Current operational status of the Finnish hospital biobanks

Authors: Werner Tuompo, Päivikki Hemmilä, Maija Wolf

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Report title
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biobank, biobank act (688/2012), hospital biobanks, biobank research, real world data (RWD), real world evidence (RWE)

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Summary
This report summarizes a survey on the current operational status of the Finnish hospital biobanks, conducted as a collaborative effort between Medaffcon Oy and the University of Eastern Finland during December 2017 - May 2018. The aim of this effort was to map and describe the field of Finnish hospital biobanking, its functionality, possible bottlenecks as well as current and future opportunities. The main objectives were to understand the current operational status of the hospital biobanks in Finland and their possibilities to act as a partner in industry-driven studies, i.e. studies that are initiated and sponsored by private sector actors such as pharma, biotechnology companies and private healthcare providers. In addition, needs and expectations regarding the developing roles of FINBB were explored.

The survey was conducted in two phases. In the first phase, a structured online questionnaire form was used to gather information about the current operational status of the biobanks. The second phase included face-to-face interviews with the representatives of the hospital biobanks to evaluate the potential for research collaborations in more detail. In total, 16 persons were interviewed. Numbers regarding sample quantities and material/data donations were subsequently updated in June 2018.

Finnish hospital biobanks have created a unique research infrastructure in Finland that has enabled the initiation of both national and international research activities. Large amounts of high-quality samples and sample-related data reside in biobanks, supporting the needs of both public and private sector. Currently, most activities in the hospital biobanks are associated with collecting new prospective samples and transferring previously collected research collections to the biobanks. The current processes regarding sample and data donations for research purposes still vary and the key needs are associated with improving data-analytical capabilities and streamlining the operational procedures. Although the operational maturity between the biobanks varies, illustrating the different stages of the newly established biobanks, there is a noticeable shared ambition and will to further strengthen the biobank-based research activity in Finland.

In the first part of this report (chapters 1 and 2), a comprehensive overview of the Finnish hospital biobanks current operational status is given. The second part (chapter 3) concentrates on the identified bottlenecks and harmonization needs. Third part (chapter 4) introduces FinBioBank (FINBB) and highlights expectations that biobanks have towards the newly established cooperative.

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Definitions – Biobank act (688/2012)

"Biobank means a unit maintained by an operator engaging in biobanking activities for the purposes of collecting and storing samples and information associated with the samples for future biobank research."

"Biobank research means research utilising the samples contained in a biobank or information associated with them for the purposes of promoting health, understanding the mechanisms of disease or developing the products and treatment practices used in health care and medical care."

"Sample means human biological material or a technical record of such material."

Definitions - Other

Data analytics in this report refers to expertise in data management and processing that is needed for fluent biobanking operations. Data analytics can be administrative or exploratory.

Data lake is a large-scale repository, that gathers both structural and unstructured information/data from several sources.

Industry-driven refers in this report to studies initiated and sponsored by the private sector actors, such as pharmaceutical and biotechnology companies, private healthcare providers etc.

RWD or Real World Data according to FDA definition; are the data relating to patient health status that is routinely collected from variety of sources e.g. electronic health records, product and disease registries etc. More broadly, RWD can be defined as any patient/individual —derived information that can be used for RWE.

RWE or Real World Evidence according to FDA definition; the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD. More broadly, RWE can be defined as any RWD-derived evidence that can be used in decision-making that aims to improve health and well-being.

Sample-related data is data that is closely related to the sample e.g. laboratory measurements, genomic data, donor health information etc. However, a conclusive definition of sample-related data in the context of biobank research is currently missing.
1. INTRODUCTION

Biobanks collect biological samples and related information from consented people for future medical research needs. In Finland, there are currently ten registered biobanks, which can be divided into regional hospital biobanks (six), national biobanks (three) and private biobanks (one). Finnish biobanks are owned by healthcare districts, universities, National Institute of Health and Welfare, organizations and private companies. Biobank operations are governed by the Finnish Biobank Act (688/2012) which came into force in September 2013. Biobank activity in Finland is directed and supervised by the National Supervisory Authority for Welfare and Health (Valvira), which also maintains a national biobank register. These activities will be transferred to the Finnish Medicines Agency, Fimea, by the end of 2019.

Research utilizing biospecimens and data collections available in biobanks has an established and growing role in the field of healthcare and biomedical research. Biobanks’ key role in the future medical research and innovation activities are recognized also in the Finnish health sector growth strategies. Genetically isolated population, comprehensive healthcare system, national registries and strong governmental support are some of the key features that make Finland an ideal country for biobank research. Also, the quality of academic research especially in genomics and the positive attitude of citizens towards medical research are elements that strongly support the capabilities of conducting high-quality biobank and related real world evidence (RWE) studies in Finland. Finnish biobanks provide unique opportunities to promote healthcare and health-related research both nationally and internationally.

An important element of the Finnish biobanking ecosystem is the joint cooperative FinBioBank (FINBB), founded by the universities and hospital districts owning the hospital biobanks. One of the main objectives of FINBB is to act as an “one-stop-shop” for feasibility and biobank study requests in the future. Development of the national availability database is in progress, providing the availability of biobank samples for different disease indications through one portal in the future. FINBB together with Finnish hospital biobanks have recently launched also “Hyvän ketju”-sample collection campaign, which aims to collect 5,000 new cancer samples during year 2018 and incorporate biobank cancer collection procedures as a part of the hospital daily routines.

