Capacities/Research Potential
FP7-REGPOT-2012-2013-1

Project No. 316254

BASTION

"From Basic to Translational Research in Oncology"

Deliverable D5.2

Report on transfer of know-how and networking

Project start date:	1.09.2012
Project duration:	42 M
Due date of deliverable:	28.02.2014
Actual submission date:	25.02.2014.
Dissemination level:	PUBLIC

Table of content

page

Attachments:

1. Report on BASTION Roundtable FROM LAB TO CLINIC
2. Chancellor's law on technology transfer special group

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

1. Introduction

Work package 5, led by the recruited Innovation Manager Dr. Karolina Dzwonek (see D5.1 report on recruitment) and Prof. Jakub Golab, addresses project operating objective no 5:

· to facilitate and increase the impact of translational studies in oncology by

i) hiring a professional innovation manager

ii) implementing efficient IP protection and innovation management schemes,

iii) organizing joint events with London Genetics and Science Business as well as the research / academic partners to transfer best-practice in science – industry cooperation and promote innovation driven translational research.

According to the concept and project objectives Innovation Manager's main goal is to **stimulate the translational process from molecular oncology research to the clinic**.

2. Deliverable 5.2 description

Deliverable D5.2 reported hereby corresponds to the task T5.2 in WP5. The aim of this task was to facilitate and increase the impact of translational studies in oncology by acquiring know-how from and initiating sustained cooperation with experienced SMEs focused on technology transfer and commercialization.

3. Task performance

Innovation Manager (IM) started her work on April 1st 2013. She has begun with focusing on several key issues to set innovation in motion within the BASTION project and the Medical University of Warsaw (MUW) in general. The first activities were **interviews with all BASTION group leaders and deep analysis of their research** results and plans in order to:

- identify possibilities for intellectual property (IP) protection,
- asses applicable potential of current research,
- plan future experiments more focused on possible implementation,
- make researchers aware of IP issues.

3.1 Trainings and workshops

Additionally IM has prepared **special trainings** for BASTION groups (Apr 15th) and for Department of Immunology (May 6th) on IP rights protection and commercialization. Up till now, IM has ran several preliminary patent searches on the inventions discovered by the BASTION researchers. She has started a close cooperation with patent attorneys and with Polish Patent Office. As a result of this

activities two patent applications from the BASTION researchers has been filled in Oct and Nov 2013 and two following are currently being prepared.

Moreover IM has ran two workshops for MUW PhD students and researchers on IP rights protection and commercialization of the research results ("Nauka w parze z biznesem" *Science to business*) on Oct 24th and Nov 7th 2013. IM provides ongoing support for MUW scientists that need advice in the subject. In order to **build closer cooperation between MUW and Cancer Center** IM ran similar training for the researchers of Maria Skłodowska-Curie Institute of Oncology and Institute of Hematology and Transfusion on Oct 9th.

3.2 Technology transfer at MUW

Extending her activities in the university IM got **involved in implementing new management schemes concerning technology transfer at MUW**. There has been designated a special working group, by the university Chancellor and deputy Rector for Science and International Relations, in September 2013 (attachment 2). The group included also:

Mr Jacek Sobczak, MUW legal representative,

Ms Beata Piekutowska, Head of Center for Preclinical Research and Technology (CePT) office,

Ms Anna Urbańska, MUW International Relations office.

The goal of the group was to evaluate the strategy for technology transfer at the university. IM has made **preliminary analysis of the MUW innovation potential** pointing out the key steps that should be undertaken at the university to make technology transfer possible. She pointed that there are no established, clear procedures at MUW supporting innovation and technology transfer. The processes are complicated and there are no clear guidelines for researchers who made a discovery. There is no motivation system for scientists that would encourage them to run applied studies and apply for translational research grants. There is no innovation management and no innovation understanding whatsoever. In the **report on MUW innovation potential**, IM identified the following key steps that should be considered in the first place:

1. Entrusting the overall technology transfer management to one particular person who would be well recognized among researchers, competent and with excellent communication skills;
2. Creating of database of all projects, patent applications, licenses and contracts with industry and assigning the task of database management and maintenance to one particular and committed person;
3. A shift from a procedure-oriented approach to a result-oriented one. Of key importance would be the adjustment of all regulations to the expectations of technology transfer process

stakeholders (the scientists, inventors, entrepreneurs and industry) to maximize the chances of reaching the main, tangible objectives;

4. Providing researchers with simple templates for Invention disclosures, CDAs, MTAs, contracts with industry, etc.;
5. Creating a "user friendly" environment for researchers with clear rules and simplified procedures;
6. Building trust internally within the organization (in particular between the administration departments and the researchers);
7. Stimulating translational research through a proactive approach and providing support in planning, preparation and execution of applied / translational projects;
8. Implementing a motivation system for researchers with affinity for technology transfer that would support their attempts to run translational studies (plan research and apply for funding) and recognize their accomplishments;
9. Monitoring and support for running projects with regular results evaluation by the person responsible for tech transfer

3.3 Consulting technology transfer professionals

To **implement good practice in technology transfer into MUW regulations** IM has consulted and started cooperation in this field with several technology transfer professionals. There were two SMEs indicated as WP5 partners in the project – Science|Business and London Genetics as well as BTM Mazovia Cluster. As London Genetics had been taken over by another company and its expert Elisabeth Foot is no longer available for cooperation, IM has 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 to find out about each other and organizes several events a year gathering top level professionals and decision makers, including members of the European Parliament and European Commission representatives. The company, based in London and Brussels, is run by leading technology journalists, including former managing editors of the Wall Street Journal Europe and Nature.

