Lääkärisanomat • Medical Journal

Biobanking in Finland & Personalized Medicine

- Biobank activities enjoy strong support by Finns
- Finnish biobanking is among the world's best
- BioDataBanks are the key to new innovations for better health
- FinnGen is a unique model for public-private partnership in genomic research

What is a biobank? p.16

• Biobanking is in the frontline of personalized medicine

Professor Olli Carpén, a member of the Steering Committee of BBMRI-ERIC

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Advancing Future Healthcare

EDITORIAL

The substantial increase in genomic data is transforming health care and disease prevention

A new era is beginning in the field of medicine, thanks to improved accessibility and scientific availability of genomic and other health data. This opens up exciting opportunities for researchers and other players in the field to make treatment, diagnostics and disease prevention increasingly personalized. This publication provides insight into this highly interesting topic. The focus is on genes, the entire human genome, biobank operations and personalized medicine, not to mention the unprecedented partnerships that modern genomic and biobank research and health technology can offer Finnish professionals. These are hot topics right now.

My interest in biobanks and personalized medicine was sparked in the fall of 2015, when I was working on the official newsletter of *Turun Lääketiedepäivät (Lääkärisanomat 2/2015)* and an article on a scientific symposium on this theme, together with **Kati Elima**, Clinical Lecturer in Molecular Medicine and Adjunct Professor at the University of Turku. The same newsletter featured an interview with MSD Finland's Policy and Communications Director, Ph.D. (Economics) **Petri Lehto**, who previously headed Finland's Innovation Policy Department at the Ministry of Employment and the Economy. Lehto gave me inspiring insight into the opportunities of Finnish biobank operations, genome strategy and genomic medicine from the perspective of individual citizens, national health, health-care resources and international collaboration and research funding alike. One of the greatest sources of inspiration for the biobank magazines I have worked on was Finland's Genome Strategy Working Group's proposal for a national genome strategy, which was published in spring 2015, with the guiding principle of "Improving health through the use of genomic data".

> *"Finland is currently one of the world's leading countries in biobank and genetic research."*

Finnish medical genetics and genomics experts and specialized bodies, such as biobanks, universities and health-care units, are internationally esteemed and sought after as collaborators. The increase in genomic data is highly welcome for Finland in many ways, and Finland is absolutely intent on tapping into the opportunities it offers to promote health care and the treatment of diseases in a bid to tackle the global health-care challenges of our times – and to be able to provide the best possible care to people around the world also going forward. "As we still have diseases with no effective treatment, there is a need for new innovations," as Professor **Aarno Palotie** states in his interview on pages 6–8. Like him, many other interviewees for this magazine are also top experts in their fields.

This special issue provides first-line information on genomics, biobanks and the advances made in related research, innovation and increasingly personalized medicine. We hope you enjoy the magazine!

M.D. Maj-Leena Tuhkanen

Interesting topics

> *"Personalized medicine means diseases are not treated or prevented solely on the basis of a symptom, diagnosis or, for example, the location of a cancerous tumor, but instead with much greater precision."*
>
> Professor Olli Carpén, p. 10–11

> *"In August 2017 initiated FinnGen research project providing genomic information for 500 000 individuals and 10 % of the Finnish population is among the foremost biobank genetics projects in the world."*
>
> Professor Mark Daly, p. 32

> *"It is very likely that FinnGen will lead to breakthroughs in disease prevention, diagnosis and treatment and build a foundation for health innovations and personalized treatments."*
>
> Professor Aarno Palotie, p. 6–8

> *"Finland is well positioned to compete for international clinical trials in the field of genetic medicine. The Finnish Biobank Cooperative (FINBB), established in August 2017, and the Finnish Genome Center (preparations for establishment of the Center are ongoing) provide valuable support in this respect."*
>
> Director, Policy and Communication
> Petri Lehto, p. 30

> *"Biobanks have many important goals: promotion of population health, identification of disease mechanisms and promotion of production development linked to health and welfare and hospital care."*
>
> Biobank Director, Sirpa Soini, p. 25

> *"The Finnish Biobanks Cooperative (FINBB) was established to serve and facilitate development of member biobanks and to provide a single entry point – one-stop-shop service model – to biobanking services on a national and international level."*
>
> CEO Marco Hautalahti, p. 20–21

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Biobanking in Finland & Personalized Medicine

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Professor Olli Carpén photo (frontpage): Hannu Aaltonen

Finnish biobanks

Valvira (the National Supervisory Authority for Welfare and Health) has granted a license to ten biobanks altogether, out of which four are operating in the whole of Finland and six biobanks in the area of hospital districts.

Read more:
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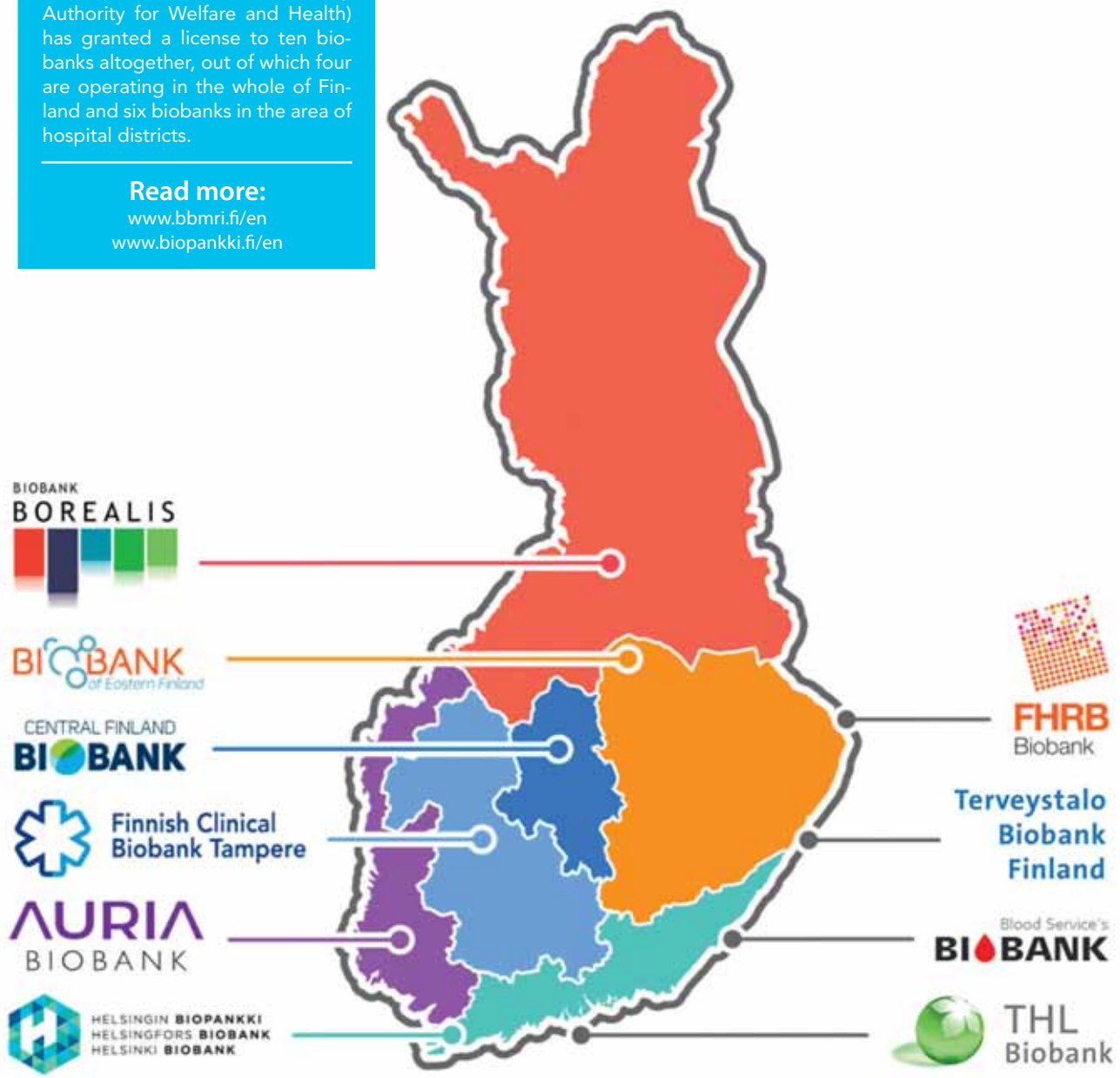
www.biopankki.fi/en



Change is inevitable!

Genomic medicine and biobanks offer Finland exceptional opportunities

Recent developments in medicine and innovations that promote health and wellbeing benefit individuals, public health and the national economy. Researchers are excited about recent advances in genetic medicine that are based on the massive increase in genomic data, i.e. information about an individual's genetic makeup.

Professor **Aarno Palotie**, Research Director of the Human Genomics Program at the Institute for Molecular Medicine Finland (FIMM), has long been one of the best-known genetic researchers in the world. In addition, he is a faculty member in two top global research organizations in genetic medicine: the Broad Institute and Massachusetts General Hospital. His past positions include a professorship at the University of California Los Angeles (UCLA), Senior Group Leader at the Wellcome Trust Sanger Institute in Cambridge and Director of the Finnish Genome Centre (the activities of which were merged with FIMM in 2007).

Palotie's research focuses on studying the genetic mechanisms underlying central nervous system diseases, such as migraines, schizophrenia, autism and epilepsy, and developing diagnostics. In recent years, he and his research group – as well as other researchers around the world – have been able to take advantage of the surge in genomic data and the major study designs that it offers. This has opened up an entirely new perspective on scientific research and on supporting and promoting health and wellbeing. It is worth noting that, thanks to new advances in the field, genetic information can increasingly be used not only for rare diseases, but also for more common ones.

In addition to his research work, Palotie is known for his significant contributions to Finnish biobank activities and genetic medicine in general. Some of his views relating to the topic are presented below.

1) There is more genomic data available now than ever before, and the volumes continue to grow. How is this affecting research on health and wellbeing?

- The increase in genomic data is very welcome and provides many new opportunities and perspectives for studying human health, wellbeing and diseases. However, it is still too early to say where these new research opportunities based on a considerably wider range of genetic information will eventually lead. Expectations are high, but we should not promise more than we can deliver. I have compared the current advances in genetic medicine with the invention of the computer: No one could have foreseen what would happen and the major role that computers would come to play in our lives.