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2. FINNISH HOSPITAL BIOBANKS

Hospital biobanks are owned by the hospital districts and universities. These regional biobanks operate in determined geographical and healthcare regions of Finland, and their population bases differ accordingly (Figures 1 and 2). Figure 3 summarizes the timeline for individual hospital biobanks initiating their activities in Finland since the Biobank Act took effect 1st of September 2013.

Current sample collections stored at the hospital biobanks consist mainly of old pathology archives of the hospital districts as well as selected research collections that have been transferred to the biobanks. In addition to these retrospective samples, all hospital biobanks gather new prospective samples from consented people. In the following sections, the sample collections of the individual biobanks are discussed.

Figure 1. The geographical locations of the Finnish hospital biobanks


2.1. HELSINKI BIOBANK

Helsinki Biobank, founded by the Hospital District of Helsinki and Uusimaa (HUS), the University of Helsinki, Kymenlaakso Social and Health Services (Carea) and the South Karelia Social and Health Care District (Eksote), covers 2 million inhabitants, i.e. almost 35 % of the Finnish population. Helsinki Biobank stands out with the largest specimen collection of the hospital biobanks, including over four million retrospective pathological samples from 1.4 million persons, transferred from HUS pathology archives and ~30 000 samples of the former Helsinki Urological Biobank. In addition, Helsinki Biobank has collected prospective samples altogether from over 46 000 individuals by the end of May 2018. Helsinki Biobank’s goal is to gather samples from 125 000 individuals during 2018, which would count 80% of the total collecting goal of the Finnish hospital biobanks for 2018. Table 1 summarizes the information for Helsinki Biobank.10

<table>
<thead>
<tr>
<th>Population base</th>
<th>Transferred diagnostic sample collections</th>
<th>Transferred research collections</th>
<th>Total prospective samples collected until 5/2018</th>
<th>Total consents collected until 5/2018</th>
<th>Prospective samples collected until 12/2017</th>
<th>Target of sample collection for year 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 000 000</td>
<td>HUS pathology archives (1982-2013) and urological biobank (2012-2015)</td>
<td>Primary sclerosing cholangitis sample collection</td>
<td>From 46 000 individuals</td>
<td>65 600</td>
<td>From 26 000 individuals</td>
<td>From 125 000 individuals</td>
</tr>
</tbody>
</table>

2.2. FINNISH CLINICAL BIOBANK TAMPERE

Finnish Clinical Biobank Tampere (FCBT) covers 1,18 million inhabitants and is thus the second largest hospital biobank in Finland in terms of population base. FCBT is owned by the Pirkanmaan Hospital District (PSHP) and managed together with University of Tampere, Kanta-Häme Hospital District and South Ostrobothnia Hospital District. Pathological archives of the Pirkanmaa Hospital District, including ~3,4 million samples from 400 000 persons and a diagnostic genetic sample collection of ~30 000 samples from 10 000 persons, have been transferred to FCBT. FCBT started to gather consents on April 2016 and prospective samples on May 2016. By the end of May 2018 FCBT has collected altogether 6 346 consents and prospective samples (including whole blood, plasma and serum sample) from 4 110 individuals. Table 2 summarizes the information for FCBT.11

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10 Information acquired from the Helsinki Biobank website (https://www.terveyskyla.fi/helsinginbiopankki/en) and interviews with the biobank personnel.
11 Information acquired from FCBT website (https://www.tays.fi/biopankki) and interviews with the personnel.
**TABLE 2. FINNISH CLINICAL BIOBANK TAMPERE POPULATION BASE AND SAMPLE COLLECTIONS**

<table>
<thead>
<tr>
<th>Population base</th>
<th>Transferred diagnostic/sample collections</th>
<th>Transferred research collections</th>
<th>Total prospective samples collected until 5/2018</th>
<th>Total consents collected until 5/2018</th>
<th>Prospective samples collected until 12/2017</th>
<th>Target of sample collection for year 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 180 000</td>
<td>TAYS pathology archives (1963-2013) and samples in genetic archives (1990-2013) (*)</td>
<td>None</td>
<td>From 4 110 individuals</td>
<td>6 346</td>
<td>From 2 313 individuals</td>
<td>From 10 000 individuals</td>
</tr>
</tbody>
</table>

*Archives containing e.g. cell and tissue samples from the heredity clinic as well as blood and bone marrow samples from individuals suffering from malignant blood diseases.

### 2.3. AURIA BIOBANK

Auria Biobank, which received its operating license from the National Supervisory Authority for Welfare and Health (Valvira) in spring 2014, is Finland’s first official hospital biobank. Auria Biobank, covering a population base of 900 000, was established by the University of Turku and the hospital districts of Southwest Finland, Satakunta and Vaasa. The biobank holds over 1 million pathology archive samples, obtained from over 350 000 people, that have been transferred from Turku University Hospital and Satakunta. Selected research collections have also been transferred, including e.g. serum collections from endometriosis patients and CLEVER1 collection from lymphoma patients treated with cytostatic drugs. By the end of May 2018, new prospective samples have been gathered altogether from 19 463 persons. Table 3 summarizes the information for Auria Biobank.

