Amiram PORATH
EuroMed Research Business Institute, Tel Aviv, Israel
amirampster@gmail.com

TRANSLATIONAL RESEARCH TOWARDS COMMERCIALIZATION – WHERE ARE THE GAPS?

Key words

Technology transfer; basic research; applied research; translational research; academy; industry; R&D.

Abstract

In the process of moving from basic research to applied research there are gaps that make the transit difficult, and thus impair the transfer of knowledge from the basic research done in academia to the practical R&D performed in the industry, and hence to the market.

There are other problems and gaps at later stages, such as the compatibility of the results to industrial needs, the regulatory gaps, etc., and some of which are sectorial and some are general. The focus in this paper is on the specific transfer from basic research to applied research from the point of view of commercialization.

The improvement of the process of the transfer cannot be done without a clear understanding of the gaps that exist in that field.

The paper describes the gaps and offers means to overcome them in a systematic way, while acknowledging that there are other ways and means as well.

Introduction

While it is an acceptable notion that for firms in order to succeed in the market place, be that to enter it, to maintain their market share or increase their derived profit, they need to innovate [22], it is not just as clear how to do so.

For technological firms, the most familiar way for innovation is to do so through R&D; however, while in many cases directed R&D seeking to innovate in a specific direction, e.g. making computer processors faster, smaller cheaper, the real breakthroughs can also be achieved via new knowledge based on basic research.

This opportunity for breakthroughs is the driving force behind the effort [8] governments, and nations make to transfer knowledge from the knowledge creators, the research organizations, to the industry [1, 13].

There have even been attempts to rank the universities according to their contribution to society measured in their technology transfer performance [5, 10, 11, 18], as well as measuring the impact the technology transfer had on the academy and industry partners [4, 6, 14] and on their organizational structure [2, 9, 12].

If we want to understand the pitfalls of the process, we need to start at the beginning and understand where the failure points are.

The process begins with basic research that is aimed at understanding the world around us, i.e. the natural phenomena, and why and how things happen, is translated into applied research, which in turn becomes development.

Applied research is research, which unlike the basic research is not intended for better understanding of nature, focuses on proving the feasibility of a specific application of the basic research. Development is the fine-tuning, economically as well as technologically, of the research of a specific application that the applied research proved as feasible.

The process may seem seamless and even simple; however, each phase changes the transfer from one mode to another and can prove very problematic.

The article below will discuss some of the differences between the phases, the personnel, the goals, the financial sources for the research, the cultural differences, and the pitfalls, especially in the early phases.

1. The Focus of Translational Research Effort

Translational Research has long been a focus point and a priority for organizations seeking to promote the move from basic research to application. In 2006, as part of making it a priority, the NIH, for example, has create the Clinical and Translational Science Award (CTSA) in addition to establishing centres focused on that research over the US [25]. However, in a research sponsored by the NIH in order to define the goals and characteristics of Translational research, it seems that there was no single definition accepted by all, and the researchers had to come with an operational definition [23]. There was an agreement with Woolfe [25] that "Translational Research means different things to different people", and the definition offered was: "Translational Research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials ad studies in humans. The second concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational research".

We can agree that, while the definition may vary from place to place, it would seem that all deal with relatively the same step, the move from basic research in the lab to an application in the real world [7, 26].

In the main discussion to define Translational Research, characterization is mainly done in the biotechnology or life sciences sector and can be linked to two main reasons – the distance from the application to the market, and the financing sources.

The financing of research and its impact on the type of research and its results has long been an issue for research (Mansfield, 1995; Hall, 1992; Hall, 2002). It would seem that the fact that basic research is so far away in terms of time and money from the market, from the identification of a target molecule in one of the cellular processes in a cancer cell to a drug in the market, that it requires further public support after the basic research before the industry can step in and take on the remaining research and approval responsibilities.

In other fields, such as in computer sciences, where the distance between a mathematical algorithm and a software application is relatively short in time and small in scale of required funding, there is less demand for public funds, and the industry can take on the responsibility closer to the basic research.

