BIOPARK
CHARLEROI BRUSSELS SOUTH

news

The Biopark Charleroi Brussels South Newsletter

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Biobanks

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BIOBANKS: COMBINING ETHICS AND FINANCE

Today, those involved (universities, hospitals, public authorities, and businesses) are fully aware of the importance of collecting, storing, and using human biological samples in an organised manner. Yet in spite of this awareness, there remain a host of organisational, ethical, and financial challenges to overcome.

The *Fédération Wallonie-Bruxelles* biobank coordination project should settle the operational issues, but the real challenge lies in how to combine ethical practice with financial viability.

A delicate balance needs to be found between patients' rights to information, obeying the law, and the need to use samples not only for academic research but also for research partnerships with industry.

While it is essential that we have access to samples for our academic research, it is also important to help our companies grow. If we fail to reconcile these different aspects in all of our initiatives, then we run the risk of weakening our industrial make-up and the accompanying research.

Dominique Demonté
Director
Biopark Charleroi Brussels South

Biobanks: a scientific and collaborative challenge

Biobanks are responsible for collecting and storing human biological samples. They perform a very useful role in research of human health, and are beginning to develop a more definite structure.

Biobanks collect and store human samples (blood, tissue, cells, DNA, etc.) for use in research. "But the word *bank* is somewhat misleading", Isabelle Salmon, head of unit at Erasme Hospital, CMMI researcher (Biopark), ULB referent for the biobank question, is quick to point out. "Unlike tissue banks for use in treatment, biobanks are dedicated solely to scientific research. They are really more of a library". A library of particular interest to clinical research into rare diseases or researches concerning specific profiles, for which a sufficient number of samples must be collected and studied. "If a researcher wants to study a given mutation in a significant number of colon cancers", Isabelle explains, "We can get samples from our biobank and request assistance from others in Belgium or abroad".

A NEW LEGAL FRAMEWORK

Collaboration is a fundamental pillar of the biobank *philosophy*. The term itself is a neologism, but *biobanking* is already a familiar activity in scientific research: "most researchers have already worked on human samples to test their hypotheses", Isabelle Salmon continues, "but they have all been working with their samples in isolation, without any overarching structure. Indeed, it is this legal framework that is now provided by biobanks". Doing the rounds of federal government in-trays since 2008, and finally passed into law just a few months ago, the new law on biobanks is structured around the patient's consent, anonymity, and traceability of the sample (see page 4), as well as the establishment of an ethical committee to govern the use of samples.

AN INTERNATIONAL NETWORK

This legislation has been long awaited by *biobankers*, but requires large scale standardisation: "we were already in meeting with ULB hospitals to discuss how best to standardise procedures and bring stakeholders

into contact. This has now gone beyond the *Fédération Wallonie-Bruxelles*, expanding to include our Flemish and even European colleagues. Facilitating cooperation is always top of the agenda", explains the researcher (see page 6). Efforts should also be made to involve businesses, including those who own human samples. "We have, for example, a partnership with ImmuneHealth (Biopark) to exchange samples according to requests made by researchers or biopharmaceutical and technology companies", she adds (see page 7). Once a national network has been formed, the goal is to secure belgian inclusion in the European biobank network, the BBMRI (Biobanking and Biomolecular Resources Research Infrastructure).

Academic or industrial researchers, doctors, patients; biobanks come into contact with a range of stakeholders in the biomedical sector, making them a scientific and collaborative challenge with a single objective: profitable biomedical research for all those involved.

Natacha Jordens

"SAMPLES ARE DIFFICULT TO OBTAIN"

iTeos Therapeutics identifies and approves candidate drugs that can stimulate the immune response against cancerous cells. The information obtained from human samples is an essential part of the preclinical development of a candidate drug and development of diagnostic testing, but samples are sometimes difficult to find. **Michel Detheux, the CEO of iTeos Therapeutics (Biopark)**, tells us more.

ARE HUMAN SAMPLES ESSENTIAL TO YOUR WORK?

The study of human samples enables us to better predict the effectiveness of a new treatment and is used to develop a *companion diagnosis:* a diagnostic test used to select the best patients and predict the effectiveness of the drug. It is an important part of the process.

