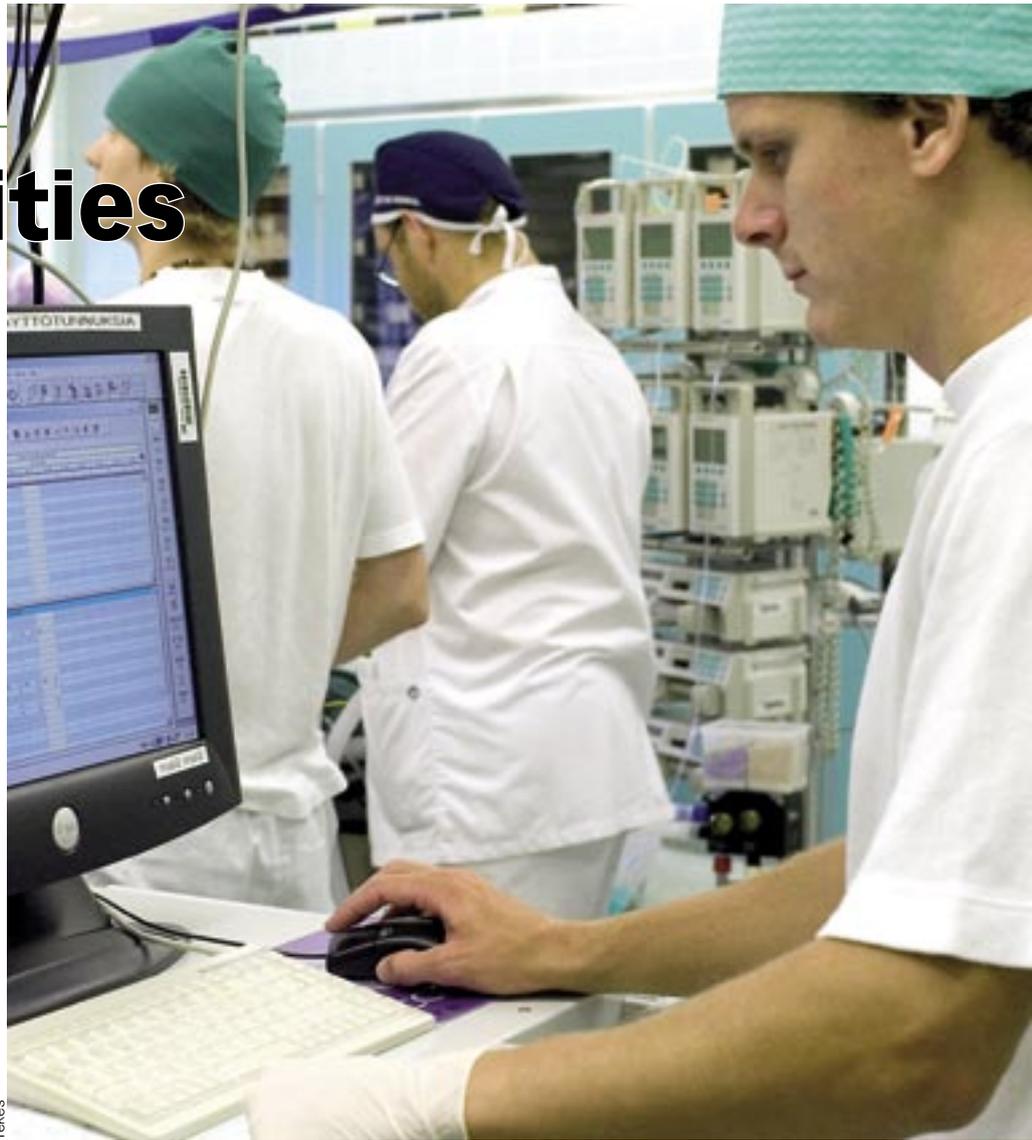


Biobanks

# Opportunities Becoming Reality

■ Popular approval for what biobanks can offer, together with the extensive know-how in the field that exists in the research community, point to a positive future for these resources in Finland. The Ministry of Social Affairs and Health has started work on drawing up legislation to regulate the sector, in partnership with researchers, holders of sample collections, and those who want access to them—to ensure that the best use is made of this information and that safety, confidentiality, and transparency are maintained at all times.



Tekeas  
Biobanks in Finland can build on strong public support. A continued positive attitude on the part of donors and strict confidentiality will be essential, however.

Kimmo Pitkänen  
and Saara Hassinen

The rapid development of molecular biology in recent years has opened up radical new opportunities for biobanks. The samples they contain can be used for research and analytical purposes in ways that would have been impossible to predict just 10 or 20 years ago. Data can be used to identify general health-related trends and characteristics, and provide the building blocks for developing new types of treatment, diagnostics, and medicines that could benefit all of us.

