
- Address the challenge of the ageing population (in line with the European Innovation Partnership on Active and Healthy Ageing)
- Improved management of Public Health expenses by improving cost-benefit approach through personalized medicine
- Strengthen the EU industrial leadership in innovation for companies (and more specifically SMEs) developing technologies, products and services by providing access to capital and support.
- Strengthen the EU's position in basic and applied science by making of Regenerative Medicine one of the thematic for EU funded research programs

Yet, there is still a long way to go before innovative RegMed products can be routinely used in clinics. The TERM project intends to contribute to the emergence of this new therapy approach by:

- Promoting synergies and cooperation between top-class European clusters,
- Deeply anchoring Regenerative Medicine in the Horizon 2020 Strategy.

Figure 11. A highly-personalized medicine



Adopted from figure from Prof. Hans-Dieter Volk

1.4.2. Dissemination and exploitation of results

Workpackage WP5 – Dissemination, communication, exploitation and mentoring WP Leader: MCS			
Deliverable	**Name**	**Due date**	**Actual date**
D5.1	Project Public Website	M6	15/09/2011
D5.2	Final plan for use and dissemination: Business plan for maintenance of tools and services	M30	
Milestone	**Name**	**Due date**	**Actual date**
M12	Identification of needs from the less advanced regions	M36	

Note: the final plan for use and dissemination (deliverable D5.2) describing the business plan for maintenance of the TERM Portal has been already described.[46]

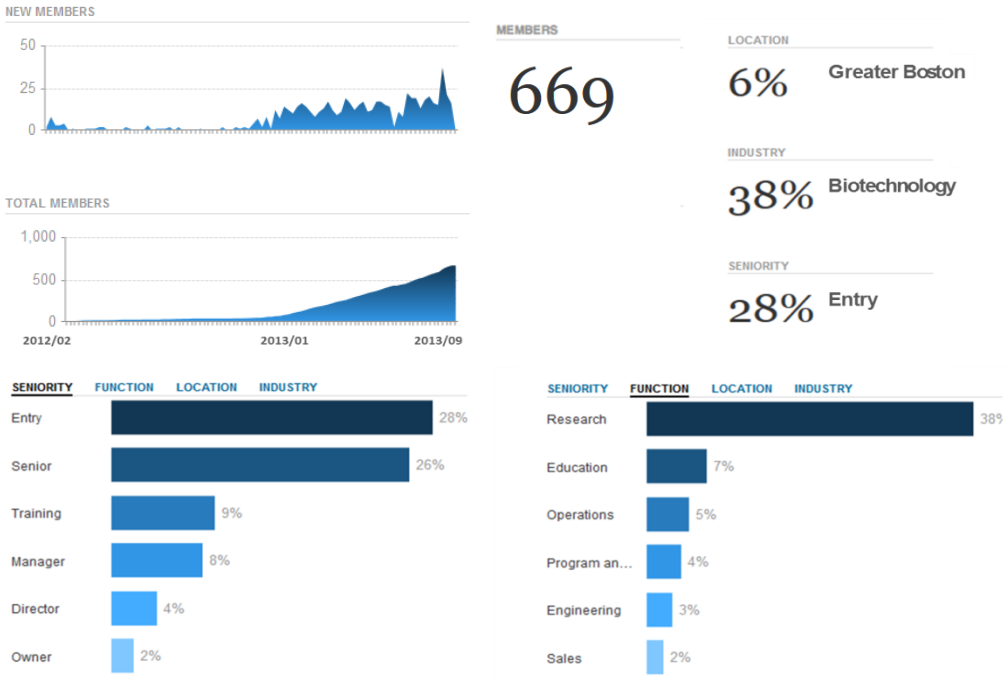
Dissemination and communication

A dissemination plan was defined in order to optimise the communication strategy and tools by providing a coherent framework, and (2) actively pursue dissemination strategy for the results generated.

The TERM LinkedIn group

As a result of the implementation of the Communication and Dissemination Plan, a LinkedIn group was created in February 2012. Since its beginning, the group counts about 669 members coming mainly from research and biotechnology fields (Fig.12). Statistics analysis shows the group membership has been experiencing a linear growth since January 2013, given rise to more than 60 discussions.

Figure 12. Statistics of the TERM LinkedIn group.



[46] See above: the description of the TERM Portal.