3.4 Workshop with Science|Business

Fulfilling the subtask:

> *Organization of events and cooperative efforts involving case study analyses, training seminars and workshops co-organized with the partnering institutions experienced in the area translational research and transfer of technologies from bench to bedside*

IM, in collaboration with Science|Business, organized an International Workshop on best practice in technology transfer, innovation management, spin-off creation and translational research in oncology brought to the bedside. The workshop *BASTION Roundtable FROM LAB TO CLINIC* took place on June 4th 2013, in the European Parliament (EP), Brussels.

BASTION roundtable

By invitation only

From lab to clinic
Best practices in translational medicine & innovation management

Preliminary programme

09:30 - 09:45	**Opening and Welcome address** • Sławomir Majewski, Deputy Rector for Science and International Relations, Medical University of Warsaw • Jakub Golab, BASTION Project coordinator, Head of Department of Immunology, Medical University of Warsaw
09:45 - 11:00	**Case studies of commercialisation of research results** Overview: • Olivier Lescroart, Intellectual Property, K.U.Leuven R&D Oncology: • Marcin Szumowski, Head of International Cooperation, Nencki Institute; Business Development Director, BTM Mazowsze Ltd. Cluster Regenerative medicine: • Daniela Couto, Co-founder and CEO, Cell2B; 2012 ACES finalist Neurology: • Sabine Bahn, Director and Co-Founder, Psynova Neurotech; 2011 ACES winner Perspective from a large company: • Ludo Lauwers, Janssen Pharmaceutica (tbc)
11:00 - 11:30	**Coffee break**
11:30 - 12:30	**Barriers to translational research in Europe: what are the challenges? What are the solutions?** *Open discussion* Main discussants: • Magda Chlebus, Director Science Policy, EFPIA • Iordanis Arzimanoglou, Strategic Advisor, Genomedica; former CEO of Biomedico Forum/Aarhus biocluster, Denmark; former CEO of Thessaloniki Innovation Zone, Greece • Jacek Sobczak, Head of Academic Center of Innovation, Vice Director of Legal Office, Medical University of Warsaw • European Commission guest (tbc) *A list of recommendations will be reported after the event by Science|Business.*
12:30	**Closing remarks**

The discussion will be moderated by Science|Business

Honorary patron

Jerzy Buzek
Member and former President, European Parliament

Featured guests

Magda Chlebus
Director Science Policy, EFPIA

Jakub Golab
BASTION Project Coordinator; Head of Department of Immunology, Medical University of Warsaw

Olivier Lescroart
Intellectual Property, KU Leuven R&D

Sławomir Majewski
Deputy Rector for Science and International Relations, Medical University of Warsaw

About BASTION

BASTION - From basic to translational research in oncology

BASTION is an FP7 funded project aiming to strengthen research potential of the Medical University of Warsaw (MUW) in the field of basic and translational oncology. This objective will be achieved through a series activities in several operating areas:

- initiating cooperation with researchgroups from leading European research laboratories and top innovation-driven commercial partners;
- fostering exchange of scientific ideas and know-how by organising workshops and international conference focused on molecular oncology;
- establishing a bioinformatics group focused on personalised medicine and strengthening the project team by recruiting experts from the area;
- strengthening research capacity by acquiring modern research equipment;
- creating a pro-innovative environment supporting practical implementation and dissemination of BASTION research to raise awareness of basic and translational oncology;
- generating economic impact and improving quality of life.

Other research partners in the project include KU Leuven, Karolinska Institutet, Radboud University Nijmegen, University College Dublin, University of Cologne, University of Verona. Science|Business provides support and expertise to the BASTION team in the fields of online communications and organisation of high-level networking events.

For more information about BASTION project, please visit
bastion.wum.edu.pl

source: www.sciencebusiness.net

The event aimed at experience exchange between MUW and KU Leuven (KUL) by presentation of case studies concerning commercialization of oncological research and roundtable discussion of experts. The workshop was dedicated to MUW and KUL scientists and technology transfer professionals. There were 8 participants from MUW taking part in this event, including BASTION project coordinator Prof. Jakub Golab and MUW deputy Rector for Science and International Relations Prof. Sławomir Majewski. Among speakers there were EP members and the director of EFPIA, providing an important input in the discussion. The honorary patron of the initiative was Prof. Jerzy Buzek, former President and now a member of the EP. For the full report on the event please see the attachment 1.

3.5 Cooperation with Leuven Research & Development

Additionally to BASTION Roundtable organizing, IM had been working at Science|Business office from June 24th until July 20th 2013. She was engaged in all activities of the company at the time of her stay, including networking, organizing events, data analysis and marketing. During her stay IM took the opportunity and started collaboration with Leuven Research & Development (LRD) - one of the leading university technology transfer units in Europe.

IM visited LRD facility in Leuven, and consulted Mr Olivier Lescroart, intellectual property specialist at LRD, about insights into technology transfer process at university.

LRD was founded in 1972 to manage innovation at the KU Leuven university. It consists of central multidisciplinary staff, that supports researchers in knowledge and technology transfer, and research divisions. LRD unit provides intellectual property rights protection, research results commercialization and spin-off creation. LRD also coordinates scientific collaboration and manages contracts on research and services between KU Leuven research groups and companies or governments. It is engaged in stimulation of entrepreneurship through network initiatives and actively supports regional development.


