



Management of Innovation in Academia: A Case Study in Tampere

Tuomo Heinonen

Abstract

Universities have an active role in research commercialisation and hence, many universities have established a technology transfer office. However, technology transfer happens too early in most of the cases and commercial potential of innovation is not clear yet. Proof of Concept, which is developed in the university, is suggested to be a solution for this. In this single case study, Proof of Concept development and technology transfer in the regenerative medicine sector are studied in Tampere, Finland. It was shown how Proof of Concepts are nurtured alongside the research in the faculty. However, sufficient funding and market understanding is needed in order to develop a Proof of Concept that is possible to transfer to industry.

Keywords: technology transfer office; tto; technology transfer; proof of concept; proof of concept centre; poc; pocc; innovation; regenerative medicine; commercialisation;

I Introduction

Commercialisation of scientific breakthrough innovations in biotechnology depends on active involvement of scientists (Zucker and Darby, 1996). Hence, close and regular collaboration is needed between industry, hospitals and academics to make sure the commercial success of biomedical research (Juanola-Feliu et al., 2012). However, most university-based inventions are licensed at a somewhat embryonic stage and because of that, further development in cooperation with the inventor is needed for commercial success (Jensen and Thursby, 2001). The other issue with early stage disclosure and technology transfer is uncertain market potential for most of these inventions (Thursby et al., 2001).

As the role of the university has expanded from traditional research and education to actively seeking opportunities to develop applications and commercialise research (Juanola-Feliu et al., 2012), spin-offs and licensing are important ways to actualise this commercial role (Hoye and Pries, 2009; Juanola-Feliu et al., 2012). For the purpose of technology transfer, many universities have established technology transfer offices (TTO) to manage and protect intellectual property of universities and to facilitate commercialisation of university inventions through licensing (Siegel et al., 2004). Establishment of start-ups (SU) is another way to transfer university research into industry and TTOs have an important role in the SU formation process (Lerner, 2005). However, it is difficult to start a new venture based on university technology and most of those ventures do not generate wealth to universities (Lerner, 2005). Hence, according to Auerswald and Branscomb (2003), the most important and critical phase in the process of innovation is between invention and product development, which is defined here as the Proof of Concept (PoC) phase and which is the main concern of successful technology transfer. When entering the PoC phase, there should exist a technical concept, which is created, protected and has commercial value. In the PoC phase according to Auerswald and Branscomb (2003) and Maia and Claro (2013):

- technology is simplified to industrial form
- production process is defined enabling cost calculation
- intellectual property is developed
- commercial concept is created and verified
- appropriate market is identified and quantified

Challenge in technology commercialisation concerns the PoC phase and especially its lack of funding (Auerswald and Branscomb, 2003; Maia and Claro, 2013). Proof of Concept Centres (PoCC) are suggested to be answers to both lack of funding in early phases of new venture and problems

associated with technology transfer. PoCC is complementary to TTO by speeding up disclosed technologies into the market (Maia and Claro, 2013) and in which funded researchers continue their research in their own laboratories (Gulbranson and Audretsch, 2008). According to Gulbranson and Audretsch (2008), PoCC needs a management team that is connected to local venture capital, technology and the industry network. A strong local business network is also needed for the reason that PoCC has to have courage to invest in unproven technologies (Gulbranson and Audretsch, 2008). Lately, Maia and Claro (2013) studied the impact of PoCC to technology commercialisation showing promising results, but in general, there is not long-term evidence about the role of PoCC in technology transfer.

2 Research questions

The aim of this study is to scrutinise the PoC approach to technology transfer and commercialisation in BioMediTech, which is a joint institute of two universities in Tampere, Finland; i.e., University of Tampere and Tampere University of Technology. One of the promising research fields in BioMediTech is regenerative medicine (RM), which is also referred to as the third discipline in healthcare beside medicine and surgery (Polak et al., 2010). In this field in BioMediTech, researchers develop both stem cell research supporting technological solutions and new stem cell therapies. However, the RM sector is emerging globally, and hence, development of PoC is especially important as there are not many companies that have enough resources to develop inventions forward. As innovation and commercialisation are central aims of BioMediTech, the following research questions for this study are relevant:

What are the specific concerns in technology transfer in the RM sector, especially in case of stem cell therapies?

How does BioMediTech overcome the challenges related to the PoC phase?

These are especially interesting questions, as in their study, Jensen and Thursby (2001) showed that a minority of licensed inventions involved some animal data and an even smaller proportion involved some clinical data, even though half of the inventions they studied were in medicine and nursing. Only 12 percent from the dataset they studied were commercially ready and for 8 percent manufacturing feasibility was clear. Therapies developed in the RM sector follow a commercialisation process similar to pharmaceuticals or biopharmaceuticals that is from animal studies to clinical trials and after three phases of clinical trials to product approval. The process is long, costs money and for university spin-offs, it is a difficult path on which to go. On the other hand, technologies and tools that support

therapies and research are much easier from a commercial point of view. In general, however, uncertainty and cost of development are just too high for these biomedical inventions, and it is for one of those reasons that TTOs are not making much money for universities.

