

Case Study report

International Innovation Ecosystem design, implementation and growth

Introduction

An ambitious plan to build a Europe wide Innovation and R&D Ecosystem in Regenerative Medicine was iterated in 2005.

The plan hinged on partnering 4 leading centres: **one on stem cells**, based in Rome, in which 4 global KOLs specialised in stem cell research on **heart, muscle and bone**, had laboratories, another in Cambridge with KOLs specialised in **neurodegenerative disease** research, another was the Centre for Bioengineering at the EPFL in Switzerland, which specialised in **biomaterials and biomimetics**, and the last was a newly launched European Infrastructure for **Clinical Trials** (ECRIN).

In each centre, an Innovation Manager was to be placed, who would perform local expertise and infrastructure Audits, map R&D initiatives and then liaise with the other Managers to create an initial R&D Ecosystem with a series of Portfolio Projects. At the time, the Innovation Managers were Dr. Jonathan Dando (CEO) and Dr. Isabelle Weiss (COO) from the company Dando, Weiss and Colucci Ltd.

The Ecosystem was then to be expanded, leveraging the networks of each of the partners to include further centres of excellence, start up companies, large companies and additional stakeholders.

Simultaneously, **funds were to be hunted**, that could be used to enable the implementation of the Portfolio Projects.

The plan was submitted to the European Commission for financial support, via the Marie Curie Industry-Academia Partnership Programme and received a favourable review, **enabling the plan to be implemented over 2.5 years with €500,000 of support from the EC.**

The project was coordinated by the Rome located centre of excellence in stem cell research.

<http://www.innovations-report.com/html/reports/life-sciences/report-74008.html>

The Project was named TransVac, for Transnational Value Chain

Executive Summary

Transvac, a strategic Private-Public-Partnership project was conceived, designed and implemented that :

- Found an effective way to manage biomedical research alliances across the geographically dispersed multidisciplinary teams in portfolio projects.
- Achieved effective knowledge management within an organisational context to enhance the level of innovation.
- Optimised research and innovation management, and translation of existing and developed new knowledge into future biomedical applications.
- Raised significant funds for all partners
- Resulted in large scale Industry Academic partnerships within an Ecosystem, dispersed throughout Europe, that included industrial stakeholders such as Novartis, Stryker, Baxter, Smith and Nephew and over 80 leading R&D teams.

Portfolio emphasis was placed on clinically translating regenerative therapies or identifying new approaches based on combination therapeutics.

Once the core entities were aligned, the Portfolio Management Office expanded the Ecosystem remit to address all potential funding and partnership opportunities, which resulted in €0.5 euros of initial funding successfully raised for the PMO, which in turn performed the following:

- €8 million raised for the core partners RTD initiatives (representing a 16 fold ROI for the core partners)
- Partnerships with 84 new teams in 11 countries
- €50 million raised for RTD
- €1.6 million raised for preclinical development
- €16 million raised for clinical trials
- €67 million in total raised for International research teams (representing a 134-fold return on the original €0.5 million investment)
- Nearly €6 million in non-dilutable capital for SMEs

The actual case study report in its entirety, originally written by Jonathan Dando and Isabelle Weiss from Dando, Weiss and Colucci Ltd can be found on the following pages.

International Innovation Ecosystems and Portfolio Project Development:

Degenerative Diseases and Regenerative Medicine

The TransVac Case study:



In September 2006, we successfully obtained financial support from the European Commission **FP6 Marie Curie Industry Academia Partnership scheme**, to develop and implement a three-year plan (**abbreviated to TransVac**) to create and optimise the management of portfolio projects between four leading European entities, which were

geographically distinct, but all working in degenerative diseases and regenerative medicine, in a virtual **and** local setting. This case study report details the project from conception to final output, indicating key factors for success in international portfolio management in this sector and indicators to assess progress.

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Regenerative medicine as a therapeutic approach is very fragmented with majority of the work being performed by individual teams specialized in materials, cellular biology, biologics, preclinical and clinical sciences. Despite the fragmentation, as a first line strategy it is starting to move to the forefront and there are increasing reports of success stories. This interdisciplinarity represents a fundamental barrier and therefore an international approach is absolutely necessary to achieve any development aims, including its potential in the long term to be translated into market impact, but this in itself creates more barriers to success.