Olivier Lescroart

Mr Lescroart shared his experience in creating awareness and transferring knowledge at LRD, the key issues that IM is dealing with at Medical University of Warsaw. He told about his activity within the Intellectual Property division at LDR, that provides:

- assessing the feasibility, patentability and market potential of an invention,
- determining a protection strategy,
- drafting and filing a patent application,
- following up on patent procedures and costs,

- negotiating and drafting NDAs, MTAs and license agreements,
- finding industrial partners.

In 2012, LRD activity provided 103 million euro income from research collaboration (including 71 mln from licensing) and 1,700 new agreements. The office manages 571 active patent families and, only in 2012, filled 135 patent applications, including 40 in PCT procedure. LRD also created 100 spin-outs, of which 84 are still active enterprises. It is clear that LRD comprises an example of the best practice in the field.

Consultations with Mr Lescroart were an excellent starting point to develop strong cooperation with LRD that can provide top level expertise in technology transfer. It would be of great importance to implement gold standard solutions in this field into MUW.

3.6 Cooperation with BTM Mazovia

From the beginning of her work in the project IM has been building close relationship with BTM Mazovia, specialized in tech transfer, IP valuation and licensing. BTM provides support and expertise for advanced projects with the potential for implementation. IM takes an opportunity to discuss current activities and projects with BTM on regular meetings (every two weeks on average). The cooperation is smooth and directed in both ways - IM became a member of the BTM board of experts on biomedical technologies http://btm-mazowsze.pl.

3.7 Cooperation with Ochota Campus technology transfer professionals

One of the common activities of IM and BTM, aiming at knowledge sharing and experience exchange, was organizing a debate of all technology transfer professionals from Ochota Campus, including BTM Mazovia professionals. The meeting took place at MUW and was very well perceived by all invited guests. There was a long discussion on the key obstacles that all professionals meet in their institutions and how they deal with them. As appeared, there is a strong need for inter-institutional collaboration and common support in the field of tech transfer. The meeting resulted in forming an informal group of tech transfer specialists and creating a common mailing list (ochota-na-transfer@googlegroups.com) to facilitate contact between members:

Institution	Represented by:
Biotech-IP, International Institute of Molecular and Cellular Biology	dr Leszek Lipinski Magdalena Powierza dr Adam Sobczak
BioTech-IP, Institute of Biochemistry and Biophysics, Polish Academy of Sciences	Hubert Ludwiczak

BTM Mazovia	Dorota Gierej dr Andrzej Kusmierz Pawel Nowicki
Institute of Fundamental Technological Research, Polish Academy of Sciences	dr Jacek Kuciński
Medical University of Warsaw	dr Karolina Dzwonek Beata Piekutowska Jacek Sobczak Anna Urbańska
Mossakowski Medical Research Centre, Polish Academy of Sciences	dr Joanna Kowalczyk
Nałęcz Institute of Biocybernetics and Biomedical Engineering, Polish Academy of Sciences	dr Hanna Goszczyńska
Nencki Institute of Experimantal Biology, Polish Academy of Sciences	Marcin Ciuk
University of Warsaw	Piotr Musiał Renata Olejnik
Warsaw University of Technology	Paweł Zych

The group agreed to meet once a month if possible, in order to exchange experiences, to support each other in their activities and to foster networking.

3.8 Events on IP protection and science-business cooperation

For the networking reasons and for acquisition of higher skills IM **actively participated in several events and workshops concerning IP protection, IP evaluation and science-business cooperation:**

1. XVIII National Conference on patent information for science and industry, organized by Polish Patent Office (Warsaw, May 13-14th 2013)

This edition of the conference was focused on good practice in cooperation between IP specialists and the inventors. The issues discussed during the conference concerned IP protection strategy for

entrepreneurs, but also patent information and data bases, which comprise an important tool for IM when running preliminary patent searches for BASTION researchers.

2. 17th ECCO - 38th ESMO - 32nd ESTRO European Cancer Congress (Amsterdam, Sep 27th – Oct 1st 2013)

IM participated in the congress as an author of two poster presentations, presented during the session "Drug Discovery" on Sep 29th. During the conference IM had several business talks on possible cooperation between BASTION research groups and pharmaceutical companies. She also aimed at getting to the right people within the companies, in order to invite them for upcoming BASTION Pharma Day. IM spoke to the representatives of:

Amgen, Ariad, Astellas, Bayer, Boehringer Ingelheim, Bristol Meyers Squib, Exelixis, GE Healthcare (Breast Cancer), Glaxo Smith Klein, Hospira, Novartis, Pfizer, PharmaMar, Roche, SANDOZ, Sanofi, Takeda, TEVA.

BMS and Astellas are the most promising follow-ups, including their confirmed participation in Pharma Day, to be organized by IM in April 2014.

3. Practical Dimension of Science (Warsaw, Oct 15-16th 2013) organized by Mazovian Innovation Network http://www.msodi.mazovia.pl/pwn/program-szkolen.html

The conference gave the opportunity to meet specialists in the field of clusters, professionals from Academic Incubators of Entrepreneurship, that have practical experience in technology transfer and start-ups. These kind of contacts are of great value for IM as possible advisory support and as speakers during workshops planned within the project.