The TERM flyer

The TERM project has been presented in several conferences (see TEMPLATE A2: LIST OF DISSEMINATION ACTIVITIES below). In addition, introducing flyers to be handed out to the respective meetings participants have been published.

The Project Public Website

A public website is a project showcase. It is one of the most important tool in a project communication strategy as it is the project's gateway and the most accessible source of information for all target groups (general public, researchers, cluster organisations, regional and national authorities, etc.). A website dedicated to the TERM project has therefore been implemented to ensure a proper project presentation as well as dissemination of the outcomes.

The TERM website has been developed according to a tender document drawn by the consortium and defining the website specifications. It has been officially launched on 16/09/2011 (M12).

The website's main strength lies in its user-friendliness both for the visitors and the editor. It was conceived in such a way that it is easy to navigate through all the pages. The back-office is also easy to master so the responsible partners do not need to follow extensive training to master the interface.

It is also practical in the sense that the website can support and host the TERM portal that will was developed later on in the project. Therefore all the TERM tools will be concentrated in one place and it will increase their visibility.

Thanks to the TERM website, it is now possible to communicate more efficiently about the project and its outcomes (Fig. 13). The following types of news have been published on the website:

- Results of the project,
- Conferences and workshops where TERM partners intend to make a presentation,
- Information related to the Tissue Engineering and Regenerative Medicine field,
- Information related to clusters' members.

The website has been regularly updated with information concerning project activities and results and information related to the TERM field. Google analytics has been activated on the website since M18 in order to collect some statistics about the website activity. Below are some basic statistics collected so far from May 2012 to September 2013:

- visits : 3,300
- unique visitors: 2,232
- pages / visit: 2.90
- pages viewed: 9,563
- most viewed pages:
    - Home page:1,923 page viewed
    - Partners section: 783 page viewed
    - Project section:805 page viewed
    - News related to the infrastructure workshop: 412 page viewed

Figure 12. Some screenshots of the TERM website.

Description of the WPs

Post of news

Description of TERM Partners

Identification of needs from the less advanced regions

During the first 18 months of the TERM project, each cluster within the consortium inventoried its regional research capacities and activities supporting development of the RegMed field. The analysis of existing skills, resources and initiatives as well as the identification of gaps allowed an understanding of the strengths and weaknesses of each cluster. The study highlighted the respective needs and the possibility to interact within the consortium in order to overcome gaps and build upon existing opportunities.

In particular, the regional SWOT analysis performed by BIA pointed out that the Tartu area was facing several issues in terms of advanced therapy-based product development:

- Lack of qualified researchers and difficulties to attract world class researchers to the region
- Underdeveloped R&D infrastructure in some TERM areas
- Difficulty to support innovation (fragmented innovation support measures, linear approach to innovation in some RTD, insufficient cooperation between entrepreneurs and universities, no specific innovation policy measures in TERM area)
- Small number of companies in TERM area and even smaller number of growth companies, absence of big Pharma companies
- Insufficient funding for research and development (lack of private sector investments into TERM area, of pre-seed and seed capital, poor commitment on the state level for midterm and long term financing)

On that basis, 4 study visits have been undertaken under WP5 task 5.3 “Mentoring Activities” with the aim to take benefit from other partners experience in the RegMed field: Gothenburg and Oslo MedCoast, Nantes, Berlin-Brandenburg and Wallonia clusters.

Conclusion of the study visits

Key stakeholders from Tartu area were invited visit biotechnology companies, facilities, science and business parks, innovation support organisations and life science education institutions. The visits aimed at:

- Familiarising BIA and Tartu regional stakeholders with the development of clusters
- Learning more about the existing infrastructures and research activities in the RegMed field
- Identifying potential partners for future joint cooperation programs.

As detailed in the subsequent TERM report[47], the visits leaded to the definition of proposals for bilateral research projects (i.e. in orthogenomics) and exchanges of know-how (i.e. on the building of clean room facility).

Based on the results achieved, the follow-up actions implemented and the feedback received from the participants, study visits appeared to be key tools of mentoring activities. They are certainly a very useful and needed instrument to support the knowledge transfer and exchange of experiences between the less advanced and more advanced cluster regions. In particular such tools as study visits help the less advanced cluster regions to better understand how successful and highly competitive clusters have been developing and what are the main sources of their competitiveness as well as what are the necessary pre-conditions and framework conditions for their success.

