Biobanking in Finland: a success story

Finland's unique biobanking landscape makes it an ideal environment for pharmaceutical and health research, as told to *Health Europa Quarterly*

Finland may be a small country, but it has big ambitions to position itself at the forefront of pharmaceutical and health research. Already, it has a proud reputation as a global leader in digital health, is home to some of the world's top talent in science and engineering, and boasts one of the most efficient healthcare systems worldwide. According to public research funding agency Business Finland, 98% of the country's patient records are available in an electronic format, while its start-up ecosystem is the second largest in the world – a fact which has no doubt contributed to it being the country of choice for major pharma giants like Thermo Fischer Scientific, Philips Healthcare and Bayer.

The Finnish Biobank Act

Central to Finland's pharmaceutical ambitions is its impressive biobanking infrastructure, which is unlike any in Europe. In 2013, a new Biobank Act came into effect which, among other things, allowed previously collected samples to be transferred to biobanks and made available to researchers, something that is integral to the success of the country's national Health Sector Growth Strategy for Research and Innovation Activities. The act also introduced the idea of 'broad consent' for new data, which negates the need for researchers and organisations to separately ask participants to give their consent for their samples to be used in every single project.

Health Europa Quarterly asked Finland's chief medical officer, Liisa-Maria Voipio-Pulkki, more about how the act has enhanced biobanking activities and the reasons behind its introduction.

"There have been biobanks in Finland for many years, perhaps the most extensive one being the haematological biobank, as well as a number of big population studies such as those carried out by THL, the National Institute for Health and Welfare," she said.

"This had resulted in tens and sometimes hundreds of thousands of patient samples just lying around somewhere, but there was no legal basis for making this historical sample collection and the data that followed available for a secondary type of research.

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"At that time, we were just beginning to understand or realise that personalised medicine was coming, and we wanted to offer patients entering the healthcare system the opportunity to give their consent to provide a biobank sample that might be used for an unknown research purpose in the future. Because that purpose would fall outside the traditional consent for clinical research, we call this 'broad consent'. It doesn't mean that you can use the patient's sample for anything at all, but you can use it for a less well defined or precise purpose – for example, cardiovascular research – than that set out in a conventional consent document.

"The new legislation was drafted for many years, and, of course, because there were no models for it, it was a totally unique exercise. It took a long time, but, thankfully, at some point the government at last decided that it was good enough and it was submitted to parliament. The parliament also asked the Finnish Ministry of Social Affairs and Health to carefully follow the implementation of the new act, which we have done ever since. We have had an official working group here at the ministry that represents all the biobanks and their owners. It is not conventional nor is it usual that the ministry takes such an operational approach or responsibility for actions in the healthcare sector, but this is what we have done.

"That really boosted the biobanks because it gave them confidence and provided a legal background to what they were doing. It took a couple more years, and some government money, for their operations to become more uniform. Originally, we hoped that we could have just one national biobank, but that was not possible. Most biobanks are owned by independent hospital districts, but the government sent them a very strong message that they had better co-operate with each other and, if they were able to develop some common processes and standards, the government would support them with some seed money and also by writing new legislation if necessary."

Voipio-Pulkki added: "This act stabilised biobanking activities in Finland, and now all the university hospitals and a couple of smaller hospitals have their own biobanks and co-operate with each other very well. THL has also been able to transfer its huge sample collections to its own biobank and some others for use as real biobank material. All in all, I think that we have achieved much of what we were looking for with the Biobank Act."

That is not to say that the operation has not been without its challenges. Voipio-Pulkki noted that the transfer of samples has not been "legally easy, practically easy, nor ethically easy". Certain procedures have thus been put in place to ensure that patients are safeguarded and their consent prioritised.

"There has to be an ethical evaluation of that transfer, and it has to be publicly announced in newspapers and paid advertisements and so on – because it's impossible to reach 100,000 people with letters – which make it clear that if you object to your sample being transferred, you have to contact such an organisation.