3 Theoretical background

Innovation in health has a broad range from science-based innovations (e.g. biotechnology and pharmaceuticals) to engineering based innovations (e.g. medical technology) (Meyer-Krahmer and Schmoch, 1998). From an innovation and commercialisation viewpoint, these two categories have different requirements and processes (Blume, 1992; Gelijns and Rosenberg, 1995). Many medical technologies have emerged in collaboration between academics and manufacturing companies (Blume, 1992), and in the current era of TTOs, engineering based innovations might be more easily spun-off to start-ups or licensed to established firms. On the contrary, science based innovations are often highly regulated when concerning human health in terms of human cells or molecules, and thus the process is longer to final product and also costs more. The two critical characteristics of innovation in medicine are that new technologies have a high degree of uncertainty, and close interaction between developers and users is crucial to the development of medical technologies (Gelijns and Rosenberg, 1994; Gelijns et al., 2001). In all the cases, firms are still important, because even though merits of new product discovery are shared between firms and academic research, firms have distinctive and global capabilities in product development, management of the regulatory process for the approval of new drugs and devices, and the marketing and distribution of innovations (Consoli and Mina, 2009).

Thus, there are two major actors in the medical technology area: academic medical centres and industry, namely pharmaceutical, medical devices and biotechnology industries (Gelijns et al., 2001). The potential new industry is cell therapy, which includes the most fascinating opportunities in the RM sector and which is the focus in this study. Academic health centres are important, as they are places where medical research, clinical practice and teaching come together. Hospitals in general are the places of clinical practice and major channels through which new treatments are introduced revealing the potential or drawbacks (Metcalf et al., 2005; Consoli and Mina, 2009). The role of hospitals should be understood more carefully also in the technology transfer activities, as hospitals and medical schools are important sources of new product ideas and advanced product-embodied technologies (Roberts and Hauptman, 1986). Similarly, Consoli and Mina (2009) claimed that research hospitals have a central role in the diffusion of knowledge, intermediating between basic science and clinical

trials and giving important practical feedback for medical device manufacturers. Also in the RM sector hospitals play an important part in innovation, and the development of products requires a tight linkage between researchers and hospitals (McMahon and Thorsteinsdottir, 2013).

Medical innovation emerges from a complex and interactive process that is distributed over academics, firms and clinicians (Gelijns and Rosenberg, 1995; Metcalfe et al., 2005; Consoli and Mina, 2009). Hence, it is important from a technology transfer point of view to understand the innovation system and its elements in healthcare. Consoli and Mina (2009) conceptualised features of medical innovation in the health innovation system (HIS) that consists of three interconnected layers, i.e. the science and technology system, service provision in hospitals and the individual sphere (Figure 1). HIS builds on the earlier literature of medical innovation and work of Metcalfe et al. (2005), who focussed on the firm centred innovation system and on the linkage between the national healthcare sector and the international medical sector.

HIS is based on gateways and pathways of change, i.e. components of the system and interactions between components over time. Nelson et al. (2011) argued that there are three different pathways for medical progress: advances in scientific understanding of a disease; advances in technological capabilities making possible the development of new methods of diagnosis, therapies and treatments; and learning in clinical practice that is important for the advance of medical diagnosis and treatment. In general, the scientific community has a growing role in innovation and in the development of new devices, drugs and applications (Toner and Tompkins, 2008), and the connection between doctors and the scientific community is important (Consoli and Ramlogan, 2008). In HIS, the scientific community includes clinical and medical staff, and different university departments, e.g. pharmacology, biology, genetics, informatics and engineering (Consoli and Mina, 2009). It is possible for the scientific community to reduce the risk of inventions to fail caused by too early technology transfers if initial validation and an application for intellectual property protection follow invention (Toner and Tompkins, 2008) as well as other important tasks in the PoC phase (Auerswald and Branscomb, 2003). Hence, the main interest in this paper locates on the relationship between scientific and technology subsystems in the HIS and how medical technology innovations in the RM sector are transferred from academia to industry and in the end to hospitals.

