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BASTION

"From Basic to Translational Research in Oncology"

Deliverable D5.4

Report on implemented IP protection and management strategy guidelines at MUW

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All reports are available on BASTION Webpage: www.bastion.wum.edu.pl

Introduction

Intellectual property (IP) *per se* is characterized by an extremely low value if it is not protected in the appropriate manner, and if such protection is not exploited subsequently. The value is being added with the exclusive rights for such an IP.

The most important feature of protected IP, in case of patents that are most relevant to MUW, is the ability to:

- ✓ exploit the invention,
- ✓ authorize others to exploit it;

for commercial purpose.

These temporary exclusive rights recompense investments in research and modernization of technology and can stop others for using it for their own purpose. Although there are established academic rules associated with the generation and ownership of IP in most institutions, it is the commercial exploitation of IP that has the major consequences for national, institutional and distinct capital creation. Governments throughout the world have recognized the requirement to protect an individual's IP rights, and have implemented procedures for this protection. In some cases protection may be legislative in framework, judicial in others. Many of the outlines for these rights are laid down by global agreements that form the subsequent basis for national strategies and legislature.

Deliverable 5.4 description

Deliverable D5.4 reported hereby corresponds to the task T5.3 in WP5. The aim of this task was implementation of efficient IP protection and innovation managements schemes at the Medical University of Warsaw.

Task performance

Implementation of the efficient IP protection strategy requires engagement of three parties – the researcher/inventor, the patent attorney and a person that plays a role of facilitator (frequently employee of technology transfers office if such exists). Innovation Manager (IM) has put a lot of effort to facilitate the process of IP management and protection linking MUW researchers with patent attorneys and coordinating the process of preparing and filing patent applications. IM established close collaboration with Patpol - a leading Polish IP company, specializing in Trademark and Design registrations, obtaining patent protection for inventions or utility models and EP validations. The Patpol team is composed of patent attorneys and lawyers focusing on intellectual property litigation as well as engineers and translators having wide expertise in various areas of technology.

Throughout the BASTION project the Patpol patent attorneys have consulted inventors from MUW with respect to patentability of the results of their scientific research.

The following projects have been selected for patent protection and Polish and European patent applications have been filed:

Subject-matter	Application	Inventors	Status
A method for diagnosing liver cancer and distinguishing the hepatocellular carcinoma form colon cancer metastasis to the liver in a patient using one or more miRNAs selected from the group consisting of miR-146a-5p, miR-125b-5p, miR-141-3p, miR-1269.	Polish patent application no. P.405648 filed on 15 October 2013 (our ref. P30817PL00)	1. Krystian JAŻDŻEWSKI 2. Kinga DYMECKA 3. Anna WÓJCICKA 4. Anna KUBIAK 5. Wojciech GIERLIKOWSKI 6. Monika MACIĄG 7. Monika KOLANOWSKA 8. Agnieszka CZAJKA 9. Marta KOTLAREK 10. Michał ŚWIERNIAK	Application pending
A method for diagnosing thyroid cancer and benign thyroid lesion in a patient in using one or more miRNAs selected from the group consisting of miR-146b-5p, miR-146b-3p, miR-221-5p, miR-221-3p, miR-222-5p, miR-222-3p, miR-181a-5p and miR-182-5p	Polish patent application no. P.406033 filed on 14 November 2013 (our ref. P30859PL00)	1. Agnieszka CZAJKA 2. Wojciech GIERLIKOWSKI 3. Krystian JAŻDŻEWSKI 4. Monika KOLANOWSKA 5. Marta KOTLAREK 6. Anna KUBIAK 7. Monika MACIĄG 8. Anna WÓJCICKA 9. Michał ŚWIERNIAK	Application pending
Use of gene expression signature consisting of SLC25A24, BIK, C9orf64, PRKAR2B, LGALS1, LHFP, IGHM, TAF9, PLCL2, TFDP2 and LIG4 for differentiation of Burkitt's lymphoma (BL) and diffuse large B-cell lymphoma (DLBCL)	European patent application no. EP14461567.1 filed on 11 September 2014 (our ref. P30919EP00)	1. Paweł GAJ 2. Radosław ZAGOŻDŻON	Application pending

Based on the above indicated Polish patent applications international applications have been filed:

Priority application	PCT application	Deadline for national phase initiation
P.405648	PCT/IB2014/065342 filed on 15 October 2014	15 April 2016
P.406033	PCT/IB2014/066057 filed on 14 November 2014	14 May 2016

Upon preparation of the patent application P.405648, a European patent application EP 2 181 332 was identified, related to the use of microRNA as a diagnostic marker. As the content of this

European patent application interfered to some extent with the subject-matter included in patent applications P.405648 and P.406033 (and the corresponding PCT applications), we explored a possibility of filing an opposition before the European Patent Office with the deadline of 10 January 2014 (our ref. OT2048EP00). However, after thorough analysis we decided to abandon this project, as reliable earlier evidence (i.e. earlier than priority date of application EP 2 181 332) with respect to lack of novelty of the subject-matter of application EP 2 181 332 was not available. Moreover, in the opinion of patent attorneys, the disclosure of patent application EP 2 181 332 had no impact on patentability of technical solution covered by patent applications P.405648 and P.406033 (and the corresponding PCT applications) and related specifically to liver and thyroid diseases.

The final project was related to search in patent literature with respect to the use of stem cells in wound therapy and a device related for application of such stem cells (our ref. PS1573PL00). We have prepared the report related to this subject-matter and analyzed the documents selected by the inventors as most relevant for their research.

Unfortunately, none of the inventors of the above patent applications was interested in estimating market value of their inventions or in at least making preliminary steps towards commercialization of their results. It clearly shows that there is a strong need at the University not only to properly manage IP rights but also to encourage scientists to commercialization process.

IP management - trainings

In order to find out about the policies and strategies on IP management successfully implemented in the leading universities and research institutes in Europe IM together with Project Manager (PM) joined two international events:

I. 9th Annual TTS Europe with ENTENTE Health Final Conference.

TTS Europe was the springtime Summit of the TTS Global Initiative. It is providing an environment conducive to university and institute technology offices and early stage biotech and healthcare

companies developing their business and technology offerings through debate, deliberation and discussion with KOLs from all stakeholder groups in healthcare and biotech innovation, ensuring the instigation of high caliber business opportunities.

The TTS enables delegates to efficiently identify, meet and instigate business with technology offices, companies and other stakeholders across the healthcare value chain, from patient groups and NGOs to large biotech and pharma companies to financiers and innovative start-ups alike. It provides a comprehensive mix and interactive format with representatives from all of the key stakeholder groups.

9th TTS Europe was combined with the final conference of ENTENTE Health, the key European funded programme designed to build expertise and best practices in healthcare technology transfer and innovation, and financing secondments of European TTOs into leading technology transfer and licensing offices, big pharma, and venture capital funds, to really learn the business of their interlocutors and build the relations and knowledge necessary to succeed in healthcare innovation.

TTS Europe participants were top international executives from:

- Academic institutions, Technology Offices and innovators
- Established and emerging biotech companies (CEOs, Directors)
- Pharmaceutical & Healthcare company executives
- Venture capital, Corporate Venture & other biotech and healthcare investors
- Senior Governmental & Non-Governmental Organizations
- Select specialized & world-class service companies

Participation in the meeting gave IM and PM the opportunity to meet professionals in the field, see good practices and consult solutions for facilitation of technology transfer at MUW. The following speakers and advisory board members participated in the meeting:

Aitana Peire – Director, Venture Valuation, Switzerland

Anders Haugland – Managing Director, Bergen TO, Norway

Andreas Leusch – Director Research Networking, Boehringer Ingelheim, Germany

Anja Zimmermann – Analyst, Ascenion, Germany

Antoine Mialhe – Policy Officer, Health Directorate – Strategy Unit, European Commission, EU

Axel Kalinowski – Manager Continental Europe, London Stock Exchange, UK

Bernhard Wu – Principal, DRI Capital, Canada

Bonny Harbinger – Special Advisor, IDEA Lab, United States Department of Health and Human Services, USA

Christian Stein – Managing Director, Ascenion, PRESIDENT ASTP-ProTon, Germany

Christian Suojanen – Co-Chairman, TTS Global Initiative, USA

Cristina Horcajada – Head of Innovation, Institute for Research in Biomedicine, Spain

Daniel Bach – Managing Partner, Aravis Capital, Switzerland

Dave Pardoe – Associate Director & Head of Growth Projects, MRC Technology, UK

Erik Vane – Director, ASTP Proton, Netherlands

Howes Gary – Partner, Fasken Martineau, UK

Ivo Roelants – Intellectual Property, K.U.Leuven R&D, Belgium

Javier Garcia – Partner, Synthesis Capital, USA

Jonathan Hepple – Founder & Director, Rosetta Capital, UK

June Lee – UCSF, Director, Early Translational Research, CTSI, USA

Kevin Noonan – Partner, MBHB, USA

Laia Crespo – Investment Manager, Ysios Capital, Spain

Lilian Wikström – Chief Executive Officer, Karolinska Innovations, Sweden

Manfred Horst – Direction, Scientific Liaison, MSD, France

Mark Treherne – Chief Executive, Life Sciences Organisation, UKTI, UK

Matthias Stein-Gerlach – Max-Planck Innovation, Manager, Germany

Michel Morant – Managing Director Ulg – Interface Entreprise- Université de Liège, Belgium

Miriam Gargesi – Healthcare Director, EuropaBio, Belgium

Mike Johnson – Divisional Director, Corporate Partnerships, MRCT, UK

Mohammed Charki – Open Innovation Strategy, Scouting & Partnering, Sanofi, France

Morris Berrie – Co-Chairman, TTS Global Initiative, UK

Olivier Lescroart – Research & Development, K.U.Leuven R&D, Belgium (project partner)

Pablo Cironi – Director of Technology Transfer, CRG – Centre de Regulació Genòmica , Spain

Pascale Augé – CEO, Inserm Transfert, France

Paul Ashley – Deputy Head of Technology Transfer, Isis Innovation, UK

Paul Tully – Partner, MBHB, USA

Ruxandra Draghi Akli – Director, Health Directorate, European Commission Directorate General for Research & Innovation, EU

Robert G. Urban, PhD – Head, Johnson & Johnson Innovation, Boston

Sally Shorthose – Partner, Bird & Bird, UK

Steve Cleverly – Isis Innovation, Head, Isis Enterprise, UK –TBC

Steve Ford – Chief Executive, Parkinson's UK, UK

Stuart Henderson – Partner, Head of Life Sciences & Healthcare Europe, Deloitte, UK

Tony Hickson – Imperial Innovations, Director Technology Transfer, UK

Vincent Smeraglia – Rutgers University, Executive Director, Office of Commercialization, USA and many other including **BTM cluster representatives**.

Discussion panel


Lecture


Karolina Dzwonek

II. Intellectual Property Management & Open Innovation in Health/Life Science

The seminar took place on 22nd June 2015, at Startup Braga, Portugal. It aimed at explaining the need for open innovation in the health/life science sector and at providing examples of how intellectual property management can play a critical role in developing open innovation by facilitating both research collaborations and the utilization of research results. The goal of the seminar was to show how health/life science firms, innovation systems actors and research groups can create greater value in their R&D activities through an intellectual property management approach to open innovation.

The participants could learn to:

- Identify opportunities where open innovation can support research and commercial goals
- Recognize different types of open innovation models and degrees of openness
- Understand the use of intellectual property as a means to govern openness
- Understand the use of licensing and other contractual mechanisms to manage open innovation for development and commercialization
- Identify background and foreground intellectual property in collaborative technology development

The seminar was dedicated for:

- Researchers who are interested in building utilization capabilities to strengthen their research output
- Entrepreneurs in the life sciences who want better analytical tools to develop commercialization strategies
- Technology Transfer Professionals who wish to enhance their holistic ability to evaluate academic research
- University Management who want better models to support the governance of research and innovation

- Policy Makers who wish to create better regulations and policies to support university research and innovation

The highest advantage for IM and PM participating in the seminar was an opportunity to meet and talk to the trainers – professionals with great experience in intellectual capital management and strategic business development:

Bowman J. Heiden, Deputy Director of Center for Intellectual Property (CIP), which is a joint development center for knowledge-based business development between University of Gothenburg and Chalmers University of Technology. Previously he was Innovation Director for the Qatar Science & Technology Park, where he was responsible for driving innovation strategy and intellectual property policy. As deputy director of CIP, Mr. Heiden currently manages the internationalization of the CIP platform and strategic industry relationships. His previous work at CIP involved strategic program development specifically focused on the building of collaborative innovation platforms to facilitate the creation and development of knowledge-based business. In this role Mr. Heiden has co-developed the Intellectual Capital Management Master program (ICM), which is a graduate education in knowledge-based business development and management for business, engineering, and law students. Mr. Heiden is also co-founder of the Gothenburg International Bioscience Business School (GIBBS), a graduate education that develops real bioscience ventures in an imbedded pre-incubator, and CIP Professional Services, which provides IP and business development services to both established firms and technology start-ups. Mr. Heiden has also developed CIP FORUM, which has grown to one of the leading knowledge-based business events worldwide. Current interests include the development of next generation university innovation systems and IP-based open platforms in the telecommunication sector.

Christoffer Hermansson, Project Manager at the Centre of Intellectual Property (CIP), the joint development center for knowledge-based business development between University of Gothenburg and Chalmers University of Technology. One of his key areas is to develop education and educate students from interdisciplinary backgrounds in law, business, life-science and engineering focusing on knowledge based business development and management. Mr. Hermansson is currently teaching in master level educations at both the University of Gothenburg and Chalmers University of Technology.

Mr. Bowman Heiden and Mr. Christoffer Hermansson - the speakers of the workshop

IP management – general strategy

There are some important milestones in IP management strategy that are universal and easy to implement in academia. These include:

- ✓ Creating the best practices before the R&D projects start:
  - ✓ *University authorities, after the amendments in national Higher Education Act, have policies relating to the ownership and exploitation of IP, good scientific conduct (including best practice recordkeeping) and to human and animal experimentation ethics as well as ownership of IP,*
- ✓ IP assets identification

- ✓ *University authorities have procedures that ensure that public money-funded researchers are made aware of the potential value of their discoveries and the issues of confidentiality and that a review process is available to identify the generation of protectable and exploitable IP, and, if considered necessary, that IP protection will be obtained prior to any public disclosure of research results*.

✓ Protection of IP

- ✓ *University authorities will have policies that make clear and binding to staff their separate and mutual obligations and responsibilities in relation to IP management and protection. Institutions should provide, wherever possible, assistance to researchers in fulfilling these obligations and responsibilities, as well as encouraging their participation in any subsequent commercialization process.*

✓ Ownership of IP

- ✓ *Determined by the existing acts*

✓ IP managing bodies

- ✓ technology transfer centers - created in the form of a University-wide unit to direct commercialization, acting on the basis of regulations (approved by the Senate, the appropriate authority of a public or non-public university - before it can function as a commercial company or foundation)
- ✓ SPVs - created by the Rector with the consent of the Senate capital company, to which the university can bring in kind of scientific research or development. Basically, the company is to be a one-man, with an exception for other public or non-public universities as a shareholder (from the beginning or in connection with the accession). Partners / shareholders of university SPV may only be universities (public limited or private limited).

✓ IP Management

- ✓ *University authorities should implement procedures that require the regular review of IP holdings, including associated commercial activities and outcomes, arising from the public money- funded research*

The aforementioned forms are strictly related to internal regulations:

- **University statute**, adopted by the senate of the university (including the scope and regulates economic activity, which can lead the university, the detailed rules for decision-making and representation of the university etc.)

- **Rules of management** of copyright and related rights and intellectual property rights and the principles of marketing, specifying in particular:

- ✓ the rights and obligations of university staff and students and doctoral students in the field of protection and use of copyright and related rights, and industrial property rights,
- ✓ the principles of remuneration of scientists (royalties),
- ✓ policies and procedures for commercialization,
- ✓ the rules for use of the property used for commercialization of university and research service;
- ✓ rules for the allocation of funds derived from the commercialization between the author being an employee of a public university and the university;
- ✓ rules and procedures for the transfer information on the results of research and development and the know-how associated with these results,
- ✓ rules and procedures for the transfer of the information on decisions relating to the adoption of the commercialization of the results and the way of transferring quota of the profits from commercialization by the public institution to the employee.

