FROST & SULLIVAN

Future Watch: Global Biobanking Market Landscape

20th May 2020

team FINLAND MARKET OPPORTUNITIES
FUTURE WATCH

BUSINESS FINLAND

About the study

Business Finland aims to provide early stage insight on trends that define future business opportunities. Emerging global bio-bank ecosystem has been acknowledged as undergoing significant changes in the near future and bringing major opportunities also for Finnish bio-bank ecosystem. In closer discussions with industry stakeholders there was a clearly identified need to understand the relative competitive positioning of the Finnish biobank ecosystem. To support in this process, Personalized health program initiated a **Future Watch study** on global bio-banking markets.

In the study, we identify key trends and their respective drivers in order to validate future growth opportunities in bio-bank markets as well as study the areas for improving the positioning and value proposition of the Finnish biobank offer in global setting. The ultimate aim is to generate insights that will be strategically actionable for bio-bank stakeholders in Finland.

At Business Finland, we create new growth by supporting companies to go global, as well as funding innovations. Our top experts speed up the identification of business opportunities around the world and help transform them into global success stories. **Future Watch** is part of **TF Market opportunities** service and it provides actionable insights from our global network for Finnish businesses and stakeholders.

More information at www.marketopportunities.fi Future Watch

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Executive Summary

THE TOTAL BIOBANKING MARKET WILL REACH $54,713 MN IN 2020 AND GROW AT A CAGR OF 4.5% IN 2020-2026 TO REACH $71,216 MN IN 2026.

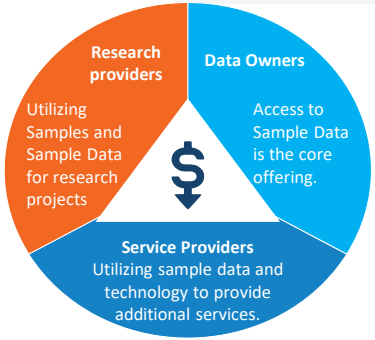
Biobank Market Trends

Drivers

- **Increase in Genome based research projects leveraging large collections of bio-data**
- **Increase in R&D activities** using biospecimens in precision oncology, stem cell research, cell and gene therapies, etc.
- **Increase in the Chronic Diseases** have utilized the large population based data of biobanks
- **Utilization of sample data for research** and **data monetization** is the **next key value** driver for the biobanks

Barriers

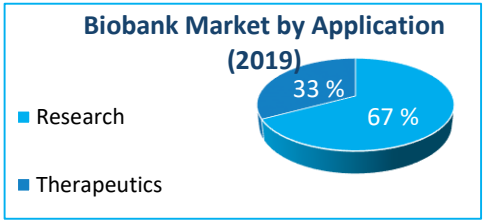
- **Legal and Ethical Challenges** remain high
- **High operational costs** for biobanks
- **Lack of standardization, lengthy procedures** and processes
- **Insufficient awareness** about Biobanking activities



The sole purpose of samples is to produce Biodata enabling patient stratification for precision medicine and the Biobanks can make use multiple business models for data monetization:

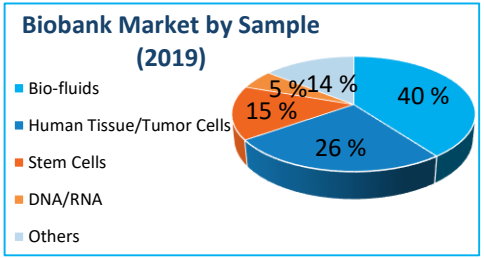
1. Research Providers
2. Data Owners
3. Service Providers

Global Biobank Market (Application and Sample)



Application	CAGR (2019-2026)
Research	4.3%
Therapeutics	5.0%

Therapeutic Applications for Biobanks are Likely to Increase with a Focus on Biomarkers, Oncology, Chronic Therapies



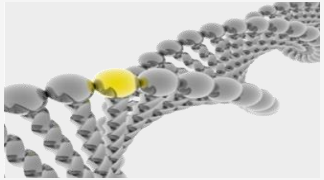
Sample Type	CAGR (2019-2026)
Bio-Fluids	3.9%
Tissue Cells	6.1%
DNA/RNA	2.6%
Stem Cells	4.6%

Growth will be Driven by Human Tissue/Tumor Cells and Stem Cells due to their Novel Therapeutic Applications in rare diseases, regenerative medicines, targeted therapies, which are the focus of commercial and academic research globally

KEY AREAS THAT WILL DRIVE THE FUTURE GROWTH FOR THE FINNISH BIOBANKS

Biobanks have evolved from sample repository centers to active research partners in personalized medicine applications

Companion Diagnostics Co-Development

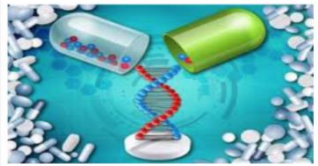


The global companion diagnostics market is expected to reach $8.1 billion by 2023 with a CAGR of 21.2% between 2017-2023. By therapeutic area the oncology segment is expected to account for highest growth rate.

Large-Scale Genome Sequencing Projects

The European next generation genome sequencing services market is forecast to grow at a CAGR of 15.4% from 2016 to 2023 to reach $605.0 million by 2023. Bioinformatics and application based services to provide competitive edge

Oncology Clinical Development



Immuno-oncology therapies are key application area in the oncology therapeutic category. The overall market for such therapies is expected to reach a revenue of $3.9 billion in 2022.

Digital Pathology and Imaging Services

With increasing need for digital workflow and technology for biospecimen assessment in pathology cases, digital information technologies offer the possibility to track the entire life cycle of a biosample

Real World Evidence Studies

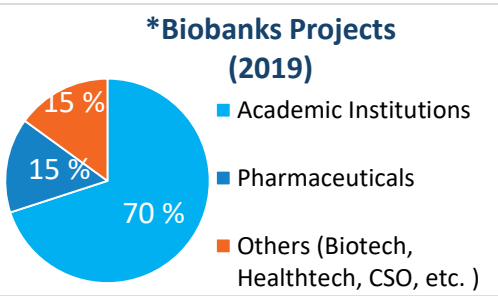
The RWE market has witnessed a number of partnership and acquisition activities as companies aim to improve their technical expertise. The focus areas in RWE solutions include use of OMICS data, cloud computing, real time diagnostics, among others

THE SHIFTING INDUSTRY PARADIGM TOWARDS COMMERCIAL PARTNERSHIPS WITH PHARMA, BIOTECH, CROS, CDMOS AND DIGITAL SOLUTION PROVIDERS IS EXPECTED TO TRIGGER THE MARKET GROWTH.

Traditional Customers ← → Emerging Customers

Academia

- Academic are the major partners of Biobanks.
- Strategic fit, well defined engagement models and robust marketing outreach can strengthen the partnership and create further opportunities to tap new customers, especially pharma.



* n=17 biobanks (based on survey)

Pharma/ Biotech

- **High sample quality, good scientific record and accreditation** are key selection criteria for the Pharma.
- **The scientific, commercial and the procurement team** is involved in the entire process of selecting the biobank, however the chief decision makers are **head of R&D and head of Procurement**.
- One Stop access to data is emerging to be a key attractive attribute for Pharma due to increasing data utilization and ease of access to data
- Value based pricing is the desired model with quality of samples, timely availability, and rarity of the samples as key attributes

CSO (CRO/ CDMO)

- CSOs focus on **sample variety, regulatory expertise, and good scientific record** as key attributes.
- With stringent project timelines CSOs tend to adopt a more flexible engagement in order to deal with dynamic demand in sample and services requirements.
- Revenue sharing model for CSOs is tied the outcomes or milestones achieved by the CSO for Pharma company

Technology Vendors

- High utilization of data services and samples for diagnostics, immunoassay studies, biomarkers, and sequencing applications.
- This makes capabilities such **as online access, integration with systems, sample integrity, among the key attributes** for the Biobanks.
- Healthtech partner with the vendors exclusively for data **using data rent model where temporary access to data is granted**.

A NUMBER OF LEADING BIO-BANKS IN THE US, UK, SWEDEN, AND DENMARK HAVE TAKEN STRIDES TO ADOPT AND IMPLEMENT INDUSTRY BEST PRACTICES IN THE LAST FEW YEARS

USA
- All of US Biobank
- NCI Biobank
- UMMC biobank
- Biome Biobank
- Kaiser Permanente Research Bank

Iceland
- Decode Genetics

UK
- UK Biobank
- CIGMR Biobank

France
- IARC Biobank

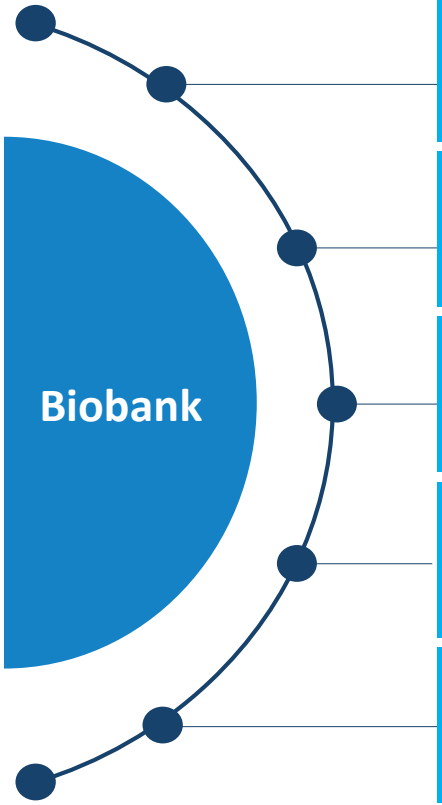
Austria
- Biobank Graz

Denmark
- Danish National Biobank
- Danish Cancer Biobank
- RBGB Biobank

Sweden
- Biobank Vast
- Uppsala Biobank
- KI Biobank
- SMB Biobank

- UK holds vast resources of biobanks, managed by academics and industry partners. UK Biobank has a **highly diverse set of funding sources including govt. orgs, charities, commercial partners, NGOs, etc**.
- Across Sweden, millions of samples with related data are held in different types of biobanks which play a major role in enhancing the precision medicine ecosystem and biobanks have robust commercial partnerships . **The presence of startups, clinical informatics, R&D centers, Biobanks, commercial organizations create an ecosystem that supports precision medicine research**
- In Denmark, the population cohorts, genomic databases, epidemiological research combined with sample management and data analytics capabilities act as key enablers for the Biobanks. **DNB has a highly sophisticated sample management system** with highly automated sample handling with 8 high-throughput Hamilton STAR robots, biomarker analysis for 6000 samples and DNA extraction for 1200 samples per day.
- Across US there are biobanks , small and large scale, focusing on population as well as diseases for **effective translational research and have a dedicated sales and marketing outreach**. **Kaiser Permanente Biobank** has an **annual budget of 2-3% for marketing activities**