2) Auria Biobank and THL Biobank received their operating licenses on 10 March 2014. Since then, ten biobanks have started operations in Finland (the Helsinki Urological Biobank merged with the Helsinki Biobank in May 2016). The task of biobanks is to collect and store blood and tissue samples and health data for medical research and product development. What is the role of biobanks and what is their contribution to Finnish and international genetic research and clinical care?

- Finnish biobanks and the material they contain are unique in the world, and they are also attracting international research investments and offer opportuni-


Linda Tammisto

ties for collaboration with top universities and other research institutes worldwide.

- It should be noted that, while there are many biobanks around the world, Nordic biobanks occupy a special position due to, for instance, their long traditions in and exceptionally good conditions for genetic and epidemiological research, i.e. research on public health. Blood and tissue samples have been collected in other countries, too. However, the practical problem in many countries is that these samples cannot be linked with registered health data in the same way as in Finland and other Nordic countries. This is one of the concrete reasons – in addition to large sample collections, health registers and progressive biobank legislation – why Finland is currently among the global forerunners in genetic medicine.

- However, biobanks serve not only for genetic research; but the material they contain also lays the foundation for a wide range of medical research. One of the fastest-growing research fields related to biobanks is research that combines genetic information and health data. It provides valuable information on the mechanisms of diseases, on prognoses, and on the effectiveness and usefulness of treatment.

3) Aarno Palotie was a member of Finland's genome strategy working group behind the proposals for the National Genome Strategy. Why should Finland invest in the operating models described in the genome strategy, such as the genome center that is currently being established?

- Thanks to the increase in genomic data and constantly evolving information technology, experts in different fields are better equipped than ever to study issues relating to health and diseases. And this opportunity should also be taken advantage of, as it provides us with new ways of meeting the challenges facing our health-care system and helps us to provide all Finns with the best possible care now and in the future. It is beyond admirable that officials from the Finnish Ministry of Social Affairs and Health have been willing and able to familiarize themselves with issues relating to biobanks and genetic medicine – in addition to the health and social services reform – and lead the preparation of the National Genome Strategy.

- The genome strategy was published in June 2015, and the proposed actions will ensure that genomic data is used effectively in health care and in decision-making relating to the promotion of health and wellbeing. Genome Center Finland will play a key role in this context. One of its main tasks will be to support the implementation of actions proposed in the National Genome Strategy. The genome strategy is aligned with the national eHealth and eSocial Strategy developed by the Ministry of Social Affairs and Health and the Health Sector Growth Strategy for Research and Innovation Activities.

- The establishment of the genome center is an investment in the health of every Finn.

4) Increase in genetic and genomic knowledge will change the everyday work of

physicians and other health care professionals in terms of examination methods, treatment and preventive health care. So far, genetic tests and information have been used to diagnose rare diseases and identify high-risk susceptibility to specific diseases. What is your vision of how the increase in genomic data will transform the treatment of patients and the maintenance of their health?

- At the moment, there are strong indications that in the future, health promotion and the treatment of diseases will be increasingly based on individual genetic information. However, genetic information will not radically change the clinical work of physicians and nurses or traditional health care functions. Rather, genetic information will become an element that complements and further specifies other examinations and treatments. Its use can mean more personalized care, improved quality of life, more effective prevention of diseases and ultimately increased longevity. This will contribute to reducing the human burden and social costs caused by the most common diseases in Finland – not to mention the positive impact that it will have on the work capacity and functional ability of Finnish people.

5) It takes some 8–12 years and costs more than a billion dollars to develop a new drug. Will modern genetic research based on a considerably larger base of materials than before facilitate and accelerate the development of new drugs and the identification of new indications for already approved drugs?

- Partly yes. For instance, genetic medicine can help to select from among several new drug targets those that should be taken further in the drug developing pipeline to become potential drugs. Once the drug has been developed and produced genetic knowledge can be used to determine to whom the new drug should be recommended based on their individual genetic makeup. Such information is important, as people can react to drugs very differently, both in terms of efficacy and harmful effects.

- A prime example of drug research drawing on new genetic information is the development of PCSK9 inhibitors that can lower LDL cholesterol. These drugs are used to treat patients with hereditary lipid metabolism disorders, such as familial hypercholesterolemia (FH).

- The pharmaceutical industry is the only party that develops new drugs, and it has invested strongly in the creation of genetic research groups recently. It's great that some of these multimillion-dollar research investments have been made in Finland and offered Finnish people long-term employment.

- As we still have diseases with no effective treatment, there is a need for new innovations. ■

References:
www.fimm.fi
www.helsinki.fi

Author: M.D. Maj-Leena Tuhkanen

Kimmo Pitkänen

Ilpo Tolonen

"Foreign investments in biobank research will also bring new jobs and wellbeing to Finland."

Finland aims to retain its position as a forerunner in genomic medicine

Finnish medical genetics and genomics experts and specialized bodies, such as biobanks, universities and health-care units, are in high demand as collaborators, even on a global scale. There are numerous reasons for this, and here we take a look at some of the main ones. Answering the questions are the Director of Helsinki Biobank, **Kimmo Pitkänen**, and the CEO of Docrates Cancer Center in Helsinki, Finland, **Ilpo Tolonen**, who comes from a pharmaceutical background.

What makes Finland a forerunner in utilizing the potential of genetic and genomic data?

Finland is an exceptional country when it comes to genetic and health-related data. We have been collecting and storing both tissue samples and other health-related data, with a long-term view, for several decades. These collections now offer an important and valuable source of data for research purposes. Finnish biobank legislation is also among the most progressive in the world, enabling the data contained in biobanks to be utilized for research related to health and well-being. So far, Finland is second to no other country in terms of attractiveness in this respect, despite the tough and ever-increasing competition in the sector.

Finland's upper hand on the international research front is the sum of many factors, the most important of which is our ability to simultaneously offer expertise and data in both genetic research and biobanks. The genotype of Finns is uniquely homogeneous, standing out from many other demographic groups when it comes to research. Finland is a global leader in the development of health technology, and we are recognized as a nation of world-class information and communications technology.

Why is Finland's National Genome Strategy also important from an international point of view?

Exciting opportunities have opened up for Finland, thanks to substantially improved, faster and cheaper availability of genetic, genomic and health data. The Genome Strategy helps us tap into these opportunities, and thereby even to make treatment breakthroughs comparable to penicillin or develop new methods related to identifying illnesses. This kind of research, however, is costly, and Finland alone does not have the financial resources required: international collaboration and partnerships are necessary. Finland's Genome Strategy and the Government's decision on the establishment of a genome center to harmonize and benefit the operations of all biobanks – as well as the establishment of the Finnish Biobank Cooperative – send an important message to international scientific researchers and funding bodies that investing here and starting up co-operation projects with Finnish experts is worthwhile. I'm very happy to see that international pharmaceutical companies and other research organizations, including universities, are interested in Finnish biobanks' resources (samples and health databases). ■

Author: M.D Maj-Leena Tuhkanen

Hannu Aaltonen

Genetic information helps in cancer treatment, among other things

Personalized medicine means diseases are not treated or prevented solely on the basis of a symptom, diagnosis or, for example, the location of a cancerous tumor, but instead with much greater precision. One such example is the genomic profiling of a cancerous tumor and the resulting choice of targeted medicine.

Professor Olli Carpén is a member of the Steering Committee of BBMRI-ERIC

Professor and cancer researcher Olli Carpén:

"Biobank operations are a source of national pride"

Biobank research that links genomic and other biological data with health data is of broad interest to researchers, and it is being used as a means of researching matters related to health, well-being and the treatment of diseases in a way that would otherwise be difficult or even impossible. Genomic data, i.e. information about a person's genetic make-up, has increased considerably and is expected to make medicine increasingly personalized.

These are very interesting times in the field of medicine, and certain aspects of the field are even headed in an entirely new direction, along with the better availability and scientific usability of the entire human genome. Researchers are excited about this new direction, and they believe that thanks to genomic research, medicine could take a quantum leap forward in certain respects. Researchers cannot, however, make promises about the future. There is nevertheless much hope in the air – and with good reason.

Olli Carpén, a professor of pathology at the universities of Helsinki and Turku, is a pioneer in the field of biobank research in Finland. He also has the honor of being the first biobank professor in the Nordic countries (University of Turku, 2013–2015). Carpén has also been a key figure in planning and launching the operations of Auria Biobank. Alongside his duties as a professor, he is also Helsinki Biobank's Research Director.

What made you interested in biobanks and motivated to work on and promote issues related to biobank operations?

- Finnish biobanks are of an exceptionally high standard and contain very diverse material. They open up entirely new, even unprecedented, opportunities for Finnish researchers and their collaborative partners to promote health and the treatment of diseases. Finland also has long traditions in both genetic and epidemiological research, i.e. national health research. Our laws also support research, and the atmosphere in which we work in this field is motivational in many ways.

Have there been any interesting developments lately on the biobank front?

- There is always a lot happening in the biobank world. One of the biggest new developments is the establishment of the Finnish Biobanks Cooperative (FINBB), which brings together, coordinates and professionally serves hospital biobanks that operate in different locations. FINBB launched its operations in August 2017

"Advancements in genomic medicine have opened up unprecedented opportunities to research and develop increasingly personalized treatment, diagnostics and disease prevention."

and is based in Turku. The establishment of FINBB was a very forward-looking decision by the Finnish Government, and it enables significantly broader and more harmonized and diverse use of the blood and tissue samples, as well as the related data, that are stored in hospital biobanks throughout Finland for research purposes. FINBB also facilitates communication and collaboration between external parties, such as pharmaceutical companies and foreign researchers and Finnish biobanks and researchers. This helps take Finnish medicine forward and brings us not only financial investments but also international recognition.

- It is wonderful to see how our healthcare system has appreciated the importance and opportunities of biobanks – both promoting clinical research and accelerating the introduction of personalized medicine as a part of patient care. One concrete example of this is Finnish university hospitals' approach of aiming to offer as many patients as possible the opportunity to participate in biobank operations. The goal is to build a sample base that is exceptionally broad even by international standards as an integral part of the hospitals' normal operations, which will go a long way in developing Finnish patient care and disease prevention. Behind this brand of nationally harmonized operations is Finland's globally unique network of hospital biobanks. With their active approach, Finnish hospital biobanks are continually consolidating their role in patient care. ■

References:
www.utu.fi
www.helsinki.fi

Author: M.D. Maj-Leena Tuhkanen

Genomic and molecular medicine are exciting!