ARE APPROPRIATE SAMPLES DIFFICULT TO FIND?

Yes, it is difficult to find a large number of samples in a short time frame. It is also hard to gain access to the patient's history while respecting their anonymity, even though this information is essential for interpreting data. For example, why does one sample come back positive while nine others are negative, when they all come from the same disease?

WOULD A BIOBANK NETWORK BE A GOOD SOLUTION FOR YOU?

If the network could provide easy access to these samples and patient history, then it would be a highly valuable resource. It would increase the number of samples available to use and help to ease the *bottleneck* that occurs when setting up quality, competitive international preclinical research.

N .J.

"USEFUL EFFORTS FOR RARE SAMPLES"

The study of human samples is an all but essential step for researchers in biomedical science. However, it is difficult to obtain sufficient numbers of certain samples, especially when studying rare diseases or particular profiles. ***Arnaud Marchant (IMI)*** *offers a glimpse into research.*

"In our laboratory, we study the transmission of cytomegalovirus (CMV) from the pregnant mother to the foetus and how the foetus manages to control the infection. In this project we are totally dependent on human samples, so we work with obstetricians who invite mothers-to-be infected with CMV to take part in the study, and collect clinical samples. But (fortunately!) only a minority of foetuses develop symptoms following CMV infection, making samples even rarer. In order to identify the risk factors and mechanisms that lead to the development of symptoms, we must carry out broader studies involving more patients. These studies could be organised nationally and throughout Europe, with precious samples collected using identical processing and storage standards. As part of these studies, our institution could even become a European biobank storing samples of CMV infected foetus, accessible to all groups carrying out work in this field".

N .J.

New legislation on biobanks

The law on biobanks has been revised in March 2013. The aim is to provide a framework for the collection of human bodily material for the exclusive use of scientific research. The new legislation leans towards transparency and information for patients.

It is common knowledge that medicine is constantly evolving and progress shows no sign of slowing. The decoding of the human genome has enabled doctors and researchers to drastically further their understanding of disease. Advances in cryopreservation mean that more samples can be stored, and data storage has been made easier with modern computers.

"Before, when a researcher wanted to inventory their samples, they had to write everything in a ledger", Myriam Remmelink, head of Erasme-ULB Biobank council explains. "The computer programmes that are now available mean that we can record and store thousands of samples together with the data that comes with them".

The European – and Belgian – powers have therefore found it necessary to comprehensively regulate biobanks and how they are used. Informed patients are one of the cornerstones of the new law, with tissue stored in biobanks generally comes from samples taken during treatment.

"We can only consider taking a sample for the biobank if there is any leftover tissue once the tests needed for diagnosis have been completed. If we don't add it to the biobank, this 'residual' bodily matter is incinerated", Myriam Remmelink continues. "Two conditions must be fulfilled when taking samples: there must still be enough matter left for diagnostic testing, and the patient must grant their consent".

The patient must grant permission before any sample can be taken, which was not previously the case: this is what we call explicit consent, rather than tacit consent (also known as opting-out).

"When a patient is admitted to the hospital, they receive a brochure that includes this information", she goes on. "If they do not object, then we can store the sample for research purposes. If they do object, we destroy any residual matter". While they represent a low percentage of patients, some refuse to donate their *human tissue* for research.

"And everyone has the right to say no!", stresses the researcher. "It is important to work on informing patients. We need to be open to discussion and remember that nothing is better at advancing medical research than working on humans. Donating this residual matter furthers medical knowledge, benefitting society as a whole".

Damiano Di Stazio

THE KEY POINTS OF THE LAW

- The patients must grant their consent before the sample can be taken. Their consent is not binding: "Once they have agreed, the patient may revoke their decision. The stored matter is then destroyed" Myriam Remmelink reports.
- Storage and use of samples must be approved by an ethical committee. Its aim? To ensure that samples are used in line with the biobank constitution and that the patients rights are not abused.
- Human tissue may not be used for commercial purposes.
- If the researchers find relevant information within a sample, they must inform the patient. "This leads to impeccable traceability" Myriam Remmelink confirms.

D.D.S.