Recommendations

However it has to be kept in mind that there are no universal solutions for cluster development and competitiveness: as clearly shown in the report, every cluster is unique in its setting and therefore no copy-paste action or direct policy transfer is possible or meaningful. However an intelligent policy learning and adaption of specific measures into the context is the way that less advanced cluster regions should precede in order to fully benefit from such visits. At the same time it has to be acknowledged that such policy learning can be more difficult and challenging than initially thought as the institutional settings, available resources, political will, etc. are often quite different between regions and therefore a right combination of understanding of its own competitive advantages with a will to act and change is a key to succeed in long term.

Apart from analysing the role of study visits on strategic level for cluster development in less advanced cluster regions we can also conclude that they have also a very important role in helping to develop the clusters on operational level. What we have in mind here is that in addition to understanding the overall framework conditions for cluster development there are also existing good practices in cluster management, which can be adapted into the local context by the cluster organisations and stakeholders in less advanced cluster regions. Those practices, methods and tools are normally more universal in nature and can be more easily transferred and adapted that so called framework conditions and therefore with much less resources and shorter timeframes significant changes can be achieved in improving cluster management approaches in less advanced regions after such study visits and particularly so if the study visits could be combined with follow-up staff exchanges between the less and more advances cluster regions and cluster organisations.

Finally it has to be kept in mind that clusters are not an abstract formation but they consist of specific companies and organisations which are represented by concrete persons and one of the very important roles of study visits is to allow companies and people from different clusters to meet and exchange ideas for future cooperation on bilateral or multilateral basis. Such meetings, even if short in duration during study visits, will allow to establish new contacts and find joint ideas for further development and such short meetings are in some cases followed up with individual visits and discussions which can lead to joint research and development projects as also successfully demonstrated in the current case by the TERM project.

As such we can conclude that study visits are a relevant and effective tool to be used for implementing mentoring activities. They provide an important input for cluster development in less advanced regions both on strategic, operational and individual level, and are thus instrumental to the increase and competitiveness, if properly planned, implemented and followed-up.

[47] TONNISSON R. “Study Visits Report”, TERM report (2013).

1.5. PROJECT DATA

Members of the TERM Consortium

ACRONYM	ORGANIZATION	LOCATION	REPRESENTATIVES
ATL	ATLANPOLE BIOTHERAPIES	Nantes, France	DUISIT, Ghislaine BAUER, Gregory TRONCHIN, Maud
MCS	MEDCOAST SCANDINAVIA	Oslo, Norway	VAALER, Stein NICOLAS, Delphine
UppBio	UPPSALA BIO	Uppsala, Sweden	AGERMAN, Karin HÖGLUND, Malin
BW	BIOWIN	Gosselie, Belgium	DRUCK, Frederic LAMBERT, Damien TIMMERMANS, Laurence
MadBIO	MADRID BIOCLUSTER	Madrid, Spain	PARDO CALVELO, Rogelio PUEYO, Angel ARMENGOD STOFFEL, Valerie
BIA	BALTIC INNOVATION AGENCY	Tartu, Estonia	TONNISSON, Rene KOCK, Sulev
BCRT	BERLIN-BRANDENBURG CENTER FOR REGENERATIVE THERAPIES	Berlin, Germany	SZEPANSKI, Sigrun
IE	INTERFACE EUROPE	Brussels, Belgium	LOHER, Marc
OSR	OSPEDALE SAN RAFFAELE	Milano, Italy	SANTARELLA, Roberto
SPW	SERVICE PUBLIC DE WALLONIE	Brussels, Belgium	FLAGOTHIER, Didier LEMOINE, Thierry
RPdL	REGION PAYS DE LA LOIRE	Nantes, France	HOLSTEIN, Martin
VINNOVA	VINNOVA	Stockholm, Sweden	JAREKRANS, Mats
Council of Uppsala	REGIONAL COUNCIL OF UPPSALA	Uppsala, Sweden	

THIRD PARTIES

UGOT	UNIVERSITY OF GOTHENBURG	Gothenburg, Sweden	EDGAR, Boo
BRG	SAHLGRENSKA SCIENCE PARK	Gothenburg, Sweden	BÖKMARK, Gunilla

The TERM website: http://www.termproject.eu/

The TERM Portal: http://community.termproject.eu/

2. USE AND DISSEMINATION OF FOREGROUND

A plan for use and dissemination of foreground (including socio-economic impact and target groups for the results of the research) shall be established at the end of the project. It should, where appropriate, be an update of the initial plan in Annex I for use and dissemination of foreground and be consistent with the report on societal implications on the use and dissemination of foreground (section 4.3 – H).