" Genomic and molecular medicine may sound either very exotic and distant to everyday life or hopelessly boring and theoretical - in contrast to what they really are. These concepts simply mean that the diagnostics, treatment and etiology of a disease is brought to the level of genes and molecules, the ultimate goal being personalized medicine. Health care professionals already daily encounter patients whose disease has been diagnosed or treated by utilizing molecular medicine. It is great to follow the big changes and huge possibilities opening up through the current developments in molecular, genomic, and biomedicine."

Clinical Lecturer in Molecular Medicine, Adjunct Professor ***Kati Elima****, Univercity of Turku*

A previous Prime Minister **Matti Vanhanen** gave his sample to biobank at a biobank bus in Suomi Areena Event in July 2017. The sample was collected by bioanalyst **Roosa-Maria Sjösten** from SataDiag. Also the Minister of Family Affairs and Social Services **Annika Saarikko** as well as Member of Parliament **Juha Rehula** gave their samples at the bio bank bus

"Moments from the FinnGen launching event in December 2017"

Studio Petteri Kitti

"The FinnGen study plans to utilize 500 000 unique samples collected by a nationwide network of Finnish biobanks."

"Every Finn can be a part of the FinnGen study by giving a biobank consent. We invite every citizen on a common journey to advance medical research and build wellbeing!"

FINNGEN

FinnGen is a concrete manifestation of the potential of Finnish biobanks

Genomic medicine and digitalization will revolutionize the ways we maintain our health and treat diseases in the future. However, to achieve this goal, high-quality research and a growth mindset supporting new types of international collaboration projects between the public and private sectors are needed. FinnGen study is a poster child for this.

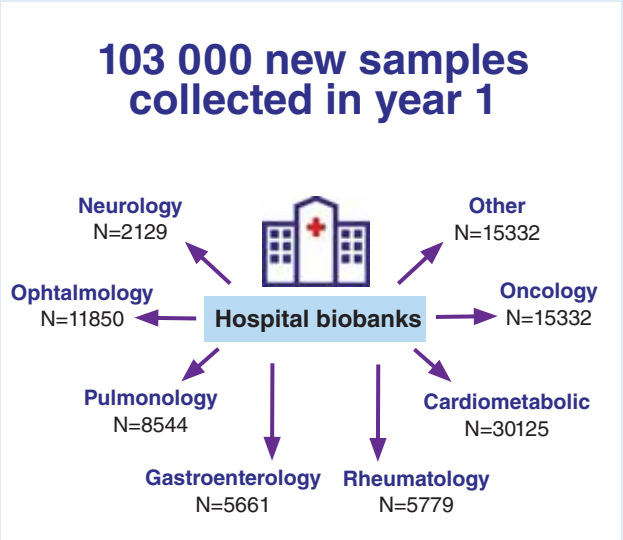
Funding FinnGen study is a big investment from Business Finland

"Business Finland wanted to support the FinnGen project, because of its potential to promote healthcare innovations and to boost the growth businesses. The study attracts international businesses and investments into Finland."

Senior Director ***Minna Hendolin***
Health & Wellbeing, Business Finland

Finland is the land of opportunities for biobank research and the FinnGen study, launched in 2017, is one concrete manifestation of this potential. It is a broad academic-industrial collaboration between the Finnish biobanks and their respective Universities, University Hospitals, the Institute of Health and Welfare (THL), the Finnish Red Cross Blood Service and several international pharmaceutical companies. With a current budget of 70 M€ it is the largest ever medical study performed in Finland.

Research Director, Professor **Aarno Palotie** from FIMM (the Institute for Molecular Medicine Finland at the University of Helsinki) has been the key person behind the study since the extensive planning phase. As the Scientific Director of the study, Palotie is excited about the immense research potential of this globally unpresented project. According to Palotie, it is very likely that FinnGen will lead to breakthroughs in disease prevention, diagnosis and treatment and build a foundation for health innovations and personalized treatments. Furthermore, it will increase the international visibility of Finnish research and biobank expertise abroad and promote us as an attractive research partner. The main responsibility of the coordination and execution



FinnGen study in a nutshell

■ Budget: 20 M€ of the project funding comes from the Business Finland (the Finnish innovation funding, trade, investment, and travel promotion organisation) and approximately 50 M€ from international pharmaceutical companies. Aarno Palotie warmly acknowledges all the participating universities, hospital districts and research organisations which significantly contribute to the study by providing their expertise and workforce for sample collection. Biobanks from all over the country have a key role in collecting new samples and data. The study also utilizes certain existing sample collections that have been transferred to a biobank.

■ The data created during the study will be used to deepen our understanding about the origins of diseases and their treatment and for prioritising drug targets based on genomic information, enabling more efficient drug development pipelines and better individualized drug treatment choices.

■ FinnGen capitalizes on Finland´s decades-long investments in Finnish health care, health registries, epidemiological research and biobanks.

■ FinnGen aims to produce comprehensive genome variant data of 500 000 biobank participants, representing one of the largest studies of this type. The genome data is combined with health data originating from multiple national health registries.

■ FinnGen utilizes the extensive longitudinal registry data available on all Finns. The opportunity to define informative and multi-dimensional phenotypes from this data is the key element of FinnGen. Data from these registers provide longitudinal, life time follow-up data from each Finnish resident. Combining data from different registries provides opportunities to construct reliable disease endpoints as well as novel long-term phenotypes of disease progression and therapeutic response.

■ During the first year, FinnGen has already delivered genotype and health data from 102 000 Finns. The amount of data will increase throughout the project, with 40–50 000 individuals added every six months. As envisioned, FinnGen has also given a strong boost to the Finnish biobank network with more than 108 000 new samples collected, 30 000 of which are included in the current data freeze.

■ Thanks to the unique cooperation model, immense potential of the Finnish research environment for genetic studies and the favorable progress of the study during the first year, FinnGen has been found as an attractive opportunity by many pharmaceutical companies.

■ FinnGen aims to open new possibilities for domestic biotechnology companies, several of which have already expressed interest and the Finnish business environment.

of the study lies with the researchers at the University of Helsinki and the progression of the sample collection at the Helsinki Biobank. Essentially, FinnGen is a national research project and its most significant findings can be found on anyone's sample and benefit people around the world.

- The FinnGen study is a globally unprecedented research project representing one of the largest studies of this type. The fact that we were able to convince our funders about the benefits of running this type of study in Finland is an indication of the Finnish expertise and we are very grateful for that! The single most important factor behind the success of the FinnGen is, however, the positive attitude of the Finns towards participating in medical research projects, says Palotie. ■

More information: www.finngen.fi

Authors: Ph.D. Mari Kaunisto and M.D. Maj-Leena Tuhkanen

Health care innovations are giving them a life-long journey they never expected

Good health is vital to all of us; as are sustainable solutions to the most pressing health care challenges we are facing globally.

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Purpose of Pfizer Finland is as well to accelerate science and develop the Finnish society.

This is just the beginning.

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PP-PFE-FIN-0237-17122018

What is a biobank?

Samples for clinical studies and diagnostic purposes have been collected throughout the history of medicine. Methods for collecting samples and consent practices have varied greatly, depending on the legislation and policies of each period. The difference between traditional sample collections and the new biobank concept is that samples collected in a biobank can be used for a variety of future research needs, not just for a defined specific research purpose.

Biobanks are composed of samples and information

In addition to biological samples, appropriate sample and donor-related information is also collected with the donor's permission. Information has been collected, for example, by questionnaires, during sampling, in the context of a medical examination, or during hospitalization. The data is stored in accordance with proper data processing and management practices, as defined by law.

Old and new biobank samples

The samples stored in a biobank can be divided into two categories according to their date of collection:

1) Old samples are samples that have been collected before 1.9.2013 for treatment, diagnostic purposes or medical research. The transfer of these samples to the biobank requires the assent of the regional Ethics Committee and the decision on the use of the samples for biobank research from Valvira.

The sample donors will be notified of the planned transfer, so that they may disallow the transfer or, alternatively, give a new informed consent for biobank research. If personal communication to each sample donor is not possible in view of the large number of samples, their age, or for any other comparable reason, the notification about the transfer of the sample collection to the biobank will be done publicly. The samples can be transferred to the biobank in both cases, as long as the donor does not forbid the transfer. The donor also has the right at any time subsequently to deny the use of samples and data in biobank research, by giving written notice to the biobank.

2) New samples that are collected from 1.9.2013 onward for biobank research will be collected based on the donor's informed consent to donate the samples to the biobank and use them in biobank research.

The use of samples in research

The samples and associated data are an important resource for medical research. The samples can be used, for example, to study the etiology of diseases or to develop and validate new diagnostic methods. The sample- and data sets can also be used for the development of personalized medicine, aimed at preventing, detecting and treating diseases in ways that are adapted to suit each patient individually. For example, there are numerous types and forms of cancer, and each patient reacts differently to the various treatments and drugs

Sairaanhoitaja-lehti/Leena Koskela

In Finland there is a strong national research nursing network. The trained research nurses have got a key role in biobank sample collection. ***Jaana Koski-Alhainen*** *was the first research nurse in Finnish biobanks.*

available. Therefore we expect that it will become increasingly important to know the specific nature of an individual tumour and to find the most effective treatment for each individual patient. This requires extensive, often long-term, studies that also combine data from various registries.

The advantages of a biobank

The comprehensive use of existing sample collections in medical research has many benefits. Citizens do not have to be invited on multiple occasions to participate in surveys and donate new samples. Also, samples that have been collected at great expense can be used more efficiently for research purposes, aiding in the development of better treatments and medications. The development work can be done in cooperation with pharmaceutical companies, so that the research results can be translated into better treatments and drugs. The success of the biobank operation relies on good cooperation and trust between donors and researchers.

Reference: www.biopankki.fi/en

Participation in biobank research

Donating samples to a biobank is voluntary. A request to donate samples for biobank research can come in a variety of ways. For example, in population studies a person can receive an invitation letter in the mail. During a hospital visit, a patient can be asked whether he or she would be interested in donating his or her samples, such as a small piece of tissue from a biopsy or excess blood taken at the laboratory visit, to the hospital's biobank.