4. "University - Business Cooperation - Driving Innovation and Growth" (Warsaw, Nov 27th 2013) organized by European Commission in partnership with the Polish Ministry of Science and Higher Education

The Forum brought together around 200 top level representatives from relevant European organizations and associations, higher education institutions, large companies and SME's, as well as national, regional and local authorities. This was a unique opportunity to share and discuss experiences and examples of good practice, to network and to learn from one another. The conference addressed issues related to entrepreneurship and higher education, institutional change and university - business cooperation, and discussed how the current and future European programs (2014–2020) are supporting and will continue to support activities in these fields.

5. Training on Intellectual Property Valuation organized by World Intellectual Property Organization (WIPO) and Polish Patent Office (Wroclaw, Nov 13-15th 2013)

This was an intensive, high level training on IP valuation, with the participation of top level professionals and authorities, including:

Ms. Alicja Adamczak, President of the Polish Patent Office

Ms. Olga Spasic, Head of Innovation Structures Section, Innovation Division, WIPO

Ms. Silvija Trpkovska, Senior Program Officer, Department for Transition and Development Countries, WIPO

Mr. Christopher R. Noble, Technology Licensing Officer, MIT, Cambridge

Mr. Thomas Ewing, Principal Consultant, Avancept LLC, USA

Mr. Andrzej Półkoszek, IP Valuation Expert, BOMIS Company

Dr Piotr Zakrzewski, Innovation Support Division, Polish Patent Office

In light of BASTION project, a uniquely valuable contact is Christopher Noble, Technology Transfer Officer from Massachusetts Institute of Technology (MIT), one of the leading institutes in United States, putting strong emphasis on scientific, engineering, and technological education and research. Eighty-one Nobel laureates, have been affiliated with the university. MIT also has a strong entrepreneurial culture. The aggregated revenues of companies founded by MIT alumni would rank as the eleventh-largest economy in the world. The mission of MIT Technology Licensing Office is to foster commercial investment in the development of inventions and discoveries flowing from the

research at the Massachusetts Institute of Technology and Lincoln Laboratory (source: http://web.mit.edu/tlo/www/). Mr Noble has great experience in licensing of the intellectual property resulting from research and offered his advice if needed.

3.9 Pharma Day

One of the assignments within 5.2 task was the organization of "Pharma open days" in collaboration with Science|Business. The event is planned for 25th of April 2014. The venue is already booked and detailed agenda is under preparation. Some of the speakers have already confirmed participation, including EFPIA representatives and Polish biotech companies developing innovative drugs.

Pharma Day will make best practice in science - industry cooperation to facilitate innovation-driven translational research. It will be a focused meeting, by invitation only, to ensure free exchange of ideas and fruitful discussions. We will gather researchers with an outstanding scientific experience in experimental and clinical oncology and biopharmaceutical companies from all around the world to make one step forward towards real translational research. We will have top level scientists in the field of molecular oncology presenting their results in light of potential new therapies or diagnostic tools. We will have Polish and international biopharmaceutical companies developing innovative anti-cancer therapies to share their needs and expectations concerning science-business cooperation. Finally – we will create stimulating ambience for networking and building good relations.

3.10 Building relations with biomedical and pharmaceutical business

Meeting the WP5 objective *to initiate new and reinforce existing relations with the local and regional biomedical and pharmaceutical business* IM has put extensive effort in building close cooperation with pharmaceutical industry. IM visited Polish biopharmaceutical companies, developing innovative anticancer therapies, including Selvita and Adamed to show the scientific potential of BASTION research groups and to identify the companies' expectations concerning science-industry collaboration. IM also met with the CEO of USP Life Sciences, who may be potentially interested in investing in research projects. Finally IM started cooperation with Helix Biopharma, providing her support in building a consortium with several institutes to develop novel anticancer therapies. If projects of the companies' involve one of the BASTION groups it would make the sentence *from bench to bedside* come true.

4. Conclusions

IM puts huge effort in changing researchers approach, to open them for collaboration and to show the profits that they can benefit from applied research. She is trying to build a bridge between BASTION research groups and entrepreneurs, especially from the pharmaceutical industry. Due to the lack of common trust and success stories to show, the task is really challenging.

The mentality of administration authorities at MUW seem to comprise one of the biggest obstacles, not only for the technology transfer but also for any formal collaboration with external partners. The procedures at the university are so complicated that even administrative employees have problems with following their own rules. This makes any project realization extremely hard and drives researchers away from any new initiatives.

There is a strong need to build entrepreneurial culture and researcher-friendly environment at the university. We need a complete shift from procedures and regulations to researchers and accomplishments. It can only be done by collaboration and a good will of all parties.

5. Corresponding estimated budget

PERSONNEL, TRAVEL, SUBCONTRACTING AND OTHER MAJOR DIRECT COST ITEMS FOR BENEFICIARY "1" FOR 18M			
Work Package 5	Item description	Amount [EUR]	Explanations
	Personnel costs	40 095,00	Salaries of the Hired WP5 leader, Co-leader (12,08 PM)
	Travel	5 617,00	Travel & accommodation within T5.2 - Workshop in the EU Parliament
	Subcontracting	22 219,00	Organisation of the workshop in the EU Parliament within T5.2; Legal, patent attorney fees within T5.3
	Organization of events	-	
	Remaining direct costs	11 710,00	Project Experts fees (3 experts)
TOTAL DIRECT WP5 COST		79 641,00	

/ - exact costs for M1-M18 will be presented in the Ist Period Report and Form C (April 2014)*