**TABLE 3. AURIA BIOBANK POPULATION BASE AND SAMPLE COLLECTIONS**

<table>
<thead>
<tr>
<th>Population base</th>
<th>Transferred diagnostic/sample collections</th>
<th>Transferred research collections</th>
<th>Total prospective samples collected until 5/2018</th>
<th>Total consents collected until 5/2018</th>
<th>Prospective samples collected until 12/2017</th>
<th>Target of sample collection for year 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>900 000</td>
<td>TYKS and Satakunta pathology archives (1969-2013)</td>
<td>CLEVER1 and endometriosis research collection</td>
<td>From 19 463 individuals</td>
<td>48 896</td>
<td>From 8 914 individuals</td>
<td>From 12 000 individuals</td>
</tr>
</tbody>
</table>

### 2.4. BIOBANK BOREALIS OF NORTHERN FINLAND

The founders of the Biobank Borealis of Northern Finland include the Northern Ostrobothnia Hospital District/Oulu University Hospital, University of Oulu, Nordlab and hospital districts of Lappi, Länsi-Pohja, Keski-Pohjanmaa and Kainuu. Biobank of Northern Finland Borealis has a 1.8 million pathology sample collection transferred from the Northern Ostrobothnia Hospital District. Borealis Biobank also stores

unique Finnish Maternity Cohort (FMC) -serum collection that includes approximately two million serum samples collected by the former National Public Health Institute of Finland (KTL) and the Finnish National Institute of Health and Welfare (THL) from nearly one million expecting mothers during years 1982 - 2016. Borealis Biobank has collected prospective samples since the end of year 2016. By the end of May 2018 altogether 12 460 consents and samples (including whole blood, plasma and serum sample) from 4 146 individuals have been gathered to the biobank. Table 4 summarizes the information for Borealis Biobank.

**Table 4. Borealis Biobank Population Base and Sample Collections**

<table>
<thead>
<tr>
<th>Population base</th>
<th>Transferred diagnostic sample collections</th>
<th>Transferred research collections</th>
<th>Total prospective samples collected until 5/2018</th>
<th>Total consents collected until 5/2018</th>
<th>Prospective samples collected until 12/2017</th>
<th>Target of sample collection for year 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>740 000</td>
<td>OYS/OUH + 4 central hospital pathology archives (1979-2013)</td>
<td>Finnish maternity cohort serum collection (1982-2016)</td>
<td>From 4 146 individuals</td>
<td>12 460</td>
<td>From 2 127 individuals</td>
<td>From 5 000 individuals</td>
</tr>
</tbody>
</table>

**2.5. BIOBANK OF EASTERN FINLAND**

The Biobank of Eastern Finland was established by the hospital districts of Northern Savo and Eastern Savo, South Savo Social and Health Care Authority (Essote), Joint Municipal Authority for North Karelia Social and Health services (Siun sote) and University of Eastern Finland. Kuopio University Hospital (KUH) pathology archives from years 2000-2013 have been transferred to biobank and transfers of old research collections are planned in the upcoming year. Prospective sample collection started in September 2016, and by the end of May 2018 samples from over 3 000 persons have been stored in the biobank. Table 5 summarizes the information for Biobank of Eastern Finland.

**Table 5. Biobank of Eastern Finland Population Base and Sample Collections**

<table>
<thead>
<tr>
<th>Population base</th>
<th>Transferred diagnostic sample collections</th>
<th>Transferred research collections</th>
<th>Total prospective samples collected until 5/2018</th>
<th>Total consents collected until 5/2018</th>
<th>Prospective samples collected until 12/2017</th>
<th>Target of sample collection for year 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>550 000</td>
<td>KUH pathology archives (2000-2013)</td>
<td>None (*)</td>
<td>From 3 072 individuals</td>
<td>5 975</td>
<td>From 2 000 individuals</td>
<td>From 5 000 individuals</td>
</tr>
</tbody>
</table>

* Several transfers ongoing

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2.6. BIOBANK OF CENTRAL FINLAND

Biobank of Central Finland is the smallest hospital biobank in terms of population base, covering 260,000 inhabitants. It is owned by the Central Finland Health Care District and University of Jyväskylä. Biobank of Central Finland started collecting consents and samples at the end of year 2017 and by the end of May 2018 5,000 consents and samples from 400 persons had been obtained. The pathology archives of Central Finland Health Care District from years 1963-2013 have been transferred to the biobank, consisting of approximately 600,000 samples from 160,000 persons. Table 6 summarizes the information for Biobank of Central Finland.  

**TABLE 6. BIOBANK OF CENTRAL FINLAND POPULATION BASE AND SAMPLE COLLECTIONS**

<table>
<thead>
<tr>
<th>Population base</th>
<th>Transferred diagnostic sample collections</th>
<th>Transferred research collections</th>
<th>Total prospective samples collected until 5/2018</th>
<th>Total consents collected until 5/2018</th>
<th>Prospective samples collected until 12/2017</th>
<th>Target of sample collection for year 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>260,000</td>
<td>KSSHP pathology archives (1963-2013)</td>
<td>None (*)</td>
<td>From 400 individuals</td>
<td>5,000</td>
<td>From 10 individuals</td>
<td>From 1,000 individuals</td>
</tr>
</tbody>
</table>

*Transfer of one research collection is in progress

2.7. TRANSFERS OF OLD DIAGNOSTIC AND RESEARCH COLLECTIONS

Finnish Biobank Act (688/2013, § 13) gives healthcare units a possibility to transfer diagnostic samples and information related to samples to biobanks. The prerequisites for the transfer include a statement by the regional ethics committee and informing registered individuals of the transfer either personally or by public notification in an official paper, in a public communication network and in one or more daily papers. With a similar type of procedure also samples and related information collected in a research study can be transferred to a biobank.