- **Regulations for the use of university research infrastructure**, specifying in particular:

- ✓ the rights and obligations of the institution and its employees, graduate students or students in the use of research infrastructure in the conduct of research and development,
- ✓ the terms of use and amount of fees for the use of research infrastructure for research and development by entities other than those referred to above point.

Best practices to be implemented in Medical University of Warsaw

The NDA

According to discussions and analysis of the available documents, there is no clear policy developed at MUW in the area of confidentiality agreements.

Legal protection of knowledge, especially before its protection via exclusive rights, can allow informing partners about research without making them public. Confidentiality agreements, often known as Non-Disclosure Agreements (or NDAs), are a common way of protecting University research and perceiving them as a trade secret and working out a commercialization strategy with external partners (potential licensors or buyers). The NDAs should be signed with limited number of partners and, above all, with the management. Before signing the NDA some specific questions should be addressed:

- ✓ Is the NDA necessary for the liaising with particular partner?
- ✓ Who are the people involved in the agreement?
- ✓ How the information will be limited and what are the possibilities of disclosing the information from both MUW and partner side?
- ✓ Are the implications of NDA fully understood by research staff? It may limit the ability to publish the study results,
- ✓ What is the effective time of the NDA expiration? When another partner may be involved?
- ✓ In case of partner audit at MUW – is there a formal documentation disclosing the route of information?
- ✓ How the control on NDA provisions will be conducted on MUW's side? Is it effective to prosecute its interests?

The example of NDA in Polish and English that could be a draft to create a template for MUW standard NDA is an attachment to the report.

Contracts with employees

The issue of employer-employee relation is vibrant for effective IP protection and technology transfer. The only possibility to protect the knowledge that was generated during the commitment to MUW is filing the patents or creating the memoranda that include the precise summary of the results generated. After the termination of the employee's contract it is impossible to distinguish between

the knowledge that is of commercial value and the competences gained during work relation with alma mater.

It should be emphasized, that all employees should have signed their terms of employment and that the document clearly assigns all IP generated in the course of employment to the company, excluding the situations, when the knowledge is generated by MUW as contract research organization. The employment terms must also ensure that responsibilities for confidential information and for supporting any formal procedures (eg. patent applications or proceedings) after employment ceases are transparent and easy to execute or litigate.

Relations with subcontractors, partners and experts

Prior analysis of the structure of contracts at MUW has shown that there is no control over the transfer of knowledge between the university and the subcontractors and contractors. It should be noted that with these partners the disclosure and IP issues are crucial both for the wealth of the University as well as for reception of the university as a center of innovation. No matter if the experts/contractors are individuals or companies, there is a need for exclusive agreement determining the consumption of foreground IP, background IP and trade secrets as well. The determination of what is a subject of information limitation is crucial also. This implicates issues in following areas:

- ✓ External disclosure of unprotected knowledge,
- ✓ Determination of exclusive rights ownership,
- ✓ Creating the instrument for litigation

The relations with subcontractors, partners and experts should involve:

- ✓ The dedicated NDA,
- ✓ The dedicated contracts: employee agreement, contract work agreement, master service agreement,
- ✓ If applicable, insurance guarantee from the subcontractor, partner or expert.

Non-infringement policy

Above all, an important deliberation is to respect third parties' IP rights. These include not only the patents, but trademarks, utility models, copyright and finally confidentiality also. A major infringement of a third party's IP rights could result in litigation that might severely damage the University both in financial as well as public confidence manner. This is a major resistor of innovations development if the non-infringement policy is not implemented.

The most important threats of infringement of third parties IP are[1]:

- ✓ **Lost profits** -- If the patent holder proves that he or she lost profits because of the infringement, the patent holder can recover money for the sales he or she would have made, as well as interest on the money owed.
- ✓ **Royalties** -- Patentees who license their inventions to other companies receive **royalty payments**, money paid by licensees for the right to use the patent. When an infringer loses a patent case, that party becomes, in essence, a licensee and may have to pay a reasonable royalty for any future sales derived from the patented product, device or technology.
- ✓ **Court costs** -- In most patent infringement cases, both parties named in the suit are responsible for their own court costs. In some cases, however, the infringer may have to pay the patent holder's court costs.
- ✓ **Treble damages** -- Finally, a court may decide to award treble damages to a patentee, especially in cases of willful infringement. This refers to a financial award worth three times the amount of the actual financial losses suffered. This may seem excessively harsh, but the government imposes stiff penalties to discourage individuals or companies from using someone else's ideas in the first place

In hypothetical situation, when the University would be launching the product (which is not exceptional these days) the way to avoid (or at least identify potential infringements) is the study of freedom-to-operate, which, because of the benefits in the future, should be carried out for each project, in which technology is the result having market value. Freedom to operate (FTO) is the ability of the technology holder to develop, make, and market products without legal liabilities to third parties (e.g., other patent holders, including consortium parties in some R&D projects, even if a suitable agreement has been signed). An actually influential FTO finding only

[1] How Patent Infringement Works by William Harris

comes under two circumstances. In one instance, a University licenses the patent, knowing it will not be sued for infringement short of a breach of the contract. In the other, final FTO status comes after settlement, in which a court finds either no infringement of the third-party patent or that the third-party patent is invalid. In some cases, a University will rely on both reasons (e.g., the product success may rely on noninfringement of some claims of a patent and invalidity of other claims)[2].

Therefore, the freedom to operate analysis should be carried out when the technology of a market value is expected result of the project.

Patentability search

Because of the rapid development of technology (especially in the medical field), before the development of any commercial project Patentability Search (analysis) should be performed.

Patentability Search is conducted before a patent application is prepared. In addition to determining patentability, this search will also:

- ✓ help the patent drafter to write the patent application that better defines the inventive contribution of the new product over the prior art,
- ✓ speed up prosecution by preempting examiner rejections, and
- ✓ improve the defensibility of the future patent by ensuring that the Examiner considers the most relevant prior art during prosecution.

What is more, some other advantages of the patentability search has been determined[3]:

- ✓ the projected commercial value of the invention;
- ✓ out-of-pocket expenses to obtain the patent, including legal fees, advertising, marketing and re-tooling costs;
- ✓ the invention's proximity to existing patented and non-patented technology (from an infringement and a commercial development perspective);
- ✓ the ability to exploit the invention during the timeframe of exclusivity granted by a patent;

[2] www.morganlewis.com
[3] Understanding the Costs and Benefits of Patent Protection By: Andrew Sherman, Esq. McDermott, Will and Emery Washington, DC

- ✓ the market value of the invention two to five years down the road, after completion of the patent application process; and
- ✓ the availability of adequate alternatives for protecting the invention, such as state trade secret laws.

Disclosure form

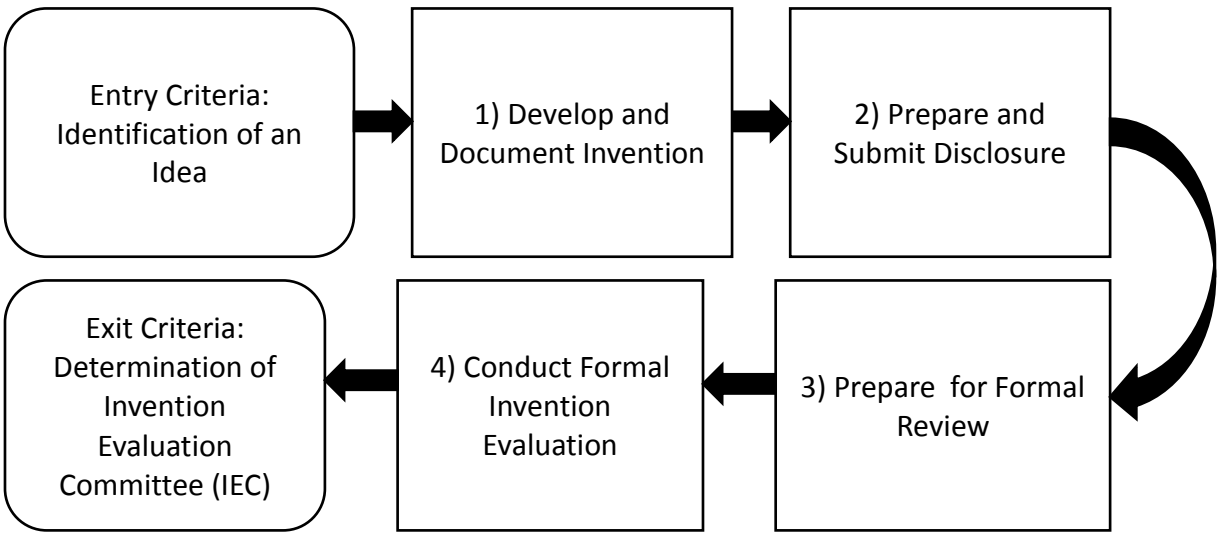
There is a need for a disclosure form development in MUW.

This form, created on the basis of discussions between researchers and university administrators is the basis both for effective selection strategy for protecting the intellectual property, as well as the best way to transfer information from research teams to technology transfer officers (TTOs).

Generated form (attached to the report) will ensure the acquisition of knowledge by the TTOs because it will contain the strategic information necessary to the initial evaluation and further processing of commercialization or the protection of technical solutions.

A general guidelines from Armament Research, Development & Engineering Center are recommended.

The general road map adopted from ARDEC is presented below:



The general questions to be addressed are:

a) What problem does the invention solve? Is the problem viable? Is there a need for solving the problem?
b) What are the current means for resolving the problem? Are there substitutions?
c) Why are the current methods insufficient for solving the problem?
d) What are the new outcomes and advantages of the invention?
e) Description of the invention including:
    - Reproduction of drawings or sketches,
    - Name, reference, and describe function of numbered elements,
    - List changes, additions, or improvements over the existing solutions,
    - Brief indication of alternate methods of creation or composition.
f) For basic inventions – note scientific principle upon which it is based, if known.

The invention disclosure form may be expanded by addressing the areas below:

a) Detailed description of the inventors,
b) Important dates in the development of the invention,
c) The assignment of the principal-investigators (inevitably needed when the technology is implemented)
d) Level of success of testing,
e) Description of data repositories,
f) Publications or disclosures made outside the University,
g) List of patents or other prior art related to the invention,
h) Description of any research relationships with other parties.

IP audits

According to WIPO best practices, an IP audit is a regular review of the University intangible assets both owed as well as shared. The reason the IP audit should be performed is to determine whether all the assets are utilized and if there is a need for continuous protection of some of the not up-to date inventions. The other advantages of conducting the IP audits are:

- ✓ to identify any threats,
- ✓ to provide a recent information for patent marketing,
- ✓ to improve negotiation position of the University.

Usually the academic units do not have the resources to conduct a full audit of all of its IP and will find it difficult to put a value to each of the components making up an IP portfolio. However, it should be noted, that IP audits are important for every innovations-oriented academia to document and value what are, in many cases, its most important intangible assets.

IP register

A TTO (tech transfer office) with specific accountability for IP should develop, maintain and oversee the IP register as a part of University's IP audit process. The person should be responsible for the registration and maintenance of the University's IP register. The register must contain the following information[4]:

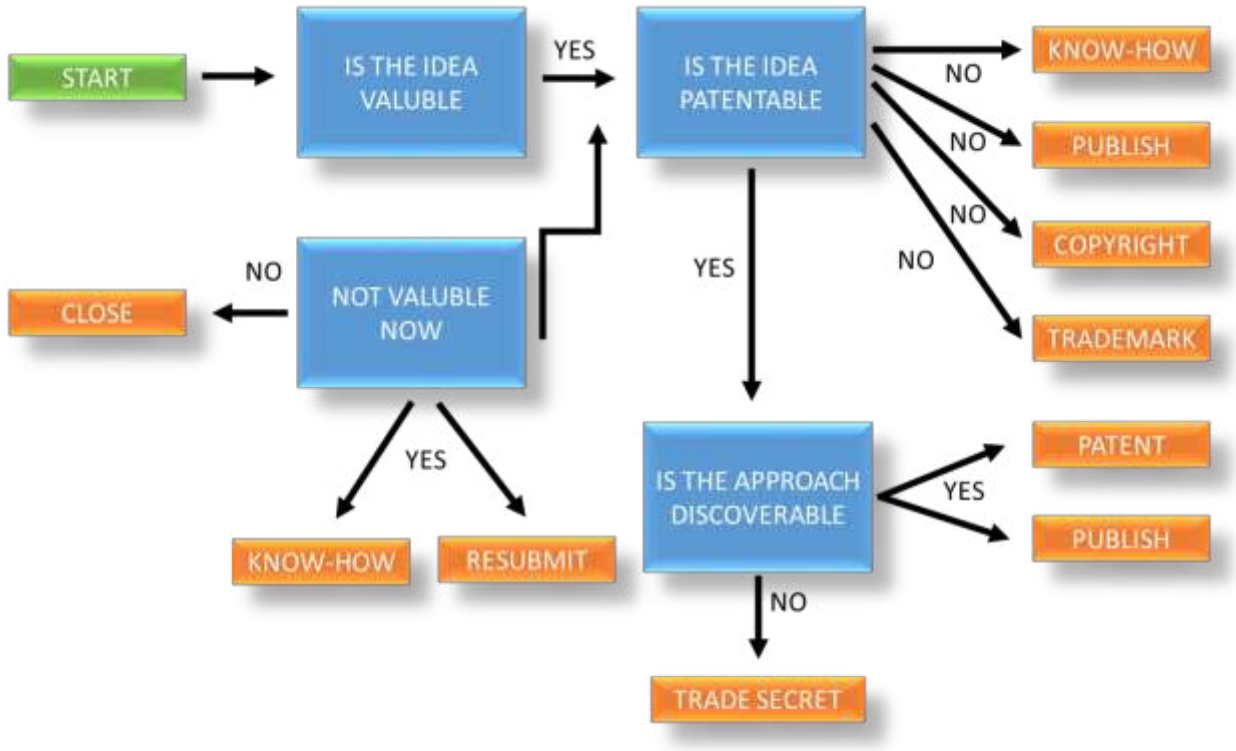
- ✓ description of the IP;
- ✓ ownership details;
- ✓ details of IP clauses contained in any contractors or consultants contracts involved with the development of the IP asset and details of where those contracts can be found;
- ✓ details of IP protection;
- ✓ the status of the current IP protection;
- ✓ the renewal dates for registered IP;
- ✓ details of any IP out of license, including details of the licensee and the nature of the license;
- ✓ details of any IP licensed-in, including details of the license and the costs;

[4] http://www.dtwd.wa.gov.au

- ✓ details of any IP enhancements developed either singly or in some form of partnership with the college;
- ✓ details of any specific agreements with individual employees involving ex gratia payments or other recognition of extraordinary involvement in creation or development of IP;
- ✓ the costs involved in the creation and commercialization of any IP and details of any royalty or commercialization revenue obtained by the University.

Disclosure process algorithm

Below the recommended decision-making process to take action on intellectual property rights is presented. The process is a universal guideline and may be implemented to MUW structures.



Patent innovation scoreboard

Each technology should be evaluated by measurable indicators adopted by both groups - researchers as well as the administration of MUW. Indicators should provide information about both the technology itself and the possibilities of its commercialization.

Criteria for assessing the technical solution should be included in the rules of intellectual property management and have transparent regulations reflected in the commercialization of the university structures.