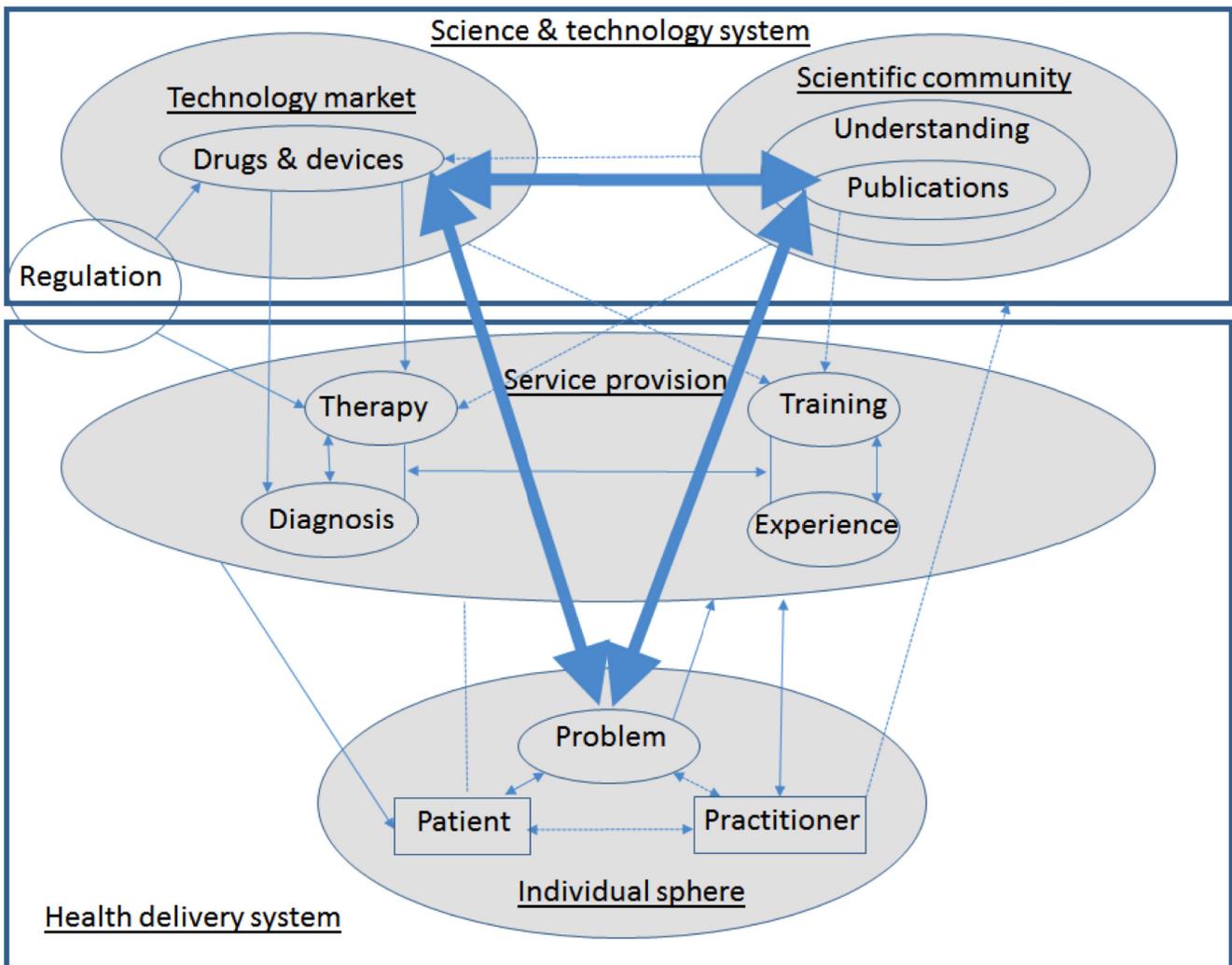


Figure 1: Health innovation system (Consoli and Mina, 2009).

4 Methodology

4.1 Background and context

Today in the regional level, BioMediTech is highly valued, e.g. the Council of Tampere Region has BioMediTech as one of their core promotions. Based on high-level scientific research, the formation of BioMediTech and especially the Human Spare Parts research programme in Tampere was an evolutionary process of several active and co-operating actors. From very early on, tissue engineering was seen to be a significant application area in the biotechnology sector of Tampere. Research groups in BioMediTech have a track record in creating patents (over 100) and spin-offs (over 10), and thus, it was natural that commercialisation was the focal point of the activities, and the aim was to get new firms in the attractive RM field.

An earlier history of BioMediTech is well documented in Sotarauta and Mustikkamäki (2014). University of Tampere, Tampere University of Technology, Pirkanmaa Hospital District, Pirkanmaa University of Applied Sciences and Coxa, the Hospital for Joint Replacement, established Regea, which is a predecessor of BioMediTech, in 2005. In 2011, BioMediTech started its operation and was granted a strategic governmental funding from the Finnish Funding Agency for Technology and Innovation (TEKES) for a strategic research programme called Human Spare Parts, with a focus to develop novel solutions in the RM sphere. At the regional level, BioneXt and Biosensing Competence Centre (BCC) shaped the way for BioMediTech earlier and in the national level the HealthBIO programme was important in other ways.

BioneXt Tampere (2003-2010) was an organisation with a mission to acquire resources, expertise and investments to Tampere. There was a focus on leading-edge research, product development, clinical application and commercialisation of biotechnology. Supported fields were tissue engineering, biomaterials, bio-ICT and immunology. Combination of tissue engineering, biomaterials and funding to professorship in stem cell research was an important basis for development of the RM field in Tampere. In 2007, two important initiatives started. HealthBIO (2007-2013) was a national programme that focused on nationally important areas of biotechnology, which was in Tampere human spare parts. In this programme, in Tampere was piloted also a new PoC financial instrument from TEKES that was aimed to help translation from research to products. The other initiative was Biosensing Competence Centre (2007-2010), which was established for the need of bridging the gap between basic research and product with a PoC in the biosensing field. BCC raised funding altogether 1.2MEUR for its operation, from which 0.12MEUR was used for commercialisation projects. BCC also invested in core infrastructure and IPR protection services. Instead of

wide application fields of BCC, focus was given to regional strength areas of tissue engineering and clinical diagnostics. BCC had a major role in establishing the regional network for BioMediTech.

One of the advantages for BioMediTech is that it locates next to the University Hospital of Tampere. In 2012, a combined research strategy of BioMediTech, University Hospital of Tampere, Institute of Medicine and Institute of Health Science, stated that 'Tampere Health Research Centre Kauppi' should be established to bring scientific breakthroughs, innovations and new businesses. In the research strategy of the university hospital of Tampere for 2014-2016, one of the three goals was presented to be to improve and combine resources for 'Tampere Health Research Centre Kauppi'. Hence, a close relationship to hospitals enables BioMediTech to utilise its innovations but also to get awareness of needs, support and feedback.

4.2 Method

Findings of this study are based on a single case study conducted in Tampere, Finland. Focus in this study was in BioMediTech and its Human Spare Parts research programme. Combined research groups and expertise from these universities allow BioMediTech to conduct interdisciplinary research and develop innovations based on different technologies and disciplines. In this study, altogether 24 interviews were conducted: 15 of interviewees were from BioMediTech, 3 of interviewees were from University Hospital of Tampere and the rest were from local and regional development agencies, Ministry of Employment and the Economy, the Finnish Funding Agency for Technology and Innovation (TEKES) and a local firm with an RM focus. Commercial aspects of the Human Spare Parts research programme and the RM sector were central in interviews that included the following themes: Research environment, finance, entrepreneurship, market, legislation, hospital environment and end-value.