OPTING OUT

Biobank legislation differs between countries. In Belgian law, informed, signed consent is required for the use of *human bodily matter* in research. This same law does, however, include two notable exceptions: the use of residual bodily matter and *post-mortem* samples. In both cases, consent is granted on an opt-out basis. "This procedure is the same as the one used in our country for organ transplants. All Belgian patients are organ donors unless they have explicitly objected", explains Myriam Remmelink.

Learn more: read *"Ethique et biobanques. Mettre en banque le vivant"*, by Myriam Remmelink, Editions Académie Royale de Belgique 2013.

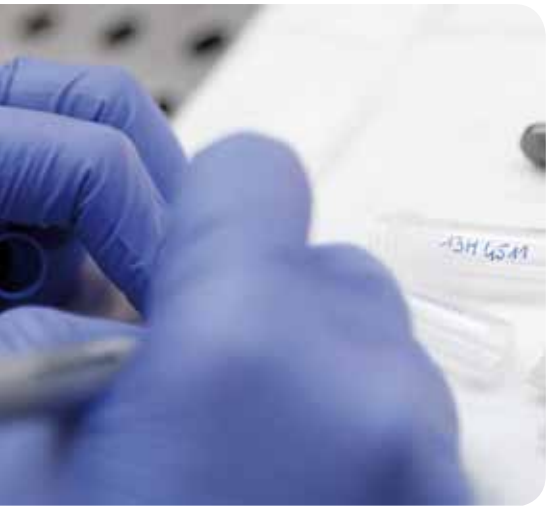
D.D.S.

The *Fédération Wallonie-Bruxelles* gets organised

With support from Minister Jean-Marc Nollet, biobanks in the *Fédération Wallonie-Bruxelles* are forming a network. Coordinated by BioWin in 2012, the regional initiative addresses both academics and business.

The need was already there: it was stated in autumn 2009 in the BioWin competition cluster's 6th call for projects. At the time, several universities and businesses wanted to launch a *biobank* platform, so BioWin created a workgroup to develop and structure demand, and coordinate stakeholders. A survey identified the needs and practices in biobanking.

In parallel, the Office of the Minister for Research, Jean-Marc Nollet, singled out *biobanking* as a priority of the ESFRI (European Strategic Forum on Research Infrastructure), with EU backing. BioWin's initial strategy was the result of the definite need expressed by those in the field, and was soon backed by the political weight of the Walloon region. A strategic memo was drafted, and biobanks were mapped with the universities'Technology Transfer Offices assistance: there are no less than 35 biobanks in the *Fédération Wallonie-Bruxelles*, of varying sizes and roles. A feasibility study was then carried out to identify the human, material, and technical resources needed to turn biobanking in the *Fédération Wallonie-Bruxelles* into a professional operation, while a European benchmark was developed.



DECENTRALISED MODEL

"We will use a decentralised structure that will organise biobanks around five geographical centres (*ULB Erasme-Bordet, UCL St-Luc, ULg CHU Liège, UCL Mont-Godinne, IPG-Biopark)*", explains Marianne Ghyoot, the biobank manager at BioWin, "The biobanks will remain in their universities or hospitals, but will also form part of a network via a computer interface that provides access to information on samples. We also need to launch an operational unit to coordinate collaboration, identify needs and respond to requests, all while making sure that quality procedures and legal or ethical standards are met".

Flanders is also organising its biobanks through the CMI *(Center for Medical Innovation)*: the aim is to collaborate with the network in the north of the country, as well as with the only federal biobank currently operational, the *Belgian Virtual Tumour Bank*, dedicated to cancer research and founded by the *Belgian Cancer Registry*. Ultimately, the goal is to have the biobanks join the European biobank network, and Belgium is currently applying to become a founding member of the BBMRI *(Biobanking and Biomolecular Resources Research Infrastructure)*.

"Once the biobank network is up and running in the *Fédération Wallonie-Bruxelles*, BioWin will work more closely with businesses that have already expressed an interest in forming partnerships, for example in logistics and transportation of samples, or preliminary collections that are not currently made by academic biobanks", highlights Marianne Ghyoot.

Nathalie Gobbe

Complementary expertise

Initially focused on immunomonitoring and the clinical study of vaccines, ImmuneHealth has since diversified its business: its clinical research unit has developed expertise in the organisation of clinical studies of the collection of biological samples and the validation of biomarkers.