Evaluation of inventions should occur at the following stages:

- ✓ The disclosure of a new invention,
- ✓ The decision whether to bear the additional costs associated with the protection of a technical solution (e.g. the extension of protection to the international path, the payment of fees for the protection of the grant of a patent, the additional costs associated with the activities of a patent attorney)
- ✓ Proceedings related to granting licenses

The following are examples of inventions assessment criteria:

Criterion	Negative	1	2	3	4	5	Positive
Novelty vis a vis state-of-the-art	Imitative						Novel
Feasibility of the invention	An Idea without technical characteristic						Working prototype

Dedicated market	Undefined						Defined
Applicable business strategy	Sell						Out-license
Competitors and existing products	Many competitors, marketed products						Limited number of competitors, competitive products in concept phase
Monopolism covered by patent	Narrow						Broad
Technology life span	Short						Long
Total score							

Recommended commercialization scenario

Below the possible commercialization scenarios are described:

IP Sales model

Sale of the intellectual property rights is associated with a single and irreversible transfer to the buyer of any rights to intellectual property. Sales model is generally considered to be unfavorable from the point of view of the University, in particular for the following reasons:

- ✓ there is a high probability that the sales of intellectual property will include buyer's requirement that MUW will refrain from further research in the area of intellectual property

rights related to the transaction. Since MUW is an academic unit, such strategy is highly unfavorable

- ✓ In the case of transfer to the purchaser of any property rights to the Invention, and then declared bankruptcy of the buyer, intellectual property becomes a component of the bankruptcy estate and may be acquired by a third party with the value different and lower than the market value

License model

To license to use the intellectual property authorizes the licensee to the commercial use of intellectual property. The granting of a license is not associated with a single transfer of intellectual property rights to the licensee. The advantage of the model is the ability to license the use of intellectual property at the same time in many fields of its use and in different territorial areas, which means that it is theoretically possible to sell more licenses than it would result from a number of patents. Licensing model is cheap for the licensor. This is the recommended commercialization scenario.

In the case of licensing model, as in the case of indirect commercialization, it is possible to use different forms of payment for the license, in particular:

- ✓ Up-front payment - paid at the time of the sale of licenses,
- ✓ Milestones payment – paid at the time of submission of applications for registration or release products on the market,
- ✓ Success fee - paid upon the successful commercialization of intellectual property, especially when they reach the SPV assumed financial parameters,
- ✓ License fee - paid as part of the benefits obtained by the licensee, and the basis for calculating the license fee should be revenue (never yield) obtained by the licensee from the sale of products derived from the invention.

Special purpose vehicles (SPVs)

Act of 11.7.2014 amending the Act - Law on Higher Education and other laws, allows academic institutions to develop special purpose vehicles (SPVs). Created by the university authorities, the company aims to commercialize the results of research&development and their implementation. This is an optional commercialization scenario.

Good practice

To implement good practice in technology transfer into MUW regulations IM has consulted and sustained cooperation in this field with several tech transfer professionals. There were two SMEs indicated as WP5 partners in the project – Science|Business and London Genetics as well as BTM Mazovia Cluster. Due to London Genetics taken over by other company and its expert Elisabeth Foot no longer available for cooperation, IM focused on Science|Business. Science|Business is an SME that connects public researchers, private funders and policy makers in the European innovation community. It runs news service to help members of the research and innovation community find out about each other and organizes several events a year gathering top level professionals and decision makers, including members of European Parliament and European Commission representatives.

Close collaboration with Science|Business resulted in preparation of the report that constitutes general guidelines on the technology transfer process, based on KU Leuven's experience, that could be easily implemented in the development strategy of the Medical University of Warsaw (attached to the D 5.2 report)

During the whole project IM collaborated with BTM cluster on evaluation of innovative potential of research projects run at MUW and other Ochota Campus institutes. IM got strong support from dr. Maciej Wierzbicki, Leader of Technology Transfer Group at BTM cluster.

To facilitate oncology projects evaluation BASTION purchased the access to the Oncology Subscription to GBI Frontier Pharma database for MUW. Access to the database for MUW employees and researchers could enable fast evaluation of applicable research projects, providing MUW scientists as well as potentially hired technology transfer professionals with current trends in preclinical and clinical studies in oncology. It can be a unique tool for new technology transfer unit that is currently being set up at MUW (and which does not have any such tools yet) to predict value of projects, to identify potential business partners and, in consequence, to increase the chance for commercialization of MUW research results. It could be a great input into increasing MUW potential in applied research in oncology and potential continuation of BASTION efforts in this field.

GBI's Frontier Pharma platform is specifically designed to support universities, research institutes and companies in identifying key trends and spotting opportunities within First-in-Class Innovation. Their reports within this range focus on indications that demonstrate a high degree of innovation, and provide a diseases overview, an assessment of current pipeline products, as well as an unique pipeline program evaluation to indicate the most promising developments to date.

Conclusions

The report and all attached materials can constitute basis to develop proper IP management at the University. There is obviously a strong need for engaging professionals with years of experience in technology transfer into the process. Lack of such competencies at MUW is one of the weakest points in the whole strategy and should have been addressed at the very beginning. Second important issue is the attitude – as long as technology transfer and commercialization of research results are not a priority for MUW and the University's authorities, they will not succeed. Making the process effective requires huge effort in terms of human resources, financial capabilities and strategic planning.

Guidelines indicated in this report, good practices and network of contacts will hopefully contribute to establish real technology transfer office with experienced, competent and open-minded team able to provide MUW scientists with support and high level service.

Corresponding estimated/* budget

PERSONNEL, TRAVEL AND OTHER MAJOR DIRECT COST ITEMS FOR BENEFICIARY "1" FOR M19-M36			
WP no.	Item description	Amount [EUR]	Explanations
5	Personnel costs	27,440.40	Salary of the WP5 Leader (6,48 PM); fee of theWP5 Co-leader (0,92 PM),
	Travel	4,288.04	Travel & accommodation (participation of IM and PM in two conferences)
			Travel & accommodation (External Experts' interview for guidelines on the technology transfer process)
	Subcontracting	22,824,48	Legal, patent attorney fees within T5.3 (6 Polish and international patent applications)
			Preparation and printing a set of documents on TT for MUW
	Remaining direct costs	21,082.61	License to cancer database
TOTAL DIRECT WP5 COST (D5.4)		75,635.30	

/* - exact costs for M19-M36 will be presented in the 2nd Period Report and Form C (October 2015)

Dr. Karolina Dzwonek

Innovation Manager, WP5-Leader

Prof. Jakub Golab

BASTION Project Coordinator
WP5 Co-leader

Warsaw, *August 2015*

MEDICAL UNIVERSITY OF WARSAW

COMMERCIALIZATION vs MY RESEARCH

What I should to know, before I will publish my research

Dear Colleagues, Students, Scientists

During last few months all of you receive information about commercialization need, news about new high-tech start-ups and new financial perspective commercialization requirements. Below You will find a short summary of the most important information, which may be useful for You in making next step decision.

COMMERCIALIZATION – IS IT SOMETHING FOR ME ?

Our answer is always YES !!!. Commercialization is not only starting new start-ups with astonishing media kick-off. Commercialization concerns both process and product innovations on all stages of development. Event narrow, highly specialize solution developed in Your laboratory, may became a crucial step for industry.

IS IT WORTH TO COMMERCIALIZE ?

Any rank or high impact publication is not giving as much satisfaction, and verifying as much of your work as practical implementation in the industry. Commercialization of Your research is not only prestige but also direct benefit like new possibility for long-term scientific collaboration, independent finance source for next, new research projects or new opportunity in Your career path.

I HAVE AN IDEA, WHAT SHOULD BE A NEXT STEP ?

When you complete Your research, and Your new work is ready to be published or presented on the conference, it is worth to take a few additional steps which will allow to evaluate the market potential of Your work and will guarantee Your IP protection.

First of all it is worth to check if the research which You have done are not highly demanded by industry. You can receive support in this area from the our tech transfer office which is collaborating with number of experts from the area of knowledge and technology transfer. Additionally the crucial step is to select proper IP protection path also with help and support from our office.

Tech transfer Office, Medical University of Warsaw
ul. Xxxxxxxxxxxxxxxxxxxx, room
e-mail: xxxxxxxxxx phone: xxxxx

MEDICAL UNIVERSITY OF WARSAW

INTELECTUAL PROPERTY, IS IT REALLY IMPORTANT ?

No matter what will be Your decision, it is always worth to support your work with a proper IP protection path, which can be developed in collaboration with tech transfer office experts. A proper IP protection is crucial for future commercialization. There is only one moment to protect your IP – before first public presentation or publication of Your research. It is also worth to know that there are at least a few ways to protect IP of Your research. A proper selection of IP protection path should be supported by expert knowledge. The potential possibilities of IP protection are as follows:

- **Patent application** – new, not obvious solution, which can be applied in industry. The patent application requires publication of detailed invention description.
- **Design patent** – new, utility solution with technical application potential, regarding shape, construction, subject with permanent form.
- **Authentication certificated notarially** – in case when author/company decide to keep crucial know-how as the company secret, it is worth to achieve notarially certificated authentication to confirm your IP right in case of patent application efforts done by potential competition.
- **Publication** – a proper selection of publication content may allow you from one side to constitute You in public domain as the author of technology, and from another side, avoiding publication of crucial IP details may allow you to protect Your solution. A proper publication content preparation is also a form of IP protection **!**

HOW OUR UNIVERSITY MAY HELP YOU IN COMMERCIALIZATION ?

Our University is open for commercialization of results of internal research. To make the commercialization process easy, fast and friendly the Senate granted a series of new regulation including:

- Terms of the research infrastructure sharing
- Terms of the copyright and related rights management and industrial property rights management and the principles of commercialization

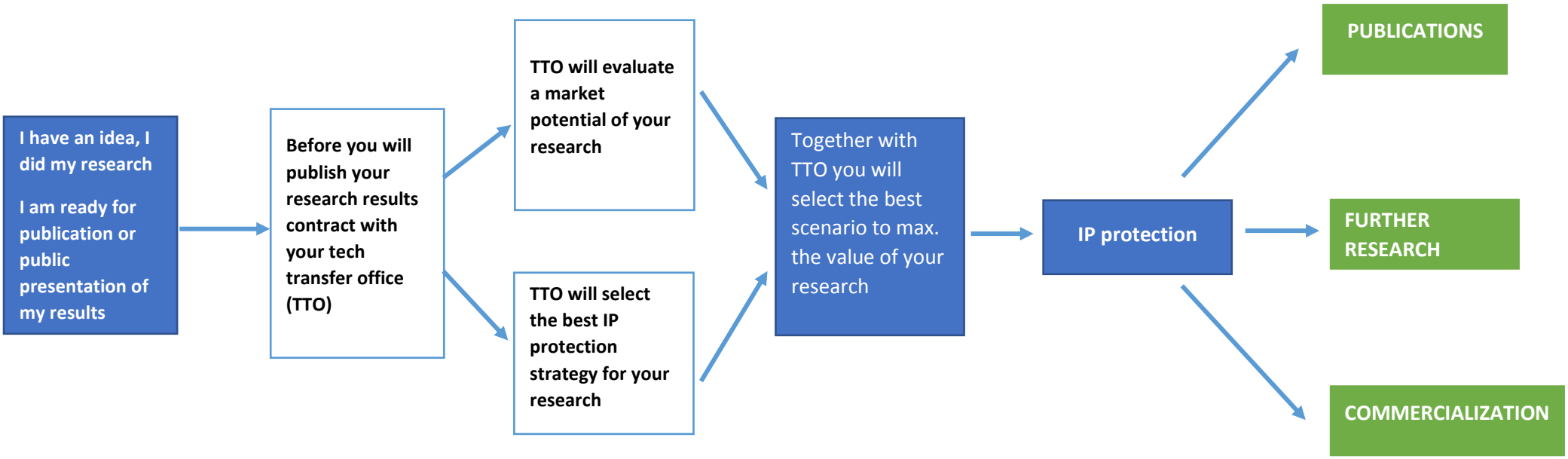
We strongly encourage you to get familiar with new terms and regulations. We strongly believe, that the newly implemented regulations will initiate a new positive movement in commercialization of Your research. Before making crucial decision, please do not hesitate to contact our tech transfer office for advice. We are eager to answer all your questions !

Tech transfer Office, Medical University of Warsaw
ul. Xxxxxxxxxxxxxxxxxxxx, room
e-mail: xxxxxxxxxx phone: xxxxx

MEDICAL UNIVERSITY OF WARSAW

COMMERCIALIZATION vs MY RESEARCH - scheme of action

What I should do to protect my IP before I publish my research

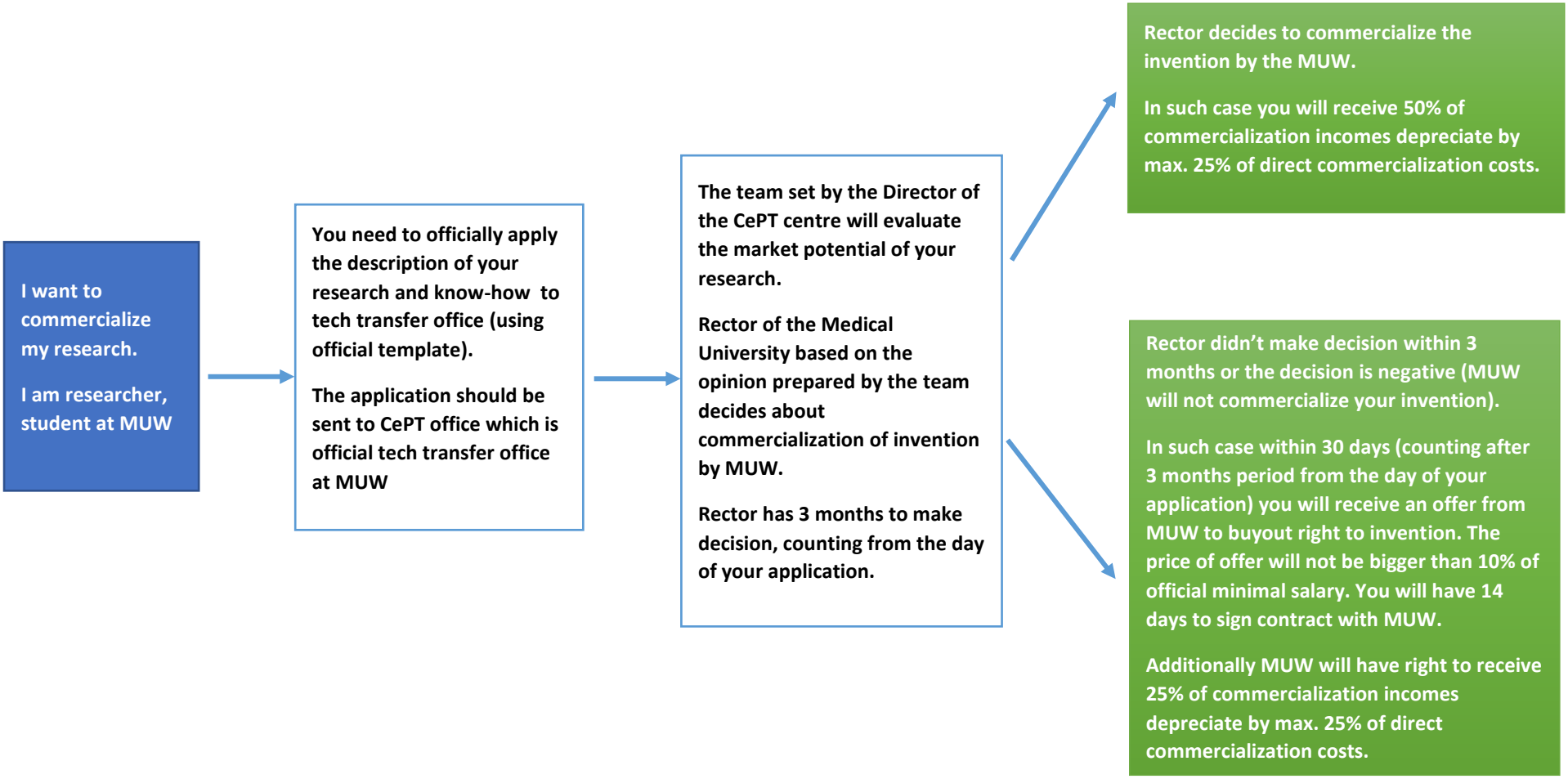


Tech transfer Office, Medical University of Warsaw
ul. Xxxxxxxxxxxxxxxxxxxx, room
e-mail: xxxxxxxxxx **phone: xxxxx**

MEDICAL UNIVERSITY OF WARSAW

COMMERCIALIZATION vs MY RESEARCH

I want to commercialize my research, what I should do ?