5 Findings

5.1 Innovation supporting environment

The aim of the Human Spare Parts research programme is to create applications and business from advanced research in stem cell and related technologies. Due to longer term funding, this research programme has had a significant impact on collaboration between different research groups allowing them to plan activities in a longer perspective and having professionals for several important aspects of innovation. The other advantage is the organisational structure of BioMediTech that supports management of innovation that emerges from their research:

1. Research programme Human Spare Parts research programme was established instead of several small and independent projects
2. Important elements of innovation were combined into this programme, i.e. strong interconnection between technology, clinical and science expertise
3. Facilities to support innovation, e.g. employed IPR experts
4. Appropriate research equipment infrastructure

Advantage of the Human Spare Parts research programme in BioMediTech is that it is able to combine technology and stem cell expertise together. Combination of biomaterials, stem cell research and supporting technology expertise is especially important and provides a competitive advantage for BioMediTech. As a result, they are able to develop new therapies, but also they are able to develop new technologies for stem cell groups for their needs. In the programme, four groups focus on stem cells and four groups focus on technology. In detail, stem cell groups focus on bones and tissues, neurology, ophthalmology and cardiology, while technology groups focus on imaging and signals, biomaterials, biomimetic environments and biosensors.

Organisation in BioMediTech supports and fosters innovation. There are personnel in core facilities and research services, which makes it possible to have help when needed. In addition, research facilities are shared between the research groups, which causes interaction between groups of different disciplines and produces new ideas. Generally, there is a lot of collaboration between the technology groups and the stem cell groups and it allows development of applications where technology is used for the advantage of stem cell research. Also clinical experience is present in the stem cell research groups and it makes the communication with hospitals easier. In those projects where real patients are involved, surgeries or other clinical operations are conducted in a hospital environment. For example, a therapy that is developed in BioMediTech is used in many clinical operations in several university hospitals in Finland, lately in Tampere.

IPR and regulations are in focal point of daily operations and for example, all publications are first checked from IPR's viewpoint if there is something that has to be protected. IPR personnel attend research meetings that allow them to follow projects and to address open questions without a need to explain background situations always. In addition, sometimes due to patent research, some ideas that were thought to be new were revealed to be already patented. In general, IPR and legal issue experts take care that patents

cover important aspects of innovation and that contracts are suitable for technology transfer purposes.

Quality and regulatory affair professionals take care that everything is in order regarding regulation issues. BioMediTech and its predecessor organisations, especially Regea, have invested a lot to research equipment infrastructure, which is essential for research groups. Investments are funded by both internal and external sources. An important part of research equipment infrastructure in BioMediTech is a GMP laboratory that enables BioMediTech to provide cells to clinical use too. Actually, this GMP level laboratory is essential for these clinical procedures where cells are used.

5.2 The interdisciplinary collaboration in innovation

Clinical needs triggered the scientific and technological development in the predecessors of BioMediTech and now in BioMediTech. For example, in the case of the bone growth therapy for facial area bones, which is discussed later in more detail, the development started from concrete clinical need. This clinical need led to research with a purpose to have a treatment based on stem cells to solve a clinical problem and cure a patient. Development of this new therapy was possible because of strong expertise in biomaterials and stem cells in the Tampere area. It was also understood that there are many problems in scientific stem cell research that can be helped by technology and thus technology experts from Tampere University of Technology joined the Human Spare Parts research programme. There was collaboration before the Human Spare Parts research programme too, but in this programme, it was even more coordinated. Technology groups are able to develop different solutions to problems scientists faced with stem cells, and it has been an advantage for BioMediTech. Thus, interdisciplinarity is an important aspect in innovations that emerge in BioMediTech and it is not only the different competencies but also the collaboration between technology groups and stem cell groups. There is also a lot of interaction between clinicians and biomedical researchers in BioMediTech. Due to that, problems that arise from clinical practice give direction and motivation to research, and thus, it is possible to help real patients with applications emerging from research. Technologies that technology groups develop in BioMediTech are essential for stem cell researchers, as those technologies enable them to develop further their stem cell based innovations.

Figure 2 presents the development process of tools and technologies. In the first phase, the technology group discusses with the stem cell group in order to find out what are the needs of the group. In some cases, a technology or tool is missing totally and sometimes there is a product available but it is not good enough. If the technology groups

is able to develop needed technology for purposes of the cell group, the technology group first develops a prototype and test it. In some cases, different technological disciplines are needed in order to get a fit solution. After development, the technology group delivers it to the cell group for testing purposes and gets feedback to develop the technology further. The development process might take time from a few months to several years depending on the complexity of the needed technology or tool. Feedback is crucial in this process of development.

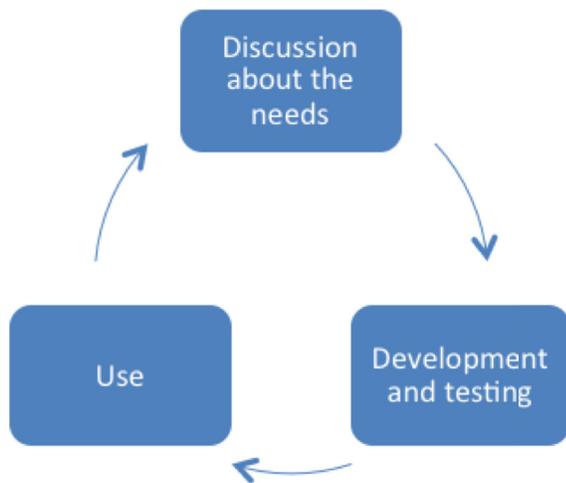


Figure 2: Iterative innovation process in tool segment where new technology is developed for purposes of stem cell groups.

