

## **Enhancing effectiveness in early stages of technology transfer and entrepreneurship: the case of a new Alzheimer's disease treatment**

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### **BACKGROUND AND OBJECTIVE**

Biotechnology is considered as one of the key technologies for the 21st century (European Commission 2007). Biotechnology is the “application of science and technology to living organisms, as well as parts, [...] for the production of knowledge, goods and services” (OECD 2005). The global biotechnology industry is still a young industry and has some unique characteristics compared to other industries. Those characteristics are, among others: increasing cost of R&D and global competition, high uncertainty and rapid change, heavy research costs, long product development cycles and the level of innovativeness of products is higher than in other industries (Khilji, Mroczkowski & Bernstein 2006 p.529; Cockburn and Henderson 1998 p.180). The biotechnology industry is dependent on academic research and therefore there is an increasing number of technology transfer and entrepreneurial activities within research institutes and universities (Kim and Marschke 2005; Branstetter and Ogura 2005). Effective and efficient technology transfer is a must today (Fontes 2001).

However several barriers exist in the innovation process. One of the main hindering factors is the difficulty of translating basic research into clinical application. New approaches are needed to bridge the gap between basic research and translation. Private Venture Capital funding or funding through a licensing deal with pharmaceutical companies are important

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means but they are not functioning at this early stage. This study will discuss a public support program (commercialization grant) which is aimed at funding basic research into this stage of commercialization (see figure 1). This public funding program has been planned to provide a framework to enhance the effectiveness of the early stage of the technology transfer process. We are using our model case study of a technology transfer project aimed at developing novel therapeutic strategy for Alzheimer's Disease to identify factors which enhance effectiveness.