Tech transfer Office, Medical University of Warsaw
ul. Xxxxxxxxxxxxxxxxxxx, room
e-mail: xxxxxxxxxx **phone: xxxxx**

NUMER SPRAWY	PROWADZĄCY

OPIS WYNALAZKU

I. INFORMACJE ADMINITRACYJNE		
A. TWÓRCY Z WARSZAWSKIEGO UNIWERSYTETU MEDYCZNEGO (WUM)		
Imię i Nazwisko Twórcy	Dane kontaktowe (email, telefon)	Procentowy udział w wynalazku
B. TWÓRCY SPOZA WUM		
Imię i Nazwisko Twórcy	Dane kontaktowe (email, telefon) oraz afiliacja	Procentowy udział w wynalazku
C. ŻRÓDŁO FINANSOWANIA DLA ZGŁOSZENIA WYNALAZKU		
Numer projektu i jego tytuł	Kategoria kosztów w projekcie	Osoba odpowiedzialna za prowadzenie projektu w WUM

A. PROSZĘ O PRZEDSTAWIENIE SYNTETYCZNEGO OPISU ROZWIĄZANIA

Pozwoli to na przekazanie sprawy do osoby wyspecjalizowanej w danej dziedzinie techniki. Opis może być przedstawiony analogicznie do abstraktu, który przesyłacie Państwo na konferencje.

OPIS

B. PROSZĘ O PODANIE SZCZEGÓŁÓW ROZWIĄZANIA

Pozwoli to rzecznikowi określić, czy wynalazek posiada cechy nowości i nieoczywistości oraz czy jego zastosowanie ma charakter przemysłowy. Wszystkie trzy cechy (nowość, nieoczywistość – poziom wynalazczy oraz zdolność do przemysłowego zastosowania) muszą zostać, w myśl artykułu 24 Ustawy Prawo Własności Przemysłowej, spełnione łącznie by wynalazek został uznany przez właściwy urząd za posiadający zdolność patentową.

B.1. PROSZĘ O PODANIE SZCZEGÓŁOWEGO OPISU ROZWIĄZANIA TECHNICZNEGO

Proszę o podanie wszelkich cech rozwiązania w taki sposób, by, teoretycznie, umożliwiało to specjaliście w danej dziedzinie powtórzenie wynalazku w warunkach eksperymentalnych.

Proszę mieć na uwadze, że w myśl przepisu art. 28 ustawy z dnia 30 czerwca 2000 r. Prawo własności przemysłowej (Dz.U. z 2003 r. Nr 119, poz. 1117, ze zmianami), zwanej dalej P.W.P., wynalazkami nie są:

- ✓ odkrycia, teorie naukowe i metody matematyczne;
- ✓ wytwory o charakterze jedynie estetycznym;
- ✓ plany, zasady i metody dotyczące działalności umysłowej lub gospodarczej oraz gry;
- ✓ wytwory, których niemożliwość wykorzystania może być wykazana w świetle powszechnie przyjętych i uznanych zasad nauki;
- ✓ programy do maszyn cyfrowych;
- ✓ przedstawienie informacji.

OPIS

B.2. ROZWIĄZANIA PODOBNE

Czy według Państwa najlepszej wiedzy istnieją na rynku produkty, lub w literaturze naukowej opisy rozwiązań, które są podobne do prezentowanego wynalazku?

Jeśli tak, prosimy o krótki opis tych rozwiązań, wraz ze wskazaniem:

- ✓ źródła informacji,
- ✓ wyszczególnieniem tych funkcjonalności Państwa rozwiązania, które są jego wyróżnikiem tzn. rozwiązują dany problem w inny sposób niż rozwiązania podobne,
- ✓ korzystnych cech Państwa rozwiązania, to jest takich, które sprawiają, że jego zastosowanie jest lepsze niż rozwiązań podobnych

OPIS

B.3. PROBLEM ROZWIĄZYWANY PRZEZ WYNALAZEK

Proszę opisać jaki problem (rynkowy, naukowy, medyczny etc.) rozwiązuje Państwa rozwiązanie. W szczególności prosimy o:

- ✓ zwięzły opis rozwiązywanego problemu,
- ✓ określenie dziedziny nauki, której dotyczy,
- ✓ podanie źródła wskazującego na dany problem (uwaga: źródłem może być powszechnie dostępna literatura, ale może nim być także osobisty kontakt Państwa z przedstawicielami przemysłu, lekarzami etc.)

OPIS

B.4. ZASTOSOWANIE PRZEMYSŁOWE

Ze względu na fakt, że wynalazek objęty ochroną patentową musi posiadać zastosowanie przemysłowe, prosimy o wskazanie przykładów zastosowania komercyjnego wynalazku.

Zgodnie z art. 24 ustawy P.W.P., przy zastosowaniu przedmiotowego rozwiązania technicznego musi być uzyskiwany wytwór lub wykorzystywany sposób, w rozumieniu technicznym. Jego zastosowanie może dotyczyć jakiekolwiek działalności przemysłowej

Proszę pamiętać, że nie tylko nowość i nieoczywistość Państwa rozwiązania są istotne dla uzyskania ochrony. Wynalazek musi realizować wyszczególniony cel o znaczeniu praktycznym. Wynalazek musi zaspokajać jakąś praktyczną potrzebę

OPIS

C. DOSTĘPNE INFORMACJE I LITERATURA

Ta sekcja jest istotna ze względu na ocenę rozwiązania i możliwość odniesienia się do istniejących pozycji literaturowych. W sekcji C, o ile posiadacie Państwo takie informacje, prosimy o wskazanie także opisów patentowych (zgłoszenia patentowe, udzielone patenty), które dotyczą tzw. najbliższego stanu techniki.

Najbliższym stanem techniki są rozwiązania posiadające wszystkie istotne cechy zgłoszonego wynalazku lub rozwiązanie bądź kombinacja rozwiązań mających możliwie najwięcej cech zgłoszonego wynalazku, dotyczące identycznego lub podobnego problemu i wywołujące zbliżone efekty.

C. 1. PBLIKACJE WŁASNE

Prosimy o wypunktowanie własnych publikacji związanych z prezentowanym rozwiązaniem. Jako publikacje własne proszę rozumieć:

- ✓ patenty udzielone i zgłoszenia patentowe,
- ✓ publikacje naukowe – prace oryginalne
- ✓ doniesienia konferencyjne

Istotnym jest zaznaczenie fragmentów lub wskazanie tych części publikacji, w których ujawniacie Państwo pewne cechy prezentowanego rozwiązania.

OPIS

C.2. PUBLIKACJE OBCE

Prosimy o wypunktowanie publikacji obcych, w tym znanych Państwu opisów patentowych, które ujawniają rozwiązania podobne do rozwiązania państwa pomysłu.

W tym miejscu niezwykle istotne będzie wskazanie różnic między rozwiązaniem obcym a Państwa rozwiązaniem.

OPIS

C.3. SŁOWA KLUCZOWE

W tym miejscu prosimy o przekazanie nam propozycji słów kluczowych, które mogą posłużyć osobie dokonującej analizy rozwiązania do wyszukania dokumentów pokrewnych. Prosimy o podanie słów kluczowych w języku polskim i języku angielskim

SŁOWA KLUCZOWE W JĘZYKU POLSKIM	SŁOWA KLUCZOWE W JĘZYKU ANGIELSKIM

D. INFORMACJE O DALSZYM PRZEBIEGU SPRAWY

Po przekazaniu opisu do wyznaczonej jednostki WUM:

a) opis zostanie zweryfikowany pod kątem wypełnienia wszystkich pól,

b) sprawa zostanie przekazana do rzecznika patentowego,

c) w trakcie analizy rozwiązania rzecznik patentowy będzie kontaktował się z Państwem w celu doprecyzowania szczegółów,

d) zaproponowane zostanie spotkanie z rzecznikiem, podczas którego dyskutowane będą zarówno cechy rozwiązania przedstawionego przez Państwa w niniejszym dokumencie jak i rozwiązań podobnych,

e) rzecznik sporządzi opis patentowy i prześle go do Państwa weryfikacji,

f) potwierdzone zostaną środki finansowe na dokonanie zgłoszenia,

g) dokonane zostanie zgłoszenie do Urzędu Patentowego Rzeczpospolitej Polskiej

AKRONIM PROJEKTU	PROWADZĄCY
DATA WPŁYWU OPISU PROJEKTU	**DATA ZAKOŃCZENIA ANALIZY**
GŁOWNY TWÓRCA (OSOBA DO KONTAKTU)	**DANE TELEADRESOWE**

FORMULARZ OCENY PROJEKTU ZGŁOSZONEGO PRZEZ TWÓRCÓW Z WARSZAWSKIEGO UNIWERSYTETU MEDYCZNEGO

INSTRUKCJA WYPEŁNIANIA

1. PROSZĘ O SZCZEGÓŁOWE WYPEŁNIENIE KAŻDEJ CZĘŚCI NINIEJSZEGO FORMULARZA
2. NA KAŻDYM ETAPIE PROSZĘ O ODNOTOWANIE KWESTII, KTÓRE BĘDĄ MUSIAŁY BYĆ DOPRECYZOWANE PRZEZ TWÓRCÓW,
3. PROSZĘ O ZAPLANOWANIE PRZYNAJMNIEJ JEDNEGO SPOTKANIA Z TWÓRCAMI W TRAKCIE ANALIZY ROZWIĄZANIA,
4. PROSZĘ O ZAPLANOWANIE SPOTKANIA PODSUMOWUJĄCEGO,
5. CZAS OCENY PROJEKTU NIE POWINIEN BYĆ DŁUŻSZY NIŻ DWA TYGODNIE. O DEKLAROWANYM CZASIE ZAKOŃCZENIA ANALIZY PROSZĘ POINFORMOWAĆ TWÓRCÓW
6. ANALIZA POWINNA ZAKOŃCZYĆ SIĘ WYDANIEM REKOMENDACJI DO WIADOMOŚCI TWÓRCÓW ORAZ OKREŚLENIEM KOLEJNYCH KROKÓW W PRZYPADKU REKOMENDACJI POZYTYWNEJ
7. REKOMENDACJA NEGATYWNA POWINNA ZOSTAĆ POPARTA ARGUMENTAMI WSKAZUJĄCYMI JEDNOZNACZNIE NA TO, ŻE DALSZY ROZWÓJ PROJEKTU W KONTEKŚCIE POZYSKANIA FINANSOWANIA NIE JEST CELOWY,
8. REKOMENDACJA NEGATYWNA POWINNA ZOSTAĆ PRZESŁANA DROGĄ LISTOWĄ,
9. PROSZĘ PAMIĘTAĆ, ŻE PRZEDSTAWIANE PRZEZ TWÓRCÓW ROZWIĄZANIA SĄ CZĘSTO DZIEŁEM CAŁEGO ZESPOŁU PRACUJACEGO NAD PROBLEMEM PRZEZ DŁUŻSZY CZAS. REKOMENDACJA NEGATYWNA POWINNA NIEŚC ZA SOBĄ PROPOZYCJE PLANU NAPRAWCZEGO,

A. OCENA POTENCJAŁU ZESPOŁU BADAWCZEGO W KONTEKŚCIE KOMERCJALIZACJI PROJEKTU

A.1. DOROBEK ZESPOŁU BADAWCZEGO – PUBLIKACJE I GRANTY

1. Proszę przeprowadzić analizę ilościową i jakościową opublikowanych prac oryginalnych, ze szczególnym uwzględnieniem publikacji zbliżonych tematycznie do przedmiotu projektu mającego podlegac komercjalizacji.
2. Proszę ocenić udział zespołu badawczego w grantach badawczych, ze szczególnym

uwzględnieniem:

- ✓ ich miedzynarodowego charakteru,
- ✓ wysokości finansowania,
- ✓ mierzalnych efektów, także w ujęciu zrealizowanych wskaźników,
- ✓ udziału w grantach mających na celu wdrożenia i komercjalizację

OPIS

A.2. ZESPÓŁ BADAWCZY I JEGO KOMPETENCJE:

1. Prosze ocenić, czy zamierzony plan związany z komercjalizacją może być zrealizowany przez proponowany zespół pod względem zaangażowania w prace dydaktyczne i statutową działaność badawczą.
2. Proszę wskazać czy wszyscy członkowie proponowanego zespołu projektowego (desygnowani do prowadzenia prac w zakresie komercjalizacji) mają doświadczenie w proponowanym obszarze technologiczno-naukowym.
3. Ocenie powinien podlegać każdy z proponowanych członków zespołu

OPIS

A.3. ZAPLECZE TECHNICZNE:

1. Prosze ocenić komplementarność planowanego sprzętu do dotychczasowego zaplecza technicznego w zespole badawczym,
2. Proszę ocenić, czy dla zaproponowanego planu rozwoju projektu znajdują się jednostki partnerskie,
3. Proszę ocenić, czy zespół może miec dostęp do okreslonej aparatury poza WUM, zwłaszcza wśród dotychczasowych partnerów,

OPIS

B. ANALIZA PROBLEMU, ZAPOTRZEBOWWANIA, KONKURENCJI I RYNKU

B. 1. ROZWIĄZYWANY PROBLEM:

1. Proszę określić jaki problem jest rozwiązywany przez produkt projektu i czy problem ten jest realnie napotykany w gospodarce, a jego dotychczasowe rozwiązywania napotykają na bariery technologiczne
2. Czy bariery technologiczne są przezwyciężane przez produkt ocenianego projektu?
3. Czy efektem projektu jest produkt czy usługa?
4. Czy istnieje problem społeczny lub ekonomiczny rozwiązywany efektem projektu, niezależnie czy jest nim produkt czy usługa?
5. Proszę określić rynek w wartościach liczbowych (uwaga: prosze powołać się na ogólniedostępne źródła informacji, w tym abstrakty do raportów rynkowych firm doradczych)

OPIS

B.2. ANALIZA KONKURENCJI

1. Proszę, na podstawie części A niniejszego formularze określic przewagi zespołu w porównaniu do innych zespołów mogących zrealizować dane badania
2. Proszę wybrać trzy, spośród wymienionych przez zespół badawczy, technologii konkurencyjnych i przedstawić jej mocne i słabe strony. Proszę określić, czy oceniane rozwiązanie wykorzystuje słabe strony rozwiązań konkurencyjnych. Proszę określić, czy oceniane rozwiązanie przezwycięża mocne strony rozwiązań konkurencyjnych.
3. Proszę określić wymierną liczbę konkurentów i określić ich przynależność instytucjonalną (jednostki akademickie, firmy etc.)
4. Proszę o odpowiedź, na podstawie odpowiedzi na poprzednie punkty, czy istnieją produkty analogiczne, rozwiązujące ten sam problem techniczny? Czy istnieją technologie będące substytutami/alternatywami

OPIS

B.3. RYNEK, ZAPOTRZEBOWANIE, ODBIORCY

1. Proszę odpowiedzieć na pytanie czy istnieje rynek na rezultat projektu oraz czy Twórcy, według przesłanego opisu, są świadomi wymagań tego rynku
2. Proszę określić jacy są ostateczni odbiorcy rozwiązania
3. Proszę o opinię czy oprócz możliwości fianansowania prywatnego, istnieje system związany z finansami publicznymi, których pozyskanie może w przyszłości wspierać rozwój technologii

OPIS

C. WŁASNOŚĆ PRZEMYSŁOWA

1. Proszę okreslić czy rozwiązania związane z projektem były przedmiotem ochrony patentowej
2. Proszę określiczy czy publikacje i doniesienia konferencyjne ujawniają rozwiązania związane z projektem w taki sposób, że osoba będąca specjalistą w danej dziedzinie byłaby w stanie powtórzyć dokonania twórców
3. Proszę, uzywając słów kluczowych przesłanych przez twórców odszukać dokumenty patentowe (np. przy uzyciu bazy GooglePatents lub Espacenet) i przekazać je Twórcom do weryfikacji zbieżności z proponowanym tematem

OPIS

D. REKOMENDACJE

1. Prosze zestawić wszytskie pozywtyne i negatywne aspekty związane z projektem,
2. Proszę o własną opnię odnośnie tego, czy przedmiotowy projekt może znaleźć zastosowanie w praktyce

OPIS

E. NASTĘPNE KROKI

DZIAŁANIE	DATA

	WOLNE POLA POD WYPEŁNIA BIURO TRANSFERU TECHNOLOGII
	WOLNE POLA POD WYPEŁNIAJĄ TWÓRCY

AKRONIM PROJEKTU	**PROWADZĄCY**
DATA WPŁYWU OPISU PROJEKTU	**DATA ZAKOŃCZENIA ANALIZY**
GŁOWNY TWÓRCA (OSOBA DO KONTAKTU)	**DANE TELEADRESOWE**

FORMULARZ ZGŁOSZENIA PROJEKTU DO BIURA TRANSFERU TECHNOLOGII

I. TYTUŁ PROJEKTU
OPIS

II. SŁOWA KLUCZOWE Proszę o podanie słów kluczowych dotyczących projektu, które pozwolą na skuteczne poszukiwania w bazach literaturowych, patentowych i rynkowych	
SŁOWA KLUCZOWE W JĘZYKU POLSKIM	**SŁOWA KLUCZOWE W JĘZYKU ANGIELSKIM**

III. GŁOWNY BADACZ	
ZAKŁAD/KATEDRA	
DANE KONTAKTOWE: ADRES, TELEFON, ADRE E-MAIL	

IV. POSZUKIWANE FINANSOWANIE	**PUBLICZNE**	**PRYWATNE**
TAK/NIE		

V. OPIS PROJEKTU
V.1. ABSTRAKT Proszę o syntetyczne opisanie projektu z uwzględnieniem problemu, który rozwiązuje, planu działań doprowadzających do osiągnięcia założonego celu.
OPIS
V.2. OBECNA WIEDZA NA TEMAT PROBLEMU, KTÓRY MA BYĆ ROZWIĄZANY PRZEZ PROJEKT, ROZWIĄZANIA KONKURENCYJNE 1. Proszę o opis stanu wiedzy w zakresie projektu. Jeśli projekt rozwiązuje określony problem (np. medyczny) proszę o podanie motywacji, które leżały u podstaw do podjęcia prac na projektem. 2. Proszę o opis rozwiązań dotychczas stosowanych w celu rozwiązania wspomnianego powyżej problemu. 3. Proszę o wskazanie w jakim zakresie proponowane rozwiązanie, będące przedmiotem projektu odróżnia się od obecnych na rynku rozwiązań konkurencyjnych/alternatywnych

4. Proszę o podanie ponumerowanych pozycji literaturowych dotyczących zarówno samego problemu, jak i potrzeby jego rozwiązania, a także tych publikacji i doniesień naukowych, patentów lub stron internetowych, które prezentują rozwiązania konkurencyjne.