The potential sample donors will receive detailed information about biobank research and data privacy issues, after which they can decide whether to donate their samples. Sample donors can also at any time withdraw their consent and prohibit further use of their samples. Samples collected prior to September 1 2013, by hospitals or in research projects, can also be transferred to the biobank. The transfer of old samples requires the assent of the Regional Ethics Committee, as well as the sample donor's consent.

The sample donor has the right to

- know where the sample taken of him or her is located
- know which studies their sample has been assigned to
- obtain general information about results from the study that the sample was used for
- decide whether to be informed about biobank research findings that may be relevant to his/her own health
- know about the research results and development work if it may have a positive impact on the patient's own disease
- cancel the consent regarding the use of the sample in a single study or in all studies
- deny the transfer of a previously donated sample to a biobank

Consent and withdrawal of consent

According to the biobank law, each sample donation requires a written consent of the sample donor or of his/her guardian. If a person is willing to donate a sample, he/she receives a consent document to fill out and sign.

The donor may later cancel the consent or restrict the use of the sample at any time without giving any reason. The withdrawal or restriction should be made in writing to the biobank, according to the biobank's specific instructions.

The withdrawal of consent is documented in the biobank's consent register, after which the samples and the information will no longer be used.

Finnish biobanks and contact persons

Valvira (the National Supervisory Authority for Welfare and Health) directs and supervises the biobank activity in Finland, and maintains a national biobank register. Before starting to operate the biobank has to obtain a licence from Valvira.

Valvira has granted a licence altogether to ten biobanks, from which four are operating in the whole of Finland and six biobanks in the area of hospital districts.

Auria Biobank

■ Auria biobank is a hospital integrated clinical biobank operating in Turku, Finland. It is jointly owned by University of Turku and Hospital districts of Southwest Finland, Satakunta and Vaasa. Auria biobank was authorized to operate in March 2014. Auria has a collection of over 1,5 million FFPE tissue samples and ongoing collection of tissue and blood samples. Clinical data generated as part of the diagnosis, treatment, and follow-up of the patients is obtained from the hospital's EHR systems and can be linked to the samples. The results from biobank studies will return to the biobank to add value to samples and to be used in new studies.

Contact Person:
Lila Kallio, Acting Director
lila.kallio@auria.fi

THL Biobank

■ THL Biobank belongs to the National Institute for Health and Welfare. THL Biobank's registered areas of research include population's health promotion, identification of factors involved in disease mechanisms, and disease prevention. THL Biobank is a country-wide biobank and hosts a remarkable collection of population and disease-specific samples for research purposes. The National Supervisory Authority for Welfare and Health (Valvira) granted THL Biobank a licence to operate on 10 March 2014.

Contact Person:
Sirpa Soini, Director
sirpa.soini@thl.fi, biopankki@thl.fi

Hematological Biobank (FHRB Biobank)

■ Hematological Biobank is owned by the Finnish Association of Hematology, Institute for Molecular Medicine Finland and Finnish Red Cross Blood Service. The Association of Finnish Cancer Patients is also involved in Hematological Biobank. Biobanks's research area covers the prevention, diagnosis, treatment and follow-up of hematological disorders. Hematological Biobank is a national biobank and collects samples and data from patients with hematological disorder in all Finnish hematological units that have made an agreement on sample collection. The aim of the Hematological Biobank is to collect a comprehensive and high quality sample and data repository for hematology research. The Hematological Biobank was registered in Valvira's (National Supervisory Authority for Welfare and Health) national biobank registry on July 15, 2014.

Contact Person:
Kimmo Porkka, Principal Investigator
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Helsinki Biobank

■ Helsinki University Central Hospital (HUCS) -area of special responsibility and the University of Helsinki have established a clinical biobank that supports the translational research done in the region, and network with national and international biobanks. The research field of Helsinki Biobank is the research done in health and medical science in HUCS area. Helsinki Biobank operates to support research which aims at promoting population health, understanding the factors in disease mechanisms or the development of health care products. The biobank obtained a licence to operate from the National Supervisory Authority for Welfare and Health, Valvira on April 21, 2015.

Contact Person:
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kimmo.pitkanen@hus.fi

Northern Finland Biobank Borealis

■ Northern Ostrobothnia Hospital District (PPSHP), the University of Oulu (UO), Nordlab and the hospital/healthcare districts of Lapland, Länsi-Pohja, Central Ostrobothnia and Kainuu have established a biobank in Northern Finland. The Biobank Borealis obtained a licence to operate from Valvira on July 10, 2015.

Contact Persons:
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Pia Nyberg, Project Manager
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biopankkiborealis@ppshp.fi

Finnish Clinical Biobank Tampere

■ Finnish Clinical Biobank Tampere (FCBT) was established by Pirkanmaa Hospital District, University of Tampere, Etelä-Pohjanmaa Hospital District and Kanta-Häme Hospital District. FCBT's role is to support disease prevention, studies on the effectiveness or side effects of treatment of patients, and studies exploiting pathological findings. The main focus of the biobank, in accordance with the research strategy defined by the University of Tampere and Pirkanmaa Hospital District, is research in cardiovascular disease, cancer, immunology and type 1 diabetes. FCBT's licence to operate was granted by the National Supervisory Authority for Welfare and Health, Valvira, on September 8, 2015. The aim is to start sample collection gradually during 2016.

Contact Person:
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biopankki@tays.fi

Biobank of Eastern Finland

■ The Biobank of Eastern Finland was established by the hospital district of North Savo, The South Savo Social and Health Care Authority, the hospital district of Eastern Savo, Siun sote – Joint municipal authority for North Karelia social and health services and the University of Eastern Finland. The Biobank of Eastern Finland aims to mediate high quality human samples and related data to medical research to promote development of new products and services that promote public health. The Biobank of Eastern Finland was registered to Valvira national biobank register on October 29, 2015.

Contact Person:
Arto Mannermaa, Biobank Professor
arto.mannermaa@uef.fi

Central Finland Biobank

■ The Central Finland Health Care District and the University of Jyväskylä established a biobank in Jyväskylä that aims to promote research and to support the development of diagnostics and treatment. The Central Finland Biobank was registered to Valvira national biobank register on October 29, 2015.

Contact Person:
Marjukka Friman, Production Manager
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Blood Service Biobank

■ The research area of Blood Service biobank is health promotion and prevention of diseases and is specialized in transfusion medicine. The biobank collects samples from blood donors during their blood donation. The Blood Service biobank was registered in the national biobank registry by the National Supervisory Authority for Welfare and Health (Valvira) on May 30, 2017.

Contact Persons:
Jukka Partanen, Research Director of the Blood Service
Tiina Wahlfors, Development Manager of the Blood Service
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Terveystalo Biobank Finland

■ Terveystalo Biobank Finland's registered areas of research include population's health promotion, identification of factors involved in disease mechanisms, and disease prevention. Terveystalo Biobank Finland was registered to Valvira national biobank register on October 11, 2017.

Contact Person:
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markku.nissila@terveystalo.com

The source of this text: www.bbmri.fi/en

Marco Hautalahti

Teijo Kuopio

Lila Kallio

Kimmo Pitkänen

CEO of FINBB – Marco Hautalahti – comes from the pharma industry

FINBB is building an ecosystem for health and wellbeing innovations

"FINBB is the missing link between experts and data. As the world's leading biobank network we advance biomedical research by offering researchers from academia and industries a one-stop-shop service model for access to biobank samples and unique health data. We want to be a key partner in biobanking globally. At this moment we are, for example, serving FinnGen Pharma Partners.

All profit FINBB makes returns to our founding partners, universities and hospital districts to reach patients´ care," says Marco Hautalahti.

Marco Hautalahti, M.Sc (Biology), MBA, has over 20 years of experience in international pharma and health care business, including roles in research and development, commercial operations, and over 10 years in general management and European leadership roles.

Hautalahti joined Finnish Biobanks Cooperative (FINBB) from Biogen International Ltd where he was responsible for Nordic rare disease business operations and commercialization in Europe and Canada. Before this, as CEO of the private Finnish cancer hospital Docrates Ltd he led its domestic and international operations and previously successfully managed and developed international reproductive health and sport health care services in diverse health care companies.

"I am absolutely enthusiastic to join FINBB at the epicenter of the Finnish biobank system, especially today with a government strategic initiative to strengthen both national and international biomedical research in Finland," says Marco Hautalahti. "Biobanking aims at improving patient outcomes and these services are expected to fundamentally change our healthcare system for the better and enable economic growth in health care innovation."

"FINBB appointed Marco as Chief Executive Officer, effective 15th of June, 2018. Marco is a dynamic leader with broad networks and I am confident he will be successful in building a functional infrastructure and a one-stop-shop service model in Finnish hospital biobanks for both academic and healthcare company scientists," says **Timo Veromaa**, Chairman of the Board of FINBB. ■

Seppo Vainio

Kimmo Savinainen

Veli-Matti Kosma

FINBB integrates services and operations – making it easier to cooperate with hospital biobanks