FINNISH BIOBANKS CAN DIFFERENTIATE THEMSELVES TO PROVIDE A UNIQUE VALUE PROPOSITION AND INCREASE THEIR COMPETITIVE STANDING WITH CUSTOMERS



Customer Acquisition	While the sample utilization of the Finnish Biobanks is at par with global standards, **much needs to be done to improve the customer acquisition strategies** in terms of: • Working with diverse customer type • Having well defined engagement models • Robust marketing and business development activities	Uppsala Biobank engages in **3 different models with the end-users**
Service Scope	Oncology Clinical Development and Genome Sequencing can be the immediate growth levers for the Biobanks while strengthening the capabilities in digital pathology, companion diagnostics and RWE studies	UK Biobank has a **highly diverse set of funding sources**. Funding includes **core funding** for sample storage and management and **project based funding** such as in genotyping, imaging studies, and biochemical markers
Social Sustainability	A greater participation in regional and international networks will enable to increase the competitive standing of the Finnish Biobanks compared to their global counterparts	**KI Biobank** collaborated with **Janssen** to for a real world evidence study using the comprehensive data from Swedish registries and research expertise of KI in Sweden. The focus research areas include- **Depression, B-cell malignancies, Prostate Cancer, Psoriasis**
Operational Sustainability	A greater participation in regional and international networks will enable to increase the competitive standing of the Finnish Biobanks compared to their global counterparts	Participation of biobanks in networks/collaboration studies: **Biome Biobank (USA)**- ignite network, emerge network. NHGRI, ISBER **CIGMR Biobank (UK)**- BBMRI, MNDA, Arthiritis Research UK, Innovative Medicines Initiative (IMI) **Uppsala Biobank (Sweden)**- Swedeheart, SCAPIS, CONCEPTION, ULSAM, U-CAN Study
Financial Sustainability	Sample management and data infrastructure capabilities of Finnish Biobanks are competitive and have seen rapid progress. One stop Shop capabilities are expected to boost engagement with the partner and data services offerings.	Biobanks such as **Danish National Biobank, UK Biobank**, have well defined pricing model for engagements and multiple funding sources

Source: Frost & Sullivan

FINNISH BIOBANKS CAN FOCUS ON SIX KEY RECOMMENDATIONS AS A PART OF THE TRANSFORMATION PROCESS.

Developing Brand Finland	• **Have a Dedicated marketing personnel for sales promotion and a dedicated budget for marketing activities** (~0.5-2% of the total) **and develop metrics to track trends** such as the tracking of sample usage, solicit feedback from customers, community engagement, shipping trends, distribution trends, and so on • Utilize **media channels as per the preference of the end-users,** such as print media and exhibitor conferences (Pharma), exhibitor conferences, e-mail marketing, print media (Biotech, Healthtech and CSO)
Create Sustainable Revenue streams	• Adopt to the global best practices such as UK Biobank to have a large number of funding sources and not dependent on short term academic funding or single commercial partners • Move beyond arbitrary pricing of samples and data and need to have well defined pricing for its ongoing engagements. Value determinants can be but not limited to market demand for the samples, rarity of the samples, severity of the disease and timely availability
Increase linkages between Biobanks and Industry	• Target the right stakeholders (both influencers and decision makers) such as Head of R&D and Head of Procurement (Pharma/Biotech), Head of Diagnostics (Healthtech), Head of Clinical Research and Procurement (CSO) • Increase participation in regional and international networks based on the complimentary fit of their capabilities with the objectives of the network • Define the engagement models which **can be based on the length of partnership, service requirements (sample and data), and internal resources of biobanks utilized** • Collaborate with the CROs and CDMOs as partners in a strategic alliance comprising Pharma/Biotech or other commercial partners • Target the right stakeholders (both influencers and decision makers) such as Head of R&D and Head of Procurement (Pharma/Biotech), Head of Diagnostics (Healthtech), Head of Clinical Research and Procurement (CSO) • Define the engagement models which **can be based on the length of partnership, service requirements (sample and data), and internal resources of biobanks utilized**

FINNISH BIOBANKS CAN FOCUS ON SIX KEY RECOMMENDATIONS AS A PART OF THE TRANSFORMATION PROCESS.

Enabling Digitization and Data Services	• Expand the data collection from the donors and increase the variety of data types viz. Exogenous data, Clinical/Dx data, OMICS data and remote care data from multiple sources **such as patient questionnaire, physical activity monitoring, environmental measures, health outcomes studies, imaging data, genotyping data and so on** • **Utilization of data services is high for the Pharma and the Healthtech segment** and data based partnerships can be explored with **data rent model under which the Biobank can grant temporary access to data to the end-users while keeping the ownership of the data with themselves** • Enhance the digitization capabilities through the Fingenius portal. Key attributes for such a portal include **easy login details, lesser complexity in access of sample information and data, less complicated navigation for additional features, contact details of the Biobank personnel, frequent updates of the Finnish Biobank activities** and so on
Capacity expansion	• Identify growth levers to in different service segments to differentiate the offerings. For example **molecular and genetic epidemiology (cancer causation), molecular pathology, and pharmacogenomics/pharmacoproteomics, single cell transcriptome analysis and so on.** • Finnish Biobank can continue to Invest in further strengthening sample management infrastructure for storage, distribution and sample variety. Focus on research repositories hosting biomedical and clinical data and consider performance attributes for track the utilization and effectiveness. • Work on retaining talent pool and hiring specialized human capital for biobanking services.
Ease of Business	• Ease interpretation of existing laws and policies around data access, sharing, sample utilization, etc. by regular hosting of **webinars, Q and A sessions** with the target audience • Have a robust **project management plan** and standard operating procedures (SOPs) with details of activities, stakeholder responsibility for the activities, delivery timelines, current status, work breakdown structure (WBS).

Vision for Next Generation Biobanking

Aim 1: Provide sample and **data management solutions** to promote a **systems biology** approach supporting clinical and translational research

Aim 2: Characterize human samples with deeper, standardized **molecular** profiling that will **catalyze** and **enrich** our translation in **precision health**

Global Biobanking Market Overview

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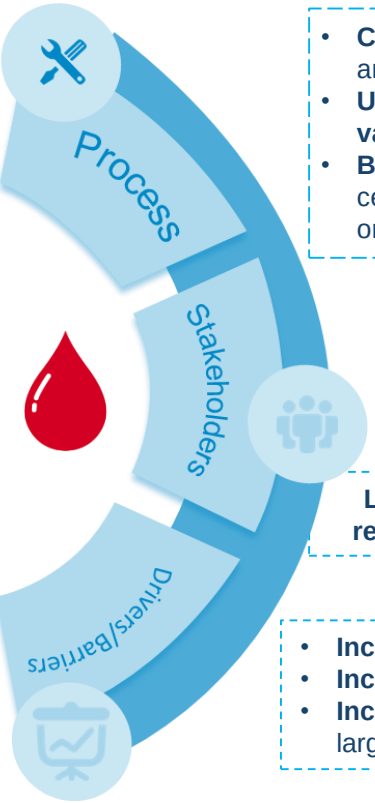
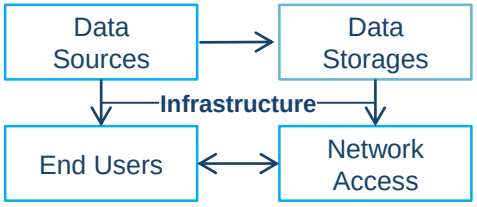
Global Market Overview

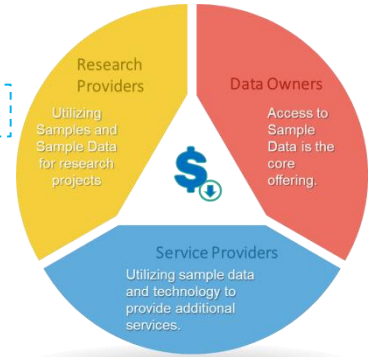
Executive Summary (1/2)

- **Collection of human samples** (blood, tissue, DNA/RNA, etc.), storage and analysis for the purpose of biomedical research.
- **Utilization of sample data for research** and for **monetization** is the **next key value** driver for the biobanks
- **Biobank Infrastructure** includes sources of data such as registries, samples, etc. centralized data storages such as genome database, regional or local network organizations and end users





Monetization



Healthcare Facilities

Universities/Academic Centers

Laws and regulations

Biobank Network Organizations

End-users

- **Increase in funding** of the biobanks by government
- **Increase in R&D activities** such using biospecimens
- **Increase in the Chronic Diseases** have utilized the large population based data of biobanks

- **Legal and Ethical Challenges** remain high
- **High operational costs** for biobanks
- **Lack of standardization**, **lengthy procedures** and processes
- **Insufficient awareness** about Biobanking activities

Global Market Overview

Executive Summary (2/2)

Global Trends

Increase in Genome based Studies
As the biospecimens are a key requirement, genome based studies in precision medicine, OMICS, and other therapy areas offer huge potential for the biobanks

Efforts towards Data harmonization
Biobanks have sought to address the challenges of data harmonization across multiple sources in order to make efficient use of the large quantity of data.