OPIS

V.3. CELE DO OSIĄGNIĘCIA

1. Proszę o podanie mierzalnych celów, które zostaną osiągnięte w przypadku otrzymania finansowania projektu,
2. Proszę przedstawić działania, które muszą być podjęte, aby przedmiot projektu mógł zostać wprowadzony na rynek,
3. W przypadku poszukiwania finansowania publicznego – proszę przedstawić jakie wskaźniki zostaną osiągnięte w przełożeniu na Warszawski Uniwersytet Medyczny
4. Ujmując odpowiedzi na powyższe pytania, proszę o określenie kamieni milowych prowadzących do zrealizowania celu

OPIS

V.4. ETAP PROJEKTU

Zakładając, że efektem projektu ma być rynkowo atrakcyjna technologia, a także możliwość doprowadzenia technologii do określonego stadium rozwoju proszę określić poziom gotowości technologicznej na wejściu i na wyjściu posługując się następującą skalą:

Zgodnie z informacjami przedstawionymi na stronach Narodowego Centrum Badań i Rozwoju, poziomy gotowości technologicznej (technology readiness levels – TRLs) to sposób opisu dojrzałości technologii oraz narzędzie służące porównaniu stanu zaawansowania prac nad różnymi technologiami. Dojrzałość technologii opisuje się od fazy konceptualizacji konkretnego rozwiązania (TRL 1), aż do etapu dojrzałości (TRL 9), kiedy ten koncept (w wyniku prowadzonych badań naukowych i prac rozwojowych) przybiera postać rozwiązania technologicznego, które można zastosować w praktyce – np. w postaci uruchomienia rynkowej produkcji. Narodowe Centrum Badań i Rozwoju dofinansowuje projekty według logiki TRL – celem większości programów jest takie dopracowanie technologii, aby można było ją zastosować w warunkach rzeczywistych (tzn. aby osiągnęły poziom gotowości technologicznej 9).

Szczegółowe informacje odnaleźć można na stronie: http://www.ncbir.pl/dla-mediow/trl-scheme/

POZIOM GOTOWOŚCI NA WEJŚCIU	POZIOM GOTOWOŚCI NA WYJŚCIU
OPIS	**OPIS**
UZADADNIENIE	**UZASADNIENIE**
OPIS	**OPIS**

V.5. WADY I ZALETY PROJEKTU/ROZWIĄZANIA BĘDACEGO PRODUKTEM PROJEKTU

1. Proszę o podanie wad i zalet projektu, zarówno w warstwie technologicznej jak i w kontekście istniejących w Państwa opinii rozwiązań technologicznych

ZALETY	WADY
OPIS	**OPIS**
OPIS	**OPIS**

VI. KOMERCYJNA MOŻLIWOŚĆ WYKORZYSTANIA WYNIKÓW PROJEKTU

1. Proszę o określenie, czy istnieje komercyjny rynek na zastosowanie wyników projektu?
2. Kto będzie ostatecznym użytkownikiem produktów powstałych w wyniku projektu?
3. Kto będzie decydował o kupnie komercyjnego produktu będącego wynikiem realizacji projektu?
4. Jaka jest najważniejsza potrzeba (rynkowa, technologiczna) związana z komercyjnym rynkiem dla projektu?

OPIS

VII. ZESPÓŁ BADAWCZY

1. Proszę o wymienieni każdego z członków zespołu badawczego

2. Proszę o podanie najważniejszych osiągnięć w zakresie własności przemysłowej
3. Proszę o wymienienie najważniejszych publikacji związanych z tematyką projektu
4. Proszę o podanie najważniejszych grantów realizowanych przez zespół badawczy, w tym projektów mających na celu wdrożenie/komercjalizację
5. Proszę o podanie informacji na temat zaplecza infrastrukturalnego posiadanego przez zespół, a niezbędnego do realizacji przedmiotowego projektu
6. Proszę o podanie zapotrzebowania na infrastrukturę niezbędną do realizacji przedmiotowego projektu

OPIS

VII. WŁASNOŚĆ PRZEMYSŁOWA

1. Proszę o informacje na temat praw własności przemysłowej związanej z projektem
2. Proszę o informacje czy w dotychczasowych pracach badawczych dających asumpt do niniejszej propozycji projektu, brali udział członkowie zespołów badawczych spoza Warszawskiego Uniwersytetu Medycznego

OPIS

VIII. DODATKOWE INFORMACJE

1. Proszę o wszelkie dodatkowe informacje, które mogą być istotne w perspektywie przyszłej realizacji projektu

OPIS

NON-DISCLOSURE AGREEMENT

THIS AGREEMENT is made on [xxxx]

BETWEEN

1. xxxxx

2. xxxxx

RECITALS

A. The Receiving Party understands that the Disclosing Party has disclosed or may disclose information relating to **"xxxxxxxxxxxxxxxxxxxxxx"**, which to the extent previously, presently, or subsequently disclosed to the Receiving Party is hereinafter referred to as "Proprietary Information" of the Disclosing Party.

OPERATIVE PROVISIONS

1. In consideration of the disclosure of Proprietary Information by the Disclosing Party, the Receiving Party hereby agrees: (i) to hold the Proprietary Information in strict confidence and to take all reasonable precautions to protect such Proprietary Information (including, without limitation, all precautions the Receiving Party employs with respect to its own confidential materials), (ii) not to disclose any such Proprietary Information or any information derived therefrom to any third person, (iii) not to make any use whatsoever at any time of such Proprietary Information except to evaluate internally its relationship with the Disclosing Party, and (iv) not to copy or reverse engineer any such Proprietary Information. The Receiving Party shall procure that its employees, agents and sub-contractors to whom Proprietary Information is disclosed or who have access to Proprietary Information sign a nondisclosure or similar agreement in content substantially similar to this Agreement

2. Without granting any right or license, the Disclosing Party agrees that the foregoing shall not apply with respect to any information after five years following the disclosure thereof or any information that the Receiving Party can document (i) is or becomes (through no improper action or inaction by the Receiving Party or any affiliate, agent, consultant or employee) generally available to the public, or (ii) was in its possession or known by it prior to receipt from the Disclosing Party as evidenced in writing, except to the extent that such information was unlawfully appropriated, or (iii) was rightfully disclosed to it by a third party, or (iv) was independently developed without use of any Proprietary Information of the Disclosing Party. The Receiving Party may make disclosures required by law or court order provided the Receiving Party uses diligent reasonable efforts to limit disclosure and has allowed the Disclosing Party to seek a protective order.

3. Immediately upon the written request by the Disclosing Party at any time, the Receiving Party will return to the Disclosing Party all Proprietary Information and all documents or media containing any such Proprietary Information and any and all copies or extracts thereof, save that where such Proprietary Information is a form incapable of return or has been copied or transcribed into another document, it shall be destroyed or erased, as appropriate.

4. The Receiving Party understands that nothing herein (i) requires the disclosure of any Proprietary Information or (ii) requires the Disclosing Party to proceed with any transaction or relationship.

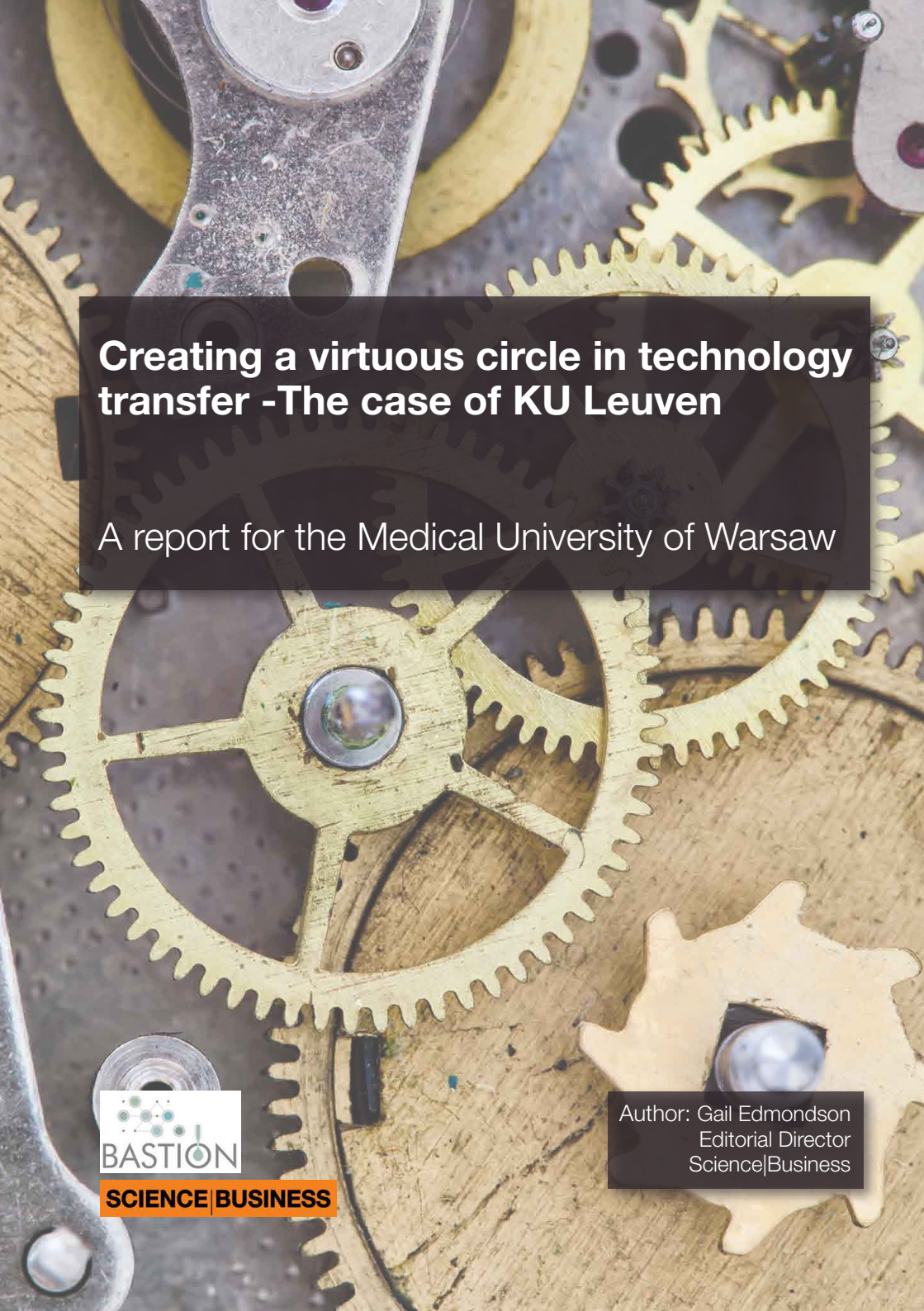
5. The Receiving Party further acknowledges and agrees that no representation or warranty, express or implied, is or will be made, and no responsibility or liability is or will be accepted by the Disclosing Party, or by any of its respective directors, officers, employees, agents or advisers, as to, or in relation to, the accuracy of completeness of any Proprietary Information made available to the Receiving Party or its advisers; it is responsible for making its own evaluation of such Proprietary Information.

6. The failure of either party to enforce its rights under this Agreement at any time for any period shall not be construed as a waiver of such rights. If any part, term or provision of this Agreement is held to be illegal or unenforceable neither the validity, nor enforceability of the remainder of this Agreement shall be affected. Neither Party shall assign or transfer all or any part of its rights under this Agreement without the consent of the other Party. This Agreement may not

be amended for any other reason without the prior written agreement of both Parties. This Agreement constitutes the entire understanding between the Parties relating to the subject matter hereof unless any representation or warranty made about this Agreement was made fraudulently and, save as may be expressly referred to or referenced herein, supersedes all prior representations, writings, negotiations or understandings with respect hereto.

7. This Agreement shall be governed by the laws of the jurisdiction in which the Disclosing Party is located (or if the Disclosing Party is based in more than one country, the country in which its headquarters are located) (the "Territory") and the parties agree to submit disputes arising out of or in connection with this Agreement to the non-exclusive of the courts in the Territory.

[Disclosing Party]	[Receiving Party]
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____
Address: _____	Address: _____
Date: _____	Date: _____



Creating a virtuous circle in technology transfer -The case of KU Leuven

A report for the Medical University of Warsaw

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Science|Business

BASTION

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This report constitutes general guidelines on the technology transfer process, based on KU Leuven's experience, that could be easily implemented in the development strategy of Medical University of Warsaw. It was commissioned by the Medical University of Warsaw as a contribution to the EU Project BASTION (From Basic to Translational Research in Oncology), a multidisciplinary science project to extend the research potential of the university and reduce the time from scientific discovery to clinical application.

Acknowledgements: The author would like to thank KU Leuven Rector Rik Torfs, LRD General Manager Paul Van Dun, Qaelum Founder and CEO Jurgen Jacobs and former LRD Innovation & Investment Manager Hannes De Wachter (now Qaelum CFO and managing partner 3Helix.be) for their insights and time contributing to this report.

Table of Contents

I. Overview

"A good technology transfer office is an essential part of a good university. Today, you can't do without one."

—KU Leuven Rector Rik Torfs

Leading research universities around the world are becoming powerful engines of innovation. The most successful institutions generate tens or even hundreds of millions of euros in annual income from collaboration with industry, patents, licensing and spin-offs. Much of that income is channelled back to researchers creating a virtuous circle for the university. At the same time, the universities that succeed at technology transfer contribute tangible benefits to society by stimulating innovation and economic growth.

Building a successful technology transfer operation, however, requires significant time and investment. Many universities have rushed to create technology transfer offices (TTOs) without the proper structures, funding or expertise. Disappointed, after four or five years, they give up before the benefits start to flow.

KU Leuven's technology transfer office, Leuven Research and Development (LRD), founded in 1972, is one of Europe's oldest and most successful TTOs and a leader in translational research. In 2014, LRD generated total revenues of €204 million for the university, capping more than a decade of sharply increasing returns. Its success is linked to best practice, and also to the strong conviction of the university leadership that technology transfer is a core function of a research university. This paper, based on interviews with senior university officials and LRD management, technology transfer professionals and a medical technology entrepreneur, highlights the lessons learned by KU Leuven over more than four decades and offers guidelines for successfully launching a university TTO today.

II. Best practice - Guidelines for setting up a TTO

1. Engagement

Start at the top. University leaders should send a signal that they are embracing technology transfer as a core role of the institution and engage with academics to build consensus.