Because all of the groups are in the Human Spare Parts research programme, there is a possibility to conduct several internal iterations easily. Finally, if the solution works and the cell team is happy with it, they might start to use the solution instead of the current commercial alternative. During the use of the product, user experience is gathered to improve the solution. However, only a small amount of batches is possible to deliver internally but larger scale production is not reasonable to expect from research groups. The outcome of these technology development projects is essential for stem cell research and therapy development. However, these developed technologies might sometimes have also commercial potential, and in the next chapter, the focus is on PoC development of these technologies but also therapies.

5.3 Proof of Concept development

The Human Spare Parts research programme was created as a strategic research programme that is between basic research and translational research. Thus, it is in the heart of the programme that product opportunities emerge and are developed further towards a PoC (Figure 3). In the early development phase, emerging inventions are patented and in the end, the goal is to license or sell the technology or spin-off a company. As development of PoC needs market understanding, commercialisation projects are established in order to obtain it from external sources. In some cases, there is a cooperation between BioMediTech and established companies to work towards PoC. In these cases, BioMediTech has a deep understanding about technology and firms have the market understanding.

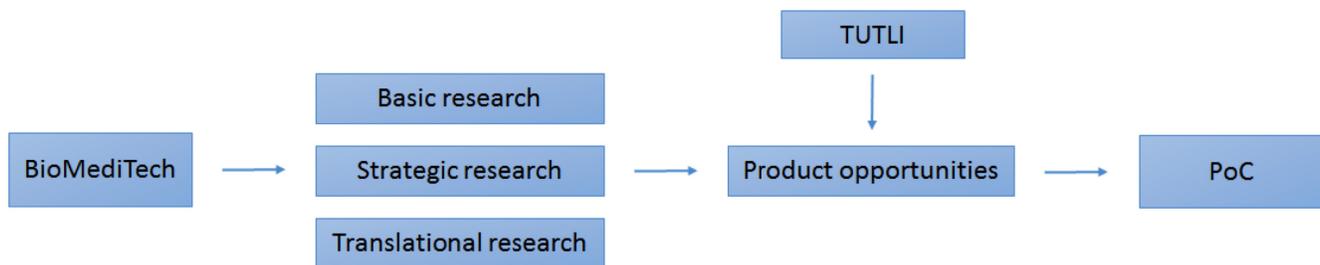


Figure 3: Steps towards a PoC in BioMediTech.

It is advantageous for BioMediTech that TEKES has a finance instrument called ‘New Information and Business from Research Ideas’ (TUTLI) to facilitate university based research commercialisation and to support it financially. The main purpose of those projects that get funding from TUTLI is to develop PoC that shows the commercial feasibility of technology. These projects are commercialisation focused and have several commercialisation related activities, e.g. initial market study, initial planning of business case, competitor analysis and study of exploitation option. The aim is to validate the concept and in some cases, the outcome is actually to change the concept, because the market is different from what was expected.

Commercialisation has been a focus area in BioMediTech, and researchers and group leaders are taught to think about commercial outcomes and applications in their research projects. However, it is acknowledged that researchers are not the right people to take commercialisation further, but they have an important expert role in the development of PoC. In BioMediTech, there are few TUTLI-financed projects established that aim to commercialise emerged innovations based on either technology or stem cells. These projects are seen as a good and important tool because they allow the development of a product concept outside the traditional research project. In these cases, it is beneficial to develop a product concept further in academia and that way make it easier for the firm to exploit it commercially. Several attributes affect commercialisation opportunities (Table 1).

	Technologies	Therapies
Exploitation	Short term	Long term
Need for funding	Moderate	High
Ease of getting funding	Moderate	Difficult

Table 1: Some characterisations of innovations.

There is a difference between technology commercialisation and therapy commercialisation. Some of the technologies are developed and proved inside the university for internal purposes and hence, there are already some proofs of technological viability. In these cases, a possibility for successful technology transfer is higher because application is in use. In case of therapies, clinical trials are required to prove the technical concept and early clinical trials should be conducted in academia because private funding for them is difficult to get due to the high level of uncertainty.

5.4 Therapy commercialisation: Bone reconstruction and transplantation

Tissue engineering is one branch of RM where human stem cells are used with scaffolds in order to make new tissue to grow some form. In the Human Spare Parts research programme one of the most promising technologies is a method to grow facial and cranial bone (Figure 4). First time in 2007, an upper jaw was fixed with a bone transplant, which was cultivated from the stem cells isolated from the fatty tissue of the patient (Sotarauta and Mustikkamäki, 2014) and over 25 patients have been treated to date. Treatments have been conducted in several Finnish university hospitals, lately in the University Hospital of Tampere. Even though several patients have been treated, there are no regular treatments in the market and clinical trials are not started yet. Instead, operations are conducted under advanced therapy medicinal products (ATMP) hospital exemption.