Dr Karolina Dzwonek
BASTION Project Innovation Manager

Prof. Jakub Golab
BASTION Project Coordinator

Warsaw, February 2014

Attachment 1

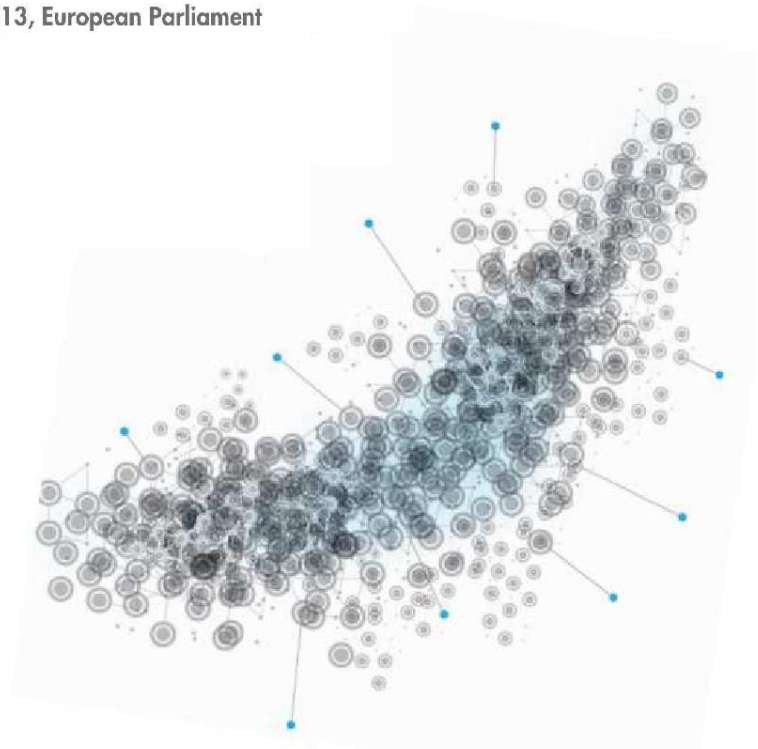
BASTION

ROUNDTABLE

FROM LAB TO CLINIC

Best practices in translational
medicine & innovation management

4th June 2013, European Parliament



Report of the BASTION roundtable

Introduction

"As national health budgets shrink, the expectations of patients are not shrinking"

Jerzy Buzek MEP and former president of the European Parliament in his opening address to experts meeting to discuss the progress and ambitions of the BASTION project, share best practice, and identify gaps and barriers in translational medicine across Europe, at a workshop held in the European Parliament, 4 June 2013

With Europe's healthcare systems facing the dual pressures of austerity-era cuts and an ageing population, there has never been a more pressing need to establish robust systems for translating rich seams of basic research into the clinic, providing improvements in patient care and generating innovative commercial products.

No one country or clinical specialism can claim to have a defined and tested formula for driving this process of translation, with pockets of best practice spread across Europe. However, it is also the case that the newer member states have further to go in building a framework for medical innovation.

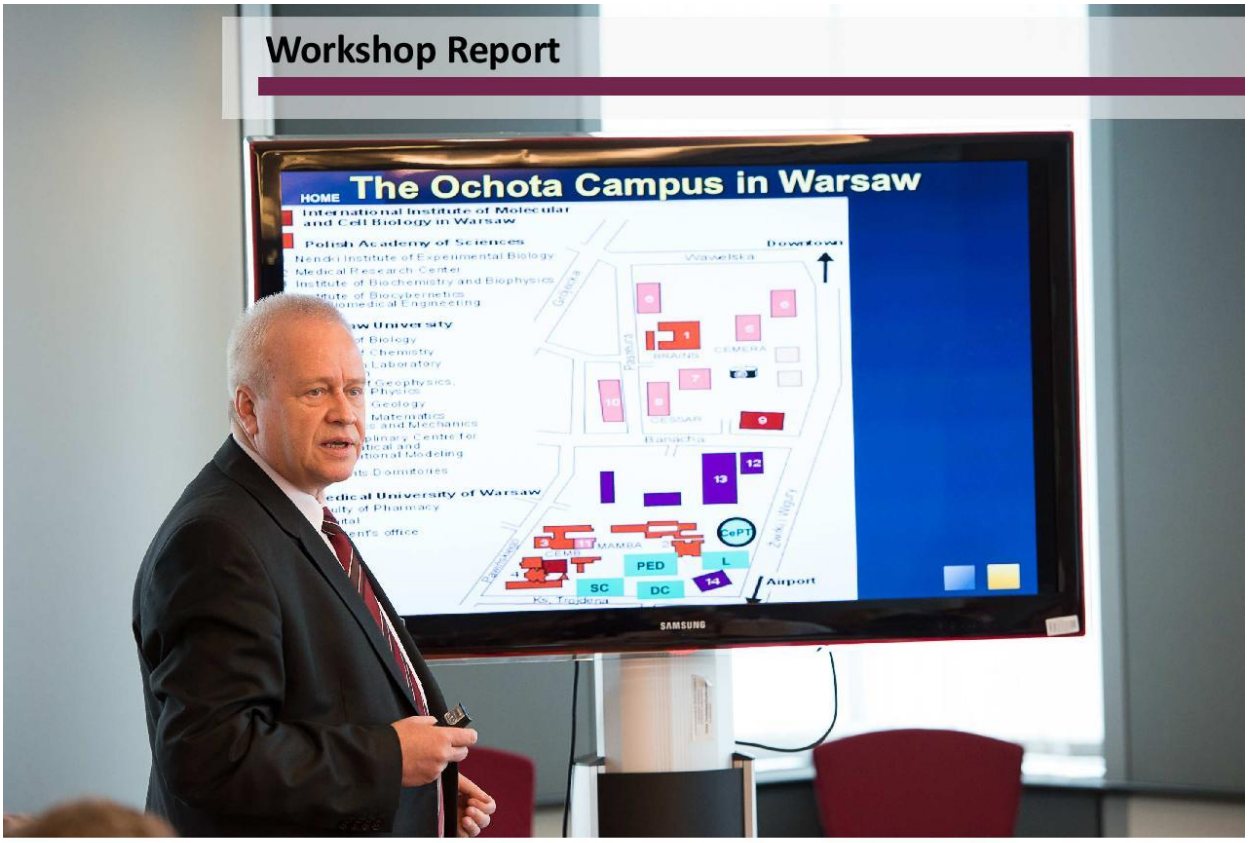
In some senses, this presents an opportunity, since it is possible to draw on the wealth of existing best practice and the evidence base of what works – and what does not.