As seen in Table 7, all hospital districts have transferred their diagnostic pathology samples to biobanks. The time period of the old sample collections differs, but the main trend has been to transfer all the samples preserved in the hospital district at the time Biobank Act entered into force. The collection sizes correlate with the population bases of the biobanks and thus it is more informative to compare the number of individuals represented in the collections, than estimated number of samples. The biggest collections are maintained by the Helsinki Biobank and the Finnish Clinical Biobank Tampere. Only few research collections have been transferred to hospital biobanks so far and the transferred collections have varied in sample cohort size from a few hundred persons (Primary sclerosing cholangitis, PSC) to hundreds of thousands of participants (Finnish maternity cohort, FMC). The research collections are desirable, due to often containing longitudinal samples from the same individual, possibility of

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15 Information acquired from the Biobank of Central Finland website (http://www.ksshp.fi/fi-FI/Potilaalle/Biopankki) and interviews with the biobank personnel.
incorporating wide range of health data, and due to the systematic collection and high-quality storing of the biological materials.

**TABLE 7. LIST OF DIAGNOSTIC AND RESEARCH COLLECTIONS TRANSFERRED TO THE HOSPITAL BIOBANKS.**

<table>
<thead>
<tr>
<th>Collection</th>
<th>Diagnostic sample collections transferred to the biobank</th>
<th>Research collections transferred to the biobank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helsinki Biobank</td>
<td>HUS pathology archives (1982-2013)</td>
<td>Primary sclerosing cholangitis (PSC)</td>
</tr>
<tr>
<td></td>
<td>4 million / 1.4 million</td>
<td>/ 800+</td>
</tr>
<tr>
<td></td>
<td>Urological biobank (2012-2015)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>30 000 / 2 200</td>
<td></td>
</tr>
<tr>
<td>Finnish Clinical Biobank</td>
<td>TAYS pathology archives (1963-2013)</td>
<td>None</td>
</tr>
<tr>
<td>Tampere</td>
<td>3.4 million / 410 000</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Genetic samples (1990-2013)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>30 000 / 10 000</td>
<td></td>
</tr>
<tr>
<td>Aura Biobank</td>
<td>TYKS and Satakunta pathology archives (1969-2013)</td>
<td>CLEVER1 research collection</td>
</tr>
<tr>
<td></td>
<td>&gt;1 million / 349 481 (adults) + 4 866 (children) + 8 786 (urology)</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Endometriosis sample collection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 000 (serum) / 3 435</td>
</tr>
<tr>
<td>Borealis Biobank</td>
<td>OYS/OUH + 4 central hospital pathology archives (1979-2013)</td>
<td>Finnish maternity cohort (FMC)</td>
</tr>
<tr>
<td></td>
<td>1.8 million / 500 000</td>
<td>2 million (serum) / 950 000</td>
</tr>
<tr>
<td>Biobank of Eastern Finland</td>
<td>KUH pathology archives (2000-2013)</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>250 000 / 100 000</td>
<td>None</td>
</tr>
<tr>
<td>Biobank of Central Finland</td>
<td>KSSHP pathology archives (1963-2013)</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>600 000 / 160 000</td>
<td>None</td>
</tr>
<tr>
<td>Total</td>
<td>~ 11.1 million / 2.9 million</td>
<td></td>
</tr>
</tbody>
</table>

**2.8. PROSPECTIVE SAMPLE COLLECTIONS**

Prospective sample collection is one of the key activities of the hospital biobanks. Collection of new samples enable large-scale studies in the future and utilization of more variable analysis methods than is possible with e.g. formalin-fixed, paraffin-embedded (FFPE) tissue samples. It is also essential to gather samples from healthy donors, enabling the distinction between healthy and disease states and identification of disease-causing mechanisms.

Currently biobank samples are collected from individuals who have provided a written biobank consent. By the end of May 2018, Finnish hospital biobanks have collected samples from over 77 000 individuals (Figure 4). So far, the collection pace of new samples has been somewhat moderate, explained in part by the limited human resources available for this task, time consuming recruitment of departments and training of new processes to the hospital staff. Some hospital biobanks have restricted their collection processes to specific patient groups or indications. Figure 4 shows the sample collection volumes until the end of 2017 (cumulative data) and the total amount of consented individuals who have donated a biobank sample by the end of May 2018. In addition, estimations of the total numbers of samples collected by 12/2018 are calculated (shown with dashed line) based on the current collection pace as provided by the corresponding biobanks. Figure 5 presents the distribution of the set goals by the Finnish hospital biobanks for collecting prospective samples during 2018. Investment and commitment to
biobank operations by the hospital district management impacts the set sample collection pace. This is well exemplified by the Helsinki Biobank, that multiplied its collection volumes after the hospital district in 2017 appointed the development of biobank activities as one of its top priorities.