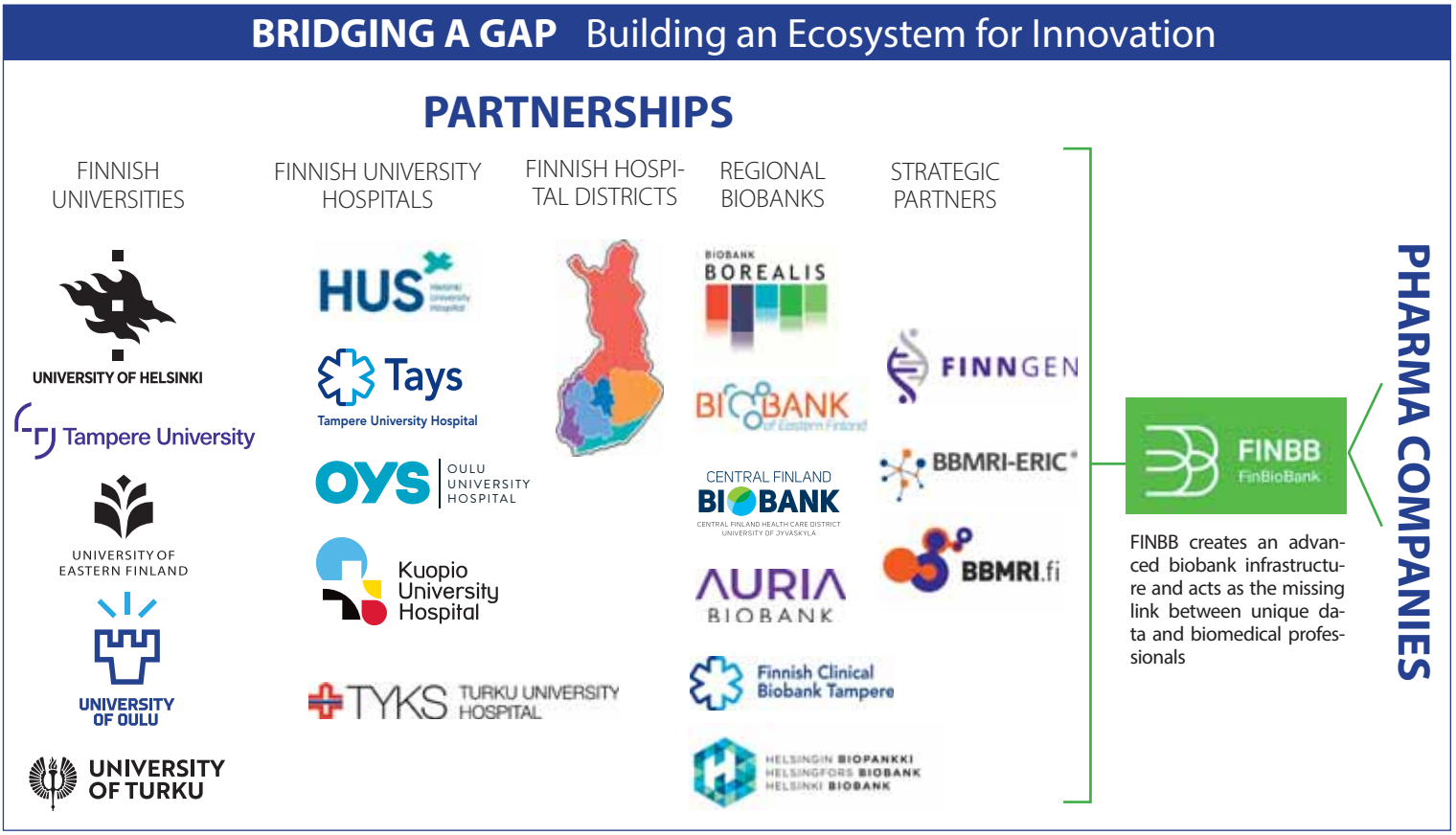
Finnish biobanks cooperative (FINBB) was established by six Finnish universities and the six largest hospital districts in the Autumn of 2017 to serve and facilitate development of member biobanks and to provide a single entry point – one-stop-shop service model – to biobanking services on a national and international level. Biobanks are expected to accelerate both academic and company-driven biomedical research. FINBB plays also an important role in the practical implementation of the national health sector growth strategy and in building the national genome and cancer centers as well as the health data service operator.

Why Finland?

Finland's unique genetic heritage is characterized by a small, isolated initial population that has experienced rapid growth over the past few hundred years. Our biobank samples and population-wide health registries will provide enormous possibilities for identifying the genetic basis of rare and common diseases. It also gives important information about preventive and personalized medicine. New treatments will be developed faster than before using samples given to hospital biobanks and health data. The most important factor is the positive attitude of Finns towards research, which it is astoundingly high. Over 90 % of Finns consent to donating their samples to a biobank upon request.

With Finland's advanced biobank law, the genetic homogeneity and public confidence in the authorities provide great preconditions for conducting top-level biomedical research. ■

Author: M.D. Maj-Leena Tuhkanen



Werneri Tuompo, Jr. Scientific Project Manager, Maija Wolf, Sr. Scientific Advisor and Development Lead, Jaana Ahlamaa, Medical and Market Access Director, Ulla Montonen, Marketing Lead, Mariann Lassenius, Sr. Scientific Advisor and RWE Lead

Medaffcon pioneering biobank and real-world evidence research efforts in Finland

Research utilizing biospecimens and data collections available in biobanks has an established and growing role in the field of healthcare and biomedical research. Finland has several key features that makes it an ideal country for biobank and other related real-world evidence (RWE) studies. These include genetically isolated population background, comprehensive healthcare system, strong governmental support and enabling legislation, as well as unique identification numbers that provide means of linking data further to national registries dating back several decades (Figure 1).

Medaffcon Oy is a Finnish company that provides expert and research services for biobank and other RWE studies. The company has been pioneering private sector-sponsored biobank research efforts since the establishment of the first biobanks in Finland (2014). Since then, Medaffcon has performed already more than twenty biobank and registry studies and has currently several ongoing, involving stakeholders from both private and public sector. The common goals of these studies are to provide means for data-driven decision-making in healthcare and work towards economically sustainable, effective and more individualized treatment care.

To showcase the activity and huge potential in Finland of advancing individualized care to national and international stakeholders, Medaffcon has recently launched Future Care Finland website, a platform that highlights Finnish innovations, technologies and applications that aim to facilitate customized patient care (www.futurecarefinland.fi).

Survey on the current operational status of Finnish hospital biobanks

As a part of the Future Care Finland effort, Medaffcon has in collaboration with the University of Eastern Finland assessed the operational status of the Finnish hospital biobanks (Figure 2).

To briefly summarize the report (fully accessible from Medaffcon website https://www.medaffcon.fi/en/materials/), Finnish hospital biobanks have created a unique research infrastructure in Finland. By May 2018, archived diagnostic sample collections, consisting of 11 million samples from three million individuals, as well as selected research collections gathered in the hospital districts, had been transferred to the biobanks. The latter includes, for example, the Finnish maternity cohort, FMC, a globally unique sample collection consisting of two million serum samples obtained from one million women stored in Biobank Borealis of Northern Finland.

In addition to retrospective samples, collected before the Biobank Act took effect, all hospital biobanks are actively gathering new prospective samples from consented people. By May 2018, close to 80 000 new samples had been collected. With the uniformly high motiva-

tion, support from the hospital districts and launch of new research efforts, such as FinnGen, the pace of collecting new samples is expected to rise quickly in the upcoming years.

Already now, just five years after the Biobank Act took force, numerous studies have been initiated that utilize biological material and related data governed by the hospital biobanks. By May 2018 there were already close to two hundred positive decisions made regarding biobank study requests. Of these, 62 % involved research efforts with public and 38 % with private sector partners. Initiated biobank studies involving private sector partners have included those conducted with Finnish commercial companies or the Finnish subsidiary of a global company as well as those conducted directly with international companies.

To summarize, through high-quality samples and associated data, the six Finnish hospital biobanks provide excellent opportunities to study diseases and facilitate the development of individualized therapies. This has led to the initiation of both national and international biobank research activities in Finland. To further advance this development, there are currently several actions ongoing in Finland that aim to support the use of health and wellbeing data. The main reform concerns the legislation regarding the law for secondary use of health and social data, the genome law and the revision of the biobank Act.

While there are currently hundreds of biobanks in Europe and only a fraction of them reside in Finland, Finnish biobanking stands out due to several strengths and has the potential of claiming the forefront in biobank research activities also internationally.

At Medaffcon, we believe that biobanks provide an enormous opportunity to advance better healthcare. We are excited to be part of this development and determined to use our expertise towards these goals. ■

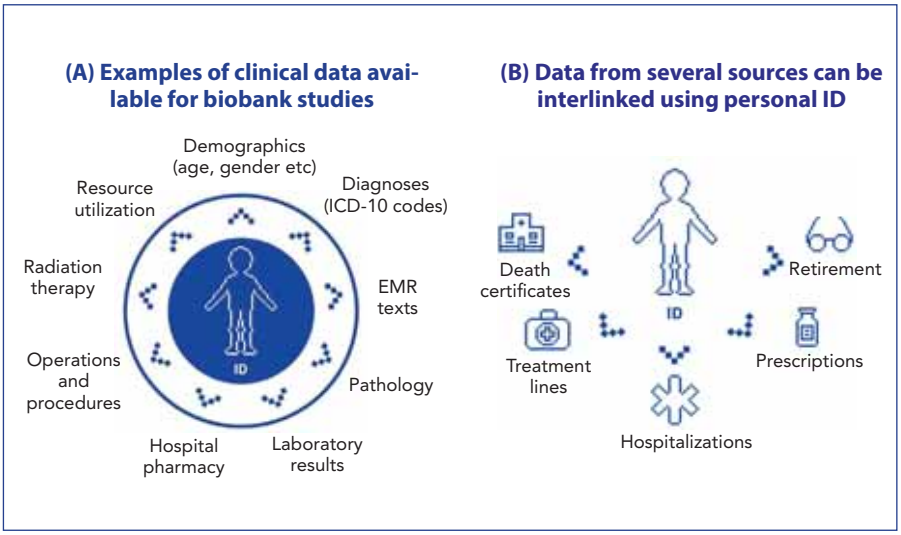


Figure 1. One of the strengths of the biobank research environment in Finland is the possibility to link health-related data from various data sources by using the personal identification number. Sample-related clinical data available for biobank studies (A) can be further linked with other relevant data residing in national registries (B). For research purposes, data is provided in a format that prohibits the recognition of individual donors.