This is the backdrop to a workshop held in the European Parliament on 4 June 2013, at which the leaders of 'BASTION – From Basic to Translational Research in Oncology', a €5.3 million project to build up the basic research and translational medicine capabilities of the Medical University of Warsaw, outlined the ambitions of the project and progress to date, and some of Europe's leading experts provided insights from their experiences on the front lines of translational research.

Translational medicine does not end with the formation of a spin-out or with getting a product into a Phase I clinical trial. It is necessary to keep going until products get to market and patients get access to them. This can be a long, drawn-out and expensive process and technology transfer and commercialisation systems need to provide support across the piece.

A number of essential elements are required to foster the development of the translational medicine ecosystem:

- The foundation stone is world class research, carried out in world class facilities.
- It is necessary to focus, and to build critical mass. No one institution, or cluster, or region has all the capabilities and collaboration with academic groups in other countries, with biotech and medtech companies, and with pharma, is essential.
- Build human capital – not only in the shape of experts in specific discipline, but scientists who understand the importance of intellectual property, are schooled in entrepreneurship and who relish working in inter-disciplinary settings.
- Universities need to explicitly acknowledge their role as generators of industry-ready knowledge and put in place the facilities and resources required to produce it.
- Provide mentors and role models.
- The scope of translational medicine should be extended to take in patient access. This means that the requirements of regulators, reimbursement bodies and payers must be taken into account at the earliest stages of a research project.
- Focus on patient need. With healthcare systems under severe pressure, innovative and effective drugs and devices that address unmet medical needs, not me-too products are required.
- The pharmaceutical industry is now looking to the early stages of research for innovation to fuel its denuded pipelines. Translational medicine needs to tap into this demand; universities need to advertise their capabilities and provide channels for pharma to access and work with academics.
- Encourage dialogue between academics and industry, discuss university research agendas with companies, and build a strong interface populated with technology transfer and commercialisation professionals.



Slawomir Majewski, Deputy Rector for Science and International Relations, Medical University of Warsaw

Building on academic heritage

As Slawomir Majewski, Deputy Rector for Science and International Relations at the Medical University of Warsaw told delegates, the university has a long history dating back to the 18th century, and today is internationally recognised for aspects of its research. However, in common with the rest of Poland and other newer member states, there is no structure for translational research and commercialisation. One aim of the BASTION project is to put a coherent framework in place.

There are some significant components on which to build, with more than 1,000 students following 17 study programmes and specialists with a focus in cardiovascular disease, oncology, immunotherapy, transplantology and infectious diseases. This scientific potential is to be combined with a €100 million investment in the Centre for Preclinical Research and Technology, (being built in collaboration with two other universities), which is due to open its doors at the start of 2014.

Another key initiative is the formation of the Academic Centre for Innovation, funded by the Polish Government as a foundation stone for improving commercialisation and technology transfer. A first step will be to educate scientists about commercialisation of their research, highlighting the significance of protecting intellectual property and building a culture of systematic knowledge management.

"So we have huge potential, with good labs, good science, and industry is coming: Amgen is talking to us; AstraZeneca is very interested in one of our projects," Majewski said.

However, there are missing pieces in the translational medicine picture, that are now being addressed by BASTION, as Jakub Golab, project coordinator described. These include:

- A low level of international collaboration
- Shortages of human capital, with no positions for regular post-docs (though this is starting to change)
- Bioinformatics
- Lack of equipment

Jakub Golab, BASTION Project Coordinator, Medical University of Warsaw

"So this is why we set up Bastion: to bring together the best research in oncology, get in touch with partners at top universities and the SMEs at the interface, create critical mass and change the face of research at our university"

Jakub Golab, BASTION Project Coordinator, Medical University of Warsaw

- Limited external awareness of the Medical University of Warsaw
- Limited understanding of the importance of intellectual property management, patenting and technology transfer

"So this is why we set up BASTION: to bring together the best research in oncology, get in touch with partners at top universities and the SMEs at the interface, create critical mass and change the face of research at our university," Golab said.

BASTION is making headway in filling the gaps, with a number of academic collaborations now in place, covering a range of research topics, an in-house bioinformatics group has been formed, new assays and animal models are in use.

BASTION is funded from September 2012 to February 2016. However, Golab estimates it will take 5 – 7 years for the full impact of the programme to be pulled through.

Learning from the pathfinders

BASTION may be in its early stages, but the defined work packages and implementation plan highlight how much has been learned from the universities that are the pathfinders in technology transfer, such as KU Leuven, which in May 2013 saw the formation of its 100th spin-off company.