"We take a prospective approach: straddling clinical research and biobanks", specifies Edwige Haelterman, the Doctor-Director of the ImmuneHealth (Biopark) clinical research unit. "90% of our samples are blood samples and their derivatives (e.g. plasma, serum, PBMC – Peripheral Blood Mononuclear Cells). Alongside this, our teams collect specific samples for particular projects, such as muscle samples taken during orthopaedic treatments, umbilical cord blood samples, or even tumour samples at specific stages".

This approach enables the partners of the non-profit-making association – academics, pharmaceutical companies, and biotech businesses – to fulfil a range of needs. "On average, we receive 1500 visits every year, during which clinical data and biological samples are collected: this demonstrates that some partners consider our work to be essential", Edwige Haelterman continues.

"There are many good reasons for researchers to come to us: we can obtain and transport fresh samples at very short notice, we can collect pairs of samples (a blood sample with a saliva sample, for example), or samples from different times (to describe kinetics) from the same volunteer: our ethical standards and cutting edge procedures are also attracting big pharma".

Does this mean that biobanks and ImmuneHealth are in competition? "Not at all", Edwige Haelterman is quick to allay this suggestion. "It all depends on individual needs and demand. We need to investigate every opportunity: if a researcher asks us for a sample from a person suffering from a rare disease, our prospective approach means that we are unable to fulfil their request within a reasonable time frame".

So while this clinical unit's work was initially to test vaccines, ImmuneHealth's role has broadened considerably to encompass the collection and management of biological samples, which now form one of the company's development strategies. ImmuneHealth is able to offer laboratories, SME, and larger businesses an additional *biobanking* resource.

Damiano Di Stazio

www.immunehealth.be

The i-Tech Incubator is born

Biopark Incubator is now i-Tech Incubator, opening up to projects from outside the life sciences field to include engineering and environmental technology.

Biopark Incubator is dead, long live i-Tech Incubator! Up and running for two years, the incubator has changed its name while serving the same purpose: to facilitate the transition from idea to business. “More than half of the projects that we support are in the life sciences field, with the rest being made up of engineering sciences and environmental technology. This expansion should continue as we have sealed a new partnership with the Walloon incubator, WSL, dedicated to engineering, and the environment being a regional priority. It was important to us to adopt a name that better suited our target audience”, explains Marie Bouillez, the head of i-Tech Incubator.

And there is a lot to be enthusiastic about: the incubator has already supported 30 projects that have given rise to three companies employing 27 people on the Biopark – MaSTherCell, a-ULaB, and OncoDNA. This is just the beginning: ten other projects are currently underway.

The incubator (in partnership with TTO ULB and AVRE UMONS for university projects) supports the people behind project as they assess their technology’s potential, set the strategic direction of the future company, form a management team, develop a business model and financial plan, and to create a company and form a management board, for those that reach the end of the process.

i-Tech Incubator can also advise the project creator on funding, help develop a funding strategy and compile an application, find eligibility for subsidies, contact investment funds or private investors, banks or other sources of funding like crowdfunding. In a single year, the incubator helped new companies to raise around €8m.

The incubator also has its own building on the Biopark that it currently home to 18 SME, occupying 68% of the office and lab space. It is an ideal opportunity for these new businesses to join an industrial and academic network, and to share experiences, especially together with IGRETEC.

Furthermore, since January 2013 the building boasts new, fully equipped

meeting rooms with video conferencing facilities, able to accommodate meetings of 2 to 80 people. It also includes a flexible workspace: six offices that can be hired by the hour, part of the BioWin Partner Port and Smart Work Center.

Nathalie Gobbe

www.i-tech-incubator.be

i-Tech INCUBATOR

Public-Private Partnerships: great results

The Walloon government has revealed its new PPP, or Public-Private Partnerships. Biopark teams account for 4/9 projects chosen for 2013: great results!

EMULVAC, SAPOVAC, OSCIRC and TREGCD70: these mysterious names conceal the new public-private partnerships underway on the Biopark. The PPP represent two years of special cooperation between academic research and industrial partners, supported by the Walloon authorities in an effort to boost development and scientific innovation. The Biopark's teams won four PPP, which are mainly continuations of existing research and partnerships.