In the context of an ageing population in which degenerative diseases are representing an increasing burden on society and the economy there is a desperate need to surpass the barriers and accelerate the clinical translation process.

Unfortunately the complexity of the field and its various avenues mean that once clinical translation is performed there is limited collective insight from one approach to another, which could be beneficial if corrected. Only a few examples exist of ideas progressed from new purposely, designed therapeutics through in vitro and in vivo evaluation to clinical trials. We therefore assembled four of Europe's leading centres with experience of performing extensive fundamental research, which has been translated to the clinic, something that is now considered a gold standard approach for effective development.

The field has been significantly changed by the simultaneous development of biopharmaceuticals, biomaterials and the more profound knowledge of developmental processes and mechanisms in biological systems. The previous paradigm of developing therapeutics for tissues with easy access or with very similar composite structures to the tissue being repaired has been increasingly replaced by advanced strategies that are bioactive alone, or are functionalized through the addition of factors,

materials or peptides which can be applied by injection. This has defined and refined regenerative medicine concepts which now encourage tissue repair using innovations that serve a temporary purpose, similar to a development process or target a critical component of the repairing tissue itself. We therefore designed an approach that represented the convergence of three strategies: reverse engineering, knowledge integration and forward development, all of which are needed for impacting the rational design of advanced therapeutics. Reverse engineering represents a key starting point for rational design: experience with application to patients provides an enormous knowledge advantage based on known patient compliance, responsiveness and applicability matched with hands on experience in addressing regulatory affairs that are the constant dynamic of any clinical usage which significantly impact costs of therapy production and patient monitoring. The Transvac teams have been involved in the prior steps of large animal modeling; therefore the precise insight and previous hands on experience in translational medicine would provide the first guidelines for further design. This was then to be complemented by a knowledge integration based the strength and breadth in all aspects of degenerative disease and regenerative medicine and development or a profound knowledge of the cell and developmental biology of the target tissues. This knowledge included information in either the normal, diseased or regenerating state which are the pivotal factors that will drive the design and forward development of new therapeutics due to a sound insight of what is precisely needed to return tissue integrity and functionality.

Working on a market dynamic we wanted to integrate, as far as possible an industrial level approach to management of academic partnerships and build a flexible innovation infrastructure which would function similar to industry and generate high performing and high impact innovations through optimising management of the collaborations.



Conceptual design

A virtual management office:

From concept to reality, we wanted to:

-Find an effective way to manage biomedical research alliances across the geographically dispersed multidisciplinary teams in portfolio projects.

-Achieve effective knowledge management within an organisational context to enhance the level of creativity occurring within academic organisations.

-Optimise research and innovation management, and translation of existing and developed new knowledge into future biomedical applications and regenerative medical products.

-Correctly develop, manage and exploit the knowledge generated by and through the work and expertise of the different entities

-Partner correctly along the value chain to initiate sustainable high level innovation

Four Research and Development partners: 1 Management team

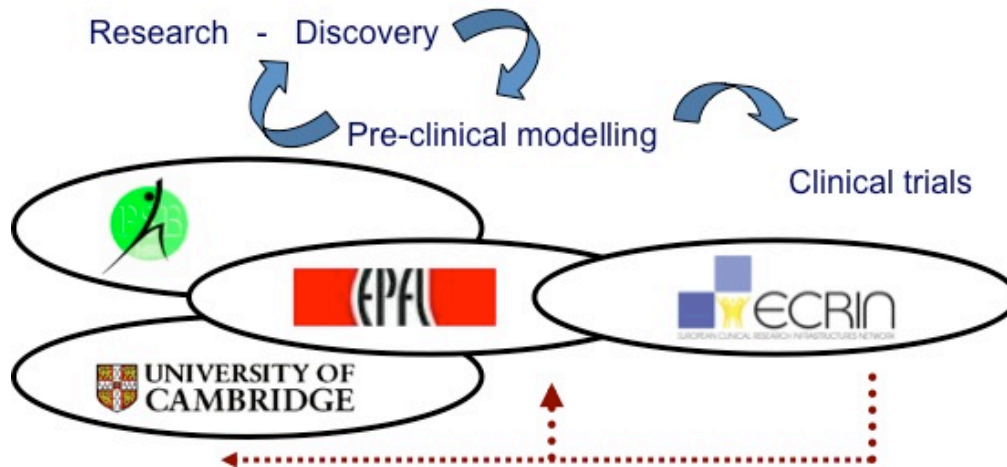
Fondazione Parco Biomedico San Raffaele in Rome (PSB): A stem cell research centre focusing on muscle, bone, cardiac and hematological tissues, directed by **Professor Giulio Cossu**.