As Olivier Lescroart, IPR Officer at KU Leuven put it, "Universities take their technology transfer role seriously, but we are learning by doing."
In translating basic research through to the clinic, initiatives such as CD3, the Centre for Drug Design and Discovery, PharmAbs, which characterises and validates novel antibodies, and the Clinical Trial Centre, "all came out of problems we encountered," Lescroart said.

Alongside basic research and teaching, universities now view the creation of industry-ready knowledge as one of their fundamental roles. Industry-ready knowledge must have some proprietary aspect to it, must be de-risked in terms of having clear-cut IP and a good safety profile, and must be market-relevant. Universities need to acquire and develop new skills, and develop or get access to new facilities, in order to generate such knowledge.

Apart from expertise in legal aspects of intellectual property, this includes adding a translational research layer, for example the capability to screen for hits against new drug targets or the resources to carry out an

Olivier Lescroart, IPR Officer, KU Leuven

academic clinical trial, Lescroart said.

It also requires seed funds to get start-ups off the ground, and incubator facilities where fledgling companies can find independence from their university roots.

Look for best practice

While spin-offs may be the most visible manifestation of a successful technology transfer office, research collaboration and consultation will form the majority of its activity. This underlines the fact that a critical component in creating a robust technology transfer infrastructure is to have good relationships with local research-intensive companies.

This presents a challenge in translational medicine in Poland, where there are few pharmaceutical companies doing R&D, noted Marcin Szumowski, Business Development Director of the BioTech Med Cluster Mazovia and Head of International Cooperation at the Nencki Institute of Experimental Biology in Warsaw.

The BioTechMed Cluster supports commercialisation of research from scientific institutions across the Ochota Research Campus in Warsaw. As a new initiative, the Cluster is looking to places where technology transfer is more mature, such as Leuven and Oxford, for best practice.

Ask the Entrepreneurs

One of the greatest sources of insights in medical technology transfer comes from scientist-entrepreneurs who have experienced this white knuckle ride at first hand.

Daniela Couto, co-founder and CEO of the Portuguese regenerative medicine specialist Cell2B, described the good and the bad of the uneven environment in which the company is attempting to navigate a path to staging a formal clinical trial of its autologous bone marrow cell therapy for treating organ rejection in transplant patients.

Daniela Couto, co-founder and CEO , Cell2B

On one hand there is a positive regulatory framework in Europe, it has been possible to attract staff with pharma industry expertise in manufacturing and quality control and the University of Lisbon provided an incubator space. On the other hand the company spent much of its existence struggling to find VC investment before persuading three business angels to back it.

"There's a problem with the limited early-stage venture capital money in Europe," Couto told the meeting.

Clinical need

The most important aspect of translational medicine is to identify the clinical need, suggested Sabine Bahn, founder of Psynova Neurotech, a company developing blood tests for psychiatric disorders. "There's a big need in psychiatric disorders, where there has been little change in how they are diagnosed over many decades," Bahn said.

Bahn, who is also director of the Cambridge Centre for Neuropsychiatric Research at Cambridge University, set up Psynova to commercialise 15 years of basic research in which she had identified distinctive biomarkers in the blood of patients with psychiatric disorders that she believed could form the basis of diagnostic tests.

One important factor in going about forming Psynova was the mentoring of Chris Lowe, Professor of Biotechnology at Cambridge University, who has himself been responsible for getting several start-ups off the ground. Another was receiving initial funding from the Cambridge University Challenge Fund. Despite this support, it was a "slalom course" to get sufficient funding, which was raised as a mixture of venture capital investment, debt finance, and support from a

Sabine Bahn, founder, Psynova Neurotech

commercialisation partner, Rules Based Medicine.

After Rules Based Medicine bought out the VC investors, it too was acquired by Nasdaq-quoted Myriad Genetics. With one test for schizophrenia on the market in the US, Bahn continues to work with Myriad to develop other diagnostics. Having access to Myriad's resources has made a big difference. "It's a relief not to have all that weight on my shoulders anymore," Bahn said.

Tapping pharma's new-found appetite for early stage research

One of the most significant and positive shifts in the translational medicine landscape in the past year or so, is the pharmaceutical industry's new-found appetite for early-stage research and its more outward-looking approach to collaborating with universities, biotechs and peer companies.

"We want to build collaboration," Araz Raoof, Global Functional Head, C.R.E.A.Te, Janssen Research and Development told the workshop. A recent example is the launch of a €5 million collaborative initiative with Belgian academic institutions and research centres to drive discoveries

to improve the prevention, diagnosis and treatment of neurodegenerative diseases.

The project seeks to attract leading researchers in Benelux to submit proposals for research in neurodegenerative disorders. Janssen Research & Development will collaborate initially with KU Leuven, University Hospitals Leuven and VIB (Vlaams Instituut voor Biotechnologie) to create opportunities for collaborative research, and will invite other academic institutions to join the project as its next phase begins later this year.

In addition, Janssen is involved in pre-competitive research being carried out by the European Union's €2 billion Innovative Medicines Initiative (IMI), and Raoof suggested that IMI can form an important element of university technology transfer strategy. Universities need to be proactive in talking about their capabilities. "The opportunities for pharma are large, there are many offers out there and the challenge is to filter them," she said.

Barriers to translational medicine in Europe

Systems for translational medicine in Europe need to accommodate another major shift in the landscape, in the shape of recently-erected post-approval barriers, including health technology assessments, and negotiations with reimbursement agencies and payers that are now putting the focus on value as much as on efficacy.