If public funds are not involved, the need for characterization and definitions is reduced, because they are not required for the prioritization and explanation of public expenditure. However, the government role in supporting the development of a knowledge-based economy has long been recognized as reducing innovation risks [16, 17]. That risk reduction can be achieved in several ways. The risk may be divided among several partners (an R&D Consortium), or the government itself may reduce the risk by getting involved in the finance. Either a grant or improved loan conditions loan are common government reducing tools [8]. However, in both cases, it is the industry that gets involved and justifies to the government the need for the support, or in other words, the benefit to the public that will be derived from such an investment of public funds. The benefit may be explained in terms of increased export, increased employment, or employment in employment challenged districts.

What happens in cases where the industry, based on the preliminary results presented by the industry, cannot assess the potential of the technology, or even define the application?

While these cases may not be characterized as basic research any more, but rather more application oriented, the industry, that engine driving the future applications to the market (not software application, but technology applications, products, processes etc.), cannot evaluate their potential and is reluctant to take the risk and get involved, even at very low commitment levels. This is normally the status of the translational projects. We will discuss some of the characteristics of translational research projects, their needs, and outline potential solutions.

The outcomes of the research in the R&D process need to be usable for the industry [20]. However, the process mentioned above normally starts without the involvement of the industry; it starts at the academic level of basic research. Therefore, from the start, the main partners in the development of the end product, which is the industry, is missing. That is to say that the input from the partner, regarding the characterization of the project and even the technology, is missing. Therefore, among the factors influencing the R&D process [20, 22], we should mention the following:

- Characteristics of basic research
- Cultural aspects
- Financing sources
- Personnel
- Expected results

2. Characteristics of basic research

In his book, Porath [20] deals with the characteristics of academic research. The main issue with basic research is the fact that it deals with understanding a phenomena and not with an application. The understanding of nature can lead to different applications, which is beyond the scope of the basic research. Therefore, basic research tends to be broader in its scope but more dis-focused than development.

Second, the understanding of natural occurrences may not be linked to any area of interest for the industry today. When the mathematics behind electronics today was developed in the 19th century, they held little interest for the industry, because they represented no application, just an enlargement of the numbers theorem. Therefore, basic research has very high risks, because the high chances of experiments failing, until the issues become clearer.

2.1. Cultural aspects

The academy, as the performer of basic research, is interested in extending its understanding. It will therefore tend to view a cancer treatment option as important as a research about nebulas in outer space. Therefore, the effort and the infrastructure invested in the research would have no direct link to the applicability of the results to real world problems. There is an indirect link via the contribution and donations in scholarships and infrastructure towards areas of general public interest.

In contrasting the cultural aspects of the partners, the industry and the academy, Porath [20] sums it in the following way: “The Academy and the

Industry cannot be treated in the same way regarding responsibility and accountability, as the different structures and cultures of them dictate a different authority and responsibility for similarly named organs in each.” The account demonstrates this point regarding the position of a department head in each.

Another point is the personnel performing the research. In the academy, most of the work, especially in an institute that teaches and researches, is performed by graduate students, combining a lack of experience, but are also more open to new ideas. Thus, their approach tends to be more innovative, but less up to industrial standards.

The R&D departments in the industry employ mostly veterans of the firms, and are therefore more conservative but also more adapt to standards and the methodology used in the firm [20].

2.2. Financing sources

The financing sources are always a problem, but, for our analysis here, we shall refer to the following aspect mostly: most basic research is supported by public funds and therefore is accountable to public scrutiny. That aspect can influence the research in two ways: The first is the appearance point of view, competition between proposals, topics to be supported, level of risk, etc.; the second way it can influence is regarding confidentiality. While the basic research in supported by public funds, the public has a right to know what is being funded [8, 20, 21]. In the industry, confidentiality is paramount and the source in many cases of competitive advantage that allows the firms to generate their income. When the two worlds meet, there is a need to transfer from the public to the confidential, and this increases some conflicts, because the basic knowledge may be public and free, but the application has to be protected for strategic reasons.

2.3. Personnel

Research personnel in the academic world consist of three main groups: the principal investigators (PI), the research assistants, and technicians. The principal investigators are the professors leading the group, who are very experienced in basic curiosity driven research, and who are mostly directing the research and not performing it any more. The research assistants are research students (M.Sc., PhD) with limited research experience (sometime accompanied by a post-doctoral students with some additional experience), following the instructions of the PI, and assisted by the technicians who have more experience but normally less formal knowledge. These groups tend to vary as students graduate and leave and new ones come in and have to learn the methodologies and technologies relevant to the research.