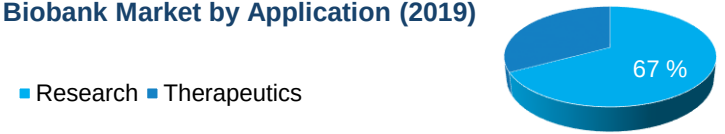
Shift towards centralization of data and samples for the purpose of research
Centralization or one access to samples is a key working area for the biobanks in order to enhance access to samples

Ethical and Legal Trends
Improvement around Compliance to Ethical/legal requirements, and patient consent laws would remain key element for the biobanking activities

Improving the financial sustainability of biobanks is a high priority
Financial Sustainability is a major challenge for the Biobanks
They have begun to explore alternate pricing/engagement models with the commercial partners with a focus on cost recovery, lower inventories, well-defined business plans, and pricing models

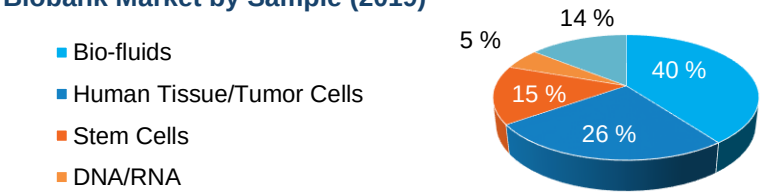
Global Biobank Market

Biobank Market by Application (2019)



Key Areas	Genetic Research, Drug discovery and development, disease specific biomarkers, translational research, diagnostics studies

Biobank Market by Sample (2019)



Key Areas	Tissue biobanking for immunotherapies, gene therapy, Stem Cell Biobanking applications in rare diseases, regenerative medicines

Key Market Themes for Biobanking

Personalized medicine to widen the applications of biospecimens in order to facilitate breakthrough treatments in complex disease areas

Shift towards **Centralization of data and samples** for the purposes of research

Managing the surge in **Chronic diseases** and healthcare costs by improving cross-continuum health management utilizing patient cohort data

Patient consent remains a major concern- Informed Consent, Broad Consent and Dynamic Consent

Increase in **Genome based research projects** leveraging large collections of bio-data

Efforts towards **Data Harmonization** across systems and samples are ongoing

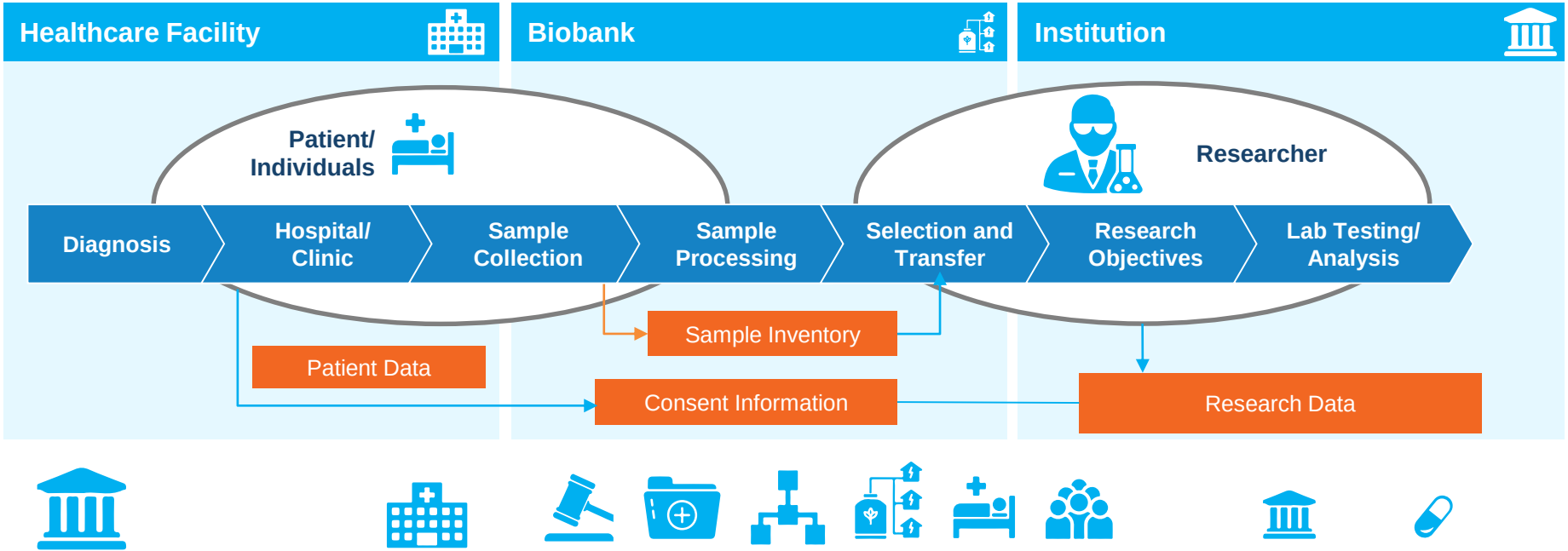
Compliance to **Legal, Regulatory and Ethical** considerations around prevailing biobanking laws remain paramount

Financial Sustainability of biobanks is of high priority since funding of public biobanks' infrastructure becoming tougher in the long run

Source: Frost and Sullivan Analysis, AMR Market Study

Biobank Value Chain: Workflow and Stakeholders

Biobanks serve as a global bridge between patients and their relationship to translational research



Regulatory bodies that enact laws regarding data use, patient consent information, data sharing and **healthcare facilities** such as hospitals

Population Biobanks (Healthy individuals Data) and **Disease Biobanks** (Patients Data), **Government** that enacts laws and maintains data registries, **Biobank network organizations**

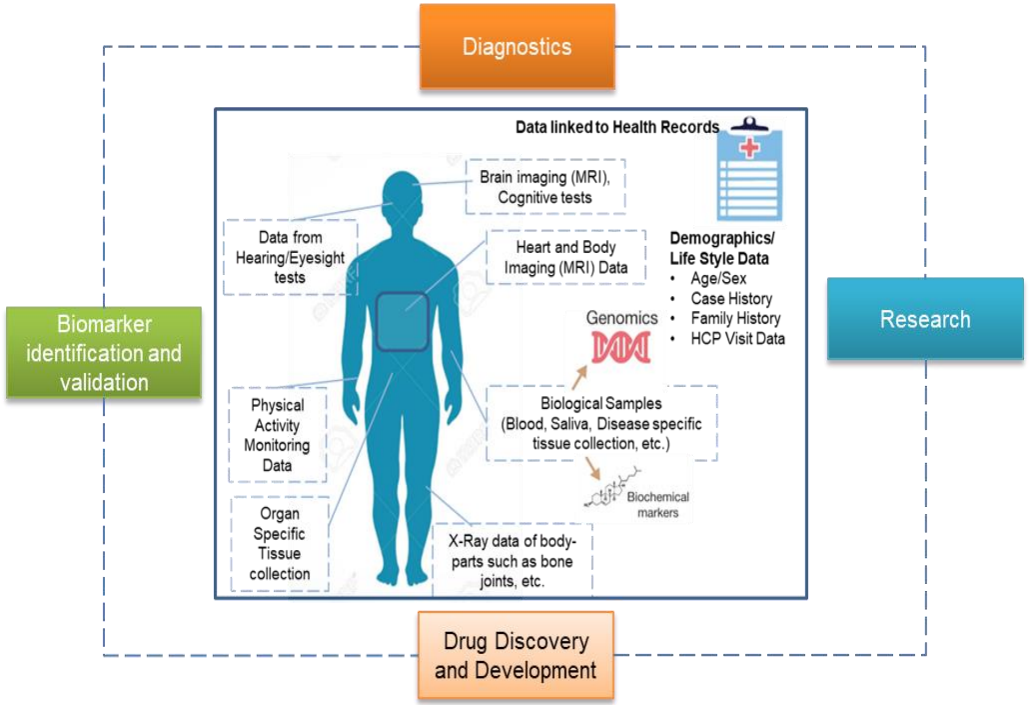
Academic (Universities, Research Institutes,etc.) and **commercial partners** (Pharmaceuticals, diagnostics, etc.) are key stakeholders

Source: Frost and Sullivan Analysis, researchgate.net

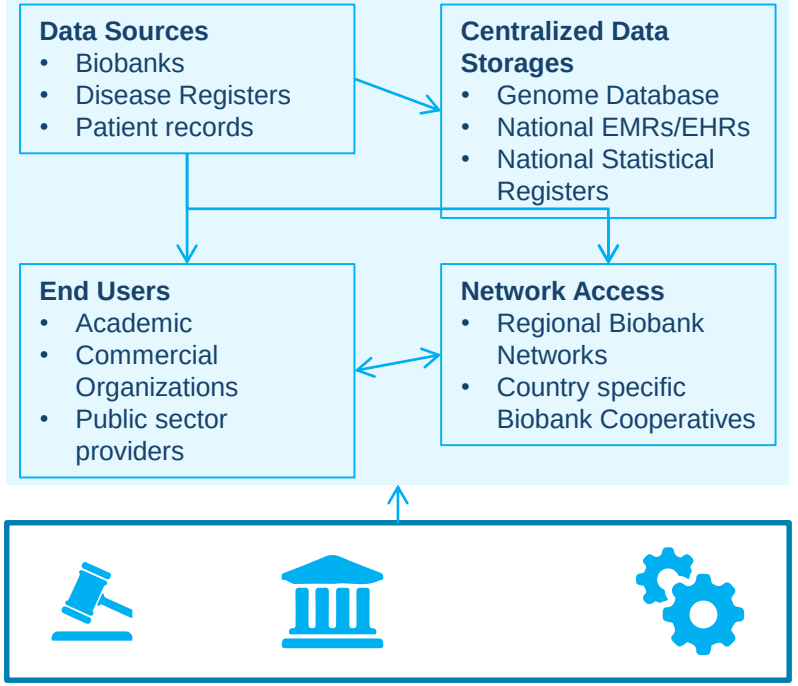
Biobank Value Chain: Sample and Data

Biobank Sample and Data (1/2)

Biobank Sample Sources and Applications



Biobank Data Infrastructure



Source: Frost and Sullivan Analysis, ukbiobank.ac.uk,

Potential Biobank Business Model for Data Monetization

Biobank Sample and Data (2/2)

Data Owners

Biobanks possess large variety of both disease specific biodata as well as healthy population data. Access to data to customers in compliance with the laws is one of the ways to utilize the sample data

Research Providers

Biobanks partner with customers based on specific research based engagements that utilize the biodata. Research could be individual level data/samples or with specific project requirements for the customer