The plan should consist of:

- Section A

  This section should describe the dissemination measures, including any scientific publications relating to foreground. **Its content will be made available in the public domain** thus demonstrating the added-value and positive impact of the project on the European Union.

- Section B

  This section should specify the exploitable foreground and provide the plans for exploitation. All these data can be public or confidential; the report must clearly mark non-publishable (confidential) parts that will be treated as such by the Commission. Information under Section B that is not marked as confidential **will be made available in the public domain** thus demonstrating the added-value and positive impact of the project on the European Union.

2.1. Section A (public)

This section includes two templates

- Template A1: List of all scientific (peer reviewed) publications relating to the foreground of the project.
- Template A2: List of all dissemination activities (publications, conferences, workshops, web sites/applications, press releases, flyers, articles published in the popular press, videos, media briefings, presentations, exhibitions, thesis, interviews, films, TV clips, posters).

These tables are cumulative, which means that they should always show all publications and activities from the beginning until after the end of the project. Updates are possible at any time.

TEMPLATE A1: LIST OF SCIENTIFIC (PEER REVIEWED) PUBLICATIONS, STARTING WITH THE MOST IMPORTANT ONES

	Title	Main author	Title of the periodical or the series	Number, date or frequency	Publisher	Place of publication	Date of publication	Pages	Permanent identifiers[48] (if available)	Is/Will open access[49]?
1	The Networking Game	Frank Lauter (BCRT)	European Biopharmaceutical Review	April 2013	Samedanltd Pharmaceutical Publishing	London, UK	2013	42-47	http://www.samedanltd.com/magazine/12/issue/195/article/3503	Yes

[48] A permanent identifier should be a persistent link to the published version full text if open access or abstract if article is pay per view) or to the final manuscript accepted for publication (link to article in repository).

[49] Open Access is defined as free of charge access for anyone via Internet. Please answer "yes" if the open access to the publication is already established and also if the embargo period for open access is not yet over but you intend to establish open access afterwards.

TEMPLATE A2: LIST OF DISSEMINATION ACTIVITIES								
NO.	**Type of activities[50]**	**Main leader**	**Title**	**Date/Period**	**Place**	**Type of audience[51]**	**Size of audience**	**Countries addressed**
1	Match-making event	BCRT		22-23 November 2012	Berlin, Germany			
2	Workshop	ATL		October 2012	Nantes, France	Infrastructure managers	35	EU (BE, DE, EE, FR, NL, NO, SP, SE)
3	Match-making	UppBio	Dialogue Forum	30 May 2012	Brussels	European Commission, cluster organisations, companies, researchers	30-40 people for the session where TERM was presented, 150-200 at the entire meeting	EU (DK; Sweden, Germany, UK, Belgium, France)
4	Workshop	ATL	GRIMIT workshop	20-21 September 2012	Nantes, France	Researchers, SMEs	80	France
5	Networking	ATL	BIO Europe	12-14 November 2012	Hamburg, Germany	Researchers, SMEs, facilities, Big pharmas, clusters	3,000	EU

[50] A drop down list allows choosing the dissemination activity: publications, conferences, workshops, web, press releases, flyers, articles published in the popular press, videos, media briefings, presentations, exhibitions, thesis, interviews, films, TV clips, posters, Other.

[51] A drop down list allows choosing the type of public: Scientific Community (higher education, Research), Industry, Civil Society, Policy makers, Medias, Other ('multiple choices' is possible).