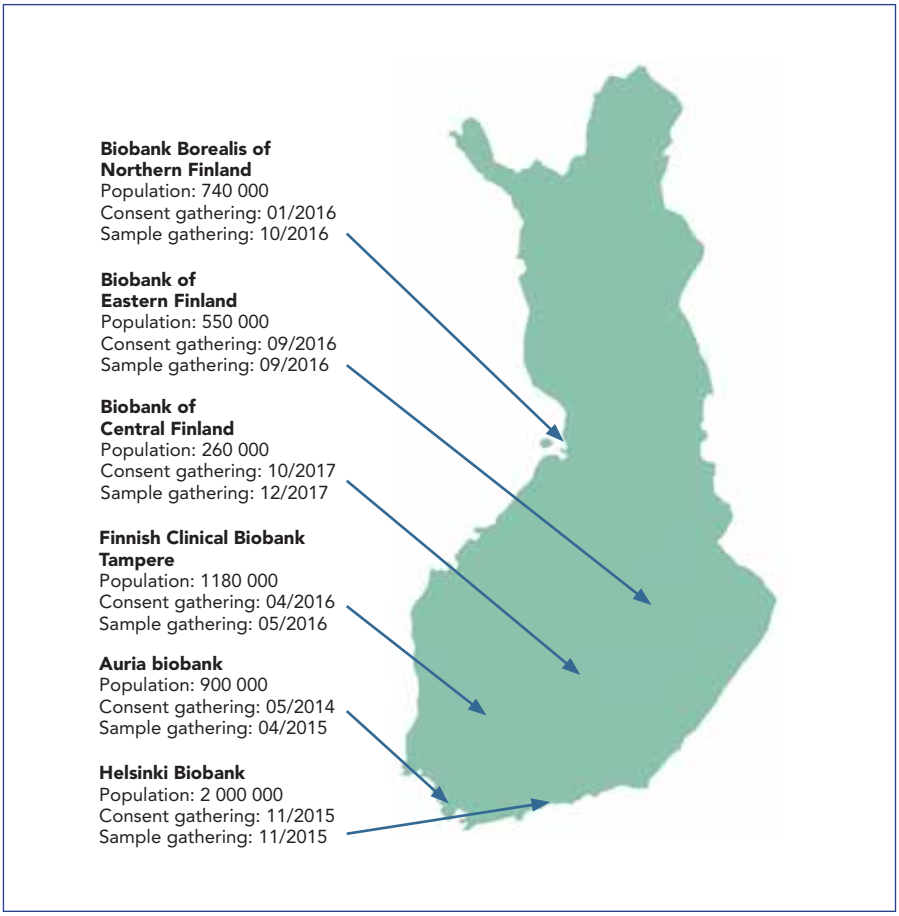


Figure 2. Finland has six registered, operational hospital biobanks. These biobanks are owned by the corresponding hospital districts and universities, and they operate in determined healthcare regions in Finland. Figure demonstrates the demographic locations of the hospital biobanks, population coverage and the timepoints of starting the consent and sample gathering. The total population base of the hospital biobanks covers 5,5 million inhabitants, which is approximately the same as the official population base of Finland.

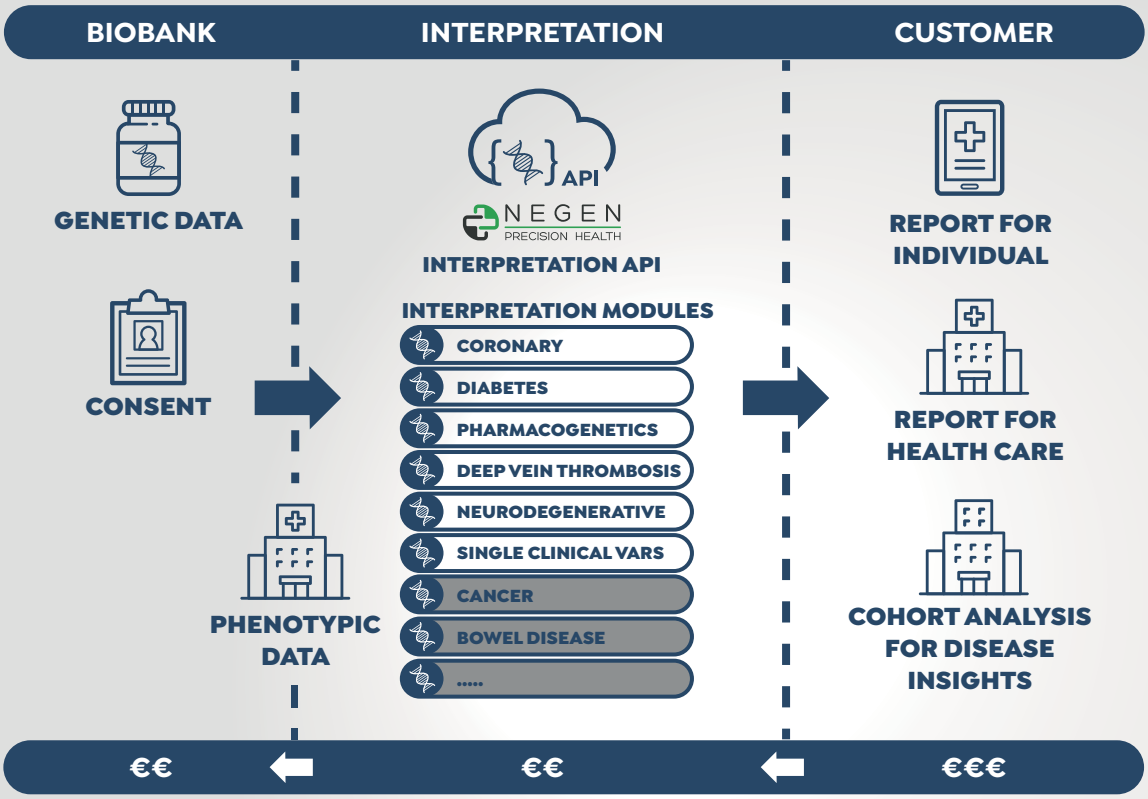
Reference: Tuompo W, Hemmilä P, Wolf M. Current operational status of the Finnish hospital biobanks. 10/2018.
Free download: https://www.medaffcon.fi/en/materials/
Authors: Werneri Tuompo, Jr. Scientific Project Manager
Maija Wolf, Sr. Scientific Advisor and Development Lead

RETURN HEALTH RELATED GENETIC BIOBANK DATA FOR SAMPLE DONOR'S BENEFIT

Donors rarely, if ever, receive any genetic health related information, even when their samples have already been genotyped or sequenced.

Cooperation between Negen and Biobank enable the return of genetic health related data in automatized and cost-effective way, for the donor's benefit.

Reported traits and features can be customized to fit the use case and available data sets.



Returning validated and actionable information to sample donors is expected to increase motivation towards donating samples which leads to even broader datasets.

LET'S MAKE BIOBANKING EVEN MORE INTERESTING AND BENEFICIAL TOGETHER

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Lila Kallio

Sirpa Soini

The Biobank pioneers are pleased with current situation and trustful with the future

There has been biobanking operation in Finland since March 2014 when Auria Biobank in Turku city and the THL Biobank by National Institute of Health and Welfare got their authorization from Valvira, i.e. the National Supervisory Authority for Health and Welfare. After that ten biobanks have opened in Finland (the Helsinki Urological Biobank merged with the Helsinki Biobank in May 2016). The THL Biobank Director, LL.M. **Sirpa Soini** and the Acting Director, Ph.D. **Lila Kallio** in Auria Biobank tell that their experience of the operating biobanks so far are excellent and encouraging for further development. Many positive cases have already happened and the future looks bright. You can get acquainted with their comments of biobanking in the enclosed text.

Director, LL.M. Sirpa Soini, THL Biobank

”THL Biobank is part of the National Institute for Health and Welfare (THL) and provides access to THL's nationwide population-based legacy cohorts collected since 1965 for research purposes. Nowadays, THL Biobank's cohorts are enriched with omics data. For instance, it started collecting DNA-samples already in 1992. THL Biobank's sample collections include lifestyle data and lab values. Thus its collections provide highly valuable and internationally unique research material. Researchers can, for example, analyse samples, interviews and measurements acquired 20 years earlier and try to find out factors that have contributed to onset of a disease later in life. If some rare type of cancer would suddenly become more common, researchers could go back to samples collected decades earlier to find out whether a viral disease prevalent at that period could have increased the risk of the disease. The linking of THL's cohorts to similar collections in other countries gives researchers a stronger tool to promote health, to study factors affecting diseases and to develop new treatments. Research collaboration is important due to the complexity of the factors behind the diseases that cause the greatest global burden.

THL Biobank grants access to biological samples and data to research projects that are of high scientific quality and impact, and that correspond with the research areas of THL Biobank.

THL Biobank, like other Finnish biobanks, has many important goals: promotion of population health, identification of disease mechanisms and promotion of production development linked to health and welfare and hospital care. Currently THL Biobank's collections include ca 200 000 study participants.

THL has coordinated the national biobank network BBMRI.fi to advance the Finnish biobank field in Finland since 2014. BBMRI.fi is an active member of BBMRI-ERIC, the European biobanking research infrastructure.

All Finnish biobanks` aim is to build a treasure-trove for the national and global medical community, helping researchers and clinicians to find novel ways to build better healthcare for everyone. We believe that biobanks are an elemental part of solving global health problems. We'd like thank our sample donors, without them our ambitious projects would not been made possible.”

Acting Director, Ph.D. Lila Kallio, Auria Biobank

”Auria Biobank has been greeted well. The infrastructure provided by Auria has increased possibilities for cooperation among academic researchers both locally, nationwide and internationally as well as for public-private-partnerships. The functions of Auria – as well as of all other Finnish biobanks – are based on the special credits of the Finnish society: public healthcare, electronic health data, operational legislation and ultimately pro-research population. These together guarantee excellent conditions to Finland to make success in biobank research and many international and Finnish enterprises like Orion Oyj (which invests ten percent of its revenue in research and product development) have been interested in the services and research possibilities offered by Auria.” ■

Author: M.D. Maj-Leena Tuhkanen

BUSINESS
FINLAND

Finland – innovation powerhouse for next generation pharma

Due to its enabling legislation, long history in clinical research and extensive digital health registers and databases, Finland offers best-in-class environment for pharmaceutical companies. The country's research & development ecosystem welcomes international partners to leverage the unique innovation platform to develop solutions to worldwide health challenges.

Pharmaceutical development is increasingly difficult. Dr. **Sampo Sammalisto**, programme manager of the Personalised Health programme at Business Finland, points out that all the 'easy' cures have already been found; what's left is the tricky business.

- On top of this, the regulation becomes stricter and stricter and financial pressure is ever intensifying. Basically, companies are expected to create better medicine faster and more cost-efficiently, but that's easier said than done, he explains.