The Brain Repair Centre at the University of Cambridge (UNI CAM): A centre which aims to understand, and eventually to alleviate and repair damage to the brain and spinal cord which results from injury or neurodegenerative disease, chaired by **Professor James Fawcett**.

EPFL Institute for Bioengineering Lausanne (EPFL): An institute focusing on regenerative medicine and pharmacobiology, specialises in chemical engineering polymeric biomaterials, in tissue engineering using stem cells as building blocks. DNA oligos, recombinant proteins and synthetic peptides are designed and expressed to encompass many functions that stimulate tissue repair directed by **Professor Jeffrey Hubbell**.

European Clinical Research Infrastructure Network (ECRIN): An infrastructure supporting multinational clinical trials in Europe coordinated by **Professor Jacques Demotes- Mainard**

Partners on the value chain



- Strategic leveraging of expertise and resources
- Quality management
- Clinical reverse engineering and project monitoring

Optimised innovation by aligning initiatives, expertise resources and insight correlated to end point application

Implementation strategy:

Hands on Management: Managers were located on site, full time in the different centres or seconded to our own offices to develop a portfolio of high impact projects, while also routinely monitoring the research, therapeutic development and funding markets (public and private)

Aligning ongoing research projects: Available physical resources and personnel expertise were assessed and then aligned into a series of portfolio projects which were then managed and implemented

- virtually using existing informatic tools
- locally through the presence of the on-site managers.

Obtaining funding to facilitate the collaborations: In the context of international collaborations this meant engaging significant effort on fund raising, and by necessity extending the different centres involved in the partnership to external entities, to fill gaps in the expertise identified to ensure the portfolio projects achieved their goals and could be funded.

Focusing portfolio projects in 2 major areas: Analysis of ongoing initiatives it was necessary to simultaneously attempt to validate existing regenerative medicine approaches, while developing the next generation of regenerative medicine tools and therapeutics. This led us to focus the portfolio projects into two cutting edge sectors.

Portfolio project sectors

Sector 1: Clinically translating stem cell therapies

Stem Cell therapies:

Clinical trials for Duchenne Muscular Dystrophy using Mesoangioblasts:

Lead by Professor Giulio Cossu, this project aims to cure DMD using muscle stem cells. To obtain funding the partnership was expanded to include clinical trials using epithelial stem cells while simultaneously performing supporting research on blood vessel generation and fundamental research on the behaviour of stem cells, including immune control and scar tissue formation. (for further information visit www.optistem.org)

Clinical trials for Parkinsons Disease using novel stem cells:

Lead by Professor Roger Barker at the University of Cambridge, this project aims to cure Parkinsons Disease using novel stem cell approaches. This is an intercontinental collaboration that not only aims to provide a cure for Parkinsons Disease but also pioneer new approaches for treating neurological diseases with stem cells. (for further information visit www.transeuro.org.uk)

Sector 2: Tissue repair based on fundamental research and combination therapeutics

Optimisation of regenerative approaches:

Identifying promoters of neuroplasticity which permit the formation of new neural connections:

Lead by Professor James Fawcett, using the CNS as a model system, the project aims to identify molecular promoters which in addition to forming new neural connections, remove inappropriate connections and stimulate strong tissue repair. While focusing on the neural system, insights obtained will also lay a foundation of knowledge which can be leveraged onto other tissues. (for further information please visit www.plasticise.eu)