Service Providers

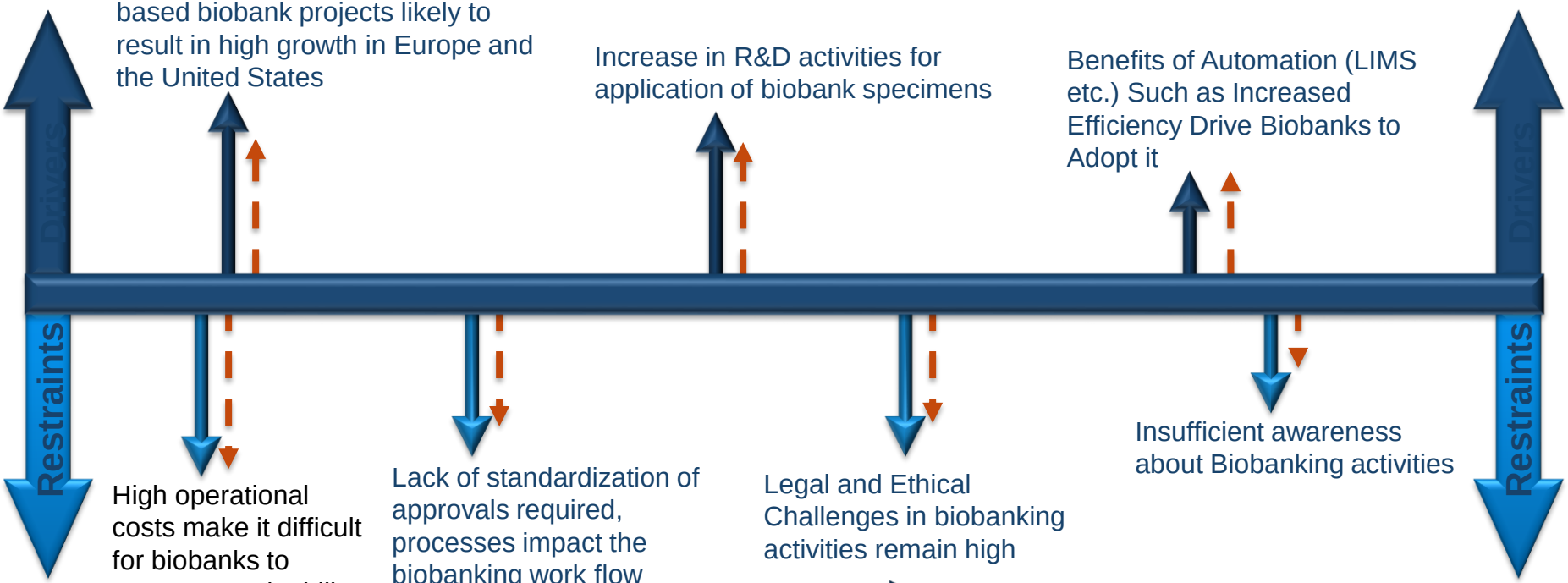
Biobanks can also make use of advanced technologies to act as a niche provider of software, services, data analytics, and related technology in specific areas such as OMICS, Population Health, Oncology, etc.

Pricing models can be a combination of Volume-based—Tiered and Value-based—Attribute approaches, Platform Licensing or Revenue/Commission Share. Data can be packaged in many ways but the ultimate outcome is dependent on the end-consumer's needs.

Source: Frost and Sullivan Analysis, vtt.fi

Global Market Trends

Immediate Growth Driver is the Increased Number of Biobanking Projects in Europe and the United States



Source: Frost & Sullivan analysis.

Market Drivers and Barriers

Trends- Drivers

Biobank Market Drivers

- **Government Funding to promote biobanking services**
  - With the focus of the Government to increase funding for disease based programs in health
  - The biobanks play a central role in biomedical research and applications owing to large and varied collection of samples and infrastructure for sample storage and processing
  - The role of biobanks in medical research has led to increase in funding of the biobanks by government or non-profit organizations

- **Increase in R&D activities such as Precision Medicines, etc. using biospecimens:**
  - Clinical trials and research based innovative activities such as personalized medicine intend to widen the applications of the biospecimens in research thus acting as market drivers for the biobanks.
  - The demand for precision medicines has seen an increase given the fact it promises breakthrough treatments in most complex disease areas
  - Biobanks stand to benefit immensely from the increasing trend of precision medicine owing to samples data they possess, fundamental to the precision medicine applications in therapy areas including oncology, psychiatry, infectious diseases, cardiology, etc.

- **Increase in the Chronic Diseases have utilized the large population based data of biobanks**:
  - Chronic diseases have seen a surge lately in most of the countries globally. Biobanks have much to contribute in terms of large patient cohort data possessed by them
  - Novel means of treatment for chronic diseases involves using a variety of samples such as stem cells, cord blood, etc. that could be provided by the biobanks
  - Such therapies are especially useful in oncology treatment and other rare diseases.

- More than 200 clinical trials are funded by the National Institutes of Health and are being carried out in the U.S. alone.
- In October 2017, National Institutes of Health granted $2.1 million to the UK ME/CFS Biobank, which represents a huge investment in biomedical research.
- The EurOPDX consortium, Europe wide tumor cell biobank, was funded an amount of 5 million Euros (2018-22) by European Union.

- Regeneron Pharmaceuticals formed a consortium with Abbvie, Alnylam Pharmaceuticals, AstraZeneca, Biogen and Pfizer to sequence the exomes of all 500,000 participants in the UK Biobank.
- Medstar Health Biobank in the US entered into a partnership with Indivumed GmbH, a Germany based oncology research company. The purpose of the collaboration was to advance the health of cancer patients through unique biospecimen collection, preservation and analysis.

- The Biobank for Molecular Classification of Kidney Disease (BMCKD) at University of Calgary, Canada is working on the precision medicine in nephrology. The biobank would provided population based biospecimen collection which would assist in disease research and biomarker studies.

Source: Frost and Sullivan Analysis, ckbiobank.org

Market Drivers and Barriers

Trends- Barriers

Biobank Market Barriers

- **Legal and Ethical Challenges in biobanking activities remain high**
  - Ethical aspects especially around donor consent, sample storage, and data transfer for research could result in legal and ethical issues.
  - Participants might also have concerns regarding the use of their samples especially for research involving commercial and profit interests. Biobanks globally have attempted to address this, for instance UK Biobank specifies that commercial companies would be allowed to access UK Biobank if they comply with the scientific and ethics requirements. CARTaGENE for example makes a distinction between commercial and non-commercial users
- **High operational costs make it difficult for biobanks to ensure sustainability in services**
  - Biobanks generally work on the funding from the institutions but due to the nature of the work involved around sample storage infrastructure, sample services, etc. cost of operations is very high.
  - Financial sustainability is a key concern for a large number of biobanks and they require more than just covering the operational costs.
- **Lack of standardization of approvals required, processes impact the biobanking work flow**
  - Biobanks functioning and the organizational work-flow necessitates them to collaborate with multiple different bodies such as Government agencies and universities.
  - On many occasions, approvals from authorities, lack of standardized collecting techniques, bureaucratic functioning hinders the streamline operational flow of the biobanking activities.
  - Challenges also exist due to varied understanding of the prevailing laws in the respective country and compliance to ensure right practices are being followed for the biobanks.

- A survey for around 45 biobanks in France and Netherlands showed that annual operational costs ranged from €200,000 (US$220,000) to €800,000 ($880,000), with an average of €400,000 ($440,000) per annum.

- As per a study in the German urban region in a sample population the respondents attitude was positive towards biobanks (71% showing willingness to donate sample). However only 31% had previously heard of biobanks.

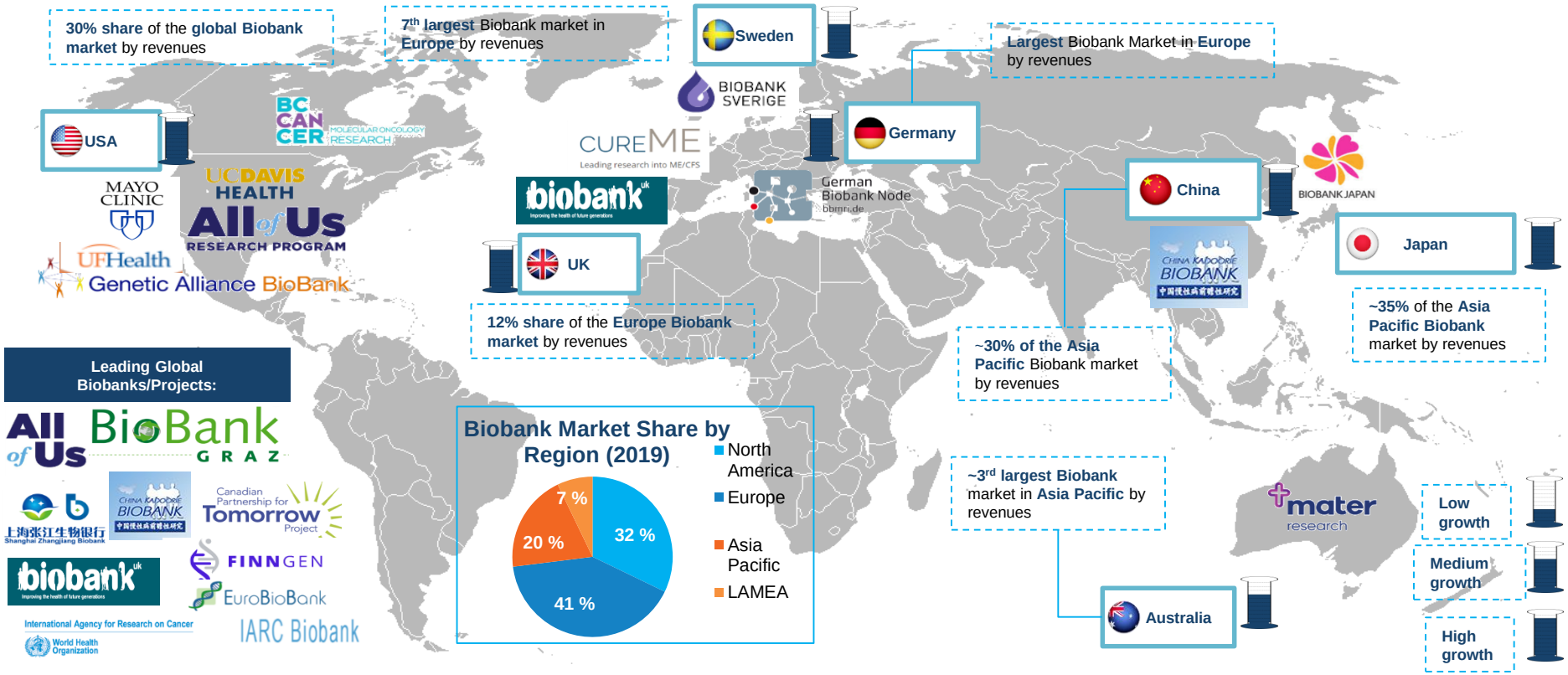
Insufficient awareness about Biobanking activities

- Lack of sufficient awareness about the biobanking activities also impedes participation from the donors for sample collection.
- While the HCPs are aware about biobank activities, simplified consent process acts as an enabler.