The conventional view is that the scope of translational medicine is from the lab bench to the clinic, but it is important to get from the clinic to real patients.

Patient access should be factored into the earliest stages of research to ensure the right data is generated for regulatory approval and for payers. "Make sure the regulators are on board, make sure the payers are involved – and at a very early stage," advised Magda Chlebus, Director of Science Policy at the European Federation of Pharmaceutical Industries and Associations.

For Arnd Hoeveler, Head of Unit – Advanced therapies and systems medicine, DG Research and Innovation at the European Commission, another change that needs to be addressed in translational medicine is its increasingly disciplinary nature. Specialists from medical technology, information technology and biotechnology need to work with each other. "Minds have to be opened up and experts brought together," Hoeveler said.

"Make sure the regulators are on board, make sure the payers are involved – and at a very early stage"

Magda Chlebus, Director of Science Policy at the European Federation of Pharmaceutical Industries and Associations

Hoeveler also acknowledged that effort is needed at an EU level to create a more robust translational medicine infrastructure. And the traditional 'publish or perish' mandate under which academics operate has to change: there need to be incentives to innovate – which may mean holding back on publication.

Whatever gaps there may be, there is also a lot of expertise in Europe. "Learn from other clusters around Europe, this will help in devising strategy," Hoeveler advised.

Marta Czanik-Kawecka of the Academic Centre for Innovation at the University of Warsaw reflected on some of the practical problems encountered in creating a translational medicine system from the ground up. Critically, there is the question of how to reach scientists and make them interested in commercialisation. There's another challenge in assessing if knowledge is industry ready and also in addressing legal issues, especially in protecting intellectual property.

The Centre for Innovation was created a year ago, and still has some way to go in building an entrepreneurial culture. But the good news is that, "young people are really interested in the opportunity to develop products," Czanik -Kawecka said.

"Learn from other clusters around Europe, this will help in devising strategy"

Arnd Hoeveler, Head of Unit, DG Research and Innovation, European Commission

About BASTION

BASTION (From Basic to Translational Research in Oncology) is a multidisciplinary project co-financed by the European Commission under the 7th Framework Programme - REGPOT 2012-2013.

The objective of the project is to build up the research potential of the Medical University of Warsaw (MUW) in the field of experimental oncology.

The scientific research of the highly professional BASTION project teams is focused on personalised medicine and the development of diagnostic and therapeutic methods customised to patients' individual needs.

The project also aims at reducing the time from scientific discovery to clinical application. Therefore much effort is put into increasing innovation within MUW and to support science and business.

More information:
www.bastion.wum.edu.pl/en

SCIENCE BUSINESS

Words: Nuala Moran
Design: Giulia Biasi
Photograph: Carlos Nomen

Roundtable Partners

The BASTION project is funded by the European Commission within its Seventh Framework Programme and co-funded by the Polish Ministry of Science and Higher Education.

Attachment 2

Dr K. Dzwonek
Zakład Immunologii

ZARZĄDZENIE NR 330 /2013
KANCLERZA
WARSZAWSKIEGO UNIWERSYTETU MEDYCZNEGO
z dnia 13 września 2013 r.

w sprawie powołania zespołu ds. opracowania strategii zarządzania własnością intelektualną Warszawskiego Uniwersytetu Medycznego dla wyboru optymalnych form komercjalizacji wyników badań naukowych i prac rozwojowych.

Na podstawie § 110 ust.1 i ust. 2 pkt 5 Statutu WUM w związku z § 40 i 41 Regulaminu Organizacyjnego WUM zarządza się, co następuje:

§ 1.

Powołuje się zespół ds. opracowania strategii zarządzania własnością intelektualną Warszawskiego Uniwersytetu Medycznego dla wyboru optymalnych form komercjalizacji, zwany dalej „Zespołem" w następującym składzie:

1) Dr Dzwonek Karolina,
2) Mgr Piekutowska Beata,
3) Mgr Sobczak Jacek,
4) Mgr Urbańska Anna.

§ 2.

1. Zadaniem Zespołu, o którym mowa w § 1 jest opracowanie strategii zarządzania własnością intelektualną na Warszawskim Uniwersytecie Medycznym dla wyboru optymalnych form komercjalizacji wyników badań naukowych i prac rozwojowych.
2. Do zadań Zespołu należeć będzie:
   1) zanalizowanie podstaw prawnych określających własność intelektualną WUM,
   2) przedstawienie aktualnych zasad zarządzania własnością intelektualną WUM,
   3) określenie stopnia zdolności do identyfikowania przedmiotu obrotu własności intelektualnej dla celów komercjalizacji,
   4) zdefiniowanie czynników wpływających pozytywnie na powstawanie i zarządzanie własnością intelektualną WUM,
   5) określenie ryzyk, które utrudniają identyfikowanie i powstawanie własności intelektualnej na WUM,
   6) przedstawienie wybranych projektów (naukowych, badawczo-rozwojowych) realizowanych przez WUM o największym potencjale do komercjalizacji.

§ 3.

Zarządzenie wchodzi w życie z dniem podpisania.

WARSZAWSKI UNIWERSYTET MEDYCZNY
Kancelaria Uczelni
16. 09. 2013
Wpłynęło dnia .....

Mgr Małgorzata Kozłowska

SAMODZIELNY PUBLICZNY CENTRALNY SZPITAL KLINICZNY w WARSZAWIE
Wpłynęło dnia: 17 WRZ. 2013
Zał. 16