The major opportunities offered by biobanks, in terms of science, health care, and industry, are particularly relevant in Finland, which has a long tradition of collecting biological samples from large cohorts of the general population and documenting health trends. A number of other countries have also launched ambitious biobank projects, and the need for international cooperation, harmonisation, and regulation is growing all the time.

### Collect, study, learn

Biobanks are based around collections of human biological samples that include comprehensive information on the health, lifestyles, and home and work environments of the people who donate them.

Depending on who manages them and whether they contain tens, tens of thousands, or millions of samples, biobanks can concentrate on a particular condition and how it manifests itself, or aim to build a balanced overview of an entire regional or national population. The diagnostic sample collections generated by hospitals and clinics can also be considered as biobanks.

Linking the biological data contained in samples with the background information on the donors of the material in question is fundamental to the biobank concept. As this information is, at least partially, sensitive

and of a confidential nature, data protection issues are a particular concern. Ensuring a seamless chain of confidentiality is also central to winning the approval and support of donors.

### Long traditions

Finland has a long track record of collecting biobank-type information stretching back many decades, held by bodies such as the National Public Health Institute.

The Finriski study, for example, which studies health trends and the risk factors behind a number of widespread chronic conditions in five areas across Finland, updated its sample collection most recently this spring. The study is a continuation of work originally begun in Eastern Finland in 1972 and updated every five years.

Blood samples taken from participants are analysed for a specific set of risk markers, and DNA isolated from the samples is used to study health risk-related hereditary traits. Research data is also collected through questionnaires and check-ups.

Participants are selected on a random basis, and participation is completely voluntary. Following the most recent round of sampling this spring, the Finriski study now has samples from some 30,000 Finns.

All in all, the various biobanks managed by the National Public Health Institute hold samples from around 200,000 people. The country's health care system holds samples from as many as two million Finns, but this resource has so far been much less used.

The material in Finnish biobanks is particularly valuable because of the homogeneous nature of the population's genetic inheritance, the well-organised nature of the country's health care system and health registers, and the availability of census data going back hundreds of years. Finnish research in the field is also among some of the most cutting-edge anywhere, and people generally are positively disposed towards this type of research.

### **Making more of data**

The unsystematic nature of legislation in the field, a lack of coordination and overall vision, and the relatively poor level of cooperation between research institutes and business have limited the use of Finnish biobank material to date, however. European legislation also does not cover biobank-related activity very clearly, although directives on data protection and the medical use of human tissue material go some way in this direction.

As a result, the Finnish authorities and the research community have initiated efforts to correct the situation. A working party on biobanks set up by the Ministry of Social Affairs and Health is due to publish its final report at the end of September this year.

The task of the working party has been to identify the key open questions in the field and present suggestions for legislation and other measures that both clarify the playing field and take the needs of international cooperation into account as well.

### **Popular approval**

The biobank working party has drawn on the results of a recent study conducted by the National Research and Development Centre for Welfare and Health and the University of Helsinki on people's attitudes towards biobanks.\*)

This confirmed that people are generally well-disposed towards them. Some 89% of Finns support research into hereditary fac-

tors, while 97% support the development of new pharmaceuticals. 84% of respondents said they would be willing for blood samples and information on their medical condition collected during a visit to a doctor to be used for research purposes. Although people were a little less sure about giving companies access to this data, 75% of respondents said they would allow their samples to be used for product development work.

At the same time, respondents stressed the importance of being asked to give their consent for how samples are used and of being able to find out if and how their samples have been used, and how biobanks operate generally.

The working party's aim is to build on this positive attitude and ensure that Finns continue to be willing to participate in health studies and research projects. It will highlight the importance of guaranteeing people's right to information and deciding if and how information on them is used. The legal position, rights, and responsibilities of researchers are also likely to be defined in greater detail.

### **New business**

Biobanks offer numerous opportunities for business and the potential for a range of new business possibilities—whether in terms of data on how well various pharmaceuticals and types of care perform and where improvements are needed, or where new diagnostic tools could be called for.

Data itself also represents a valuable product for bioinformatics and software companies that are able to combine and process it to produce value-added information on who benefits most from what sort of drugs, when, and under what conditions, for example.

To ensure that this type of information is shared fairly and equitably and that society as a whole benefits, the working party has prioritised the importance of balancing the needs, responsibilities, and rights of all those involved. The hope is that improving the legislative framework will result in more systematic and transparent procedures and encourage new types of cooperation between the public and private sectors. Many

research institutions and hospital districts have already begun reforming their own structures and practices in advance of these changes. □

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\*) Sinikka Sihvo, Karoliina Snell, Aaro Tupasela, Piia Jallinoja, Arja R. Aro, Auli Hämäläinen, Elina Hemminki. *Väestö, biopankit ja lääketieteellinen tutkimus – Suomalaisten suhtautuminen lääketieteellisten näytteiden käyttöön*. Stakes Työpapereita 18/2007. In Finnish only. To be published by the National Research and Development Centre for Welfare and Health in September 2007.