Source: Frost and Sullivan Analysis, cartagene.qc

Global Market Size

The total Biobank market in 2019 was $52,103 millions. Europe was the highest contributor to the biobanking Market, APAC is Expected to witness the highest growth



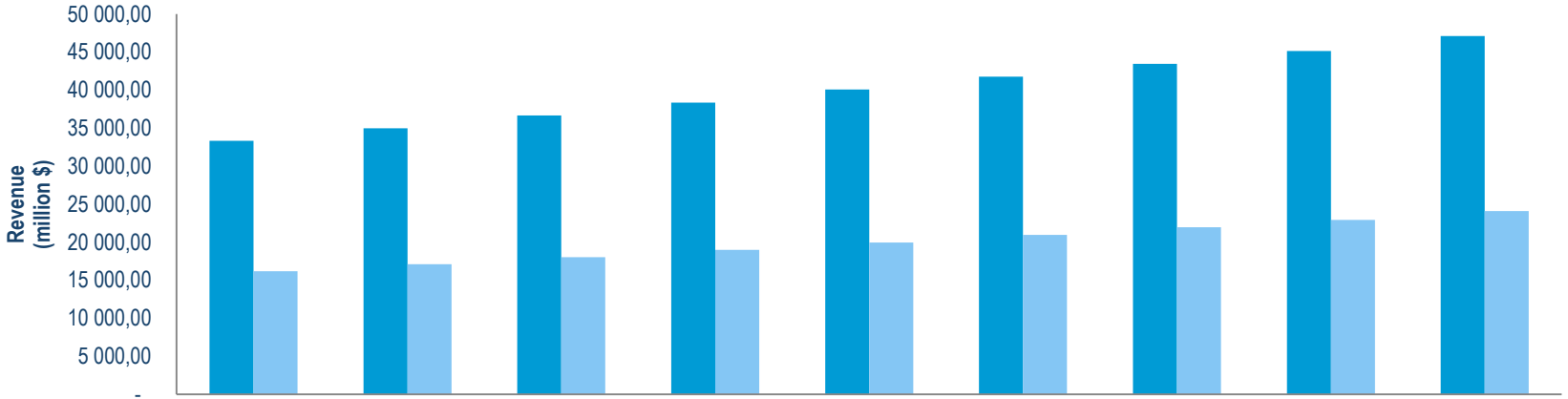
Source: AMR Market Study, Frost and Sullivan Analysis, genomeweb.com

Global Market Size

Current Landscape- Global Market Size- By Application

- The total biobank market will reach $54,713 million in 2020 with research contributing more than 60% of the total revenues generated.

Biobanking Industry, by Application- Global, 2018 – 2026(e)
CAGR 2019-2026: 4.6%



	2018	2019	2020	2021	2022	2023	2024	2025	2026
Research	33 347,45	34 991,93	36 666,72	38 362,92	40 070,40	41 777,70	43 472,09	45 139,52	47 109,92
Therapeutics	16 201,65	17 111,42	18 047,01	19 004,43	19 978,87	20 964,78	21 955,77	22 944,71	24 106,18

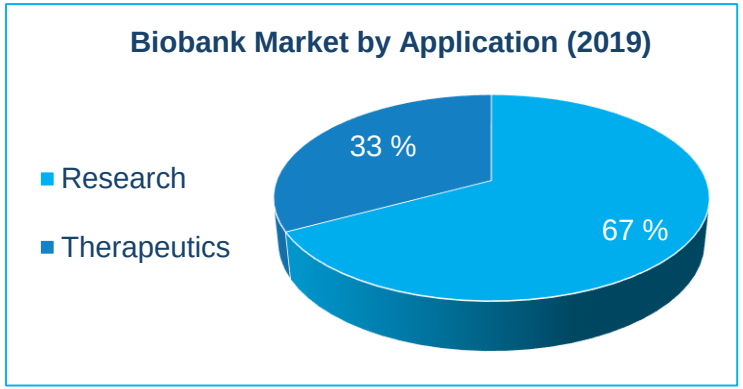
Research segment is the highest contributor to the global biobanking market and anticipated to reach $47,109 million by 2026 with a CAGR of 4.3% in 2019-2026. Therapeutic segment is likely to witness growth at a CAGR of 5.0% in the same period.

Source: Frost and Sullivan Analysis, AMR Study

Global Market Size

Therapeutic Applications for Biobanks are Likely to Increase with a Focus on Biomarkers, Oncology, Chronic Therapies

The total biobanking market reached $52,103 million in 2019 growing at a CAGR of 4.6% in 2019-2026 to reach $71,219 million in 2026. Research segment is the highest contributor to the global biobanking market and anticipated to reach $47,109 mn by 2026 with a CAGR of 4.3% in 2019-2026. Therapeutic segment is likely to witness growth at a CAGR of 5.0% in the same period to reach $24,106 mn by 2026 .



Application	CAGR (2019-2026)
Research	4.3%
Therapeutics	5.0%

- The share of therapeutics in the global biobank market is likely to increase in the next few years with increase in number of project collaborations with the commercial vendors such as pharma, diagnostic companies etc.
- Utilization of samples in early stage or discovery phase in clinical trials has long been observed. However the focus is likely to increase as pharmaceutical companies can see potential opportunities in easy accessibility of sample and data for greater applications across major therapy areas such as cardiovascular, oncology, nephrology, etc.
- Furthermore commercial partners are also likely to exploit the use of large sample data of biobanks, available from patient registries, disease registers, population databases, etc., in real world evidence studies in the late stage of drug development, contributing to therapeutic segment growth.
- Samples in the biobank are the input for most of the research conducted in wide variety of areas such as identification of disease-relevant biomarkers, transplantation research, and investigating the underlying genetic mechanisms of certain common diseases.

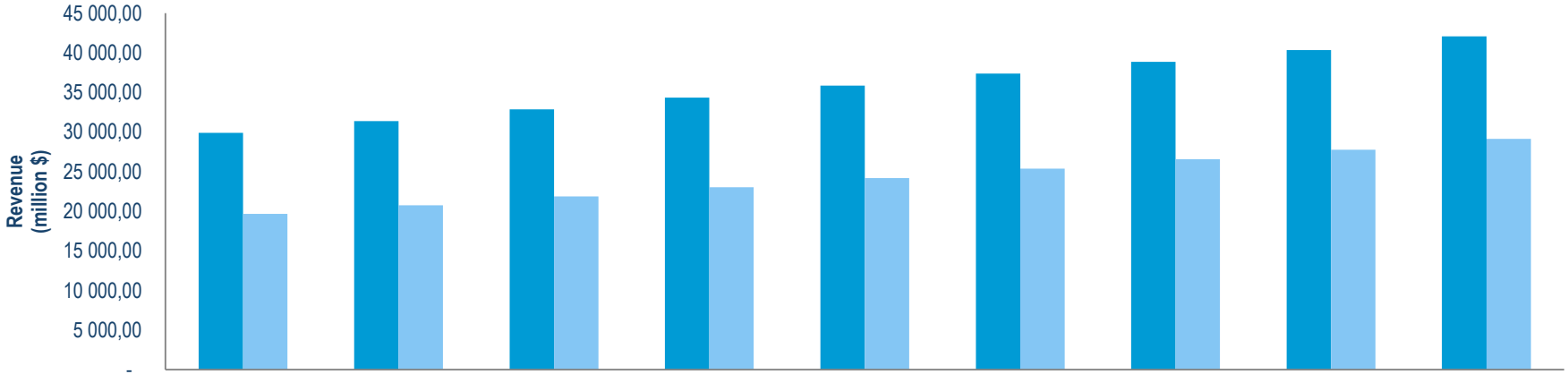
Source: Frost and Sullivan Analysis, AMR Market Study

Global Market Size

Current Landscape- Global Market Size- By Biobank Type

- Standalone segment, ones that do not share the database with third-parties, are likely to reach revenues of $32,845 million in 2020.

Biobanking Industry, by Biobank Type in Global, 2018 – 2026(e)
CAGR 2019-2026: 4.6%



	2018	2019	2020	2021	2022	2023	2024	2025	2026
Standalone	29 903,32	31 361,64	32 845,50	34 346,89	35 856,67	37 364,57	38 859,18	40 327,95	42 068,55
Partnership	19 645,78	20 741,71	21 868,23	23 020,46	24 192,60	25 377,91	26 568,68	27 756,28	29 147,55

Partnership segment, that provide samples from different locations to authorized users, is expected to register a CAGR of 5.0% (2019-2026).

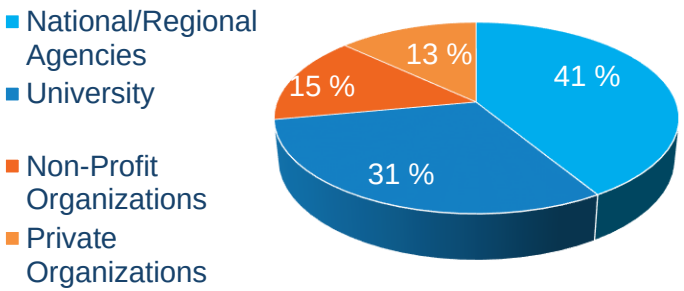
Source: Frost and Sullivan Analysis, AMR Study

Global Market Size

Private Biobanks Share will Increase with Greater Commercialization Potential

National/Regional Agencies segment was the highest contributor to the biobanking market, with $21,507 mn in 2019 and is anticipated to reach $28,507 mn by 2026, registering a CAGR of 4.1%. University segment is anticipated to reach $21,828 mn by 2026 at a CAGR of 4.5%. Private Organizations segment are expected to witness growth at a CAGR of 5.6%, during the forecast period.