Thus, companies are looking for reliable solutions that enable conducting high-quality research and development in an efficient manner. This is where Finland can step in to help: the country's lengthy tradition in medical research, highly educated clinicians and research professionals, organised and established infrastructure and, perhaps most importantly, wide-ranging and readily available digital data offer huge opportunities to both local and global innovators.

For example, the relatively recent Biobank Act allows for previously collected samples to be transferred to biobanks and made accessible to researchers. The act also comprises the concept of 'broad consent', meaning that researchers don't need to ask for permission to use samples in new projects.

An excellent enabler in a trust-based society

Sammalisto notes that Finland and its institutions, such as the National Institute for Health and Welfare THL, have traditionally gathered extensive records of socioeconomic and medical data, which forms a strong base for health sciences. As technology advances, the existing databases are of unprecedented value.

- The Biobank Act is an excellent enabler and very innovation-friendly. One of its exceptional features is the 'recall option', which allows for researchers to invite biobank sample donors to take part in further research projects, Sammalisto tells.

Today, the coverage of population-based digital health registers and patient records is 100 % and the development of integrating individual's real-life data, MyData, to the national patient information system KANTA is well on the way.

- When biological sample and data collection began several decades ago, no one could predict how precious this asset would eventually become, says Dr. **Minna Hendolin**, Senior Director of Health & Wellbeing at Business Finland.

Sammalisto mentions the personalised medicine project FinnGen as the flagship of Finland's attractiveness for foreign pharmaceutical investments. The project combines genome information with digital register data to better grasp the health effects of our genomes, and ultimately it aims to improve health through genetic research as well as identify new therapeutic targets and diagnostics.

Adding to existing databases, Finns tend to be keen to take part in many different types of studies. Sammalisto emphasises that as Finland is a very trust-based society and officials and academics are well-respected by the general public, participation rates can seem sky high in comparison to many other countries and are often admired by foreign researchers.

Closing all possible gaps

Boosting the pharmaceutical and health industries is high on the government's agenda, too. Hendolin compliments Finland's interest in advancing enabling legislation. The National Health Sector Growth Strategy for Research and In-

novation (2014–2018) work has focused primarily on closing all possible gaps that could hinder the country from becoming a global forerunner in the health industry and creating strong centres of expertise and innovation ecosystems in the country.

The Biobank Act is an obvious example of the government's support for innovation, and the changes proposed to the law will make it fully compliant with the EU's General Data Protection Regulation (GDPR). There are also other forthcoming laws on genomics as well as the secondary use of social and health data that will improve the legislative environment but also set the framework for important infrastructures National Genome Centre and Data Permit Authority as well as Data Service Operator.

Both Sammalisto and Hendolin see Finland building research and innovation ecosystems that entwine public and private organisation and institutions.

- In addition to the national health policies and the investments to infrastructure that are meant to support the development of a fruitful research environment, there are many strategic and policy initiatives regarding the utilisation of artificial intelligence and other exponential technologies throughout the whole society. All these put together, we're creating an intelligent and competitive environment to do business in Finland, Hendolin tells.

Global giants taking note

Finland is in a unique position, both within the European Union and globally. Sammalisto notes that what makes Finland different from others isn't just one thing but rather a rare combination of factors, ranging from electronic medical records, innovation-friendly legislation and pro-research citizens to the fact that the country hosts one of the largest population isolates in Europe, which can help make genetic discoveries faster than in heterogeneous populations, as well as unique identification numbers that allow for combining medical data across multiple sources.

Finland is also constructing a national structure comprising service operators and licensing authorities, ensuring that pharmaceutical companies and other researchers have access to all needed information under just one (figurative) roof. For example, the Finnish Biobank Cooperative (FINBB) offers biobanks services related to sample and data processing, law and communications.

Many global pharmaceutical giants are already leveraging Finland's capabilities and expertise, with FinnGen as the largest public-private programme. Individual biobanks, like Auria in Turku, have several ongoing projects with global pharma clients.

- Biobanks often provide the platform for new medical innovations, which can then be commercialised, and new enterprises will be born. The medical industry is global by default, because health concerns each and every one of us, Sammalisto says. ■

Author: Anne Salomäki

Anssi Linnankivi

Studio Petteri Kitti


Tarja Jalava and Arndt Schmitz

Studio Petteri Kitti


Juha Laine

Pfizer Finland is very pleased with Finnish biobanks

"Finnish biobanks have been open-minded, flexible and professional partners for Pfizer Finland. This is the message we constantly tell to our New York headquarter. For instance our registry study about metastatic breast cancer produced valuable information about treatment of the disease.

However, in our activities with biobanks and hospitals we aim further. For instance in the breast cancer study a novel visualization of reporting the treatment lines were developed by PhD **Antti Karlsson** at Auria Biobank. Moreover, we have supported to NLP approach (natural language processing) in order to analyze non-structural information. Antti Karlsson has developed the NLP algorithm that can classify smoking status of patients from the text even better than human. The same approach can also be used for detecting the stage of breast cancer. Earlier this work demanded a lot of manual work.

In our company´s activities we don't only focus on traditional ways of production of real world evidence. Together with the very skilled experts from the biobanks and hospitals we can explore innovative ways of producing the data and reporting the results."

Senior Health Economics Manager
***Juha Laine**, Pfizer Oy*


Kimmo Aro


Heikki Ukkonen

Ulla Roine/Kuva-Paijula Oy

Customers comments about biobanking in Finland are excited and encouraging

"The Finnish Biobank Cooperative (FINBB) was established in August 2017, and it creates excellent opportunities for research collaboration with Finnish hospital-based biobanks. No other country has a similar setup, and it thus provides a clear competitive advantage to Finland. It enables closer collaboration whereby things can be developed and fostered together for the benefit of the patients.

"Finland has refined the biobank operations into a world class innovation opportunity, and Finland has good chances of taking on the mantle of a pioneer in personalized medicine. The pharmaceutical company Bayer has had excellent experiences of collaborating with Finnish biobanks."

*Dr. **Arndt Schmitz**, Head of Research Biobank at Bayer AG (Germany), and **Tarja Jalava**, Head of Clinical Project Management II Oncology Strategic Business Unit at Bayer (Finland)*

"There is a lot of work to do. For example, biobank research is needed to develop new molecules and diagnostic tools, such as genome profiling, to support timely and effective treatment selection."

*Medical Director **Anssi Linnankivi**, Roche Oy*

"Collaboration with a Finnish biobank enabled the validation of the predictivity for our genome based risk assessment analysis for Finnish national diseases, coronary heart disease and type 2 diabetes. Without this kind of collaboration, the predictivity of the genomic panels used, would be a lot more based on an assumption. We are enthusiastic to continue our collaboration with the biobanks."

*CEO **Kimmo Aro**, Negen, Finland*

"The ongoing FIN-HF heart failure patient characterization study, which is conducted in collaboration by Novartis Finland Oy, Turku University Hospital and Auria Biobank, has brought important information to help physicians and nurses on the treatment of these patients. The study has also brought global knowledge about the specific characteristics of different heart failure types as well as health care resource use and thus helps to guide the treatment decisions. It has been surprising how broad information we have been able get from a retrospective biobank study."

*Chief Physician, Docent **Heikki Ukkonen**, Turku University Hospital and Medical Advisor, Ph.D. **Jenni Huusko**, Novartis Finland Oy*

Author: M.D. Maj-Leena Tuhkanen

A new era in medicine is dawning as genetic and genome information increases in volume

"Finland could become the model country for utilising genetic information and a global trailblazer in the field. The first signs are already there," says Petri Lehto, Ph.D. (Economics), Director, Policy and Communication at MSD Finland Oy, previously Head of Innovation at the Ministry of Employment and the Economy.

Petri Lehto is well versed in issues related to the health industry and has been actively involved in their development for several years. Lehto assumed the post of Director, Policy and Communications at MSD Finland Oy at the beginning of 2015. Before this, he held the position of Senior Adviser for industrial affairs at the Ministry of Employment and the Economy. In his previous duties, Lehto focused particularly on the direction of Finland's innovation policy. At MSD, too, Lehto is interested in promoting innovation activities in cooperation with actors and experts representing various sectors of industry.

"This is an interesting time in Finland. However, Finnish economy needs new openings in industry and new activity. On the other hand, there is considerable potential for growth and development, including opportunities related to the samples and health information stored in Finnish biobanks. Utilisation of this information could put Finland on the global map and attract huge investments from international investors," says Petri Lehto. He believes that Finland is well positioned to compete for international clinical trials in the field of genetic medicine. The Finnish Biobank Cooperative (FINBB), established in August 2017, and the Finnish Genome Center (preparations for establishment of the Center are ongoing) provide valuable support in this respect.

"Genetic research is developing at leaps and bounds. This is mostly due to the fact that thanks to new technology, we have seen a dramatic reduction in the time needed for genome sequencing – analysing the full gene map of the human genome – and the associated costs within the past few years. At the same time, medical research combining genetic and health information has also become one of the fastest-growing research sectors. "

"Finnish experts in genetic medicine are internationally recognised and respected, and we now have an excellent opportunity to showcase our strengths and attract investments to Finland."

Author: M.D. Maj-Leena Tuhkanen

SIG accelerates enterprises

The Genome Industry Special Interest Group (SIG) was funded by Healthtech Finland in August 2017 aiming to accelerate the production and application of genomic data and genetic tests in health care and for people's well-being overall. Ph.D. **Jari Forsström** was the first elected chairman from Abomics Ltd. "There are technologies, such as pharmacogenetics, available for the health care systems to utilize. The Genome Industry is thriving to get these innovations as part of the system and available for all. Improving the patient safety and cutting costs is relevant for all," says Forsström.

Terveystalo Biobank Finland is the first privately owned biobank in Finland

Terveystalo Biobank Finland was granted a license by Valvira (the National Supervisory Authority for Welfare and Health) on the 12th October 2017. Dr. **Markku Nissilä** works as the responsible director in close collaboration with business administration director **Lasse Parvinen**, who is in charge for clinical trials and biobank activities within Suomen Terveystalo Plc. Mr. Parvinen and Dr. Nissilä regard biobank activities as one of the core functions of Suomen Terveystalo as a means of bringing personalized healthcare to the customers. Suomen Terveystalo is focused on working age population and provides occupational healthcare services to 800 000 people across Finland, as well as specialist healthcare close to a million customers. Terveystalo Biobank Finland is part of Suomen Terveystalo Plc, listed on OMX Helsinki (TTALO).