2. Autonomy

Structure the TTO as an autonomous unit of the university with the power to make legal contracts.

3. Funding

Dedicate sufficient budget for at least three full-time equivalent professionals to set up and launch the TTO.

4. Expertise

Hire professionals who understand industry and have experience in technology transfer. They should be facilitators and dealmakers who have experience bridging the university-industry divide.

5. Incentives

Design incentives that channel the rewards of engaging with industry back to university researchers.

6. Industry collaboration

Focus first on industry collaboration to learn how it works. Don't rush to develop spin-outs without first learning how to work with industry.

7. Service mentality

Provide excellent service to academics in every aspect of technology transfer.

8. Catalyst role

Actively engage with professors and industry. And connect researchers within the university. Innovate on the job. Avoid the role of rubber-stamping projects.

III. The Leuven Research and Development story—a model of successful technology transfer

"One out of every three euros of KU Leuven's total research funding is provided for by the tech transfer office."
- LRD General Manager Paul Van Dun

When KU Leuven launched its technology transfer office, Leuven Research and Development (LRD) in 1972, it was rare to see European academics collaborating with industry, and KU Leuven was no exception. Its rector and a handful of professors with experience in industry had a vision of the benefits a TTO could bring the university, and led the way.

In setting up a technology transfer office, it's important to do two things, says KU Leuven Rector Rik Torfs: "You need to convince researchers there is nothing wrong in taking in their own hands the development of technology. That's one element. And you have to maintain unity throughout the university so everyone is convinced of the fact that technology transfer is positive for the university as a whole."

That is a delicate balancing act, says Torfs, "because the university is a house with many rooms and everyone has to feel at home. You have to do both things: Stimulate those who are in a position to do technology transfer and also reassure everybody that this will enrich and not impoverish the university."

KU Leuven's leaders struck that balance from the beginning, creating a strong foundation for LRD's growth and success. Today, KU Leuven ranks among the world's most productive universities in technology transfer. Between 2005 and 2014, industry contracts, licensing and patents generated nearly €1.4 billion in revenue for the university. The university also has nurtured and taken a stake in 105 spin-outs, that raised €675 million in external capital over the past decade, including seven initial public offerings. Eighty-seven spin-outs are still active employing some 4,200 people.

Forty years on, KU Leuven's belief in the importance of technology transfer has become mainstream: Governments around the world are championing innovation and the development of new technologies to address societal challenges as a top policy priority. "Now it is generally recognised that a university has not two missions but three—education, research and transfer of knowledge," says Torfs. The transfer of knowledge is a social task, making sure that what comes out of the university is of benefit to society.

Technology transfer is also increasingly important to universities as the collaboration of science and industry accelerates breakthroughs in fields such as nanotechnology, material science, energy and translational medicine. Drugs invented in Leuven and now on the pharmaceutical market include tPA (Genentech), Jetrea (Thrombogenics), and Tenofovir (Gilead). "It is imperative to have a technology transfer office," says Torfs. "If you don't do that, it may be that fundamental research (in some fields) won't function well anymore…and the university risks isolation," says Torfs.

At the core of LRD's success is the creation of a well-funded, expertly staffed organisation, with its own financial service and its own legal service, dedicated to serving the academic community. "We stand with one leg in the market and one in academia. You can't run a TTO the way you run a faculty or department. So it's a strange thing in a university. That's one thing KU Leuven understood early on," says LRD General Manager Paul Van Dun. LRD has statutory autonomy, as does the University of Leuven Hospital. "That's very important for people in industry," adds Van Dun. "There's consistency and continuity. We can stick to what we say."

Maintaining a balance between the three goals of the university is key, says Torfs. Of course we are proud about our LRD division and we want to foster it … There is of course a risk of neglecting fundamental research. There should be no contradiction. Some people say it should be A or B but that's not the case. It's a matter of a good equilibrium."

10 steps to a successful TTO launch:

There is no one-size-fits-all model for structuring and growing a successful TTO. Each university must adapt best practice to its own culture and legal structures, say technology transfer experts at KU Leuven. By studying successful models, a university can begin to shape an approach that is best suited to its academic community, research strengths and history.

The operating principles and strategies listed below have guided the creation of LRD's structure and technology transfer practice, contributing significantly to its success.

1. Start at the top with strong commitment by university leaders

The cornerstone of a successful university TTO is the strong personal endorsement and support of its rector or president. Academics typically are not inclined to collaborate with industry and promoting technology transfer involves a significant change of culture as well as a reorientation of university priorities and funding. University leaders must signal that the role of the university is broadening, address academics scepticism and actively win buy-in before a new TTO is launched.

A newly created TTO is unlikely to succeed without a committed rector, says Van Dun. "No matter how good the research, how much money you have, no matter how much industry is interested, if you do not have full endorsement from the top of the university, creating a successful TTO will be very difficult," he says. "And I really mean really difficult." Van Dun traces the success of LRD to a series of rectors who had successfully worked with industry and believed technology transfer should become a core activity of the university.

Universities without any technology transfer experience will likely face opposition to the notion of launching a TTO. How should its leadership respond? "First of all never close a path when there is even a small chance [there] can be some agreement for the future. Remain open minded," advises Torfs. "Second, create trust—first of all within [the] institution so that you don't alienate a percentage of the university while trying to foster technology transfer. And third, don't be afraid. You need courage for the first and excellent communication for the second."

Many professors and researchers underestimate the potential use of their research simply because they don't think about technology transfer, Torfs says. University leaders can promote a shift in behaviour by helping academics understanding that a technology transfer office will help them reap the benefits of their own research efforts without losing it or selling it to big companies or entrepreneurs for almost nothing. "That's indeed something [that] should be fostered by helping academics valorise their breakthroughs," he says.

Once the TTO is established, it should seek out eminent professors who have experience collaborating with industry and create a couple of initial success stories, which will help establish credibility, understanding, and interest among researchers. In 1972, LRD set to work with a cadre of distinguished KU Leuven professors who were leaders in their fields. Together with the strong backing of university management, the engagement of prominent, highly respected professors and their initial success stories helped reduced academics' scepticism and galvanise interest in technology transfer. "Make sure a couple of well-respected professors set an example – it doesn't have to be a huge financial success," says Van Dun.

Over the course of time, KU Leuven's leaders have intervened repeatedly to evolve its structure and funding. During the 1990s, as KU Leuven's revenue stream from technology transfer started to rise significantly, university management took the opportunity to reinforce the LRD's autonomy and funding. "For this institution, tech transfer is not only something that has been going on for more than 40 years, it is really embedded in this institution," says Van Dun.

Reflecting the importance of technology transfer at KU Leuven, university management recently revamped its categories for evaluating and funding research projects across all fields, from a system with many categories to a simple three-tiered approach: fundamental research, applied research (where basic research and possible applications meet) and the valorisation of research. "People can be in only one of those three levels. It's much simpler than in the past," says Torfs. "It's very helpful."

Previously, projects were judged on their size and a complicated patchwork of additional conditions. The underlying idea of the new structure is that it is based on the stage of research, says Torfs, from basic research to valorisation with an intermediate level. "That helps people to see more clearly what they are doing."

2. Dedicate sufficient funding

Technology transfer can generate an enviable stream of income for a university and increase its financial autonomy. But getting to that stage requires significant investment and time. A newly founded university TTO may not reach breakeven for 8-12 years, Van Dun says, and some may take even longer.

Even if a TTO is lucky enough to sign several licensing contracts, for example, licences typically take years to deliver significant income. "Our most successful licenses in terms of revenues today, are based on inventions [in the] 1990s," Van Dun says. "You might have licensing fee or milestone payment up front. But the big money kicks in when the product is on the market." Of course, the delay generating real returns can be particularly long in the case of translational medicine.

As a result, a university committed to developing a TTO must dedicate part of its budget to the task. Inevitably, that means channelling funds away from research and education to tech transfer—a very difficult debate at a time when budgets are under pressure. "You cannot do tech transfer and hope that industry brings in the money," Van Dun warns. "That's not how it works. It has never worked that way. We are fortunate here that after 40 years…the operation is self-supporting."

During the first 10 years of LRD's operation, KU Leuven granted it a budget to hire several seasoned technology transfer professionals and set up an autonomous operation. "If we had to survive with a percentage of the income we produced back then, we would not have had enough of a working budget," says Van Dun.

Insufficient funding will undercut the initial success of a TTO as qualified business development talent is in high demand and expensive. At the same time, a small staff will be limited in the number of researchers it can ably serve, risking a mismatch with high expectations. A TTO can take a passive approach or proactive approach. It can wait for principal investigators to come to the TTO with an invention disclosure or mandatory legal intervention. Or it can seek out researchers and help them increase the value of their ideas or invention in the market, considering different valorisation options. In the proactive approach, external support can help optimise the process, says De Wachter.

Tempting as it may be, universities should avoid relying solely on government subsidies as a main source of financing a TTO. Government funding is unlikely to be sufficient and can fluctuate or dry up completely, leaving a young TTO in the lurch. Over the years, LRD has received government subsidies but they were simply added to the working budget of the university, which remained constant. So government funding allowed LRD to expand its staff and services at a faster clip.

A second disadvantage of relying on government funding entirely is the loss of independence. "First the university must make structural investments to set up a TTO," says Torfs. "You also need autonomy from the government. That's often forgotten. Governments should leave the university alone when they want to invest in tech transfer." Governments may seek to stimulate tech transfer—but their efforts are often insufficient. It's also better for the university board to provide sufficient funding and autonomy to the TTO to develop technology transfer itself—in the way it deems best, KU Leuven experts say.

Many universities make the mistake of expecting technology transfer to quickly become self-funding, paving the way for disappointment. "That's where a lot of tech transfer programmes fail," Van Dun cautions. Rectors and governments that invest in TTOs want to see results within their period in elected office, which typically is 4-5 years. "A new TTO cannot have significant results in 4-5 years unless you already have a lot of things on the plate just ready to sign off," Van Dun says.

A case in point: Several Central European universities which launched TTOs amid strong enthusiasm several years ago now are suffering from unrealistic expectations and waning support, Van Dun says. University managers are beginning to doubt the TTO mission and wonder whether they hired the right people. "That's not fair," says Van Dun. "You cannot expect results in 4-5 years."

Annual revenues from technology transfer at KU Leuven first reached €20 million in the mid-1990s, more than 20 years after LRD's founding. Today, the path may be shorter, says Van Dun, but much will depend on the engagement of university management and researchers, and the expertise offered by the TTO staff.

Today, revenues generated by LRD enable KU Leuven to be less dependent than other Flemish universities on government funding—another advantage. "It gives us more autonomy vis-à-vis the government and it stimulates the professors," says Torfs, "because for them, technology transfer is useful and profitable."

3. Ensure autonomy and flexibility

Many universities regard technology transfer as an administrative function—an office where academics must go to "get permission" to work with industry, Van Dun says. LRD is successful in part because its aim from the beginning was to help professors collaborate with industry—and it was given the autonomy to bridge two very different worlds.

"We stand with one leg in market and one in academia. You cannnot run a TTO the same way you run a faculty or department," explains Van Dun. "A TTO is a strange element in the university environment. That's something this university understood early on. We have two entities with statutory autonomy – LRD and the university hospital. "The university said rightly, running a hospital is different than running a university. The same goes for tech transfer. We operate [in a] very autonomous way."

LRD is a one-stop shop covering every aspect of commercialisation and industry collaboration as well as financial, human resources and legal services. "That means everything is done under one roof here," says Van Dun. LRD's autonomy helps in collaborating efficiently with industry. "If a company that had contact with us six years ago and contact today, they know we operate in [a] consistent way. There's continuity and consistency, which is very important. We can stick to what we say," says Van Dun.

LRD's independence allowed it flexibility to adapt to a changing external environment and opportunities. "If I would have made a job description of my own job 10 years ago, probably only 30 percent would still be valid today. You see so many opportunities, and if the TTO is autonomous, you have the ability to jump on them. We've set up several schemes here in [the] university, several joint structures with other parties which were not in our job description. But when we saw the opportunity, we said we have to do something."

Rigid structures above all can undermine a TTO's ability to best serve academics. "That's in my eyes the difference between a successful and less successful tech transfer office. As soon as you reduce your job to rubber stamping—namely the TTO is the office that has to check agreements with industry, and get a rubber stamp—then you reduce it to a controlling function. And that's exactly the place where you do not want to be as a TTO," says Van Dun.

"As soon as you are perceived by research community as an administrative office, you might as well the close the doors because you will not be able to do the job that way," he adds.

Granting a university TTO legal and operational autonomy could create controversy. KU Leuven addressed that issue by ensuring that LRD's operations,

however independent, came under the umbrella of one university, says Torfs. "It doesn't create conflict as long as it remains clear that LRD follow the global values of the university. The same is true for the hospital."

4. Create a clear mission to serve

LRD was founded with a strong service culture, dedicated to helping researchers advance their work and reap benefits from it. That focus has played a key role in helping win over university researchers and promoting technology transfer at KU Leuven. "We give great service to the academics," says Van Dun. "We are a service unit—the only reason we exist is because professors want to work with us."

KU Leuven's professors see the LRD as a place to go for help connecting with industry on every level and help advising them on the best way to do it. "They like to come to use because they know we can get things done," says Van Dun. "We will help them quickly and facilitate their research. They look at LRD in a totally different way."

In addition to technology transfer services, LRD helps professors with many tasks that do not directly produce income for the university but help academics advance their research. For example, LRD staff process 800 material transfer agreements a year which are legally required if a KU Leuven professor wants to use a cell strain or software developed in another university for an experiment.

"We have one person working from morning to evening dealing with only material transfer agreements. For us, it is very important to process them swiftly because it is very important to the professors. We don't make a single penny with it. That's why we decided to offer the service—so they come to us. It helps to get them in our office and then we learn more about the work they are doing.

"Most researchers no matter how much they like us will not pick up [the] phone and tell us I am working on a certain topic. By being in regular contact with academics for a variety of things, LRD receives an automatic flow of vital information that increases their efficiency. It means we have early view and buy-in on what they [are] doing. [It's an] important signalling function," says Van Dun.

For Van Dun, one word sums up the role of a university TTO: "We are a facilitators. That is the culture of a successful TTO. We are the ones professors can go to. We are the ones that go to them to help them get the research to market. We make sure the benefits they get from bringing their research to the market can be reinvested in their research. That closes the loop."

LRD staff also act as catalysts helping connect different KU Leuven departments with each other. In one instance, Van Dun's team connected a KU Leuven biologist with the head of the intensive care unit of the university hospital after realising that neither one knew of the other's work, but both were working on complementary research.

"We brought them into contact and they developed a joint research programme. For me that is also a way of tech transfer. Don't forget, every university divided and subdivided in faculties and departments. Especially if you are sizeable university like ours – not all professors know each other let alone what research [is] going on. Tech transfer is one of [the] few functions within a university where you have overview on everything going on in the university.

"If we can connect the dots over barriers of departments that's usually something quite liked by the professors because it advances their research. Again, in [the] short term, when doing so, probably this is not bringing in significant commercialisation opportunity. But it helps professors and maybe the outcome of their research is good and then there may be something that could be commercialised.

5. Offer incentives - A winning formula for academics

A clear factor in the success of LRD is the strong incentive KU Leuven created for researchers to engage in technology transfer. Eighty-three percent of the revenues generated by licensing, patents, collaborations or spin-outs flows back to KU Leuven's academics to invest as they see fit in research-related expenses, including lab equipment, lab technicians or a new computer.

"You need to have an incentive for researchers to engage in technology transfer, especially in universities that have no tradition working with industry," says Van Dun. In the case of KU Leuven, the funds are held in accounts owned by the university but the professor holds the authority for investment. "That is a very, very motivating factor," he adds.

"It makes a huge psychological difference," agrees former LRD Innovation & Investment Manager Hannes De Wachter, now managing partner of 3helix.be, an international technology transfer consultancy and business development company. "Consider the university as an umbrella with many virtual companies managed by its principal investigators (PI) in collaboration with the TTO. The PI is the virtual CEO of this company. He is able to manage his own R&D funds, increase research staff, expand infrastructure and even pay himself a bonus."

KU Leuven itself receives 17 percent of technology transfer revenues to cover overheads, half of which are channelled back to fund LRD's operations.