Regulatory and societal environments for stem cell therapies are rather advantageous in Finland. For example, regarding facial bone growth, the board of directors of the local hospital district gave their consent to the first clinical operation (Mesimäki et al., 2009). Regarding the therapy itself, ATMP hospital exemption allows clinical operations without official clinical trials, even though only limited amount of operations are allowed to be conducted every year. However, a possibility to do even a restricted amount of treatments might be a good evaluation point for investors to see if treatment and its concept is reasonably efficient for a business purpose. In this case, the first versions of therapy were not commercially viable enough and further development of PoC was required.

Even though treatments have been conducted and there is a know-how to cultivate bone tissue from stem cells, it is not totally understood why it all happens. This is why clinical trials are needed in order to verify the therapy scientifically. A regulatory pathway for this therapy is similar to the traditional regulatory path, for example in pharmaceuticals, but fewer patients are needed in later phases of the clinical trial. This regulatory pathway costs a lot of money and for universities it is difficult to fund it alone. Another issue is that even regulators do not totally know how to regulate these kinds of new products. There are discussions with regulators in BioMediTech about what they are actually required to do. The next phase in this development process of the new therapy is to start clinical trials. First, it is required to conduct pre-clinical studies, in which animal models are used, taking approximately 3 years. Currently this phase is started to prepare. Then clinical trials must be conducted including 3 phases and over 200 patients. Altogether clinical trials might take 5 years. After that, product approval from public and national authorities is needed. In the RM sector

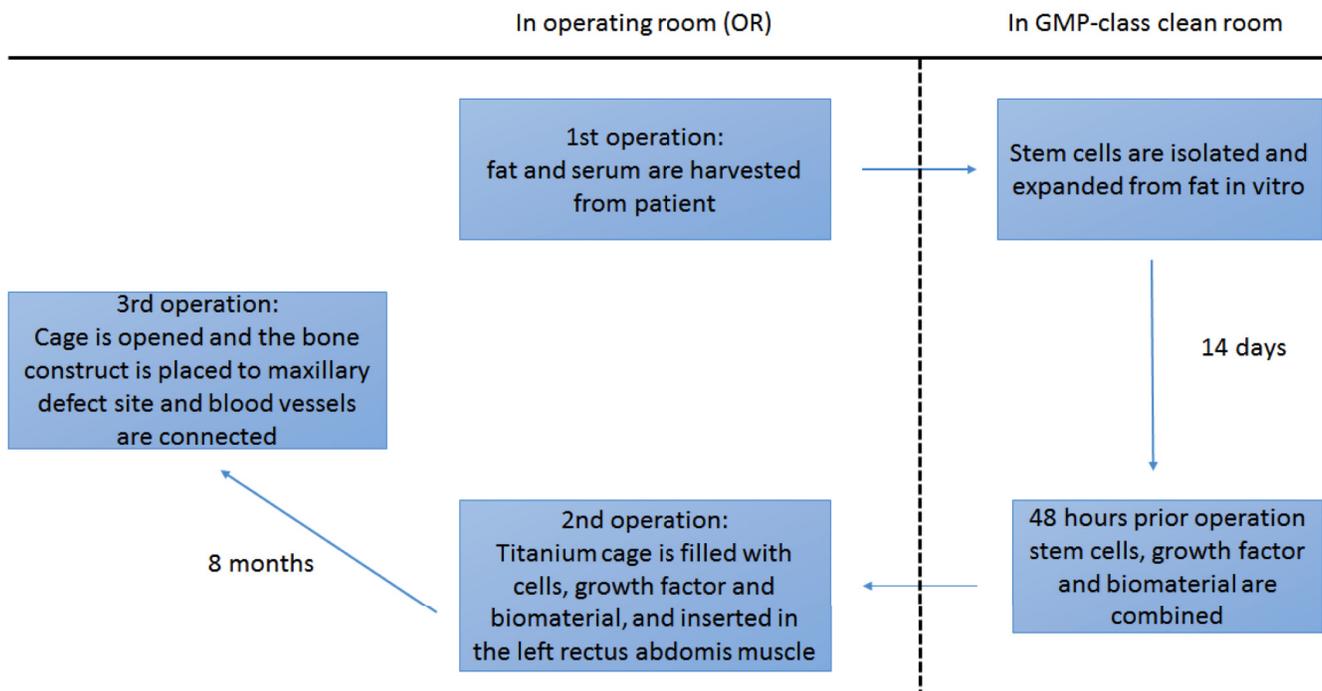


Figure 4: Schematic sketch of bone reconstruction process conducted in 2007 (Mesimäki et al., 2009).

regarding technology transfer, early clinical trials in the development of therapies should be conducted in academia. Venture capitalists would not invest in RM sector companies until later phases of clinical trials (Parson, 2008) that make the supply of funding a problem in the technology market. Actually, lack of funding in the PoC phase is not only restricted to the RM sector and therapies, but is a general problem (see e.g. Auerswald and Branscomb, 2003). Even though PoC and early clinical trials could be conducted in academia, it is not likely that the public sector alone could develop new therapies on the required scale (Mason and Dunnill, 2008). As Mason and Dunnill (2008) say, it is maybe possible with a small number of patients (Phase I/II and early Phase II), but after that also the private sector is highly needed. In the end, even after successful and approved products, there is a big uncertainty if nations with public hospitals and insurance companies want to give reimbursement for the new product.

6 Discussion

There are innovations developed and used in BioMediTech that are in some cases more suitable for use of research groups than alternatives in the technology market, even though these innovations are not commercialised solutions yet. Some of the solutions are used even in the patient care. The important question here is how to commercialise these innovations for the wider population use. It seems that traditional technology transfer from university to industry is just not appropriate enough, as academia has not developed those technological inventions far enough, and hence, the actual business potential is not known (Thursby et al., 2001). The other challenge is that inventors and scientists are needed in the process (Zucker and Darby, 1996; Jensen and Thursby, 2001).