FinnGen study, launched in December 2017, is expected to increase the sample collection efforts nationally in the upcoming years. The project aims to collect 280 000 new samples through the Finnish biobank network. All hospital biobanks are participating in this effort and have agreed to individual sample delivery amounts for the study. The samples and related genotyping data produced in the FinnGen study will be stored in biobanks and are subsequently accessible for future biobank research studies\(^{17}\).

The practices for prospective sample collections are expected to be updated by the new revision of the Biobank Act currently ongoing. Such updates may include, for example, enabling the use of samples taken primarily in connection to patient examination and care also for biobank research if the patient does not specifically forbid the use of it\(^{18}\).

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\(^{17}\) [https://www.finngen.fi/en/](https://www.finngen.fi/en/)


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2.8.1. Biobank Consent and Sample Collection Processes

The most common way of collecting biobank consents in the hospital biobanks is to inform the individuals of the biobanking principles by sending a written biobank consent form along with the hospital invitation letter. The consent attached to the invitation letter provides people the opportunity to familiarize themselves with the matter in their own pace and obtain further information during the hospital visit if needed. Helsinki, Auria and Central Finland Biobanks also have the option for giving a consent online. Electronic consents simplify the consent gathering from the sample donor’s point of view. After giving a consent online, the person can donate a blood sample in the hospital laboratory.

The biggest challenge of the consent and sample collection processes of the hospital biobanks is to reduce the lag between consent and sample donation time points. Depending on the hospital biobank process, there is a varying time period before the request(s) for the biobank sample is available in the electronic laboratory system. This is prone to lead to situations where individuals have already received the needed care, before the biobank sample request has been processed and the next visit to the hospital or laboratory may be far in the future. This partly explains, why there are more consents than prospective samples collected in the hospital biobanks as seen in Figure 6. Some biobanks also accumulate consents due to not having enough resources to process the biobank samples in the laboratory.

Helsinki Biobank has launched a new approach for advocating prospective sample collections by hiring so called “biobank ambassadors”. These ambassadors are representatives of the biobank and their task is to inform people and gather new consents. In Helsinki, ambassadors have been collecting consents e.g. at HUSLAB service points, where ambassadors are able to meet people just before the laboratory visit. This provides an opportunity to receive consents and make biobank sample requests before the
blood sampling following right after. Considering the amount of consents and samples collected, the use of ambassadors has been effective in Helsinki Biobank. The biobanks have gathered consents also during hospital/university events and public events such as “SuomiAreena”. Figure 7 presents the distribution of the set goals for collecting consents at the Finnish hospital biobanks during 2018.

**Figure 6. Cumulative numbers of collected consents and prospective samples until 5/2018.**

**Figure 7. Comparison of the set goals for collecting consents during 2018.**
2.9. PERSONNEL RESOURCES

Personnel resources vary between the hospital biobanks and is likely to reflect the magnitude of operations and level of the overall operational maturity. The personnel resources of biobanks have increased during the steady development phase after their establishment. Biobanks acknowledge the importance of enhancing operations, especially in laboratory and sample collecting procedures. It is expected that the personnel quantities will keep growing as the biobanks evolve further. In the future new employees are needed especially in tasks involving data analytics, as the role of data utilization in biobank research increases.

<table>
<thead>
<tr>
<th>Table 8. Personnel Resources of the Biobanks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Full-time employee</td>
</tr>
<tr>
<td>Half-time employee</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

2.10. SAMPLE AND SAMPLE-RELATED DATA DONATIONS

Sample and sample-related data donations for research has started in all biobanks. By the end of December 2017, there were a total of 308 biobank studies completed in Finland (including all Finnish biobanks). The pace of performing biobank studies is accelerating yearly.

Academic research efforts have started in several hospital biobanks and approximately 50 % (57/120) of these projects have been conducted with Auria Biobank. Industry-driven biobank research studies have been almost entirely limited to Auria Biobank. In this report we have included information on those studies that have received a positive decision for sample and/or sample data request by the end of May 2018. As shown in the Figure 8, there are a total of 195 positive decisions for biobank studies, of which 62% include research efforts with academia and 38% with private sector. Furthermore, industry-driven studies can be divided into projects with Finnish commercial companies or the Finnish subsidiary of a global company (65%) and international research projects (35%). Figure 9 represents the total distribution of studies performed in Finnish hospital biobanks. As shown in the figure, biobank studies have been concentrated to three biobanks: Auria Biobank (62%), Helsinki Biobank (22%) and Borealis Biobank (12%).

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A total of 49 sample/sample-related data donations have been done for research projects driven by Finnish companies or the Finnish subsidiary of a global company. 45 (92%) of these donations have been done by the Auria Biobank. 26 projects have been done with global companies and 19 (73%) of them have been conducted in Auria Biobank.

**FIGURE 8. NUMBER OF POSITIVE DECISIONS REGARDING SAMPLE/DATA REQUESTS FOR BIOBANK STUDIES.**

**FIGURE 9. DISTRIBUTION OF THE POSITIVE DECISIONS ON SAMPLE/DATA REQUESTS BETWEEN BIOBANKS (TOTAL OF 195 DONATIONS).**
2.10.1. **INDUSTRY-DRIVEN BIOBANK STUDIES**

Figure 10 shows the distribution of companies involved in Finnish industry-driven hospital biobank studies. This information is based on all the abstracts publicly available in the biobank websites. Currently three biobanks have published abstracts on their websites and two of them have industry-driven studies published. These 39 privately funded studies were conducted with 14 different companies\(^\text{20}\). Majority of the companies represent the big pharma. In addition, in several of the industry-driven biobank research efforts, involvement of a commercial expert / research service company, such as Medaffcon, is included.