At the same time, the LRD funding mechanism empowers professors to demand excellent service from LRD. In the mind of the professor, the revenues are generated on the basis of their research results. "That means, if we take part of the turnover, because it is our working budget, every single professor will look at us and say, "'You get part of my money, make sure you help me because I'm paying you,'" says Van Dun.

"That's an atmosphere I like. It keeps our people sharp–we cannot offer poor service to the professors because immediately there would be a broad level of complaint. It prevents our people from becoming, some kind of lazy civil servant who thinks he or she has a job for life," he adds. "The professors really feel they are the ones who should be served."

6. Hire experts with knowledge of industry and academia

Finding the right people to launch a university TTO can make the difference between success and failure. "Expertise is absolutely critical, especially when you are starting out," says Van Dun. Above all, a TTO needs people who understand both industry and academia and who can talk to both professors and managers. Experienced, senior-level staff establishes a TTO's credibility.

"You want researchers to develop an automatic reflex to contact the TTO as soon as they have something to commercialise," says De Wachter. That reflex grows from trust.

By contrast, staffing a new TTO with people who have no experience in technology transfer is likely to prove disastrous. The first interactions between the new TTO and professors will establish its reputation on campus and negative feedback will severely undercut trust and credibility, says Van Dun. "Professors who dare to take the first step and explore tech transfer will never come back if they are served by people who are not capable. And they will spread the word that the advice the TTO gave was bad—that they drafted a bad contract or said things that were not true," he says. "When you start out, you only have one chance."

If trust is missing, researchers may simply deal with industry on their own. "That often results in sub-optimal valorisation or plain out damage control," says De Wachter. "From a legal and financial point of view, contracts should pass through the TTO. You do this by providing good service"

Operating a professional TTO requires a bare minimum of three people, says Van Dun. Ideally the three should be experts who have worked both in academia and in industry, including a generalist who knows "a little bit about everything" including how to "negotiate with a company and how contracts are written."

Two of the staff should focus on collaborative research broadly, including everything from small consulting agreements to setting up meetings with industry between a specific professor and a company. They should also visit companies and ask what is needed and what kind of services the university could perform. Ideally, one would be a little more specialised, for example in medical technology if this is an important segment in your university.

LRD started with 2.5 full-time staff equivalents in 1972 and today it employs 85 people, of which roughly half are support staff and half are doing pure technology transfer. Ultimately, the investment in human resources will depend on the size of the university and the number of disciplines covered, Van Dun says. "It's impossible to run an effective TTO for a wide variety of disciplines with one or two people." KU Leuven, for example, has 1500 principal investigators.

The intellectual property (IP) and business development staff totals 10. All have had education in IP and several have backgrounds in medical technology and ICT. Their role is to identify deals and collaborative opportunities. They talk with researchers to understand what they are doing and with industry to understand where there is a possible fit.

LRD's spin-out department has a staff of seven. Nurturing spin-outs is something the university and the government like to see, and it is time consuming.

LRD employs five legal experts and Van Dun insists all must have dealmaker skills. "Of course, they need to know the law. But I need negotiators and facilitators in the first place. And that's the kind of person that will be respected and appreciated by the professors. They want to see deal makers who tell them how a collaboration can be structured and what is needed—someone who says, maybe if we twist the proposal this way, we can ask for a higher budget than the one you proposed."

Roughly half of LRD's staff work on finance, structuring and administering collaborations and other issues such as material transfer agreements.

7. Walk before you run: focus first on collaborative research

Many tend to think about high-flying spin-outs as the ultimate aim of technology transfer, but the vast bulk of TTO activity at LRD and other highly successful TTOs remains collaborative research. And newly founded TTOs should focus on working with industry.

"Tech transfer does not start with creating spinoff companies. It starts with developing affinity with industrial partners," says Van Dun, noting that it is far easier to start out with collaborative research than creating spinoff companies. "It doesn't make sense to create a spin-off company if a professor doesn't know how a company works, has never done consulting and has never worked with a company."

Nonetheless, professors approach Van Dun from time to time and propose setting up a company based on their research. "If he or she never worked with industry before, a spin-out is suicide," he says. "It is not a coincidence that only after 20 years, we created venture fund at KU Leuven." Collaborative research also produces the greatest stream of revenue for LRD, says Van Dun.

8. Seek (or create) expert partners that will really make a difference

A university TTO can benefit from partnerships and networks but should build them selectively. The following LRD partners highlight relationships that have helped LRD develop successfully.

Leuven Inc. Innovation Networking Circle (http://www.leuveninc.com)

KU Leuven cofounded Leuven Inc. in 1995 with another Leuven based technology institute, Imec, and several companies and financial institutions to help strengthen the bridge between researchers, high-tech entrepreneurs, industry and investors in the fields of micro-electroncis, engineering, health and medical technology, ICT, life sciences food and materials.

"It was a private initiative," says Van Dun. The co-founders hired one person to run Leuven Inc. full time and set up meetings between academia and industry." Leuven Inc.'s Chairman is Koenraad Debackere, managing director of KU Leuven R&D. Board members also include a VC senior investment manager and the corporate research managers.

Leuven Inc. organises small events focused on specific research topics as well as seminars for up to 200 people. The small events, which draw 20-30 experts together from research and industry, are particularly productive, says Van Dun. "If you have couple of hours where industry and university researchers are talking together about a topic of common interest, the likelihood of getting a research contract at such a meeting is much higher than when there are 300 people in the room."

Leuven Inc. also organises a monthly entrepreneurship café either in a university department or at a company, including an informal talk or a discussion on very specific themes such as stem cell therapy followed by a tour of the lab or facility and then an informal sandwich-and-beer happy hour. "We can see in reality that some of the contracts we conclude in

industry find their origin in these meetings," says Van Dun. And it doesn't require a lot of work to bring people together, he adds.

Leuven Inc., which has a board of seven founding members, did not seek or receive government subsidies and was profitable from its launch. "The aim of Leuven Inc. is to bring academics and industry managers in touch with each other. Almost all the creative input and work comes from the person who heads Leuven Inc. She is constantly chasing opportunities to put our research in the spotlight—that's the kind of person you need," he says.

"We believe in a bottom up approach—in getting people around the table with common goals," says Van Dun. Networks organised only top down may have ambitious goals, he says, but "at the end of the day, it boils down to whether professors are really participating—whether there are 2 or 3 who like to work with each other," says Van Dun. "Professors are not going to do research because there is a network. They will not reach out to industry because there is a network. Building networks is very useful if it builds on strengths that you already have, not the other way around. Sometimes [a] top down approach is too disconnected from what can be done on the floor."

Professional technology transfer associations offer expert advice in setting up a university TTO, developing best practice, and training staff, says Van Dun, who has worked closely with ASTP-Proton over the years. All the new LRD employees attend ASTP-Proton's three-day introductory training course, Fundamentals of technology transfer, which is organised twice a year.

ASTP-Proton
(http://www.astp-proton.eu)

ASTP-Proton is a not-forprofit European TTO association that seeks to establish and exchange best practices for knowledge and technology transfer and train professionals. It hosts seminars and offers a service to assess and help improve existing TTO operations. ASTP-Proton, the result of the merger of two EU TTO associations, also collects and publishes data and success stories. Proton was created in 2003 with financial assistance from the European Commission and became self-supporting in 2007. The next introductory course on the Fundamentals of Technology Transfer takes place September 23-25 and is in Leuven.

PraxisUnico
(http://www.praxisunico.org.uk)

PraxisUnico is a UK TTO professional network. Also the result of a merger, it focuses on best practice in the commercialisation of academic and public sector research. Services include workshops and seminars. Members include 120 universities, 60 corporate members, VCs, angels, patent agents and government agencies and charities that fund research.

Private third-party IP and business development partners—the virtual TTO
Creating a successful TTO is a long-term challenge and investment and business development activities require significant expertise. "Universities with limited resources may find it preferable to outsource business development by partnering with private companies that offer the services of a virtual TTO," says former LRD Innovation and Investment Manager De Wachter.

One successful model is the UK-based IP Group Plc, which has invested in 90 university spin-outs from partner universities. Since its 2003 listing on London's AIM stock exchange, it raised €175 million of net proceeds and manages a pool of €120 million to invest in technology transfer at 12 partner universities.

While top tier universities have the resources to invest in a highly professional TTO, De Wachter says, others may lack the resources or the full endorsement of university leaders to commit sufficient funding. "Usually, there is a lack of resources at the beginning. This is the Catch-22. Everyone thinks they should go for technology transfer, but it's hard to get started given the long-term investment horizon and unknown return on investment. You need a minimum team of senior people with TTO experience, and this can be difficult and expensive," to do internally, De Wachter says.

Another element that can prove thorny in setting up a TTO is establishing legal autonomy to enter into contracts with industry, which is a key aspect of best practice. "This is an element where you can run into some walls in the university structure," De Wachter says. "In general, it takes a lot of customising and tailoring of the strategy to reach milestones in a university setting, just because of the way universities are managed and structured." There can be a lot of inertia, for example, if decision-making powers have to be reconsidered.
If university management is reluctant to establish an autonomous TTO, partnering with a private third-party IP developer may be an effective alternative. For one, implementing a decentralised structure for a university TTO is often challenging. "This is a strategy that most universities have a lot of difficulty embracing. It requires a shift from central power to a decentralised model," says De Wachter.

"From a practical point of view, a TTO could spend a lot of time trying to implement a best-practice structure. Or, you could say, we are going to outsource this tech transfer activity…to capitalise on momentum and secure a minimum level of service quicker. A third-party TTO can provide business development resources, access to venture capital, and guarantees to ensure a minimum service level."

9. Set up a seed fund only after everything else is working

KU Leuven launched a university seed capital fund, Gemma Frisius Fund (GFF) in 1997 as a joint venture between the university, the KBC Group and BNP Paribas Group. The goal of the fund is to support the creation and growth of KU Leuven spin-outs.

Van Dun notes that the seed fund was set up 25 years after the launch of LRD. "Yes you need partners to create a seed fund," says Van Dun. But above all, you need an existing entrepreneurial eco-system to attract co-investors. "It is not a coincidence that KU Leuven created a venture fund 20 years after it set up the TTO," says Van Dun. If we had tried to create a venture fund at end of 1980s or early 1990s, it would have been a failure—I'm absolutely sure. Because the company ecosystem was not yet there."

Instead of co-founding a seed fund, a university could also simply partner with an existing one: "If there's an opportunity to link with a seed fund, definitely go for it," says Van Dun. "But bear in mind that it's a Catch-22. VCs and angel investors are usually only interested if you have sufficient deal flow.

It's very difficult to get investors hungry to set up something with no track record or deal flow."

Van Dun advises universities with limited staff resources to invest in staff that will develop contract research as opposed to spin-outs. "It's much harder to do spin-outs. You need management capital and mature projects. Consulting and contract research much more within reach."

Once a university has established a vibrant start-up, reaching out to investor groups and venture capital networks is useful. "I try to attend meetings [with] people in [the] investment community. All the people in my office dealing with spin-outs have contacts with investors. If someone meets an interesting investor, we spread the word through out the office. So everyone is aware."

KU Leuven also has hosted for several years the Benelux Venture Forum – a private initiative connecting 60-70 high tech investors with early-stage companies, including a match-making event where young companies can present themselves in a speed dating programme and then engage in follow-on meetings.

LRD also is connected to the Business Angel network for the Flemish regional (Business Angels Netwerk Vlaanderen) and regularly sends projects for review.

10. Tout your success

Part of a TTO's role is marketing its achievements. "You need to tout every little success you have," says De Wachter. "Whether it's closing a licensing deal, helping win a competitive grant, or creating a spin-out, spread the news widely among various stakeholders in university, industry and university management."

Forty-two years after its founding, LRD still spends a great deal of time making its successes visible to KU Leuven researchers. That's because creating in academics a mentality open to technology transfer is "a trickle-down process that takes time," Van Dun says.

LRD's offices showcase successful KU Leuven inventions and technologies now on the market. "It doesn't have to be next Google or something that brought in a lot of money. We have those," says Van Dun. Just as valuable, he says, is a simple success that helps researchers realise, "Hey, that's something my well-respected colleague did. I can do that too."

IV. Conclusions

Bridging the world of academia and industry is not easy. Building a successful TTO requires individuals who believe strongly in its mission and have the skills and knowledge to see opportunities academics do not and negotiate the best deal possible. During the course of researching this paper, experts linked with KU Leuven repeated three intangible elements in setting up and running a TTO that are vital to success: flexibility, adaptation of best practice and long-term commitment.

A successful TTO must remain flexible because technologies, markets and opportunities are constantly shifting. LRD's role has changed over the years and its staff is continually seeking new opportunities. "If I would have made a job description of my own job 10 years ago, probably only 30 percent would still be valid today—because you see so many opportunities. If you can be autonomous as a TTO, you have the ability to jump on opportunities. You can create new things and explore new collaborations," says Van Dun.

The commitment of university leaders is critical. Changing attitudes is a long-term process. The TTO is a platform to enable technology transfer. But the most important input is the interest and motivation of academics to engage with industry. Without them, the pipeline for technology transfer is blocked. "You need your professors, you need the buy-in of researchers. That is the clay you have to work with," says Van Dun.

Today, four decades since the launch of LRD, KU Leuven's leaders continue to communicate about the role and value of technology transfer. "We have a long tradition in technology transfer and we continue stimulating it—one has to foster valorisation," says Torfs.

Technology transfer "done well" benefits society and adds to the lustre of a university. "Creating a good TTO is part of creating a good university, and a necessary part," Torfs argues. "Today, you can't do without it." Yet he insists on a broad and inclusive approach that doesn't promote one aspect over another. "When company sees university just as a business partner without additional wisdom, it loses its soul. What's important is to take care of the profile of the university as a whole."

V. Case study of a KU Leuven Spin-out: Quaelum N.V.

During his 10 years as a researcher in the field of quality control in radiology at the University Hospital Leuven, Jurgen Jacobs never imagined he would run a company. Even when he and a team of researchers developed software that could measure the technical accuracy of radiology devices and improve patient safety, no one thought about creating a spin-out to commercialise the breakthrough.

"Our idea was to give away the software to other hospitals to improve quality," says Jacobs, a software engineer and computer scientist who led the research.

Jacobs is now chief executive of Qaelum N.V., a fast-growing three-year-old medical technology start-up that rapidly has become a European market leader in quality control for x-ray devices. Corporate partners include FujiFilm Medical Systems and Agfa. The company's revenues are forecast to more than triple to €1.75 million this year after growing 46 per cent in 2014.

Qaelum's successful launch highlights the role a well-run TTO can play in helping university researchers understand the commercial potential of their scientific breakthroughs. LRD, the 42-year-old technology transfer office at the KU Leuven, zeroed in quickly on the market opportunity, provided business development expertise and guidance—and helped Jacobs make the leap from academic to entrepreneur.

The first encounter: technology transfer office as catalyst

Jacobs' first contact with LRD had nothing to do with starting a company. After Jacobs together with the team of Professor Hilde Bosmans published their research results, they installed their new quality control software platform at University Hospital Leuven, and began giving away the software to other hospitals. Suddenly, a growing pool of users was clamouring for software support services and Jacobs found himself doing the work between 10 pm and midnight.

Stretched between his day job as a researcher and the exciting application of his work in a real-world setting, Jacobs proposed to the hospital's head of medical physics and quality assurance, Professor Hilde Bosmans, that he work 1-2 days a week doing professional services for the growing field of users, to maintain and extend the software—and earn a bit of income for the department.

To make sure the services were structured to avoid legal complications, Bosmans set up a meeting with the TTO, whose staff quickly recognised the commercial potential of the ground-breaking software. Working 1-2 days a week on professional services made no sense, LRD staff told them, because the effort lacked scale. Jacobs should either take the technology global, they said, or remain a researcher.

"The most important thing LRD did was help us shift our mind-set," says Jacobs. "We were giving away the product for free and offering to do some services on the side. They said, 'Let's go for a company that will be successful around the world. The globe is the market.' The opportunities were much, much bigger than we imagined."