Hence, the right time for technology transfer is a major question, and depends on several attributes like what is the technology and how is it regulated. In case of stem cell therapies, after successful early clinical trials, potential technologies could be transferred to the ownership of the company to get a private funding for it. Figure 5 presents a system level simplified sketch of innovation process based on findings of this study and health innovation system. It points out different aspects of a system level picture where the public sector, scientific community, technology market and health delivery system all are important elements.

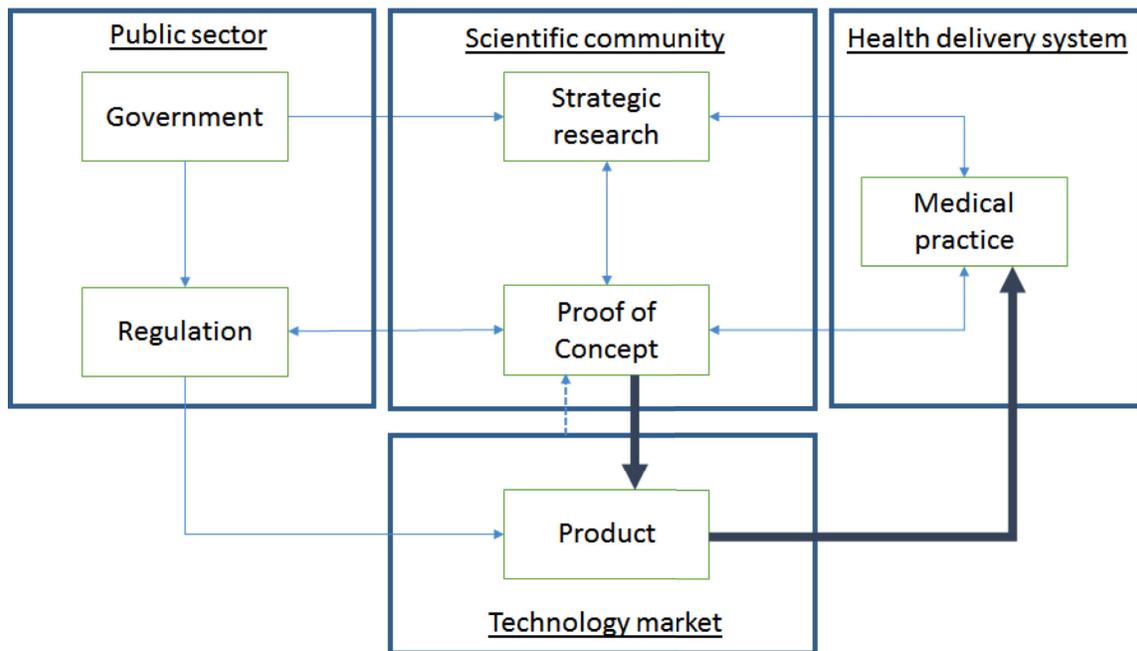


Figure 5: Simplified sketch of innovation process and technology transfer value chain between academia, industry and hospital (bolded arrows).

For the challenges of too early technology transfers, PoCC is suggested to be an answer. In the case of BioMediTech, the approach is different from the one that studies describe (Gulbranson and Audretsch, 2008; Maia and Claro, 2013), because technology transfer activities and development of PoCs are involved so deeply to daily operations. Also part of PoC funding is not from BioMediTech itself, but from public sources. The major challenge for BioMediTech is that in Tampere or in Finland, local venture capital, technology and industry networks do not exist for the RM sector, and thus it is not possible for the management team to connect to these locally, as Gulbranson and Audretsch (2008) emphasised. Hence, international connections are especially important and needed for a flow of information from technology market to PoC. However, the advantage for BioMediTech is the close connection to medical practice, and thus it is possible to get first-hand experience very early in the development of technologies.

An optimal situation in the therapy development would be that PoC is developed in co-operation between clinicians, academics and business experts to support successful technology transfer and commercialisation. In BioMediTech, there are no entrepreneurs readily available, and thus, the market understanding is acquired from business expert sources to guide the development of PoC. However, the challenge for them will be how to attract entrepreneurs in the later phases where spin-off is founded or PoC is transferred to an existing firm.

7 Conclusion

In this study, the aim was to study technology transfer activities and PoC development in BioMediTech. Two research questions concerned PoC development in BioMediTech and technology transfer in the RM sector generally. The important finding of this study was that there is a strong connection between strategic research and health delivery system as was described in the case of bone growth therapy. In this case, clinical experience is gained with real patients even though there is no commercial product existing. Clinical experience is important for the purposes of technology transfer, as it gives some proofs of viability of application. However, supply and value chain for new products are complicated crossing the scientific community, technology market and finally health delivery system in case of therapies or medical devices. The important question is how to transfer PoC from the scientific community to the technology market and facilitate institutionalisation of it to hospital service. Thus, in the PoC phase also customers have to be taken into account, as they are the main sources of feedback for innovation.

The other finding was that product opportunities are nurtured longer in the faculty for PoC development. Funding from governmental agencies is used in this development in order to understand the market and to prepare commercialisation of both technologies and therapies. In addition, there is a cooperation between BioMediTech and firms in PoC development. In the RM sector, development of therapies has a high level of uncertainty and it is difficult to get private funding for early clinical trials. Thus, universities are required to conduct early clinical trials themselves if they want to develop a new therapy in the RM sector. Development of therapies requires a wide range of expertise about stem cells and related technologies and hence, combination of different technology groups and stem cell groups and their common goal seems to be advantageous.