**FIGURE 10. DISTRIBUTION OF COMPANIES INVOLVED IN INDUSTRY-DRIVEN HOSPITAL BIOBANK STUDIES.**

2.11. **CLINICAL EXPERTISE WITHIN BIOBANKS**

Clinical expertise has an essential role in biobank research. Clinical experts provide key input to validate the data and help the data-analysts to define the required data. Biobanks do not, however, have a structured process to involve clinical experts in the biobank studies. Although all the biobanks have their own clinician contacts, there are no continuous contracts with these clinical experts. So far researcher/biobank has recruited and managed co-operations with clinical experts on a case by case basis.

During the interviews, biobanks pointed out that they would benefit from having an active network of clinical experts. There has also been growing interest from clinical experts’ side to participate in biobank

research. A structured model for engaging clinical experts in biobank research would thus be beneficial for both parties.

2.12. USAGE OF HEALTHCARE RESOURCE DATA IN BIOBANK STUDIES

Healthcare resource utilization (HCRU) is an important element in biobank and associated real world evidence (RWE) studies. This information is widely accessible in patients’ healthcare records. Parameters of HCRU include e.g. emergency room (ER) visits, outpatient visits, inpatient stays, utilization of laboratory services, treatments and operations, sick leave days etc. This kind of data is desirable in many studies, enabling analyses of the economic value of treatments, comparison between different lines of treatment and assessments of treatment effectiveness. HCRU data has been gathered for decades for assessing profitability in healthcare districts and is thus widely accessible. Figure 11 shows how HCRU data can be combined with other data elements in a biobank and associated RWE studies in assessing e.g. health economic efficacy of healthcare interventions.

In this survey, we found that all hospital biobanks have the potential to gather HCRU information. However, there is no clear consensus whether the HCRU information is considered as sample-related data and thus can be utilized in biobank research studies.

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21 Figure 11 obtained through interview with Medaffcon health economist Jarmo Hahl.
3. CURRENT BOTTLENECKS AND HARMONIZATION NEEDS IN BIOBANKING

In this survey, some bottlenecks and harmonization needs in the processes of conducting biobank research studies and regarding biobanking operations in general were identified. These involved mainly the varying processes regarding sample and data donations for research purposes, limited resources regarding data analytics, limited or non-existing access to data lakes and the non-uniform interpretation of the biobank study definition. In this section we discuss these topics shortly. Solving these issues is vital in ensuring the flow of new biobank studies in Finland.

3.1. AVAILABILITY REGARDING PROSPECTIVE BIOBANK COLLECTIONS

Enormous quantity of samples and related data provides capabilities for longitudinal retrospective studies. As described in chapter 2.7, the Biobank Act has enabled the transfer of old diagnostic samples gathered before 9/2013 to biobanks. These old diagnostic collections constitute an extensive base for samples and related information that can be utilized for biobank research. The collection of prospective biobank samples, started gradually after the establishment of the biobank operations, has not yet reached the same sample coverage. This inflicts a problem where the newer biobank collections represent only a fraction of the patient population compared to the hospital and research archives gathered before 9/2013. Considering, for example, studies that utilize information on treatments that have been introduced just before 2013, there is a significant imbalance between data availability for time periods before and after 9/2013 due to the different consent requirements. To study samples/data collected before and after 2013, the newer samples/data must have an active consent according to the biobank act. This fact must be considered in study designs where the timeline spans over 2013. In some healthcare districts this coverage gap can be compensated by accessing local registry data.

3.2. DATA ANALYTICS AND DATA LAKES

Data analytics has an important role in biobank-based research studies. This is natural considering that data processing and analyses is essential in studies with large quantities of data. Expertise in data processing and data analytics is required in several phases of biobank-based research, for example in gathering and combining data from several databases, in obtaining unstructured information from patient medical records by specific data mining and text mining procedures and in performing versatile statistical analyses on the obtained data.

Based on our survey, 80% of the biobanks reported having data analytics resources in their usage (Table 9) and some of them have established related services. It is, however, noteworthy to mention that all biobanks found their resources limited or at least having the need for increasing the data analytics capabilities as well as funding to enable that. For example, Auria Biobank, providing currently the most advanced data analytics services, stated that increasing resources for developing data analytics capabilities would be one of the most beneficial steps in enhancing their operations.
Hospital data lakes are large-scale information databases were structured health information (for example ICD-10 codes) and unstructured information (for example smoking status or other information obtainable from medical reports) is collected. Data lakes solve problems regarding data integration and accessibility as they simplify the data, make it more easily accessible and interpretable. Hospital data lakes, that biobanks utilize, are built side-by-side with hospital registries and databases and should in principle contain all the sample-related information. Figure 12 demonstrates the elementary functions of data lakes. Currently, 50% of the biobanks have the possibility to utilize data lakes in their biobanking operations (Table 9). These same biobanks also have the possibility to utilize data mining tools.