EMULVAC - SAPOVAC

EMULVAC and **SAPOVAC** are focused on researching and understanding how vaccines adjuvants, work in partnership with GSK-Biologicals. EMULVAC focuses on "emulsion based vaccine adjuvants" as used in seasonal flu vaccines, while SAPOVAC will research saponines, used notably in a malaria candidate vaccine. "These two vaccines adjuvants are already used at GSK-Bio", explains Stanislas Goriely, the **IMI** programme coordinator. "But they are developed empirically, without ever fully understanding the mechanism in action. This is what we are trying to shed some light on". Researchers will try to understand which molecular pathways are activated by these vaccines adjuvants, causing the stimulant effect in cells of the innate immune response. This understanding could improve current vaccination strategies in terms of both effectiveness and reactogenicity. "While we do not really know how vaccines adjuvants work, we cannot understand their undesirable effects", the researcher explains. GSK-Bio and Stanislas Goriely's team will continue their collaborative work began in 2004 when the IMI was created.

OSCIRC

OSCIRC is an abbreviation of "circulating osteoblasts" in French, the precursors of bones found in the blood, and at the heart of this PPP. "Most osteoblasts are normally found within the skeleton", explains Valérie Gangji, head of the Rheumatology and Physical Medicine Department at Erasme Hospital. "In fractures, some of them enter the bloodstream and are able to recognise and move towards the damaged bone, before attaching themselves there. However, the factors that cause this phenomenon are as yet unknown", she continues. The goal of this PPP, sponsored by the spin-off **Bone Therapeutics** (Biopark), is to understand what causes the osteoblasts to enter the bloodstream, and what guides them towards fracture sites. What is on the cards? The possible development of cell therapy to correct bone diseases like osteoporosis, osteonecrosis, or pseudoarthrosis. "Existing cell therapy requires local injections to the site of the fracture. By understanding the mechanism behind circulating osteoblasts, we may be able to develop intravenous treatments", explains the researcher. A less invasive technology that would be especially welcome in the treatment of young children.

TREGCD70

Last but not least, the **TREGCD70** project is a continuation of the CIBLES excellence programme, which achieved completion in December 2012. In this programme, Muriel Moser's *Immunobiology* team (**IBMM**) learned that some regulatory T lymphocytes are able to control the inflammatory immune response by reducing expression of the CD70 molecule on the surface of dendritic cells, the watchmen of our immune system. This reduction correlates with a transfer of the CD27 receptor at the surface of the same cells. "In more concrete terms", explains the researcher, "the lymphocytes 'send' their receptor to the dendritic cells via a kind of intercellular channel, a never before seen immune system process. This transfer probably plays a role in reducing the immune response, but we do not yet fully understand how". The PPP, sponsored by GSK-Biologicals who already sponsored the CIBLES project, will aim to understand this process and harness it to control immune reactions, especially in auto-immune diabetes.

Natacha Jordens

In brief

NEW FOUNDATIONS FOR CELL THERAPY

On Wednesday 12 June, the spin-off Bone Therapeutics and Promethera Biosciences laid the first stone of their new building in Gosselies, with Government Ministers Jean-Claude Marcourt and Jean-Marc Nollet in attendance. The new building will house new production facilities for the two companies to manufacture their cell therapy products for use in the treatment of bone and liver diseases respectively.

These new facilities will consolidate the Biopark's "cell therapy" strategy, which began in 2011 with the creation of MaSTherCell, a company that provides its clients with the infrastructure needed to make *cell-medicine*.

Scheduled to open in 2015, the new Bone Therapeutics and Promethera Biosciences building will stand opposite the i-Tech Incubator, providing Biopark with Europe's largest cell therapy production facilities.

N. J.

The future building of Bone Therapeutics and Promethera in 2015.

GSK VACCINES SCIENTIFIC AWARD

Paediatric doctor, IBMM researcher, and postdoctoral researcher at Murdoch Childrens Research Institute in Melbourne, **Pierre Smeesters** won the GSK Vaccines scientific award granted every three years by the *Académie Royale de Médecine de Belgique*. The prestigious award was granted in the presence of Princess Mathilde, and comes in recognition of Pierre Smeesters' research into streptococcus A.