Development of PoC in academia seems to work well in BioMediTech. However, it is too early to say how well the model used in BioMediTech is working, as commercial output is not available yet and PoC developments are still going on. Another limitation of this study is that the Human Spare Parts research programme in BioMediTech is relatively small and focused, and is established in order to get new products. However, this study suggests that PoC development is important in order to do successful technology transfer, and in this process PoCC does not have to be an isolated entity but it could be more integrated to daily operations of the university.

8 References

- AUERSWALD, P. and Branscomb, L. (2003). Valleys of death and Darwinian seas: Financing the invention to innovation transition in the United States. *Journal of Technology Transfer*, 28, 227-239.
- BLUME (1992). *Insight and industry: on the dynamics of technological change in medicine*. MIT Press, Boston.
- CONSOLI, D. and Mina, A. (2009). An evolutionary perspective on health innovation systems. *Journal of Evolutionary Economics*, 19, 297-319.
- CONSOLI, D. and Ramlogan, R. (2008). Out of sight: problem sequences and epistemic boundaries of medical know-how on glaucoma. *Journal of Evolutionary Economics*, 18, 31-56.
- GELIJNS, A. and Rosenberg, N. (1994). The dynamics of technological change in medicine. *Health Affairs*, Vol. 13(3), 28-46.
- GELIJNS, A. and Rosenberg, N. (1995). The changing nature of medical technology development. In: Rosenberg, N. et al. (Eds.), *Sources of Medical Technology: Universities and Industry*. National Academy Press, Washington D.C., pp. 3-14.
- GELIJNS, A., Zivin, J. and Nelson, R. (2001). Uncertainty and technological change in medicine. *Journal of Health Politics, Policy and Law*, 26(5), 913-924.
- GULBRANSON, C. and Audretsch, D. (2008). Proof of concept centers: accelerating the commercialization of university innovation. *Journal of Technology Transfer*, 33, 249-258.
- HOYE, K. and Pries, F. (2009). Repeat commercializers, the habitual entrepreneurs of university-industry technology transfer. *Technovation*, 29, 682-689.
- JENSEN, R. and Thursby, M. (2001). Proofs and prototypes for sale: The licensing of university inventions. *The American Economic Review*, 91(1), 240-259.
- JUANOLA-FELIU, E., Colomer-Farrarons, J., Miribel-Catala, P. and Valls-Pasola, J. (2012). Market challenges facing academic research in commercializing nano-enabled implantable devices for in-vivo biomedical analysis. *Technovation*, 32, 193-204.
- LERNER, J. (2005). The university and the start-up: Lessons from the past two decades. *Journal of Technology Transfer*, 30 (1/2), 49-56.
- MCCMAHON, D. and Thorsteinsdottir, H. (2013). Pursuing endogenous high-tech innovation in developing countries: A look at regenerative medicine innovation in Brazil, China and India. *Research Policy*, 42, 965-974.
- MAIA, C. and Claro, J. (2013). The role of a proof of concept center in a university ecosystem: an exploratory study. *Journal of Technology Transfer*, 38, 641-650.
- MASON, C. and Dunnill, P. (2008). The need for a regen industry voice. *Regenerative Medicine*, Vol. 3 No. 5, 621-631.
- METCALFE, J.S., James, A. and Mina, A. (2005). Emergent innovation systems and the delivery of clinical services: The case of intra-ocular lenses. *Research Policy*, 34, 1283-1304.
- MEYER-KRAHMER, F. and Schmoch, U. (1998). Science-based technologies: university-industry interactions in four fields. *Research Policy*, 27, 835-851.
- NELSON, R., Buterbaugh, K., Perl, M. and Gelijns, A. (2011). How medical know-how progresses. *Research Policy*, 40, 1339-1344.
- PARSON, A. (2008). Stem cell biotech: seeking a piece of the action. *Cell*, 132(4), 511-513.
- POLAK, J., Bravery, C. and Prescott, C. (2010). Translation and commercialization of regenerative medicine. *Journal of the Royal Society Interface*, 7(53), S675-S676.
- ROBERTS, E. and Hauptman, O. (1986). The process of technology transfer to the biomedical and pharmaceutical firm. *Research Policy*, 15, 107-119.
- SIEGEL, D., Waldman, D., Atwater, L. and Link, A. (2004). Toward a model of the effective transfer of scientific knowledge from academicians to practitioners: qualitative evidence from the commercialization of university technologies. *Journal of engineering and technology management*, 21, 115-142.
- SOTARAUTA, M. and Mustikkamäki, N. (2014). Institutional entrepreneurship, power, and knowledge in innovation systems: institutionalization of regenerative medicine in Tampere, Finland. *Environment and Planning C: Government and Policy*, 32, 1-16.
- THURSBY, J., Jensen, R. and Thursby, M. (2001). Objectives, characteristics and outcomes of university licensing: A survey of major U.S. universities. *Journal of Technology Transfer*, 26, 59-72.

TONER, M. and Tompkins, R. (2008). Invention, innovation, entrepreneurship in academic medical centers. *Surgery*, 143(2), 168-171.

ZUCKER, L. and Darby, M. (1996). Star scientists and institutional transformation: Patterns of invention and innovation in the formation of the biotechnology industry. *Proceedings of the National Academy of Sciences USA*, 93, 12709-12716.