Tailoring combinations of biomaterials and morphogens for tissue and disease specific regeneration:

Lead by Professor Jeffrey Hubbell, this project represents a catalogue of over 60 different portfolio sub-projects. Targeting the restoration of blood supply, biomaterials with highly tissue specific applicability are being combined with selected tissue growth stimulators to regenerate damaged and diseased tissues of the blood vessels, the skin, bone, cardiac muscle, skeletal muscle, the peripheral and central nervous system. (for further information visit www.angioscaff.eu)

Metrics of success



Financial summary

Half a million Euros of EC financial support for 11 Transvac teams leveraged to generate:

- 8 million€ for the core partners RTD initiatives
- Partnerships with 84 new teams in 11 countries
- 50 million€ raised for RTD
- 1.6 million€ raised for preclinical translation
- 16 million€ raised for clinical trials
- 67 million€ in total raised for European research teams
- Nearly 6 million € for SMEs

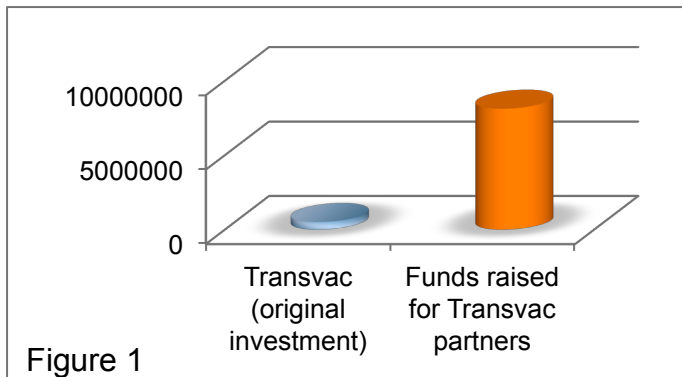


Figure 1

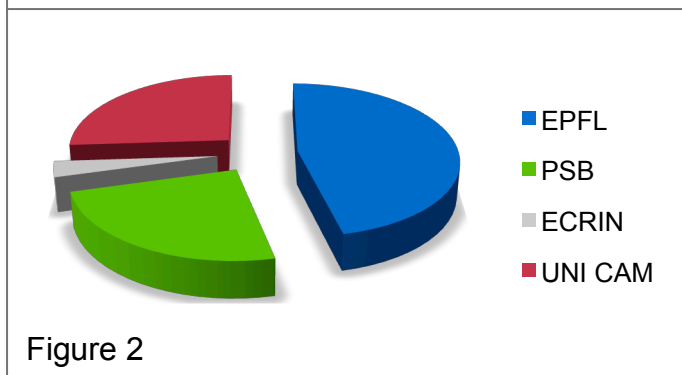


Figure 2

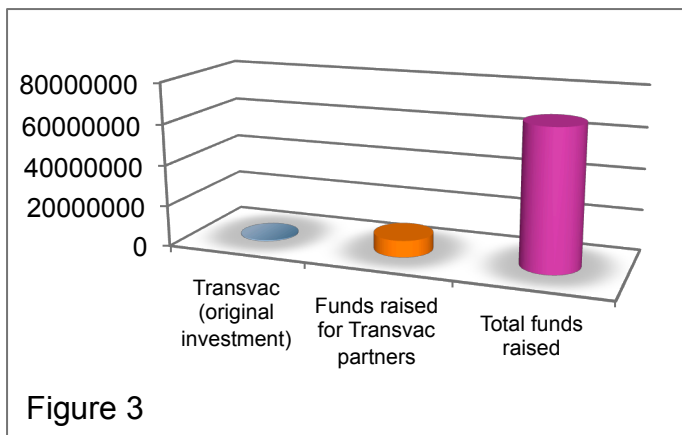


Figure 3

Financial details

The Transvac project and its partners were funded at a level of 0.5 million€ by the European Commission almost exclusively for the recruitment and payment of innovation managers. Developing the portfolio project plans was matched with extensive fundraising to finance the different projects. By the termination date of the project, just over 8 million€ had been raised for the specific portfolio projects (Figure 1) representing a 16-fold return on the initial investment.