In the industrial world, most of the R&D teams are made of experienced permanent engineers or other sector relevant research personnel with a lot of acquired experience, and the teams normally are more permanent, since members stay at least for the whole project duration. They are more in tune with the interests of the organization, adapt to sector or discipline standards and more aware of the economic implication of their research results.

The academic teams are less experienced and less consistent in their view, and, in most cases, less aware of the relevant industrial standards or economic implications of their research results. They are also normally less efficient (due to reduced experience) and do not follow the rigorous standardized testing methodologies the industry uses. Therefore, in many cases, their results are not applicable for the industry, and the tests need to be repeated in a more standardized way in order to comply with industrial standards.

2.4. Expected results

The expected results from the research are different. In the basic research, the expected results are theoretical and form a better explanation regarding certain phenomena. They are expressed in explanatory terms and try to predict certain general experimental results. This might normally take the form of a scientific publication (book article and similar), and if are patentable, the patent would tend to be rather wide.

The R&D results are normally more specific and are application specific. In that way, they are also different in the fact that they relate to an application or product; therefore, even as a patent, they are normally more specific and narrow in their claims[1].

Table 1 summarizes some of the differences discussed above. The differences have to be bridged in order to pass from one research environment into the other. This is the main difficulty in translational research.

Table 1. Summary table

Characteristic	Academic Research	Industrial R&D
Cultural aspects	– Open Culture – exchange of opinions and results – Curiosity driven	– Confidentiality – secrets, patents, confidentiality agreements – Application / market driven
Financing sources	Mostly Public, philanthropy	Mostly private, self-financing
Personnel	Curiosity driven, less experienced, temporary	Application driven, long term employment,
Expected results	Excellent science	Market adaptable, standardized.

Source: Author.

[1] One can always find examples to the contrary, but this is generalization.

3. Translational research

The move from one research environment to the other is the main goal of the translational research. Some of the work may require repeating the research done in one way as basic research, again in compliance with industrial standards and requirements. Economic considerations, performance levels, competing technologies, and other considerations need to be introduced into the research at this point, as well as confidentiality, regulatory issues, and intellectual property aspects. This is the type of research that takes the improved understanding and translates it into an application / product / technology. This move is not simple, and, in a way, it is a limiting step, because it narrows down the focus of the activity.

It is well known [23, 25] that the move from basic research to application R&D is not easy due to all the reasons mentioned above.

However, the difficulty in defining the application is more than a set back at formulating the research plan, because it has a negative impact on the financing of the research.

As mentioned above, public funding, either from governmental (from regional to super-national) or from philanthropic sources, can be used for basic research financing, since this is understood to be for the public good.

R&D is normally financed by the industry or at least in partnership with it [8], which is fine as long as there is a product, process, or at least a technology involved.

When we are no longer dealing with basic research, nor can the industry evaluate the value of the research results, so as to become involved (in the financing as well as in the research), the classical financial means become scarce. This is not just a question of will. The evaluation terms for basic research do not apply here anymore, and the industrial evaluation methodologies cannot be substantiated at this stage. Therefore, it is difficult to evaluate what to support. Therefore, it is at this specific stage that great ideas can become "stuck."

Another issue to bear in mind is the sector of translational research target industry. There are some parameters that explain the scope of the problem of translational research. As described by some authors [7, 15, 25, 26], translational research seems to interest Life-Sciences organizations, e.g. the NIH, as in that specific sector the problem is a major hurdle in the commercialization of knowledge.

It would seem that the distance (measured in time and money invested) from basic discovery to the market has a significant influence on the problem or translational research.