**Figure 12 Principle of data gathering to hospital data lakes.**

**Table 9. Resources for data analytics and access to the hospital data lake.**

<table>
<thead>
<tr>
<th></th>
<th>Helsinki Biobank</th>
<th>Finnish-Clinical Biobank Tampere</th>
<th>Aura Biobank</th>
<th>Borealis Biobank</th>
<th>Biobank of Eastern Finland</th>
<th>Biobank of Central Finland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data analytical resources</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Access to hospital data lake</td>
<td>Yes</td>
<td>No (**)</td>
<td>Yes</td>
<td>No (**)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Possibility to mine medical records and unstructured information</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

* Access to information database somewhat equivalent to data lake
** Data lake building in progress

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22 Figure 12 obtained through interview with Medaffcon bioinformatician Iiro Toppila.
3.3. INTERPRETATION OF THE BIOBANK ACT (688/2012)

During the interviews, biobanks were asked about their policy on biobank studies that do not involve sample analytics but utilize the sample-related data only. As shown in Figure 13, three out of the six biobanks considered that it is possible to conduct studies using only sample-related data, while two of the biobanks did not yet have a clear opinion on the matter. Only one of the biobanks considered studies using only data challenging in terms of the current legislation. However, all of them agreed that it should be possible to perform studies only using sample-related data in the future.

![Figure 13. Distribution of the interpretation concerning studies using only sample-related data.](image)

Often in RWE study designs sample analytics is left in a minor role and the value of the samples is seen in the data they feature. Possibilities to perform step-wise studies, with an option to proceed to sample and data analytics only if the set criteria defined during the preceding data analysis part is fulfilled, are increasingly needed. We envision, that possibility of performing step-wise studies (such as shown in Figure 14) would increase the quantity of studies, as the economic risk associated with the study would be smaller. Most importantly, this would ensure the meaningful use of precious biobank samples, avoiding the reproduction of information that might already exist.
4. EXPECTATIONS TOWARDS FINBIOBANK

FinBioBank (FINBB), a joint operative of the hospital biobanks, was established in autumn 2017 by the six universities and hospital districts that own the Finnish hospital biobanks. While the core functions are yet to be fully established, the key functions of FINBB include providing a one-stop-shop service and access to biobanks’ sample collections in a centralized manner.

In this survey, hospital biobank representatives were asked, how they see the future role of the biobank cooperative. Common opinion was that there is a need for harmonizing the procedures and operations between the biobanks. It was pointed out, that it would be beneficial that processes, such as collecting and storing samples, would be similar in every biobank. There is also a need for clarifying the interpretation of the Biobank Act. Currently, for example, the interpretation of sample-related data varies between the biobanks. Some of these issues are likely to be solved by the upcoming legislative changes.

It was also suggested by some representatives that FINBB could provide guidelines concerning the pricing of biobanked samples as well as the services that biobanks offer i.e. sample handling, analytics and feasibility requests. Table 10 summarizes the expectations towards FINBB and current activities of the cooperative.

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**Figure 14. Example of a step-wise biobank study.**

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feasibility to check for the desired population (e.g., ICD-10 codes). If study criteria’s are fulfilled, advance to the next phase.</td>
<td>Deep feasibility to check for particular specialties and traits (e.g., treatment-lines, treatment regimens and outcomes). No data donations involved, feasibility results provide only availability of suitable cases. If study criteria’s are fulfilled and sufficient population base is acquired, advance to the next phase.</td>
<td>Actual biobank study phase according to study plan. Sample and data donations from the biobank.</td>
</tr>
</tbody>
</table>

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4.1. FINBB “HYVÄN KETJU” CANCER SAMPLE COLLECTION CAMPAIGN

“Hyvän ketju” is an initiative started by FINBB that pursues to gather 5,000 new cancer samples to biobanks. The effort has two main objectives and it is coordinated by FINBB. The first objective is to collect cancer samples (freshly frozen tissue samples and liquid biopsies) using standardized methods. This will be used to harmonize the sample collection procedures nationally. The second objective is to improve Finnish sample collections and to further develop Finland’s high-profile research environment.

As seen in Table 11, cancer sample collection has started in all hospital biobanks, involving collection of samples from several different cancer types.

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**Table 10. Summary of the expectations towards FINBB and current activities of the cooperative.**

<table>
<thead>
<tr>
<th>Expectations towards FINBB</th>
<th>Projects/development areas ongoing by FINBB</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Common methods and rules</td>
<td>• Development of the national availability database</td>
</tr>
<tr>
<td>• Interpretation of the laws</td>
<td>• Development of &quot;one-stop-shop&quot; method</td>
</tr>
<tr>
<td>• Statement on the definition of biobank studies (applying samples vs. studies using only sample related information)</td>
<td>• &quot;Hyvän ketju&quot; cancer sample collecting project</td>
</tr>
<tr>
<td>• Harmonization of sample collecting procedures and sample prices</td>
<td></td>
</tr>
<tr>
<td>• Market access</td>
<td></td>
</tr>
<tr>
<td>• Statements of the use of unstructured lifestyle information</td>
<td></td>
</tr>
</tbody>
</table>

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**Table 11. Types of cancer samples collected in the Hyvän ketju campaign.**