Allocation amongst the four RTD partners correlated with their position on the value chain and roles, as defined by ongoing projects (Figure 2). The fundamental and early stage therapy validation entities (the PSB and the University of Cambridge) each received roughly equivalent amounts corresponding to around 25% of the funds raised for each partner. The EPFL, sitting more in the central component of the value chain received just over 46% of the funds, with the remaining 4% being allocated to ECRIN, whose role in reverse engineering and providing regulatory insight implied a more consultative role.

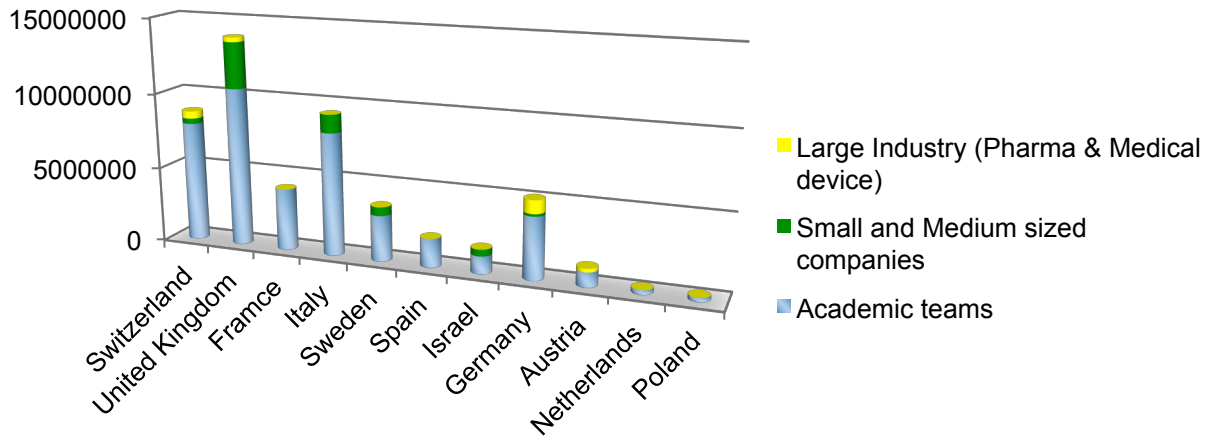


Figure 4

Additionally on a broader scale, in the scope of the strategy for developing extensive and sustainable portfolio project plans, and ensuring clinical and product focus, partnering was extended beyond the core four partners. The funding market in which sources of funds for international collaborations are limited, and funding agencies require a 'critical mass' of all the skills and resources necessary for implementation also drove this strategy. As such by the end of the TransVac project, the partnership had been expanded to 84 expert teams in degenerative disease and regenerative medicine, and collectively we raised nearly 67 million€ for the whole initiative (Figure 3), representing a staggering 134-fold return on the initial half a million euros provided by the EC.

Analysis of this total amount, indicated that the core TransVac countries received the majority of this funding (Figure 4), as we primarily focused on developing new partnerships with other entities local to these core partners, but there was

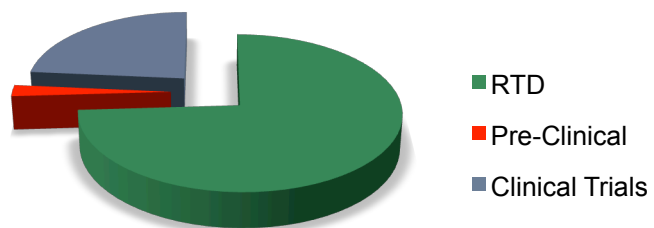
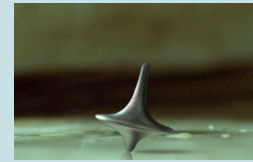


Figure 5

also a good financing for the teams that were not located close to these core teams. At the industrial focus, Small/Medium (SME) and large European Pharmaceutical and Medical Device companies respectively received 8.5% and 2.8% of the funds raised (Figure 4).