Streptococcus A has become increasingly common over the past twenty years, and is a killer in developing countries, causing the deaths of over 500,000 people every year. Pierre Smeesters coordinates a multi-centre research programme, and together with his researcher and clinical colleagues he has described a new model for immunity to this disease. Their analysis has discovered a new "common ground" shared by its different forms that should enable a single, effective vaccine to be developed that works against most of the strains encountered around the world.

N. G.

BIOPARK IN CHICAGO

The Biopark attended the Biotechnology Industry Organization (BIO) Annual Convention over the 22-25 April in Chicago. It was an opportunity for the ULB and its Technology Transfer Office (TTO), as well as Delphi Genetics, OncoDNA, and the i-Tech Incubator to maintain and expand their contacts with active biotech companies. The BIO convention is the world's largest biotechnology industry event, and this year there were 13,594 visitors from 63 countries, 2800 companies, and 1700 exhibitors in attendance.

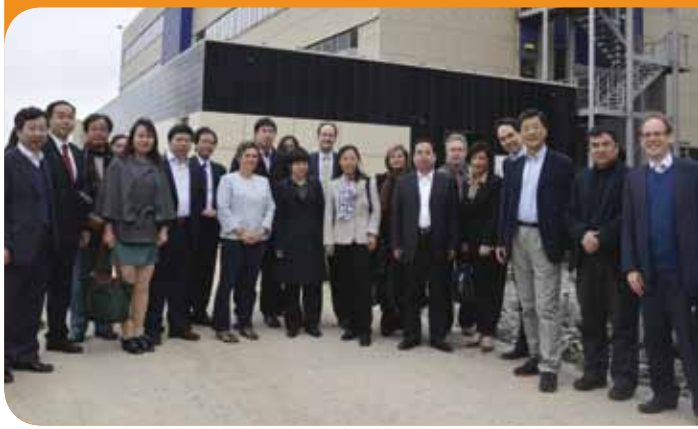
F. M.

FROM CHINA AND LITHUANIA

Representatives from the University of Beihang (China) were in Charleroi to visit the Biopark. The delegation (see below) headed by the Dean of Beihang University, Prof. Huai Jinpeng, came to meet our researchers. After visiting the campus and seeing a brief overview of the work carried out at the IBMM (Institute of Molecular Biology and Medicine) and CMMI (Center for Microscopy and Molecular Imaging), the visitors met stakeholders in the aerospace sector, the Chinese university's strongest subject. The visit was also an opportunity to forge professional connections between professors, and to consolidate the relations between the two universities.

A few days later Lithuania was also invited to the Biopark. A delegation headed by the Lithuanian Minister of Education and Science, Dainius Pavalkis, visited the CMMI.

D.D.S.



In brief

LIFELONG LEARNING: OPEN DAY AT CHARLEROI

In partnership with Biopark Training, UMONS will hold a "Lifelong learning evening" in Charleroi on 26 June, from 5.30pm to 9.00pm (Boulevard Joseph II, 38-42). The evening is aimed at graduates from the *Hautes Écoles*, universities graduates, and adults looking to continue studying. The evening will be composed of two parts: a reception providing an overview of the available courses and stands for bespoke training, and then closing cocktails.

For further information and to sign up:
www.umons.ac.be/formationcontinue
patricia.lorent@umons.ac.be

D.D.S.

LIFELONG LEARNING AT THE ULB: A NEW DIRECTOR

This spring, the Director of Biopark Training, Arnaud Termonia, took over the ULB's Lifelong Learning Service. His appointment is both in recognition of his work at Biopark Training (which he will continue to manage), and part of a strategy to open up to new sectors, both in Brussels and Wallonia, and form new partnerships.

D.D.S.

STRATEGIO IS BACK

After the 2012's success, the STRATEGIO course is making a comeback on 13 September. Its aim? To fill the gap between science and management, enabling managers in the life sciences and health sectors to acquire cross-disciplinary management skills. These interactive courses are mainly intended for biomedical sector managers and bring together renowned academics and businesspeople.

For more information visit:
http://www.biopark.be/bioparkformation/strategio.html

D.D.S.

ACADEMIE UNIVERSITAIRE WALLONIE-BRUXELLES

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