6	Networking	ATL	BIO BOSTON + "Cluster Hours" organised by CEBR	18-21 June 2012	Boston, USA	Researchers, SMEs, facilities, Big pharmas, clusters	10,000	World
7	Congress	BCRT	World Stem Cell Regenerative Medicine Congress	21-23 May 2012	London, UK	Industry, Academia		World
8	Conference	BCRT	World Stem Cells & Regenerative Summit	3-5 December 2012	West Palm Beach, Florida, USA	Industry, Academia	1,300	World
9	Conference	BIA	Nordic Orthopaedic Federation Conference	1-4 May 2012	Tallinn, Estonia	Medical Doctors and Researchers	420	Nordic + Baltic countries
10	Conference	BIA	European Cluster conference	18-20 April 2012	Vienna, Austria	Cluster Managers, Policy Makers	285	EU, NO, CH, Russia
11	Conference	ATL	Commercial Translation of Regenerative Medicine (Marcus Evans conference)	28-30 November 2012	London, UK	Researchers, SMEs, regulotory	100	EU, US
12	Networking	ATL	BIO Europe Spring	11-13 March 2013	Amsterdam, the Netherlands	Researchers, SMEs, facilities, Big pharmas, clusters	2200	EU
13	Conference	BIA	Week of Innovative Regionsrope	4-5 June 2012	Krakow, Poland	Policy Makers, Innovation Experts	350	EU
14	Networking	BW	BIO partnering Future Europe	8-9 October 2012	Brussels, Belgium	CEO, CSO, CFO, Project Managers, investors, business developers	800	Europe – USA
15	Mentoring	BW		February 2013	Wallonia			

16		ATL	Biomarker & Personalised Medicine Mission - French Health Clusters	24-25 May 2012	Philadelphia, USA	Researchers, SMEs, Big pharmas	250	US
17	Workshop	ATL	Gen2bio	31 March 2011	Angers, France	Researchers, SMEs, facilities	350	France
18	Forum	MCS	ScanBalt	23 September 2011	Heringsdorf, Germany	SMEs, universities		ScanBalt region (Scandinavia and the Baltic countries)
19	Networking	ATL	BIO Europe Spring Barcelona	11-13 March 2013	Barcelona, Spain	Researchers, SMEs, facilities, Big pharmas, clusters	2100	EU
20	Conference	BCRT	Regenerative Medicine Foundation Conference	1-19 October 2012	Charlotte, NC, USA	Academia	300	World
21	Congress	ATL	10th Congress of the French Society of Cell and Gene Therapy	6-8 June 2011	Nantes, France	Researchers	150	France

2.2. Section B (Confidential[52] or public: confidential information to be marked clearly)

2.2.1. Part B1

The applications for patents, trademarks, registered designs, etc. shall be listed according to the template B1 provided hereafter.

The list should, specify at least one unique identifier e.g. European Patent application reference. For patent applications, only if applicable, contributions to standards should be specified. This table is cumulative, which means that it should always show all applications from the beginning until after the end of the project.

The table is not applicable to the TERM project, which did not lead to IP rights.

TEMPLATE B1: LIST OF APPLICATIONS FOR PATENTS, TRADEMARKS, REGISTERED DESIGNS, ETC.					
Type of IP Rights[53]:	Confidential Click on YES/NO	Foreseen embargo date dd/mm/yyyy	Application reference(s) (e.g. EP123456)	Subject or title of application	Applicant (s) (as on the application)

[52] Note to be confused with the "EU CONFIDENTIAL" classification for some security research projects.

[53] A drop down list allows choosing the type of IP rights: Patents, Trademarks, Registered designs, Utility models, Others.

2.2.2. Part B2

The table is not applicable to the TERM project, which did not lead to IP rights.

Please complete the table hereafter:

Type of Exploitable Foreground[54]	Description of exploitable foreground	Confidential Click on YES/NO	Foreseen embargo date dd/mm/yyyy	Exploitable product(s) or measure(s)	Sector(s) of application[55]	Timetable, commercial or any other use	Patents or other IPR exploitation (licences)	Owner & Other Beneficiary(s) involved
	Ex: New supercond uctive Nb-Ti alloy			*MRI equipment*	*1. Medical 2. Industrial inspection*	*2008 2010*	*A materials patent is planned for 2006*	*Beneficiary X (owner) Beneficiary Y, Beneficiary Z, Poss. licensing to equipment manuf. ABC*

In addition to the table, please provide a text to explain the exploitable foreground, in particular:

- Its purpose
- How the foreground might be exploited, when and by whom
- IPR exploitable measures taken or intended
- Further research necessary, if any
- Potential/expected impact (quantify where possible)

[19] A drop down list allows choosing the type of foreground: General advancement of knowledge, Commercial exploitation of R&D results, Exploitation of R&D results via standards, exploitation of results through EU policies, exploitation of results through (social) innovation.

[55] A drop down list allows choosing the type sector (NACE nomenclature) : http://ec.europa.eu/competition/mergers/cases/index/nace_all.html

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