Just over 50 million€ was raised for the RTD based fundamental and conceptual design of new therapeutic approaches, equal to 74% of the total funds raised, with pre-clinical translation (relevant and controlled animal modeling) receiving just over 2%; The remaining 24% was applied to clinical trials (Figure 5). Within the clinical trial allocation, unsurprisingly the greatest expenditure correlated to the cGMP (current good manufacturing practise) costs of producing the therapeutics prior to application to humans.

Spin-off companies and projects



Spin off Companies

Having routine and immediate access to cutting edge and unpublished data, while understanding market need permitted us to address business based innovation and identifying new products that could be generated from the data and inventions generated from the portfolio projects.

Adstem SA – based on the research of Doctor David Sassoon and Doctor Giovanna Marazzi, a novel stem cell has been identified which is activated in response to tissue damage and can regenerate the damaged tissue. This stem cell is being leveraged to generate screening tools which will permit the rapid validation of novel therapeutic strategies with a clearly defined target.

Promimetic Ltd – based on the research of Professors Giulio Cossu and Dror Seliktar (Technion Institute), stem cells and biomaterials are being combined to generate state of the art tissue engineered muscle which could be used as both a direct therapeutic and also as a therapy delivery vehicle.

Spin off Projects

As each portfolio project and the sub-portfolio projects advanced, we expanded our approach of portfolio management to include all the new partners. Evaluating resources, expertise and ongoing initiatives, further alignment and project development was initiated. This led to spin off portfolio projects in which knowledge gaps and barriers identified as critical for the success of regenerative medicine were targeted.

Modular design of regenerative therapeutics that target the immune and scar tissue processes: Lead by Professor Jons Hilborn from the University of Uppsala (a

partner in the biomaterials project indicated above), teams were integrated from the EPFL, the PSB and from the project performing clinical trials for muscular dystrophy and 8 other leading specialists in regenerative medicine. More ambitiously the project has been expanded to the global sector of regenerative medicine, integrating nearly 20 teams from around Australasia (Singapore, Malaysia, Australia, Japan, China) to generate a world-class network that is tailoring materials that modulate the immune response following tissue damage and decrease scar tissue formation. In both cases these are critical aspects to control for effective tissue repair.

Development of biopharmaceutical strategies that stimulate endogenous stem cells to repair damaged tissue:

Lead by Doctor David Sassoon of the UPMC in Paris (a partner in the project addressing clinical trials for muscle disease), teams were integrated from the tailored biomaterials and the clinical trials for muscular dystrophy projects (EPFL, University of Frankfurt, IFOM Milan, E Medea Lecco, and the Universitat Pompeu Fabru) to address the development & delivery of novel biopharmaceuticals that stimulate endogenous stem cells, decrease scar tissue formation, modulate the immune response and promote blood vessel growth. In this project, partners have been mapped by expertise and resources along the drug development pathway to generate the necessary critical mass for success, which also includes the implementation of 3 new clinical trials using biopharmaceuticals.

Lessons Learnt

Over the previous 3 years we have managed to reach major milestones in the development of portfolio projects across large geographic dispersion and make it sustainable. Mainly based in Europe, a melting pot of different cultures which is known to affect effective collaboration, several insights were revealed which permitted success across all cultural barriers and environments: different nationalities, academic and industry, fundamental and clinical, chemistry, biology, engineering and physics.

Invest in skilled management personnel:

Hiring experienced and qualified management personnel were critical. Ideal managerial candidates should have a PhD in a related field, international experience (preferably on another continent), have been exposed to the business environment, be entrepreneurial and very happy functioning outside of their comfort zone. Their motivation should be success, and once settled should be allowed to take initiatives. They should also be well paid and rewarded, including integrating their personal commitments into their professional ones; the returns made in salary investment, while permitting them to maintain professional focus and personal balance are returned at multiples that even we found surprising. This is one skill-set that only receives extensive investment in the top centres, but to ensure success, all European centres to some extent should mimick other continents and invest correctly in a dedicated, experienced and skilled innovation management office.