Biobank Market by Ownership (2019)



Ownership	CAGR (2019-2026)
National/ Regional Agencies	4.1%
Universities	4.5%
Non-Profit	5.0%
Private	5.6%

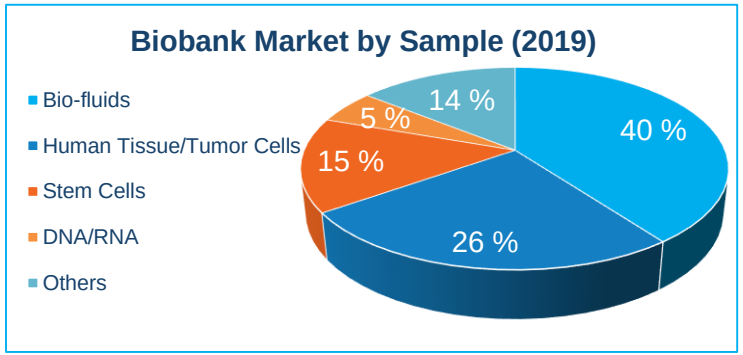
- Biobanks are generally associated with hospitals, health departments of universities, etc. as they are the sources of samples as well as research oriented activities
- Facilities offered by the universities that aids the biobank activities spans in the form of active research programs in the universities, access to a large network of researchers with wide areas of competencies, innovative programs and initiatives in life science research and the opportunity for funding
- As the interest and awareness about the biobanking increases private organizations are expected to increase their share of biobanking activities in the future, though largely self-funded
- National/Regional Agencies and Universities are likely to hold the dominant share of the biobanks
- Non-Profit Biobanks are primarily dependent on external sources of funding for their biobank activities

Source: Frost and Sullivan Analysis, AMR Market Study

Global Market Size

Growth will be Driven by Human Tissue/Tumor Cells and Stem Cells due to their Novel Therapeutic Applications

Bio-fluids segment was the highest contributor to the biobanking market, with $20,716 mn in 2019 and is anticipated to reach $27,064 million by 2026, registering a CAGR of 3.9%. Stem Cells segment is anticipated to reach $10,752 mn by 2026 at a CAGR of 4.6%. Human Tissue/Tumor Cells segment are expected to witness growth at a CAGR of 6.1%, during the forecast period.



Sample Type	CAGR (2019-2026)
Bio-Fluids	3.9%
Tissue Cells	6.1%
DNA/RNA	2.6%
Stem Cells	4.6%

- Biofluids such as blood samples, serum, urine, etc. are the most commonly used samples and are likely to hold the majority share due to their high utility and simplified access of the samples
- Share of samples such as Human Tissues/Tumor cells, are expected to increase due to rising number of oncology studies where the application of the tissue samples is highly utilized. The advancement in treatment care in clinical research for cancer has seen a shift towards biotech derived therapies such as immunotherapy and gene therapy.
- DNA/RNA extraction from the samples are also expected to increase their share of the samples with the increase in genome studies, precision medicine applications, etc.
- Stem Cell applications are likely to grow in areas such as rare diseases, regenerative medicines, targeted therapies, etc. which are the focus of both commercial and academic research globally. The Biobanking market for Stem Cells is expected to seize the growth opportunity due to its facility of preservation of the stem cell samples in temperature controlled conditions and making them easily accessible to researchers.

Source: Frost and Sullivan Analysis, AMR Market Study

Country Level Analysis

Finland

Market Overview

Executive summary

- Finland is the **3rd most advanced digital** economy in the EU
- The **Biobank Act** has played a major role in transformation of the biobanking ecosystem. **Broad Consent** is a key differentiating factor in Finland
- Finland is home to **one of the largest isolated population** cohorts in Europe

- The **Finnish Biobanking landscape** is rapidly evolving with a total of 10 biobanks- majority of them hospital based, population based and one private biobank.
- **FINBB** provides access to data through a network of six hopsital biobanks and the THL biobank.
- Finland is also member of the **BBMRI consortium** in EU for the shared IT infrastructure in Finland

- Availability **of health registry data, legacy sample collection, and linkage to personal identification number**
- **National Genome Strategy** aims that by 2020, genomic data will be effectively used in healthcare

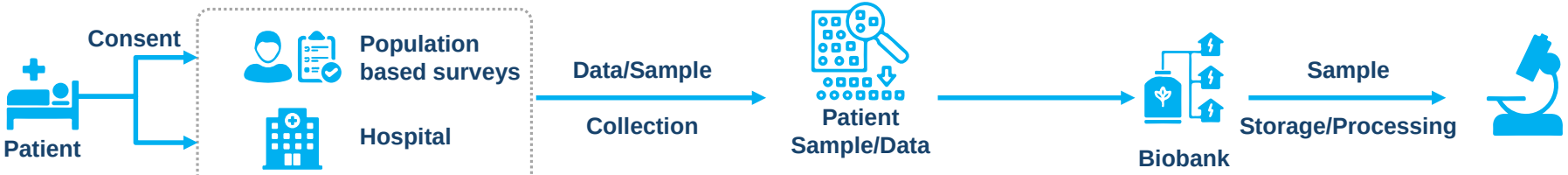
- **Pilot studies** in Finland regarding **personalized medicine** are in progress
- **FinnGen** study is the cornerstone of personalized medicine application in Finland at a large scale and a model for industry-biobank partnerships

- **Academic institutions** form the major chunk of customers, however, **commercial engagements** with **pharmaceutical firms, diagnostic companies, healthcare technology firms, CROs**, etc. would be the focus in future
- **Interoperability** between platforms, advanced tools for **efficient data integration**, increased **utilization of data lakes** and cohorts and **focused marketing efforts** for **services promotion** are **key operational areas** for the Finnish Biobanks in future
- **Financial sustainability** would largely focus on having **right pricing strategies** for services and efforts are being made towards providing one stop shop biobanking services.
- While the patient consent for sample donation for research is high in Finland, there are **concerns regarding the use of patient data in commercial engagements.**

Source: Frost and Sullivan Analysis

Biobanking Data Infrastructure

Biobanks Infrastructure



Data Harmonization

Biobanks possess multiple levels of data such as clinical data from hospital records/registries, sample data, digital images, etc. Biobanks use advance data analytics tools for integration and harmonization of the data from these multiple sources,

IT Infrastructure

BBMRI is the IT infrastructure for shared biobanks in Finland. its aim is to promote high quality, research-based use of the sample collections and associated data of the biobanks. BBMRI provides specialized IT systems support to the biobanks whereas Elixir, and intergovernmental organization in Europe provide cloud storage services.

Sample Management Services

Biobanks have specialized equipment that carry out high quality automatized processing of samples.

Network Access

FINBB provides access to the network of data for six hospital biobanks and THL biobank. Fingenious is the portal to connect to the FINBB biobanks with a single click.

Advanced analytics and **big data solutions** to enhance process efficiency, and **interoperability** with multiple data sources would be key to enhancing the outputs from the existing IT infrastructure

Source: Frost and Sullivan Analysis, elixir-finland.org,finbb.fi

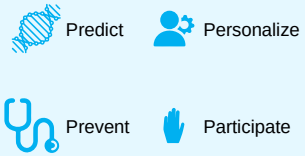
Biobank Initiatives

Biobank Applications (1/2)

Biobanks are likely to play a key role in transitioning towards personalized medicine using specimens, medical records and AI based tools

Current
Reactive Medicine

Future
Personalized Medicine



- Biobanks possess the necessary **sample data** and **infrastructure** required for advances in **personalized medicine.**
- Factors include c**omprehensive EMR, health registers, homogenous genetic data, government support and an advanced biobanking ecosystem.**
- Integrated pathways to enable personalized medicine includes **OMICS data generation, analytics, integration of phenotype** information using advanced analytics tools.
- **Hospital biobanks** with **integrated** and **streamlined consent formats** and **sample collection** are poised to play **major role** in the development of personalized medicine in Finland.
- **Population biobanks** through the large sample **repository of healthy individuals** data can focus on preventative studies based on genetic information, which could be utilized for **preventive personalized medicine.**
- Developments including the act on the **secondary use of health and social data**, **FINBB**, and **personalized medicine pilots** are likely to support the objective of personalized medicine.

P5.fi Study 2018-2023

THL Biobank

- The title of the P5 Study comprises the words **predictive, preventive, personalized, participatory, and population health**.
- The study recruited participants based on FinTerveys 2017 project by THL and the individuals have provided biobank consent for this study.
- One of the key goals of the study is to analyze **how people will respond to their genetic information** and **whether** they **will be amenable to making lifestyle changes** based on the **individualized risk factors and information conveyed**

Potential Applications (Precision Medicine)

- Predictive Biomarkers (Oncology, etc.)
- Genotype and Phenotype measures (Clinical Biomarkers, Gene expression, Metabolite Profile)
- Preventive Care (Disease identification in early stages, adequate diagnosis and differential treatments
- Population Health (Public Health Surveillance)

Source: Frost and Sullivan Analysis, futurecarefinland.fi

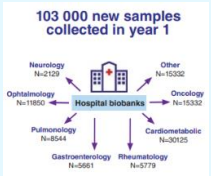
Biobank Initiatives

Biobank Applications (2/2)

The FinnGen study is the cornerstone of personalized medicine application in Finland at a large scale. The project is likely to have positive implications on the biobank partnerships with pharmaceutical manufacturers and medical research in Finland.

FinnGen Study (Background)

- The FinnGen study is one of the most broad academic-industry collaboration examples in the area of personalized medicine.
- The project aims to collect the **genome and national health register information** of 500,000 Finns using the nationwide network of biobanks in Finland.
- FinnGen brings together Finnish Universities, hospitals and hospital districts, THL, blood banking services, biobanks and international pharmaceutical firms.



FinnGen Study(Implications)

abbvie, MERCK, gsk, Biogen, SANOFI, Celgene, AstraZeneca, Pfizer, Roche

Application Areas

- **Understanding disease mechanisms**, and making meta analyses between similar international studies.
- Example of **one stop shop principle-** individual biobanks and partners can benefit from large data cohorts.

Growth Opportunities

- **Commercial engagements with Pharmaceutical manufacturers** in potential areas- drug discovery process, patient response to therapies, discovery of genetically validated targets, etc.
- Expanding the customer base based on **identification** of the **customer needs** in disease research areas and **biobanks data services capabilities.**

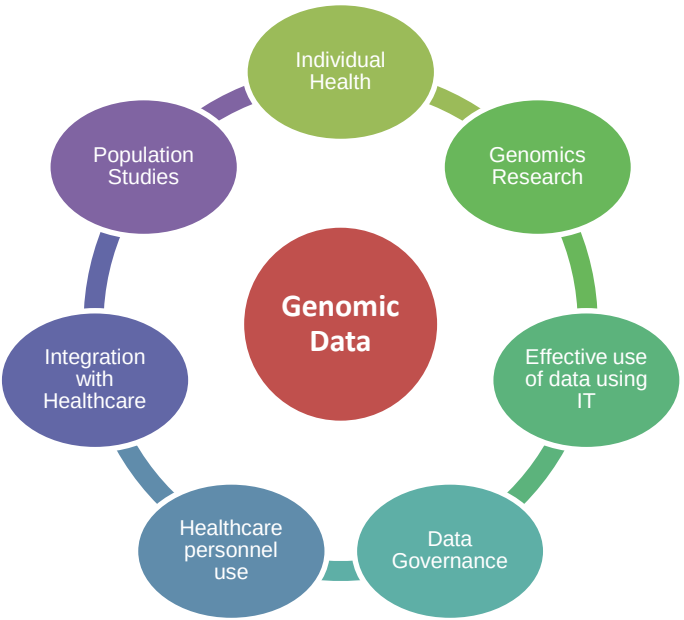
Source: Frost and Sullivan Analysis, sciencebusiness.net

Biobank Initiatives

National Genomic Strategy

In 2015, the National Genome Strategy became effective in Finland with an aim that by 2020, genomic data will be effectively used in healthcare and promotion of health and wellbeing.