Considering another sector marine transportation, for example, if a basic research performer developed and substantiated a new theory about wave propagation in the ocean and now wishes to develop that understanding into a more efficient marine engine, the industry (mostly large and seeking innovation) may decide to finance the translational research even before they can show feasibility, due to their ability to see the market application and to the relatively low risk, which is year maximum to show feasibility and perhaps even energy efficiency. On the other hand, a researcher who found a new receptor on a cancerous cell and decides that it may be a useful target for a counter cancer drug is far away from the approved drug – drug candidate identified, in vitro essays, anti-toxicity, in vivo essays, animal models, formulation, dosage and other steps – before clinical trials will be required, and in each step, the drug candidate may fail with all costs unrecoverable, so that no industry will take it at this point (in fact at a much more developed stage only).

The large number of such false candidates only increases the reluctance of the industry to become involved before a much more advanced developmental stage. It is not just the financial angle, but also the managerial limitation of managing so many conflicting projects at the same time.

Therefore, if you wish to increase the flow of technology from the basic knowledge research organizations, translational research should get some attention.

4. Characteristics of a Translational Research Support program

The discussion above indicates that the translation requires some specialized environment. It cannot be wholly academic nor can it be wholly industrial. There are currently two main solutions: (1) the research program for translational research, where the research organizations cooperate with the industry on a project basis, through the mediation and support of a government entity (This is an ad-hoc solution, which has the advantage of flexibility as the partners and topics change from project to project, while having the disadvantage of a lack of experience, both in the translational research and in the cooperation between the partners); (2) the second is a national translational research institute (e.g. TNO in the Netherlands), which has the benefit of experience and therefore efficiency, but has the disadvantage of a significant fixed cost on the national budget, and a heavy investment in infrastructure and personnel.

A support program for translational research should observe several ground rules in order to maintain its effectiveness:

1. The program should make sure that the end results of the projects it supports can be commercialized:
   a) Define the results as such; and,
   b) Make sure that the technology is protected and in a condition to be commercialized (owned by the commercializing entity, not infringing others, etc.).

2. It should support only translational research that is based on basic research; otherwise, it will become a program for basic research, or a product development program.
3. Industrial involvement should be limited so as to avoid the product development program trap, but it should exist on some level to assure that the definition of the end results is effective.
4. It should make sure that it does not fall into the endless research support trap. Projects should have a beginning and an end within a pre-set time limit.
5. Evaluation guidelines should be set to conform to the principals above.

It may seem that this is just the definition of a national industrial research institute. However, there are some problems with that concept.

– Who "pulls" the basic research from the academy into the institute?
– Do you also add another stage of knowledge transfer from the academy to the industrial research organization?
– What do you do when a basic understanding can be developed into applications in different industries (sectors)? Who takes charge?

The biggest problem is always the cost. A program financing projects is more flexible and less costly than a research institute with permanent employees, investment in infrastructure, and administration.

Conclusions

Translational research is becoming recognized as a barrier for technology commercialization, especially in certain sectors, and it is getting more attention by organizations in these sectors.

The difficulties in translational research stem from the move from one research environment into another, a limbo where the existing financial and evaluation tools are not well adapted to cope with the demands.

The existing solutions, including the industrial national research organizations, such as CNR, CNRS, INRIA, TNO and others, function efficiently once they have developed the means to identify the basic research they would need for their clients, but they still suffer from the disadvantage of significant investment in infrastructure and the lack of organizational flexibility. In the ever faster changing world of technology, this could become a major problem.

The needs of translational research are identified and the critical characteristics of a support program are defined. This is an intriguing solution, as I should know fully well, because – I manage such a program.