The Finnish Red Cross Blood Service (FRCBS) runs its own biobank, and it's easy for donors to join the Blood Service Biobank in connection with blood donation. Biobank samples can be given at all ten blood donation centers and since January 2019 also in mobile blood service sessions all around the country.

Blood donors can also help via biobank. Photo of nurse Riina Heikura (left), Satu Koskela donating blood and Elina Salokangas, Tiina Wahlfors, Jonna Clancy and Jukka Partanen who all work with Blood Service Biobank.

Blood Service Biobank – a new dimension for extending donors help

Blood Service Biobank has had a busy start

The Blood Service Biobank was established in summer 2017 and started collecting samples in the end of 2017. This Biobank is special as it has the potential to compile a valuable collection of blood donor samples and information. The Blood Service Biobank will facilitate for instance research on blood donors' health and wellbeing. In addition the collected samples can be used in medical research for example as a control group.

Blood donors can be considered as healthy individuals who are willing to help others. Regular donors can also be sampled several times over the years and at the same time also health and life style data can be asked. It is also likely that the same individuals will consent to the hospital biobanks if getting sick. This makes an excellent opportunity to study predictive biomarkers and develop methods for disease prevention and prediction overall.

The Finnish Hematology Registry and Clinical Biobank promotes research on hematological disorders

The Blood Service is also involved in the Finnish Hematology Registry and Clinical Biobank (FHRB), which collects samples and data from patients suffering from hematological diseases. The objective is to support the development of new methods for the diagnostics and treatment of hematological disorders and improve the prognosis of patients suffering from these disorders. ■

Reference:
www.bloodservice.fi

Author: M.D. Maj-Leena Tuhkanen

The Association of Cancer Patients cooperating and developing Hematological Biobank

" Biobanks are key players when new cancer treatments are developed. This is why Cancer Patients are willing to do their share by increasing biobank awareness and tell about biobanks' activities. The more high quality samples biobanks are able to collect and the more biobank research develops the better are the changes for patient to survive for example from cancer. At the moment every third Finn will get cancer during their life time."

Executive Director ***Minna Anttonen****, The Association of Cancer Patients*

Professor Mark Daly, Director of the Institute for Molecular Medicine Finland (FIMM), HiLIFE, University of Helsinki

Unique Finnish genomics scene attracts top scientist to cooperate and work in Finland

High-quality biobanking and biobank reseach attracts talents to Finland. An excellent example of this is Professor **Mark Daly** from the Broad Institute of MIT and Harvard and Massachusetts General Hospital. The University of Helsinki has recruited him to lead the Institute for Molecular Medicine Finland (FIMM) in spring 2018.

Daly is a distinguished scientist who has made major contributions to human genetics and genomics during his 20-year career. While spending most of his time nowadays in Finland, Daly will still continue his active role as Institute Member and co-director of the Medical and Population Genetics Program at the Broad Institute, establishing a close partnership between the University of Helsinki and Broad Institute.

- I am extremely pleased that Mark Daly has taken the helm of FIMM at this time when lots of interesting things are happening in genomics locally and nationally, says **Jukka Kola**, the Rector of the University of Helsinki.

During the first ten years FIMM has focused on translational research and utilizing genome data to empower disease prevention and personalised treatment and currently has a staff exceeding 200 and an annual budget of 20 M€. FIMM is also part of the new Helsinki Institute of Life Science HiLIFE at the University of Helsinki.

- Mark Daly's recruitment exemplifies our new strategy to invest into top research and partnerships, commented **Tomi Mäkelä**, the chair of the recruitment committee and Director of HiLIFE. ■

Authors: Ph.D. Mari Kaunisto and M.D. Maj-Leena Tuhkanen

Who is Mark Daly?

Professor Mark Daly has made seminal discoveries in understanding the details of the structure of the human genome and developing software tools to analyse the impact of genetic variations on various diseases. His own special interest in science are autism, ADHD and other psychiatric diseases as well as inflammatory diseases. Daly has over 400 scientific publications, and in his new job he will be the top cited scientist in Finland with over 130 000 citations.

"In August 2017 initiated FinnGen research project providing genomic information for 500 000 individuals and 10 % of the Finnish population is among the foremost biobank genetics projects in the world. And there are so many new opportunities in which partnership with the Finnish population can advance research and industry in a world-leading fashion – and at the same time have Finns first in the world to receive the medical benefits of genome information in clinical settings. I envision FIMM can become the pre-eminent institution in human genetics in Europe, including through the new partnership between the University of Helsinki and Broad Institute, together with the Nordic EMBL Partnership in Molecular Medicine. This will provide an outstanding opportunity for FIMM, and research throughout Finland, in the coming years," says Daly.

"Research-positive atmosphere and active development of the infrastructure and services which researchers need are some of the advantages of HUS as an employer and research and innovations partner."

CEO Juha Tuominen, HUS

An excellent example from Finland:

HUS and AMCH are globally in frontline of biobank and clinical research

The Academic Medical Center Helsinki (AMCH), one of the best medical campuses in Europe, brings top research, teaching, and medical care together every day. The core of AMCH's work is close cooperation between the Helsinki University Hospital (HUS) and the University of Helsinki. In addition HUS is strengthening cooperation in clinical research together with, among others, Aalto University, universities of applied sciences and the private sector.

HUS – as well as other university hospitals in Finland – is actively involved in clinical research which creates new information, which forms the basis for future healthcare including biobanking and personalized medicine. On behalf of HUS, professor **Anne Pitkäranta**, HUS Research Director, says that the hospital management appreciates high-class clinical research as a critical function and a competitive advantage rather than just an expense. This creates a positive climate for research and attracts talents to HUS.

– Clinical research is important to us all and it requires broad-range multidisciplinary co-operation. Most of HUS's over 2000 doctors and a growing amount of other health and social care professionals are active in clinical research, Pitkäranta continues.

HUS offers concrete support to researchers

The HUS Research Center employs a research director and seven other staff members. The HUS Research Center aims to create a better framework for individual researchers, an international environment and a well-developed research infrastructure and career opportunities, which ensure innovation in research.

– I am very happy and proud, that AMCH produces more than 2000 new scientific publications and more than 130 theses on the wide range of research each year – without forgetting the numerous clinical reach and biobank sample collecting every day in HUS. We are making future improvements in health and well-being now! ■

Author: M.D. Maj-Leena Tuhkanen

The ambassadors of biobank spread an important message and they have gained more agreements than expected!

Sami Koskelainen (left), Leila Sandvik, Anna Blubaum, Vili Kostamo, Inari Linkola, Lotta Räsänen ja David Griffin

Professor Mikko Niemi, one of world's leading pharmacogenetics experts believes:

"Finnish biobank research can achieve breakthroughs in pharmacotherapy"

Finland is one of the global pioneers in genomic medicine and health technology at the moment. This offers an excellent environment for new fields at innovations in pharmacogenetic research and the development of more personalized pharmacotherapies. These are the thoughts of **Mikko Niemi**, Professor of Pharmacogenetics at the University of Helsinki and the Chief Physician at HUSLAB, who has been one of the best-known and most awarded and cited researchers worldwide in his field for years now.

- Things are looking exceptionally good for drug development at the moment and we are experiencing interesting times in this field. There is a lot to look out for, Niemi says.

Virtual patients help choose the right medication

Our understanding of the human genome, or the complete set of humans' DNA, has increased significantly in the past few years and genome-based research will expand the ways in which genomic information is used in pharmacotherapy. This is also the goal of the ongoing pioneering project of Mikko Niemi and his research group. The goal of the research project is to develop a model that can be used to select the best cholesterol-lowering drug (statin) for a patient based on their individual genetic makeup and other personal characteristics.

- In a way, the digital model now being developed is a virtual patient which is used to simulate the benefits and disadvantages of different drugs on individual level. The development of the model is well underway and its functionality is set to be tested in a randomized study. If the model works, the same principle can be applied to other drugs as well in the future, Niemi believes.

National center for drug development is most welcome

The government of Finland has decided to establish a national drug development center. The center is intended to operate as an independent research institute that works together with universities, University Hospitals and other research organisations. Mikko Niemi sees that employees of Finnish biobanks and University Hospitals all have in-depth knowledge and experience of clinical trials, and he hopes that these organizations could be actively involved in the operations of the new center.

- Finland satisfies all the requirements of becoming a trailblazer in personalized medicine, and the drug development center is an important step towards this goal. ■

Reference: www.husresearch.fi

Author: M.D. Maj-Leena Tuhkanen

Biobank Professor Arto Mannermaa looks brightly to the future

Finland is among the top countries within biobanking and we can expect that the biobank research done – like research concerning the whole genome of an individual – can even lead to breakthroughs in advancing public health and holistic care of diseases. Research in biobanks increases strongly and this sets demands also to universities as well as to establishing new professorships. At the moment there is one biobank professor in Finland: Professor of Personalised Medicine and Biobanking **Arto Mannermaa** at the University of Eastern Finland. He is also the Research Leader and Associate Manager of the Biobank in Eastern Finland.

Author: M.D. Maj-Leena Tuhkanen

TERVEYSTALO BIOBANK FINLAND

The first privately owned biobank in Finland

Terveystalo Biobank Finland is part of Suomen Terveystalo Plc, the largest healthcare service company in Finland. We offer versatile healthcare, occupational healthcare and specialist services in approximately 180 clinics around Finland. The laboratory network is the largest in Finland. Our customers include private individuals, companies and communities, insurance companies and the public sector. Nearly 9,000 healthcare professionals work at Terveystalo. We have more than 3 million appointments with a physician annually.

Terveystalo Biobank Finland works in close collaboration with Terveystalo Clinical Research which is the largest site management organization in Finland. Almost one million people have given their consent so we can contact them based on their health information. This offers a unique opportunity to pre-select and recruit suitable research subjects quickly and cost-effectively. The new insights that can be found from the clinical and genomic data Terveystalo is working with, can improve the quality of healthcare as well as drug development.

We would be happy to discuss any research idea. Please contact chief physician **Markku Nissilä** at +358 40 078 8020, markku.nissila@terveystalo.com or business administration director **Lasse Parvinen** +358 40 525 5481, lasse.parvinen@terveystalo.com

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