"It has gone very well so far. Very few people have refused the use of their sample for purposes other than those for which they were originally collected, so it has gone very smoothly."

A new version of the Biobank Act is currently in preparation, which Voipio-Pulkki hopes will be submitted to parliament by the end of this year. She attributes this revision to two reasons:

1) Now that the act has been in place for a number of years, it is clear that certain details and paragraphs need clarification.

2) In 2018, a new General Data Protection Regulation (GDPR) became operational that represented a complete overhaul of data privacy regulation across every sector.

Strong government backing is key to success

The Biobank Act is a clear example of the Finnish Government's commitment to fostering the kind of research and development environment necessary for Finland to flourish on the world stage. Dr Sampo Sammalisto, a programme manager at Business Finland, told *Health Europa Quarterly* that the government's "proactive support" of health sector innovation has been central to Finland's success, pointing to the Biobank Act and forthcoming laws on genomics and the secondary use of social and health data as evidence.

He highlighted as further examples the national health sector growth strategy, which puts the pharmaceutical sector at the heart of future economic growth, and the establishment of a national neuro centre and upcoming national drug development, cancer and genome centres – a concerted effort to construct a wider pharmaceutical and healthcare ecosystem.

The importance of collaboration and the Finnish Biobank Cooperative

Collaboration between these centres and Finland's biobanks will be instrumental to their success. To encourage this, in 2017 six Finnish universities and the six largest hospital districts came together to form FINBB, the Finnish Biobank Cooperative, which is intended to provide biobanks with services related to sample and data processing, law and communications, as well as playing an important role in the practical implementation of the health sector growth strategy and in building the national genome and cancer centres.

Marco Hautalahti, who joined FINBB as CEO in June 2018, told *Health Europa Quarterly* that horizontal collaboration between the centres will be key to achieving the sought-after research ecosystem in Finland.

He added that the co-operative will be not a one-stop shop but a "one-access shop" for biobank materials for academics and pharmaceutical/diagnostics companies looking to do research or business in Finland.

"To have a single point of access in this manner is quite unique," Sammalisto noted.

Voipio-Pulkki is similarly optimistic about the role of FINBB and its relationship with the forthcoming centres; however, she also acknowledged that some of the "biobanks who are most advanced are maybe a little bit hesitant about how much they will benefit from these new kids on the block".

She added: "I think that, in order to make the best out of all the data and the registries that we have in this country, the biobanks need other companions, other authorities and other actors. In fact, some of the burden will be taken away from the biobanks, and we hope to facilitate and speed up their actions by adding other actors to the ecosystem."

Ingredients for success: innovation, education and public support

Aside from government backing, something else that is central to the current and future success of biobanking and pharmaceutical research in Finland is its much-celebrated education system. Sammalisto explained that education is "100% free of charge" in Finland.

"For example, I have a PhD in genetics, and I paid €0 for my education. It was all covered by the taxpayer. What that means is that we have a highly educated workforce, so in many rankings the concentration of engineers and scientists *per capita* in Finland is among the highest in the world. As a result, it's very easy to find skilled labour and it's very cost-effective to do R&D in Finland."

Public support and participation will likewise play an integral role in the country achieving its ambitious health sector vision. Hautalahti told *Health Europa Quarterly* that there is a wide acceptance for biobanking among the Finnish population, and many Finns are very willing to contribute biobank samples and take part in different kinds of studies and research.

Sammalisto agreed: "We are very innovation-friendly in Finland, so when you want to do scientific or clinical research, recruitment for studies happens much faster than in many other countries."

This support is evident in the personalised medicine project FinnGen, in which genome information is being combined with digital healthcare data in an effort to better understand how our genome affects our health. Business Finland has contributed €20m of the project's €60m budget, and Sammalisto sees it as a significant investment in Finland's future.

"We see this as an important opportunity for new pharmaceutical innovation, which in the end will benefit both the individual patient and society," he told *Health Europa Quarterly*.