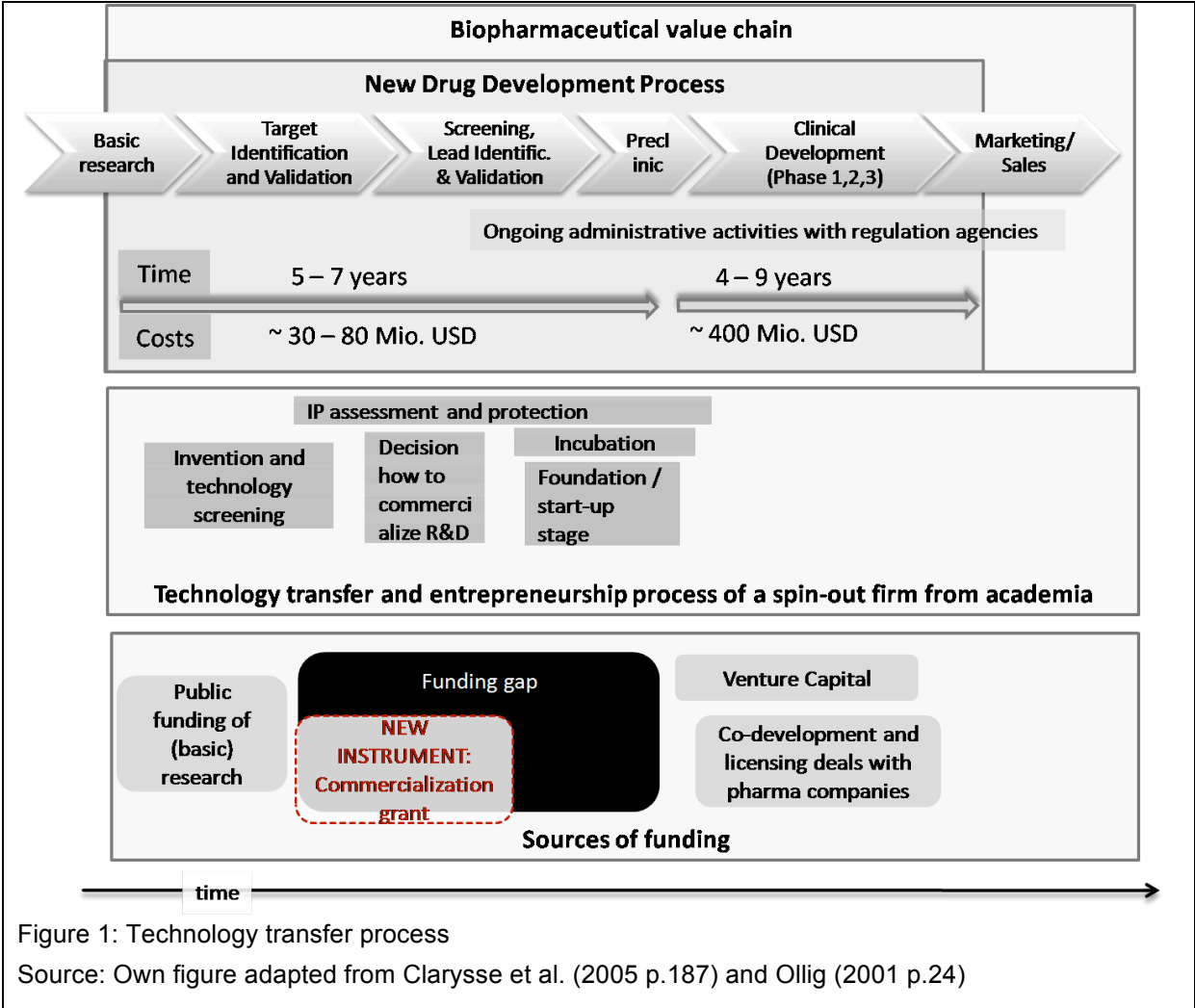


Figure 1: Technology transfer process

Source: Own figure adapted from Clarysse et al. (2005 p.187) and Ollig (2001 p.24)

## **CONCEPTUAL AND METHODOLOGICAL BACKGROUND**

### **New commercialization grant**

Recently the German federal ministry for education and research started a new program called “ForMaT – Research within a Team for the Market” to foster knowledge and technology transfer. The commercialization grant focuses specifically on early stages of the technology transfer process to identify and evaluate technologies for application in new products and services as well as to prepare the actual transfer of technology and knowledge. Within one project scientists from various disciplines are supported by business developers who are working as a “transfer team”. The program is designed to have two phases. Initially, in the first stage (6 month) researchers and business developer collaborate to identify new technologies or scientific results with commercial potential. The academic researchers present the scientific idea and the business experts evaluate its commercialization potential. The developers also evaluate the potential concerning scientific (e.g. proof-of concept) and economic parameters (e.g. market, competition, intellectual property protection). The funding for this first stage is 100.000 Euro. The second stage of the program (2 years) has the objective to develop the technology until it can be commercialized and to prepare the transfer of the technology (e.g. starting a spin-off, license patent). The total budget for the second stage is up to 2 million Euro to fund staff (nine researcher and one business development position), equipment, external services, conferences, etc.

### **The MIGRATA case study**

A case study approach was chosen for the present research. To conduct explorative research the author Yin describes the case study as a research strategy when investigators want to “retain the holistic and meaningful characteristics of real-life events- such as individual life cycles, organizational and managerial process, [...]” (Yin 2003 p.2). Case study research should be applied when a contemporary phenomenon is analyzed within its real-life context and especially when the boundaries between phenomenon and context are not evident. Data collection and analysis has been performed according to Yin (2003).

Within the ForMaT program the following biotechnology project has been funded which is used as a case study for further explanation of the characteristics of the program. The case study is a project based with a high level of innovativeness (radical innovation) in the early stage of the biopharmaceutical innovation process. The project is located at the Max-Planck-Institute of Molecular Cell Biology and Genetics in Dresden and is named MIGRATA

(“Membrane Intervention and Genomewide RNAi Approaches Towards Alzheimer’s Disease therapy”). It aims at the development of an innovative treatment for Alzheimer’s disease based on research findings of Kai Simons and his research team. These findings were patented and also published (e.g. in SCIENCE: Rajendran et al. 2008). The current stage in the biopharmaceutical value chain is at the end of basic research (see Figure 2). The extension of the proof-of-concept project to preclinical trials required further research. The MIGRATA project is funded by the ForMaT grant to enhance the technology transfer process and to prepare for commercialization. Within the first stage an interdisciplinary team (two biotechnology researchers and two business- and innovation manager) did a technology screening and evaluation to prepare a concept for commercialization. The team analyzed aspects such as customer segments, the market and competition as well as patents and the freedom-to-operate with additional expert interviews and workshops to discuss the feasibility, the challenges in the development process. The next steps for the MIGRATA project are further R&D and the decision for a commercialization strategy (spin-off, license, etc.). Based on this decision a business plan will be conceived.