National Genome Strategy (Goals)



Key Impact of the Genome Strategy

- The Genome Strategy is likely to **pioneer the international collaborations** and research funding in a bid to tap the indigenous genomic data in Finland.
- The establishment of a **National Genome Center** by the Government is likely to act as a **key enabler** of the implementation of the actions proposed in the Strategy.
- Collaborations with pharmaceutical firms especially in the areas of rare diseases, **breakthrough treatments** or develop new methods to **diagnose illness** would be enhanced by the implementation of the strategy.

National Genome Center

- **Research funding** is also likely to be improved as a result of the **partnerships and collaborations** in such projects where financial viability is a key factor in the execution of the studies.
- Stakeholders are however wary about the **need for a robust integrative mechanism** of genomic data along with the **patient data system, health registry and other such data sources**, in order to **prevent silos** of large volumes of data with less meaningful use.
- However the stakeholders are optimistic regarding the steps taken by the Government such as establishing Genome Center, Finnish Biobank Cooperative- which will send an positive message to the **international community to invite participation in the project.**

Source: Frost and Sullivan Analysis, julkaisut.valtioneuvosto.fi

Regulatory Scenario

Biobank Act

In 2013, the Biobank act became effective in Finland and considered to be a game changer in the Finnish biobanking ecosystem. It brought about **legal basis for the collection and storage of samples** and **strengthen overall supervision** of biobanking activities in Finland.

Biobank Act, 2013

- The Biobank Act passed in 2013 is a **key enabler of the Biobank ecosystem** in Finland.
- The act ensconced registration of biobanks, **protection of the sample donors and rights, broad consent, transfer of prevailing collections to biobanks and infrastructure** to combine samples and data from health records.

Biobank Act passed in 2013 in Finland → Amendments to the Biobank Act

Impact of the proposed new amendments of the Biobank Act

- The Biobank Act passed in 2013 is **expected to undergo amendments and revisions.**
- The amendments are likely to address the concerns and **remove ambiguity around sample related data, prospective sample collection techniques** and other provisions.
- **RWE studies in Finland** are also likely to be **positively** impacted if the amendments come into force, especially if there comes a consensus whether the **healthcare resource utilization** (**HCRU) information** collected by the hospitals **could be utilized in biobank research studies**. The changes in the revised Biobank Act are also related to the **Act on the Secondary Use of Health and Social Data**, which was accepted in March 2019, that deals with using data in other- secondary- purposes than for which it was originally collected.
- The proposed biobank Act is also expected to **better comply with the GDPR** requirements.

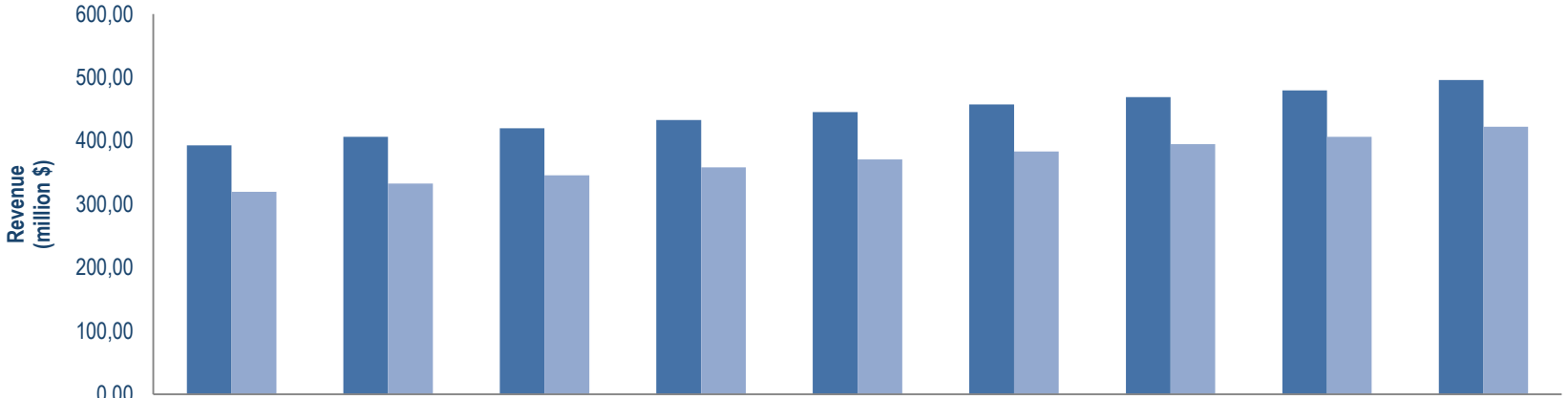
Source: Frost and Sullivan Analysis, alusta.uta.fi

Market Overview

Current Landscape- Finland Market Size- By Application (1/3)

- The total biobank market in Finland will reach $765.04 million in 2020 with research contributing more than half of the total revenues generated.

Biobanking Industry, by Application in Finland, 2018 – 2026(e)
CAGR 2019-2026: 3.1%



	2018	2019	2020	2021	2022	2023	2024	2025	2026
Research	392,95	406,41	419,69	432,70	445,33	457,44	468,88	479,56	495,74
Therapeutics	319,65	332,51	345,37	358,14	370,72	383,00	394,85	406,17	422,29

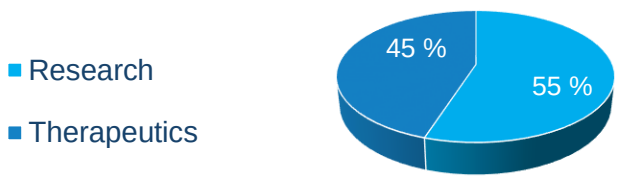
Research segment is the highest contributor to the Finland biobanking market and anticipated to reach $495.7 million by 2026 with a CAGR of 2.9% in 2019-2026. Therapeutic segment is likely to witness growth at a CAGR of 3.5% in the same period.

Source: Frost and Sullivan Analysis, AMR Study

Biobank Application Trends

While research remains the core application segment of the Finnish Biobanks, studies such as FinnGen can drive the shift towards commercial engagements

Biobank Market by Application (2019)



- The research segment of the Biobank sector is expected to be the major contributor in the future however there is a likely increase in the therapeutic applications in the Finland Biobanking Market over the next few years
- Factors that could drive the increase of therapeutic research include greater focus on studies with industry partners, need to improve financial viability of the biobanking operations and growth opportunities in areas such as RWE, OMICS studies, etc. where higher chances of commercial engagements are likely

Highest Growth Category	
Category	**CAGR (2018-2026)**
Research	**2.9%**
Therapeutics	**3.5%**

- Linkage of health data with personal identification number in Finland lays the foundation of the biobank sample data to be utilized not just for genetic research but for **wide range of medical research in disease mechanism understanding, disease prognosis, effectiveness of treatment and so on.**
- **Precision Medicine Research, OMICS studies, oncology, hematology,** are some of the key areas where the biobanks are actively involved in research projects. Initiatives such as the **National Genome Strategy,** and **FINBB** are further likely to **enhance the utilization of biobanking samples** for research owing to improved data sharing, and harmonized procedures
- Partnerships with pharmaceutical companies are likely to drive the growth of the therapeutic segment in biobanking services in **drug discovery and development. RWE studies** is also a potential area for collaboration owing to highly rich **data ecosystem of registries, samples in Biobank** and the growing need for **real world evidence.**

Source: Frost and Sullivan Analysis, AMR Market Study

Market Overview

Current Landscape- Finland Market Size- By Sample Type (2/3)

- Bio-fluids are the top sample contributors (by revenue) to the Finland biobank market and likely to reach $293.8 millions in 2019.

Finland Biobanking Market Revenue, Sample Type, 2018-2026 ($Million)

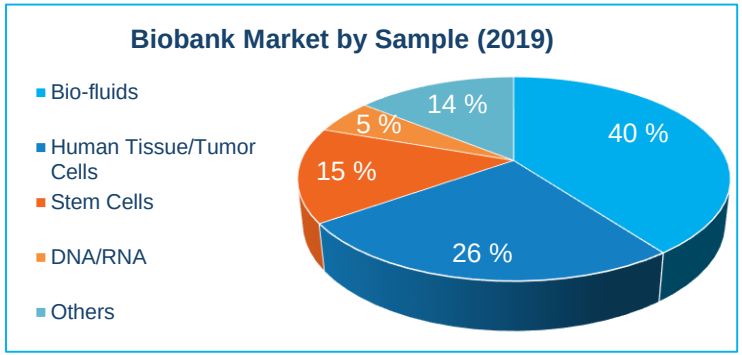
Sample Type	2018	2019	2020	2021	2022	2023	2024	2025	2026	CAGR (2019-2026)
Bio-fluids	285.1	293.8	302.3	310.5	318.3	325.8	332.6	338.9	348.9	2.5%
Human Tissue/Tumor Cells	178.9	188.4	198.1	208.0	217.9	227.8	237.5	247.1	259.8	4.7%
Stem Cells	106.9	111.4	115.3	119.2	123.0	126.7	130.2	133.5	138.3	3.1%
DNA/RNA	39.2	39.9	40.5	41.1	41.6	42.0	42.3	42.5	43.1	1.1%
Others	102.6	105.4	108.8	112.1	115.2	118.2	121.1	123.8	127.8	2.8%
Total	712.6	738.9	765.1	790.8	816.0	840.4	863.7	885.7	918.0	3.1%

Highest growth is expected to be in the human tissue/tumor cell category with an anticipated CAGR of 4.7% in 2019-2026, followed by Stem Cells with a CAGR of 3.1% in the same period.