Empower and pro-actively develop the young scientists: The young scientists, from both the academic and industrial sectors are the motors for success.

The worse possible structure for international portfolio management is the T shaped management approach. If the partners have agreed to collaborate, the contractual constraints have been agreed upon, and the project plan defined let the young scientists get on with it. They know what works and what does not and once trust is established they will move the projects forward, while simultaneously developing new ideas. A 'can-do' culture matched with advanced training so that all project members understand all the components of the project generates advances that are both fascinating and bewildering when matched with correct resource management.

Embrace and champion the portfolio approach:

Portfolio management is typically considered an 'industrial or applied research model' however fundamental research can also be managed with a similar approach and scientific sparks fly when the two sectors are combined under the same management scheme integrating diverse disciplines. On at least 10 different occasions having access to brand new data, while understanding what is happening in all other portfolio projects permitted us to network teams, and solve problems; applied approaches could be used to solve fundamental issues and vice versa.

Generate an innovation culture: Establish a culture, which leverages the virtual, and the physical environment. Physical meetings of the portfolio team members every 6 months, matched with formal web conferencing for portfolio project monitoring and ad hoc web conferencing for brainstorming resulted in teams that want to work and want to innovate. Projects advanced faster than anticipated, and decisions to close projects because they were not advancing were made sooner in such an environment. It became easier to identify what

could be protected for later commercialisation and what data was missing for potentially high impact publications; which by avoiding T shaped management actually makes the Group or Department head's job fun again. They became essentially the purveyors of quality control of the new data and the strategic drivers for new projects.

Focus on value: Value perceptions for the different actors of a portfolio project are very different. Publications, innovations and inventions have different priorities amongst the sectors and levels, however it is essential to proactively manage the portfolio in such a way that all value generators are considered equal. Most importantly, for the portfolio manager they should be actively monitored, coordinated and communicated; by focusing on all three simultaneously while understanding how each value generator is developed and exploited for monetary return permits a higher level strategic management.

A high impact publication is more easily leveraged into monetary return for sustainable development than an invention, and about 90% of the projects we have monitored we consider publication the greater short to medium term liquidity generator. This by no means suggests that we shy away from invention protection, but considering the costs of legal protection, we only consider this approach a feasible value generator if all the resources necessary to generate the value are to hand: expertise, physical infrastructure, entrepreneurial drive, experienced CEO, defined and known customers and some idea of where the investment is coming from to kick start the commercialisation process. In best case

scenario's only after we have identified and collated these factors do we consider restructuring the portfolio project plan to fast track development so that high value and quality intellectual property is generated as the seed for commercialisation

Keep it simple: Complicated plans with large portfolio project teams spread across a continent simply do not work. By recognising that any given portfolio project, if correctly executed, occupies around 10-15% of a skilled scientist's working time by keeping the project plan simple, milestones correctly defined, the project team small and communication channels open advances are almost guaranteed. Ignoring any one of these factors creates confusion, which if left uncorrected can spiral the project downwards and spoil any future potential collaborations.

Monitor the knowledge silo's: Each research team has immediate access to enormous amounts of information, which is traditionally untapped. Upto 90% of what sits inside a group's refrigerator and therefore their collective brain remains unexplored and uncommunicated. In a virtual environment by complementing the portfolio project meeting with virtual 'total science' presentations, the team members are encouraged to present in a department like meeting all their ongoing research initiatives which typically integrates in research from their local team members who may not be members of the portfolio team. If matched with virtual training courses, in which the same scientists have to structure the information being presented in a didactic way, a collective knowledge base is generated which serves as the foundation for identifying non developed ideas which with incremental investments can generate significant returns.