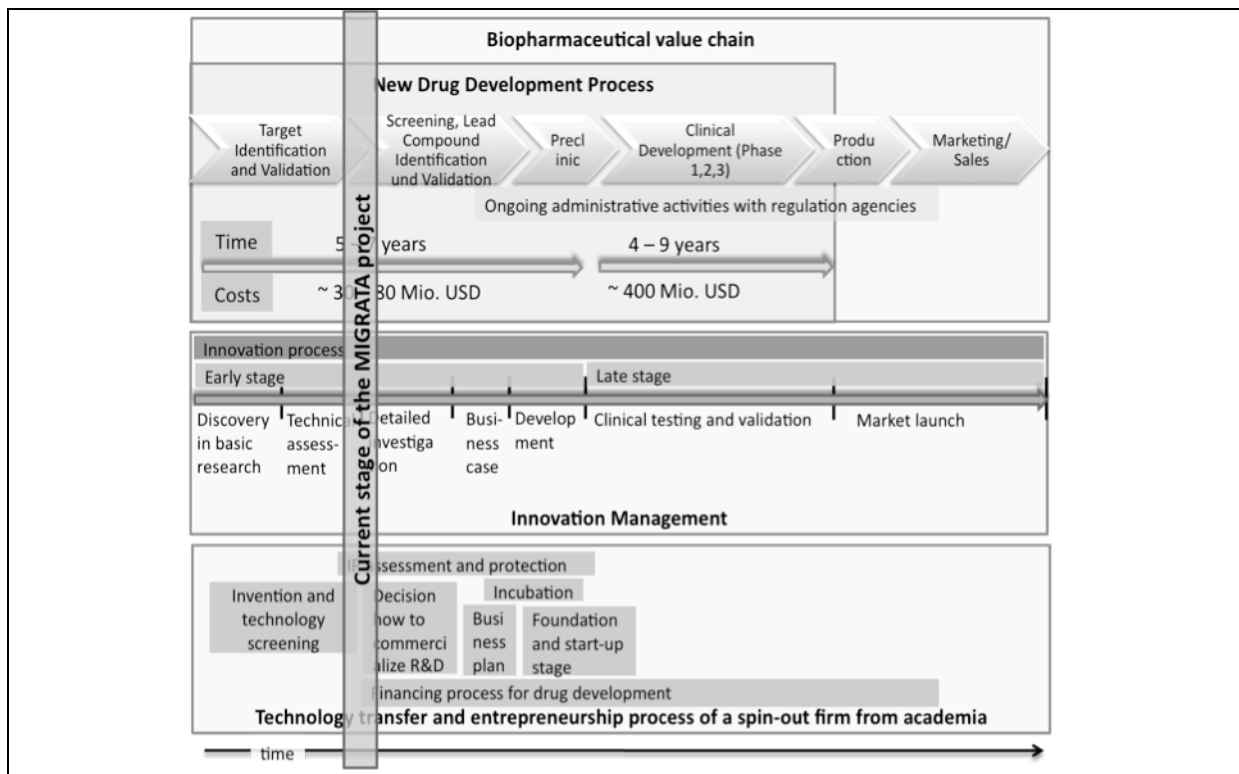


Figure 2. Current stage of the MIGRATA project in the biopharmaceutical value chain, innovation and technology transfer process

Source: Own figure

## **Performance measure of present study**

Performance measures for technology transfer are generally number of patents, revenue based on licenses and number of spin-offs (Bozeman 2000). However, for the present case study the output criterion is related to early stages of the transfer and innovation process. Characteristics of early stages of the innovation process are (Klink 2008): (a.) high degree of fuzziness relating to the idea for a new product or technology, (b.) a high degree of uncertainty for the product and project, (c.) a low level for standardization within the process, (d.) resources utilized are relatively small compared to late stages of the innovation process and (e.) activities are performed by an individual person or a small project team employing experimental, trial and error approach rather than structured, well planned and very detailed strategy.

Therefore, the performance measure of early stages is an effectiveness measure (to achieve an aim) rather than an efficiency (input/output relation). For this study, effectiveness of early stages of the technology transfer process relates to: (1.) writing of a project proposal with preliminary market/ competitor/ IP analysis and a positive internal (e.g. by administration of institute, TTO) or external evaluation (e.g. a public authority which decides about a pre-seed spin-off grant) to receive further support to continue developing in early stages of the innovation process and (2.) generation of a product concept (containing the commercialization strategy, e.g. in form of a business plan for a future spin-off) as the result of the early stage of the innovation process, its positive internal or external evaluation (e.g. licensee, VC investors) and the subsequent technology transfer (e.g. new spin-off, license patents behind innovation).