The future of Finnish health innovation

Looking ahead, Sammalisto and Voipio-Pulkki both envision a future in which Finland is a global forerunner in not only pharmaceutical research but also personalised medicine. According to Sammalisto, who heads a programme on the latter at Business Finland, this status could come as soon as 2025.

"We see ourselves as a very good pilot country for leveraging patient data and turning them into Real-life personalised health solutions, which are also solutions for the whole world," he said. "Thanks to the level of our universal healthcare and our innovation capacity, we believe that Finland can do it."

Voipio-Pulkki is likewise confident that Finland has what it takes. For her, the main challenge now is to how best to combine traditional population-based public health interventions with a personalised medicine approach.

She told *Health Europa Quarterly*: "When it comes to personalised medicine, it is no longer a question of whether or not you want to adopt it; it is already here. From the government's point of view, it is our responsibility to guarantee that our patients have equal access to the benefits of personalised medicine in terms of efficacy, value for money and medical outcome value, and to decide how best to take these into account and implement them in the planning and design of our services."

Thanks to efforts such as these, no matter what the future holds, it is clear that it is bright for pharmaceutical research in Finland.

Biobanking in action: the FinnGen project

Speaking to *Health Europa Quarterly*, research director Aarno Palotie, of the Institute for Molecular Medicine Finland (FIMM) at the University of Helsinki, provided further insight into the ambitious FinnGen project.

What are the objectives of the FinnGen project?

The FinnGen project aims to collect the genome and national health register information of 500,000 Finns, which is almost 10% of the population. UK Biobank is a good example of a similar-sized project, the difference being that our samples have mostly been gathered from hospital patients and legacy collections, the subjects of which are already old. We therefore have many more disease events than UK Biobank, whose samples have mostly been collected from the working-age population and so don't encompass as many adverse health events.

We need very large datasets in order to understand health trajectories and also to understand genetic and environmental contributions to health, wellbeing and disease development. In particular, what projects like FinnGen provide is an opportunity to both understand comorbidities, i.e. the link between different chronic diseases, and make meta-analyses between other large studies like UK Biobank and the US programme All of Us.

Essentially, then, FinnGen allows us to increase the data size to such a large number that we can then employ efficient data mining and analysis techniques to improve our understanding of disease mechanisms.

FinnGen represents one of the very first personalised medicine projects at this scale and brings together nine biobanks, not to mention a number of universities, hospital districts, pharma companies and so on – what challenges have you encountered as a result?

Even though Finland is better placed to carry out these kinds of large-scale studies than most other countries, and even though our governmental institutions have done an awful lot to facilitate this type of research and been very forward looking in doing so, it's still a bureaucratic nightmare to conduct such a project as FinnGen. The number of various approvals that are required and the complicated processes that we have to go through to get them is still hugely significant.

Now that Europe is moving more and more towards digitisation and this idea of using data to improve our health, we need to be able to make these bureaucratic processes simpler. Unfortunately, the recent General Data Protection Regulation (GDPR) hasn't made things any easier. I'm afraid that from a researcher's perspective, the GDPR is somewhat old-fashioned and has forgotten research. Europe will certainly face more challenges if the implementation of the GDPR isn't streamlined.

What is it that makes Finland such an ideal landscape for conducting studies such as the FinnGen project?

There are five cornerstones to this:

1) Finland is the largest population isolate in Europe, which provides certain advantages, especially in terms of identifying low-frequency variants associated with or predicting for disease. Genetic discoveries can therefore be made much faster and more easily than in more heterogeneous populations.

2) Like all Nordic countries, Finland has health registries that have collected health users' data for decades. They are in an electronic format and they can be combined using a personal identification number.

3) Finland has a long tradition in epidemiological studies, for which samples have been collected over decades. Already, we have a legacy collection of some 200,000 Finns' data.

4) Genetic research is active and ongoing.

5) The support of the Finnish Government is very strong. The Biobank Law has now enabled broad consent and several bills are currently in parliament that will further simplify the use of health data for research. Even if doing this type of research is still a bureaucratic nightmare, the fact that the government and institutions are very supportive of it has made an enormous difference.

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