Total and routine market analysis: Market analysis typically centres itself in one sector at a time, generating reports and insights, which while useful can be one-dimensional. The major benefit of hiring PhD level managers, is that by default of their training they are highly skilled in screening enormous amounts of information and extracting the pertinent facts, which are mentally recorded and then linked with new facts from other sources (future and historical), which catalyses strategic development. Portfolio managers, ideally should screen on a monthly basis: all potential funding opportunities (public, private, foundations, charities) that are related to their projects; the activities of patient associations and the initiatives they are implementing in supporting carers, monitoring promising advances and communicating research (better still, establish a relationship with the associations for the development of mutual trust); scientific publications based on defined key words, which by default informs the

managers not only of the competition but also novel targets for the outcomes of the portfolio projects; the industry as a whole from the pipelines of large pharma or the managers not only of the competition but also novel targets for the outcomes of the portfolio projects; the industry as a medical device companies to emerging small companies with limited resources, but unlimited innovation. Finally the economy and political scene as a whole should be monitored, through which the socio economic impact of the portfolio projects can be measured integrating social drivers and regulatory barriers.

Establishing such analyses needs time, in our experience between 3 and 6 months for a newly hired manager to become completely familiar with all the issues, but once in place, the routine monitoring becomes easier and information can be integrated into the overall strategy of the portfolio project catalogue.

Key take away on the design and implementation of an Ecosystem

- Start with a select group of partners that form the core critical mass
- Make sure they are aligned and organized around mutual strategic goals
- Expand the Ecosystem as a function of asset/know how/knowledge gaps
- Non dilutable low risk funding is critical for project success
- Make sure all Ecosystem team members receive an equivalent training in the key core areas of the ecosystem (in this case biomaterials, stem cells, clinical translation)
- Keep all decision makers in your key partners and external stakeholders informed of all decisions, actions and results

We will be leveraging our portfolio management insights into a more global partnering environment and continue to facilitate advances that can address degenerative diseases with regenerative medicines; in light of their impact based on the increase in the ageing population and the costs of medical treatment.

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**Summary of some of key Ecosystems built
(neurological focused Ecosystems were built and run by Dr. Isabelle Weiss)**

Coordinated by Prof. J Hubbell, performed contractual and fiscal design, operational design, milestone and project management for a 33 partner, 8 diverse jurisdiction (University, Institute, Hospital, small and large Companies) 4 year convergent technology project, with 110 simultaneous portfolio projects, aimed to conceptually and preclinically validate novel regenerative therapeutics for bone, skin, heart, vasculature, neural, and muscle tissue. Project budget of £10 million, headcount of 180 scientists, administrators, managers, solicitors and accountants (Angioscaff project)

Coordinated by Prof. G. Cossu, performed contractual and fiscal design, operational design, milestone and project management for a 18 partner, 6 diverse jurisdiction (University, Institute, Hospital, small and mid-sized Companies) 5 year collaboration which clinically assessed cell therapeutics for muscular and epithelial disorders. Project budget of £9.5 million, headcount of 65 scientists, administrators, managers, solicitors and accountants (Optistem project).

Coordinated by Prof. J. Hilborn, performed contractual and fiscal design, operational design, milestone and project management for a 20 partner, 8 diverse jurisdiction (University, Institute, Hospital, small and large Companies) 4 year convergent technology project aimed to generate state of the art bioengineering for bone, heart and muscle repair. (Biodesign project).

Coordinated by Dr. D. Sassoon, performed contractual and fiscal design, operational design, regulatory compliance, milestone and project management for a 16 partner, 6 diverse jurisdiction (University, Institute, Hospital, small and large Companies) 5 year collaboration which clinically assessed (phase I and IIa) NCE therapeutics and developed biological therapies aimed to stimulate endogenous stem and accessory cells to repair the damaged tissue in situ. Extensive interaction with key stakeholders in the form of charities and patient associations a core part of the project activities (Endostem project).

Coordinated by Prof. C. Ffrench-Constant, performed contract and fiscal management for a 3 year European-U.S.A.-Canadian partnership of 6 research teams performing early stage research on disease mechanism and target development for treating Multiple Sclerosis. Funded by the National Multiple Sclerosis Society.

Coordinated and funded by the National Multiple Sclerosis Society, a partnership of 38 global teams (U.S.A, Europe, Canada, Australia) was planning and designing the optimal approach for clinically assessing a novel therapeutic for treating Multiple Sclerosis. I was tasked with the design and roll-out of virtual information management structure to permit global coordination.