## **FINDINGS AND IMPLICATIONS**

The ForMaT program provides a framework for enhancing effectiveness in early stages of the technology transfer process for the MIGRATA project. The main determinants enhancing the effectiveness of the early stage are as follows (structured according to the level where they can be mainly influenced):

Level of support program (ForMaT):

- The commercialization grant (ForMaT) partly bridges the finance gap and provides funding for the transfer project to achieve a stage in development where

commercialization is possible. The grant provides the necessary amount of funding of staff costs (researchers and business people), consumables, equipment, etc.

- To enhance effectiveness there should be a flexible, situation- adapted use of resources with possibilities to change plans as well as a continued access to obtain sustainability. The commercialization grant should have the flexibility to collaborate with third parties and companies without any budget limitations. The ForMaT grant had the disadvantage that only 10% of the total sum could be used for expenditures to third parties.
- The structure of the program ensures interdisciplinary teams. Business developers are integrated early in the team who perform economic evaluations and prepare commercialization
- A continuous team contributes to effectiveness, but it is necessary to integrate and exchange people when skills and knowledge are needed to meet requirements of the innovation process. The commercialization grant should always give enough time to search for suitable team members. In addition, there is also a need to close the funding gap between phase 1 and 2 of the ForMaT program to ensure the continuity of the transfer team.

#### Organizational level:

- Access to research infrastructure of the institute (e.g. High-Throughput-Screening facility) is a crucial resource for transfer teams
- When researchers see technology transfer rather as “additional job” than as part of their job that hinders effectiveness. Therefore, technology transfer should be part of institute/university objectives (independent of whether the institute is a basic or an applied research institute) and then objectives should be implemented.

#### Team level:

- Transparency in the team and effective communication when being involved in search and evaluation of information to produce a commercialization concept (innovations with a high level of innovativeness such as the MIGRATA project have large information gaps in the early stage of the innovation and transfer process). There was a potential for principal-agent problems between researcher and business developer because there are differences in objectives. The principal investigator who could have

the aim at funding research and his lab and the business developer tries to push for commercialization.

- Information source: Researchers should be utilized by business developers as an important information source to understand the ecosystem of the innovation
- Guidance of project should be pragmatic based on current project-specific aims. There should be an external influence to guide the project when resources are overused or milestones are not met.
- Funding should be a means, not as the end of the technology transfer process. The team should utilize multiple financing sources, beside the key source, the commercialization grant.

Individual level:

- Requirement of predefined roles for team members that are suited to the task is crucial for effectiveness. When defining roles it is important to differentiate elaboration and decision making tasks. Each team member should be assigned a specific task or sub-project to distribute responsibility in an efficient matter.
- Researchers should focus on the transfer project and be willing to commercialize. The presence of a project “champion” ensures sustainability which enhances effectiveness.
- In a research team building and sustaining individual absorptive capacity is no challenge for researchers. However, one issue was a lack of knowledge of later more applied R&D activities (e.g. lack of knowledge about the steps of the new drug development process).

Across Europe and in the US, several programs similar to the German ForMaT grant are on the rise focusing on early stages of technology transfer (screening, evaluation and concept generation). In Switzerland, the Confederation’s innovation promotion agency (CTI) promotes early stage inventions and commercialization. The Tuli program of Finland and the VINN program of Sweden are similar programs. These programs enable accelerated drug discovery in the academic setting and such funding measures ensure that adequate pre-clinical research could be done. By fostering collaboration between researchers and business developers, the grant promotes a fruitful interdisciplinary program and provides training for both sides of the innovation process. Criticisms to such translational research is

also on the rise. One issue is whether academia should concentrate on the basic aspects of science and should be free of the clutches of commercialization. Indeed, commercialising a product, let alone the long way to bring an idea to preclinical stages, is a long- winding and an expensive path. Most pre-clinical innovations do not reach the market and not all marketed products are successful. However, to realize or evaluate at an early stage (initial research stages) whether an idea/concept has the potential to reach the market is a wise approach. Whenever, a novel strategy or technology is developed, a common path is to patent the findings and patenting demands resources and this is a costly process. Programs such as ForMaT provide a framework for enhancing effectiveness of early stages of the technology transfer and innovation process and provide means to evaluate the potential early enough to boost the innovation process. Both sides, science and business will unite forces to evaluate and realize the commercial potential.



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