References

1. Agrawal A. and Henderson R., (2002): Putting patents in Context: Exploring knowledge transfer from MIT. Management Science, Vol. 48, No. 1, pp. 44–60.
2. Arundel A. and Geuna A. (2004): Proximity and the use of public science by innovative European firms. Economy, Innovation New Technologies Vol. 13(6), pp. 559–580.
3. Bronwyn H.H. (1992): Investment and research and development at the firm level: Does the source of financing matter? National bureau of economic research working paper 4096.
4. Cohen W.M., Nelson R.R. and Walsh J.P. (2001): Links and impacts: The influence of public research on industrial R&D. Management Science vol. 48, no.1, pp. 1–23.
5. Crespi G.A., and Geuna A. (2005): Modelling and measuring production: Results for a panel of OECD countries. SPRU working paper.
6. Di Gregorio D. and Shane S. (2003): Why do some universities generatre more start-ups than others? Research Policy, Vol. 32, pp. 209–227.
7. Drolet B.C. and Lorenz N.M. (2011): Translational research: understanding the continuum from bench to bedside. Translational Research, 157 (1), pp. 1–5.
8. EU Horizon 2020 – http://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020 – Downloaded on November 10th 2014.
9. Fontana R., Geuna A. and Matt M. (2003): Firm size and oppeness: the driving forces of university-Industry collaboration. SEWPS paper no. 103.
10. Geuna A. and Martin B.R. (2003): University research evaluation and funding: An international comparison. Minerva, Vol.41, pp. 277–304.
11. Geuna A. and Nesta L. (2004): University patenting and its effects on academic research: The emerging European evidence. SPRU working paper.
12. Geuna A., (2001): The changing rationale for European university research funding: Are there negative unintended consequences? Journal of economic issues, Vol. 35, No. 3, pp. 607–331.
13. Gibson M. (ed.), (2002): The University Culture of Enterprise – Knowledge transfer across the nation. Universities UK.
14. Jacobson, S. and Rickne, A. (2004): How large is the Swedish 'academic' sector really? A critical analysis of the use of science and technology indicators. Research Policy Vol. 33, pp. 1355–1372.
15. Jaffe, E.S. (2009): The 2008 WHO classification of lympjomas: Implications for clinical practice and translational research. ASH Education Book vol. 2009 (1), pp. 523–531.
16. Luukkonen, T. (1998): The difficulties in assessing the impact of EU framework programmes. Research Policy, 27(6), pp. 599–610.

17. Luukkonen, T. (2000): Additionality of EU framework programmes. Research Policy, 29(6), pp. 711–7124.
18. Mowery, D.C., Nelson, R.R., Sampat, B.N. and Ziedonis, A.A. (2001): The growth of patenting and licensing by U.S. universities: an assessment of the effects of the Bayh-Dole act of 1980. Research Policy, Vol. 30, pp. 11–119.
19. Porath, A. (2013): Reuse of excess research data for new researches. In Rahman, H., & Ramos, I. (2013): Ethical Data Mining Applications for Socio-Economic Development (Advances in Data Mining and Database Management (Admdm) Book).
20. Porath, A. (2010): Collaborative Research in Management, inside-out. Sage Publications Ltd. London, UK.
21. Porath, A. (2007): From a university into a research institute, the story of the Israeli research universities. Review on International Comparative Management New Issue V9.
22. Rosenberg (1990): Why do firms do basic research (with their own money)? Research Policy, 19(2), pp. 165–174.
23. Rubio, M. (2010): Defining translational research: Applications for training. Academic Medicine, Vol. 85 (3), pp. 470–475.
24. Slaughter, S. and Leslie, L.L. "Academic Capitalism: Politics, policies and the entrepreneurial university". The John Hopkins University Press, Baltimore MD, USA.
25. Woolfe, S.T. (2008): The meaning of translational Research and why it matters. JAMA 299(2), pp. 211–213.
26. Zerhouni, E.A. (2007): Translational research: Moving discovery to practice. Clinical pharmacology and Therpeutics, 81, pp. 126–128.

Badania translacyjne ukierunkowane na komercjalizację – gdzie są problemy?

Słowa kluczowe

Transfer technologii, badania podstawowe, badania stosowane, badania translacyjne, uczelnie, przemysł, B+R.

Streszczenie

Proces przechodzenia od badań podstawowych do badań stosowanych obarczony jest problemami, które utrudniają transfer wyników prac badawczych prowadzonych w sektorze B+R do zastosowań gospodarczych.

Na późniejszych etapach procesu wdrożeniowego istnieją również dodatkowe bariery, jak np. kompatybilność wyników badań z faktycznym zapotrzebowaniem przemysłu, które są barierami charakterystycznymi dla danego sektora lub całego przemysłu. W artykule skupiono się na procesie przechodzenia od badań podstawowych do badań stosowanych, ze szczególnym ukierunkowaniem na późniejszą komercjalizację wyników prac badawczych. Omówiono najczęściej spotykane problemy dotyczące procesu transferu i zaproponowano sposoby radzenia sobie z nimi.