<table>
<thead>
<tr>
<th>Types of cancer samples collected</th>
<th>Helsinki Biobank</th>
<th>Finnish Clinical Biobank Tampere</th>
<th>Auria Biobank</th>
<th>Borealis Biobank</th>
<th>Biobank of Eastern Finland</th>
<th>Biobank of Central Finland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Several different types of cancer samples.</td>
<td>Several different types of cancer samples in the near future.</td>
<td>Currently gynecological, gastroenterological and urological cancer samples.</td>
<td>Urological (kidney, urinary tract, prostate), rectum and uterus adenocarcinoma cancer samples</td>
<td>Gastroenterological, gynecological, urological and breast cancer samples.</td>
<td>Gynecological cancer samples.</td>
<td>Several different types of cancer samples.</td>
</tr>
</tbody>
</table>

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23 [https://finbb.fi/hyvanketju/](https://finbb.fi/hyvanketju/)
5. CONCLUSIONS

This report summarizes a survey conducted by Medaffcon Oy and the University of Eastern Finland during December 2017 - May 2018. The aim of this effort was to map and describe the field of Finnish hospital biobanking, its functionality, possible bottlenecks as well as the current and future opportunities. The main objectives were to understand the current operational status of the hospital biobanks in Finland and their possibilities to act as a partner in industry-driven studies.

Finnish hospital biobanks have created a unique research infrastructure that has enabled the initiation of both national and international research activities in Finland. Biobanks provide excellent opportunities to study diseases and facilitate the development of e.g. personalized medicine through high-quality samples and related data. In addition to academic research, Finnish hospital biobanks support the needs of industry-driven biobank and real world evidence studies.

The survey showed that operations in all hospital biobanks have started to take form and that currently most activities are associated with collecting new prospective samples and transferring old research collections to biobanks. Large amounts of high-quality samples and sample-related data reside in biobanks, supporting the needs of both public and private sector. While Auria Biobank has been a forerunner in biobank activities in Finland, also other Finnish hospital biobanks have developed their activities substantially. For example, Helsinki Biobank has invested to sample collection procedures and, similarly as Biobank of Eastern Finland, to data availability resources. Overall, the motivation for facilitating and executing sample donations for high-quality research is uniform and high in all biobanks.

This report addresses also some of the identified common bottlenecks affecting biobanking. At present, some differences in the operational maturity between the hospital biobanks can be recognized. This can be seen, for example, in the pace of prospective sample collections and quantities of initiated projects. Heterogeneity in the quantities of donations and prospective samples can be somewhat explained by the different time points of starting biobank activities but are also affected by the commitment of the hospital districts.

Obtaining a uniform interpretation of the definition of biobank research and overcoming the data processing and availability difficulties remain to be solved. It is vital to acknowledge the importance of collected health information and increase capabilities of accessing study-relevant information accordingly. Also, getting access to more recent diagnostic collections, gathered after 9/2013, is highly anticipated. It is a crucial requirement to advance studies on indications where major advancements in regards of new treatments have recently occurred. Considering the needs of the private sector in biobank studies and recognizing the importance of industry-driven studies are also central. Artificial division into academic and privately funded studies should thus be avoided.

Solving the above-mentioned matters will advance the operations of the biobanks further and strengthen Finland’s role as a preferred country in conducting biobank research studies. Towards this task, FINBB could act as an administrator in solving these concerns and harmonizing the procedures nationally. The new legislative efforts currently ongoing are also expected to clarify the interpretation problems and streamline the biobanking procedures in Finland.

There are currently hundreds of biobanks in Europe, with only a fraction of them in Finland. Finnish biobanking, however, stands out due to the high-quality sample collections, strong governmental support, legislative efforts and national registries that have been built over decades and allowing data linkage through the unique social security number to the corresponding samples. Finland is a small country but
for the reasons above and due to being a genetic isolate, has the potential of claiming the forefront in biobank research activities also internationally. This momentum is, nevertheless, time sensitive and thus supporting the further development of Finnish biobank and related ecosystem activities should be prioritized at a national level. Ultimately, this would facilitate the launch of new R&D and innovation activity in Finland, provide a valuable source of international funding through collaborative efforts and, in the end, facilitate the introduction of novel solutions towards better health for all citizens.
6. ACKNOWLEDGEMENTS

Several thanks are needed for facilitating the progress of this report. Most of all, we want to thank all the personnel and representatives of the hospital biobanks for participating the interviews and actively commenting the draft report. We also want to thank FinnBioBank former CEO, Johanna Arola, for the support during the project initiation and the ideas concerning this project. Also, we want to acknowledge our collaborators from the University of Eastern Finland, especially Professor Päivi Eriksson, for commenting the draft report.

7. CONFLICT OF INTEREST

Medaffcon is a privately-owned contract research company based in Espoo, Finland. Company’s main clients consist of pharma companies and public healthcare providers operating in Finland and abroad.

Medaffcon is the first company in Finland to perform industry-driven biobank studies. Currently the company has been involved in more than dozen biobank studies since 2014. Because of Medaffcon’s heavy attachment to the Finnish hospital biobanks already in an early stage, it was natural to proceed on this project. Medaffcon´s top priorities on this study was to investigate current operational status of the Finnish hospital biobanks to strengthen the collaboration possibilities in future studies. The development of Finnish biobanks assists company’s own and general interests in conducting biobank-based research studies.

During this project, Tuompo has been working as a trainee at Medaffcon. At UEF Tuompo is majoring in molecular medicine, in the faculty of health sciences, at the department of biomedicine. In addition, this project has included active discussions with the department of innovation management at the UEF faculty of business due shared interests in national biobanking operations.