In the summer of 2010, LRD encouraged Jacobs to take a crash course on becoming an entrepreneur to learn about

Qaelum N.V. at a glance

University of Leuven spin-out:	Qaelum N.V.
Founded:	November 2011
Launch of operations:	February 2012
CEO/Researcher-founder:	Jurgen Jacobs, former software engineer and researcher at University of Leuven Hospital exploring new approaches to quality control of x-ray devices
Employees:	2012: 3 July 2015: 16 Dec 2015: 20*
Product:	Software system for quality control of x-ray machines and mammography screening devices
Business model:	Software as service (pay by volume of use). Software measures and analyses patient radiation dose and compares those measurements against growing volume of data over time to improve the system
Revenues:	2012: €28,000 2013: €372,000 2014: €542,000 2015: €1.755,000* *estimate

business plans, start-up financing and intellectual property (IP) rights. For five months, he worked at the hospital during the day and spent his evenings writing a business plan for a spin-out. Every 3-4 weeks, he met with LRD to check on progress.

From manual audits to machine learning

Jacobs was keen to develop a new market for improved quality assurance in mammography screening—following a decade of research and testing quality assurance software. The potential market opportunity loomed large—the European Union was preparing a directive that would require every European country to test mammography-screening devices and regularly report quality findings.

At the same time, Jacobs had been extending his software to other radiological devices and to patient radiation dose monitoring. He had incorporated machine learning in the software to assess the growing pool of patient data over time and generate new insights about different patient groups and optimum radiation doses. Building in intelligence enabled the software to interpret patterns in the errors it encountered.

Jacobs knew first-hand about the risk of exposing patients to a high radiation dose. When his son was born two months early in 2009 weighing 1.5 kilos, a junior radiologist told him hospital protocol required him

to do a computer tomography (CT) scan of the lungs of the two-hour old infant—even though the chest-x-ray showed no obstruction. Jacobs was alarmed by the risk of unnecessary damage to his son—from the CT scan's high radiation dose and convinced the radiologist not to do the CT scan.

The experience with his own child galvanised Jacobs' interest in patient radiation dose monitoring. Soon he and his colleagues began evaluating how many times children receive CT scans that are not needed or are scanned with completely wrong parameters and settings for a child. "That means you get beautiful images but potentially triple the dose of radiation needed," he says. Further work led to the ability to do continuous monitoring of CT examinations, capturing all the data and training the system to look for patterns and generate warnings to operators if settings did not match the patient profile.

When Jacobs presented the idea of continuous monitoring of CT examinations at a conference, many colleagues were sceptical, given the volume of data involved. But Jacobs was convinced the effort would prove beneficial. "If you have so much data, you can train the system to look for patterns," he said. "And that gives you insights."

"That was a huge mind shift," says Jacobs. "In the past, we monitored x-ray devices manually once every year and sometimes even every three years because the government said we had to do it. But if you do it completely automatically, you have a huge data set to do machine learning and analytics, and that gives you the basics to improve quality."

By 2011, Jacobs' software had the ability to warn hospital technicians that the x-ray dose was wrong. "Already, the concept was so new that it was a real selling point," says Jacobs. Instead of giving hospital staff raw data, the software interpreted the data. Further development has made the software capable of automatically signalling to technicians the statistically correct settings for a given patient taking a given exam.

Sorting out intellectual property rights

The most difficult step in creating Qaelum was negotiating who owned the IP rights to the software and securing the rights for the company. Sorting out IP issues often is contentious, especially when many researchers have contributed to the innovation, and TTOs typically lead the process. LRD played a pivotal role, Jacobs said. Finding a solution that satisfied all of Qaelum's stakeholders from researchers and hospital management to other university hospitals using the software took LRD's legal staff nearly seven months.

"The diplomacy needed at that moment is crucial, and at that point in time the entrepreneur is not in a strong position," says Jacobs. "It was good to have (LRD) in between and trying to find the best position for the researchers, the university and the other stakeholders."

Because Jacobs was employed as a researcher by the University Hospitals Leuven, the task was more complicated. "We spend the longest time trying to find an equilibrium in writing the contract between university and hospital," Jacobs said. Because he was employed by the university hospital, the technology had to be transferred by the university hospital. But since the hospital is part of

the university, the university also had to approve the IP agreement.

The previous distribution of Jacob's software for free created another challenge to sorting the IP rights. LRD and Jacobs agreed that Qaelum should buy out the technology from the university and hospital and own it outright instead of licensing it. But the hospital already had given software away to screening centres all over the country. "In our case, the biggest problem was that we had existing customers of the hospital who wanted to continue using the software. Because we were proposing to buy out the technology, there was a conflict. We had to figure out how other hospitals could continue using the software. LRD took on the role of diplomat, working to find a rights and payments agreement that satisfied all parties.

"LRD played a very objective role," said Jacobs. "If you don't have an objective party between investors and yourself as the technology expert, things can go very wrong ... LRD definitely made a difference."

Validating the technology

While the LRD experts were working on the IP issues, Jacobs set up a virtual company in the LRD incubator and began testing the market potential for Qaelum's software. The goal was to reduce the technology and market risks to the point where Jacobs could make a convincing pitch to KU Leuven's seed capital fund, Gemma Frisius.

To reduce the risk of launching the company with only one product—mammography quality assurance—Jacobs developed a second potential service on the same software platform: monitoring patient radiation doses.

Because the quality of x-ray devices degrades over time and can fluctuate, universities and hospitals must test them regularly—a process traditionally done by a physicist at periodic intervals—a subjective process with limited oversight. Qaelum's software service allowed hospitals to check radiation device quality and x-ray dose in real time, assessing the results against standard benchmarks and alerting hospital staff immediately to errors.

"LRD helped us see the full potential of the technology," said Jacobs, "and if you see the full potential to grow a business, you create a very different business plan."

Broadening the scope of the business was a smart move. Qaelum's management and its seed investors originally expected mammography screening to be the company's core product. But in 2011, as Jacobs and LRD were putting the final touches on the business plan, the implementation deadline for the EU directive was delayed, dampening the demand for mammography quality control services. So Jacobs switched Qaelum's product focus to patient radiation dose monitoring.

"In the business plan both businesses were taken into account," says Jacobs. "It was important that we had a 'Plan B.'"

Researchers often focus on a single product. "The risk is having a one-trick pony," says Hannes De Wachter, former LRD innovation and investment manager and current CFO of Qaelum.
A good technology transfer office grooms spin-outs to pivot and survive in fast-changing market scenarios. "You need to build in sufficient resilience in the IP, technology and business plan," De Wachter says.

Qaelum's Plan B entailed collecting all the information about radiation doses that a patient receives in the hospital and analysing whether the dose levels were correct. "If they was not, the software tries to understand why and how to correct future dosing," Jacobs says. The ability to analyse the findings and to develop insights from growing pool of x-ray data helped set Qaelum apart from the competition.

The quest for seed funding

Grooming spin-out founders to raise capital is another core TTO responsibility. "When you present the business case in front of a venture capital type of jury, things get serious," says De Wachter. "It helps in making the entire project very concrete—and the feedback you get is extremely valuable."

During the incubation period, LRD helped Jacobs obtain "gap funding" including a €100,000 proof-of-concept grant, to close the development gap and groom the spin-out for a pitch to investors.

With a well-honed business plan and cutting-edge technology that already was in use in hospitals, Jacobs search for a first set of seed investors went smoothly. KU Leuven's seed fund Gemma Frisius, the university hospital and a business angel together with four private individuals invested €500,000 in cash and the technology was valued at $650,000, giving Qaelum a valuation at its launch of €1.1 million.

"If your idea and plan is OK, the money will always find you," says Jacobs. At the time of incorporation, the university's 42.5 per cent stake in Qaelum was worth €488,750.

Going to market

When Qaelum launched its services on the market in February 2012, it offered a novelty—one software platform for total quality monitoring (TQM) of all devices in the radiological department of hospitals and research labs. Its software-as-service approach was more cost-effective and more reliable than traditional manual quality evaluations. Qaelum's ability to compare this data to benchmark data in real time gave hospitals a baseline against which they could constantly judge the quality of their radiation department, says Jacobs.

Traditionally, x-ray departments did an evaluation once every three years. "We try to make the quality monitoring of radiology devices a commodity that is constantly done by software," says Jacobs. "We first do a baseline evaluation. If a hospital wants to try to improve patient safety and efficiency and do an evaluation every month, they can track the impact on quality."

Qaelum's novel approach to radiation device quality assurance and patient safety helped the company win together with consultancy Deloitte a €2 million two-year grant from the Flemish Research Fund for Industrial Science and Technology. The study focuses on improving the quality and safety of radiological devices, as well as healthcare economics and workflow.

"We don't collect data just for the data. We want to create understanding of the data. By combining analytical tools and other dedicated software solutions, we try to create insights and understand what the data really mean. That's how you can optimise quality and efficiency," says Jacobs.

Though Qaelum's market prospects looked good, Jacobs wasn't taking any chances. As soon as the company was incorporated, he sprinted to make sure the company had its own quality in order, including ISO certificates. "Because we had them, the big companies wanted to collaborate with us," says Jacobs. "We started from the beginning with huge focus on quality ourselves. If want to bring quality to hospitals, we have to be quality minded ourselves."

A first success came quickly. In the summer of 2012, four months after Qaelum's market launch, Jacobs signed a distribution contract with Fujifilm Healthcare to market its software platform together with Fujifilm's database for medical images (Picture Archive Communication System, PACS).

"We needed a PACS system and they wanted to differentiate their database from other systems," says Jacobs. While the alliance with Fujifilm, which has 10 per cent of the EU market for PACS systems, didn't create a huge revenue flow, it gave start-up Qaelum "gigantic credibility," says Jacobs. "Suddenly after four months we were at all the key radiology conferences in the booth of one of the major players.

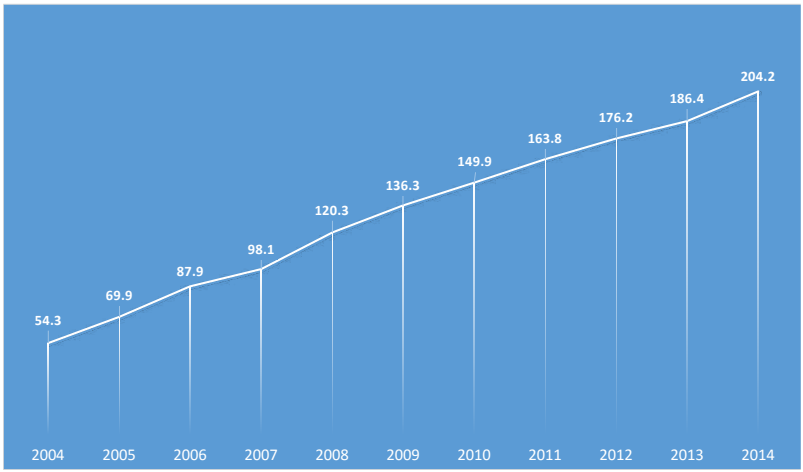
The alliance with Fujifilm helped Jacobs clinch a second contract 2012 with all NHS hospitals in the UK involving an x-ray dose database of 2.6 million patients per year—the biggest available database of its kind. Both deals gave Qaelum a giant leap in market visibility. Without it, "you are a small spin off company with 2-3 people," says Jacobs, "and no one knows you or cares about you."

In 2013, Qaelum won a global distribution agreement with Agfa, a former competitor, and together with Agfa, Jacobs is now preparing to enter the US market. "We are the only company that developed a complete and total quality monitoring tool," says Jacobs, whose rivals include giants such as GE, Bayer, Philips Healthcare and Siemens.

Today, three-and-a-half years since its launch, Qaelum's software checks radiation doses on 10 million patients a year across Europe - more than any of its rivals. "The reason to start a company is to make a difference," says Jacobs, an academic-turned-entrepreneur well on his way to achieving that aim.

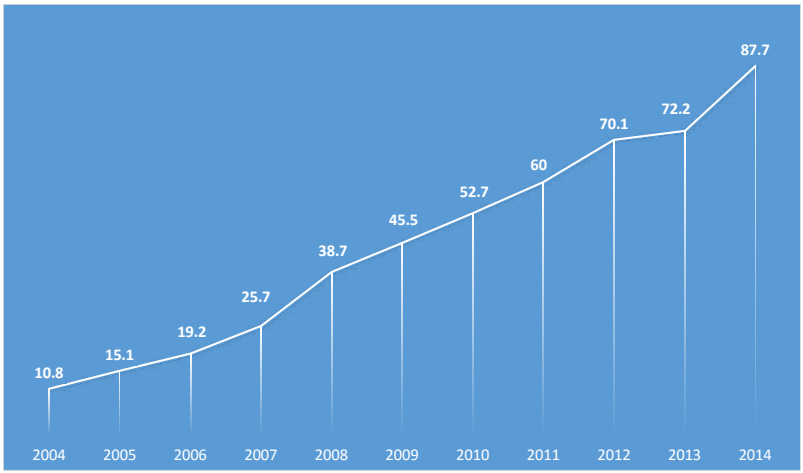
VI. Annex

LRD Total Revenues - Millions of Euros



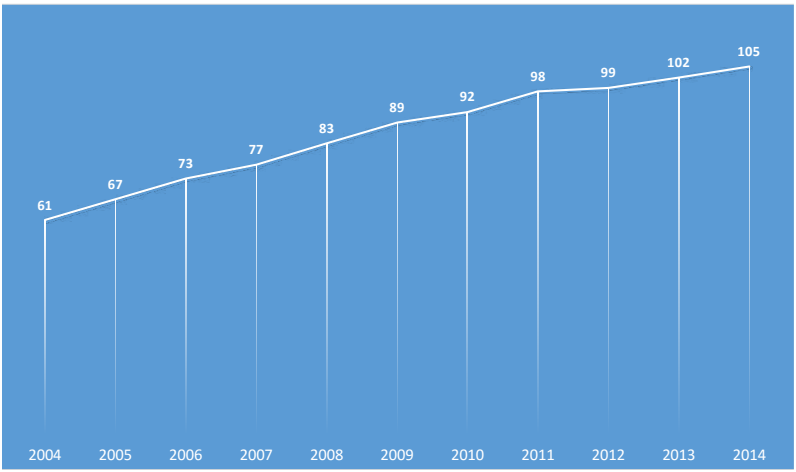
Source: Leuven Research and Development

LRD Licensing income - Millions of Euros



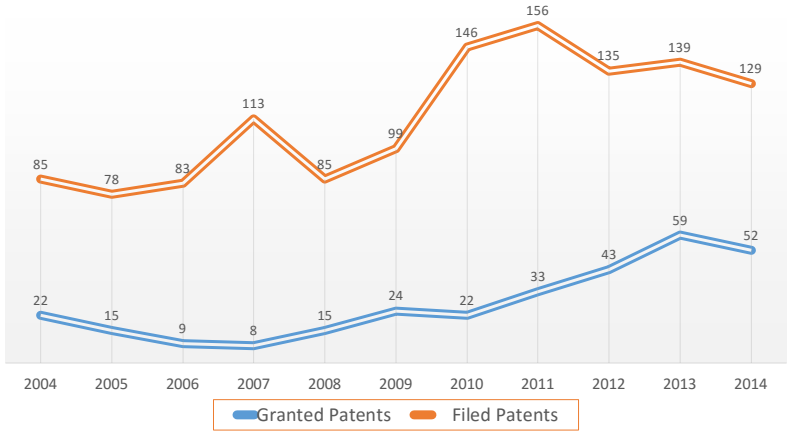
Source: Leuven Research and Development

LRD soin-outs: Total KU Leuven spin-outs with university investment



Source: Leuven Research and Development

LRD Patents



Source: Leuven Research and Development

Translational Medicine: Major drugs invented at KU Leuven

- tPA (Genentech)
- Jetrea (Thrombogenics)
- Brivudin: marketed under the names Zostex, Brivirac or Zerpex
- Rilpivirine: research and discovery done in Leuven but no patents
- Cidofovir: licensed to and commercialised by Gilead (CMV eye infections)
- Adefovir: ditto (HBV infections)
- Tenofovir: ditto (HIV infections)
- Valacyclovir: also Leuven inventors on the patent; commercialised by GSK ("Valtrex")

KU Leuven Research and Development

Founded in 1972 Employees: 82		
Three activities		
Contracts and collaborative research • 1774 new agreements per year	**Intellectual property** • 150 invention disclosures per year • More than $100 million in royalty income per year • 70 licenses per year	**Spinning out companies** • 105 spin-outs to date (only companies in which the university holds a stake) • 7 initial public offerings • 4200 direct employees
2014 data		

Source: Leuven Research and Development

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