Source: Frost and Sullivan Analysis, AMR Study

Biobank Sample Trends

Biofluids are expected to retain the dominant share for sample types, however, human tissue and stem cell applications have a greater potential to be used in research and therapeutic applications



- Biofluids such as blood samples, urine, serum, etc. are the most commonly used samples in various research studies by the Biobanks
- As the focus of oncology studies are likely to become significant in the coming years, human tissue/tumor cells sample type would be a high growth category
- DNA/RNA sample applications in Finland are also likely to be positively impacted with greater feasibility in OMICS studies, genome sequencing applications, and so on.
- Stem Cell applications is another sample type that is expected to increase its share owing to increases in rare disease research, C&G therapies, etc.

Highest Growth Category	
Category	**CAGR (2018-2026)**
Bio-Fluids	**2.5%**
Tissue Cells	**4.7%**
DNA/RNA	**1.1**
Stem Cells	**3.1**

- Human Tissue/Tumor Cells are **mostly utilized in cancer research**. Finland is among the **leaders in cancer research in Europe** supported by an ecosystem of **robust data infrastructure** such as **Finnish cancer registry**, **Finnish Cancer Center (FICAN),** and research organizations and societies dedicated to cancer studies.
- **Fresh frozen tissue samples, and liquid biospies** are highly utilized in areas such as **cellular level genomics**, **biomarker studies for diagnosis**, **imaging and bioinformatics**, **metabolism** and novel administration and **modeling of cancer drugs.** This trend is likely to contribute to the growth of the segment in Finland
- **Stem Cell sample segment** growth in Finland is likely to **be enhanced** from its applications in **organ replacements**, **neurodegenerative disorders**, cancer, cardiovascular diseases, etc. The **Finnish Stem Cell Registry** works on stem cell transplants such as in leukemia, myloma, lymphomas, etc. It serves ~100 transplants in Finland and abroad each year

Source: Frost and Sullivan Analysis, AMR Market Study

Market Overview

Current Landscape- Finland Market Size- By Ownership Type (3/3)

- National/Regional Agencies and Universities owned biobanks contribute to majority of the biobanks revenues in Finland and will reach $375.2 million and $227 million in 2019 respectively.

Finland Biobanking Market Revenue, Ownership Type, 2018-2026 ($Million)

Ownership Type	2018	2019	2020	2021	2022	2023	2024	2025	2026	CAGR (2019-2026)
National/Regional Agencies	362.7	375.2	387.6	399.8	411.7	423	433.8	443.9	459	2.9%
University	218.7	227.0	235.2	243.4	251.3	259	266.4	273.5	283.7	3.2%
Non-Profit Organizations	110.0	114.5	119.0	123.5	127.9	132.2	136.3	140.3	146	3.5%
Private Organizations	21.2	22.2	23.2	24.2	25.2	26.2	27.1	28.1	29.4	4.1%
Total	712.6	738.9	765.1	790.8	816	840.4	863.7	885.7	918	3.1%

Private organizations are likely to be growth drivers with an anticipated CAGR of 4.1% in 2019-2026, and emergence of new private organizations cannot be ruled out given the increasing government expenditure on the biobanking services.

Source: Frost and Sullivan Analysis, AMR Study

Denmark

Market Overview

Executive summary

Ecosystem

- There are a number of biobanks in Denmark with different therapeutic focus, however the **Danish National Biobank (DNB)** serves as a major collaborator of samples across the country
- Some of the key Biobanks include PKU Biobank, Patobank, Danish Cancer Society, etc.

Regulatory Scenario

- There is **no separate legislation** for biobanking and the activities are governed by the **Data processing act** and approval from the **research ethics committee**
- The Act is the main law governing how and when personal information is processed, and applicable to both electronic data processing as well as manual processing of data kept in a register

Data Infrastructure

- Denmark has a **high quality data collection** which dates back to decades.
- **Linkage** between the patient registers and biobanks **(through PIN**) offers advantage to Denmark in terms of large scale health research

Initiatives

- **DNB is the largest biobank** in Denmark owned by Statens Serum Institut (SSI) and established primarily with the support of **Novo Nordisk Foundation**, and other partners including **Lundbeck Foundation** and **Ministry of Science, Innovation and Education**
- DNB hosts the **Biobank register**. It is the **platform** for **linkage of data** from **Biobanks and National registers**.

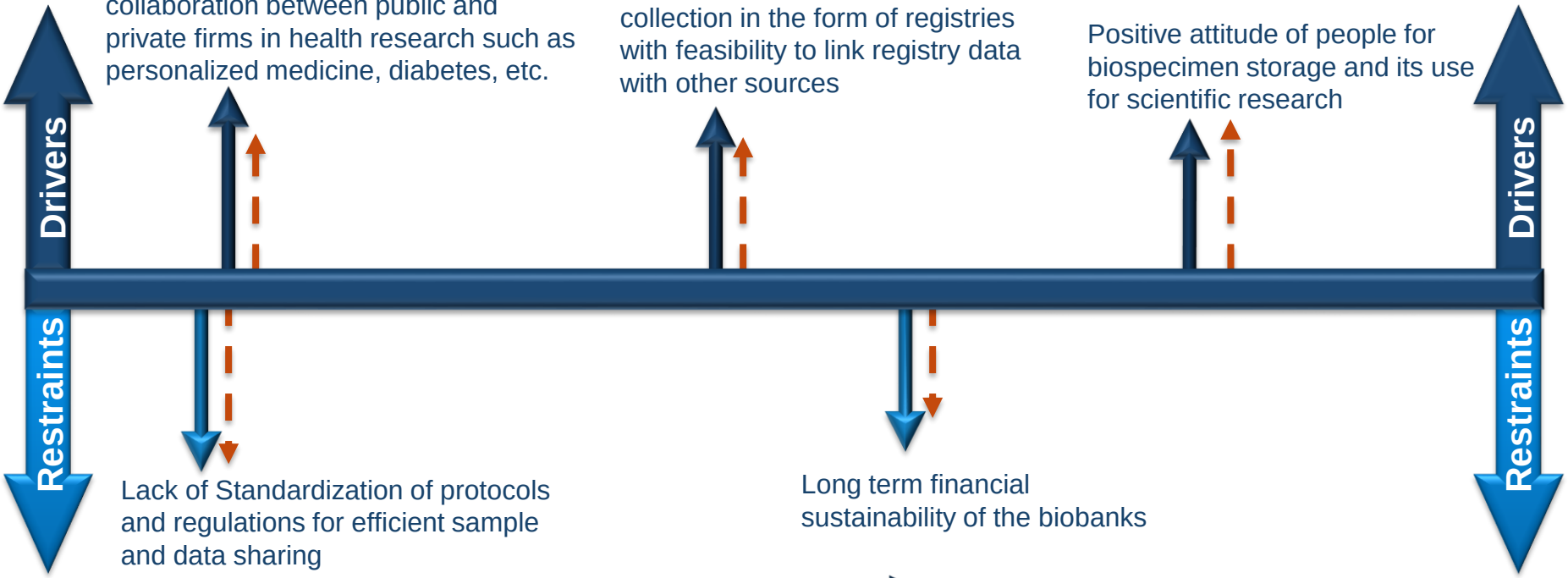
Market Analysis

- Research Applications form ~66% of the total biobanking market while 34% is for therapeutic based applications. While biofluids are the dominant market share holders for biospecimens, the **human tissue samples and stem cells samples are expected to grow by 5.9% and 4.3%** CAGR (2019-2026) respectively
- Highly evolved cross collaboration, well-funded projects, and focus on key therapeutic segments such as **Stem Cells, Oncology**, are driving the precision medicine applications in Denmark. Furthermore Stem Cells Research is highly advanced in Denmark with **strong backing from industry** partners (Novo Nordisk) and **universities**
- Some of the key programs include **National Danish Strategy for Personalized medicine** (2017-2020), **Life Science Bioclusters** that act as centers of excellence, etc.

Source: Frost and Sullivan Analysis

Drivers and Barriers

High degree of public-private collaboration and availability of large cohort data registers are major drivers for biospecimen demand in Denmark



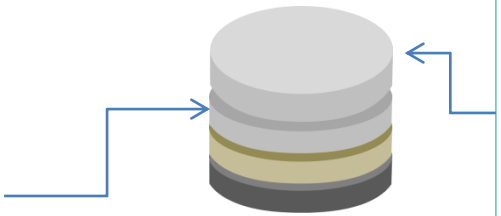
Source: Frost and Sullivan Analysis

Biobank Data Infrastructure

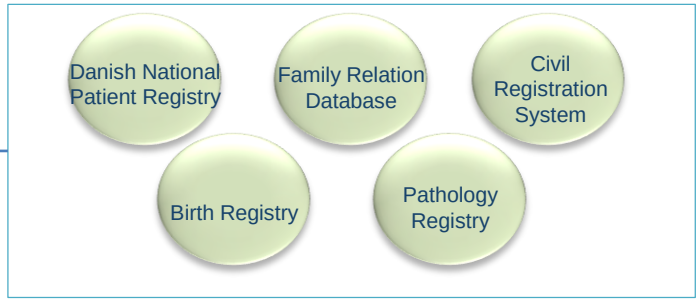
Linkage between the patient registers and biobanks (through PIN) offers significant advantage to Denmark in terms of enabling large scale projects in health research

Danish Biobanks

- Hospital Biobanks
- Pathology Biobanks
- National Biobanks
- Cancer/Disease Biobanks
- Neonatal Biobanks



National Registers*



Denmark has a long history for collecting data and storage in the form of national registries that includes health, social security, labor, population statistics

- Denmark has a **high quality data collection** system which dates back decades. For example cancer incidence has been registered for the whole country since 1943, information on twins are available for cohorts born after 1870
- As all the Danish citizens have a **unique personal identification number**, **linkage between the nationwide registers** and other data sources from the biobanks is feasible

Non-Exhaustive

Examples of Danish Registers

Danish Register	Content	Start year
National Patient Register	Hospital Diagnosis/Operations	1977
National Health Service	Providers/Services in primary care	1990
Multiple Sclerosis Registry	Incidence of patients with MS	1949
National Diabetes Register	Diabetes diagnosis information of patients	1995
Cancer Registry	Incidence on all malignant oncology types	1943

Source: Frost and Sullivan Analysis, lif.dk

Biobank Initiatives

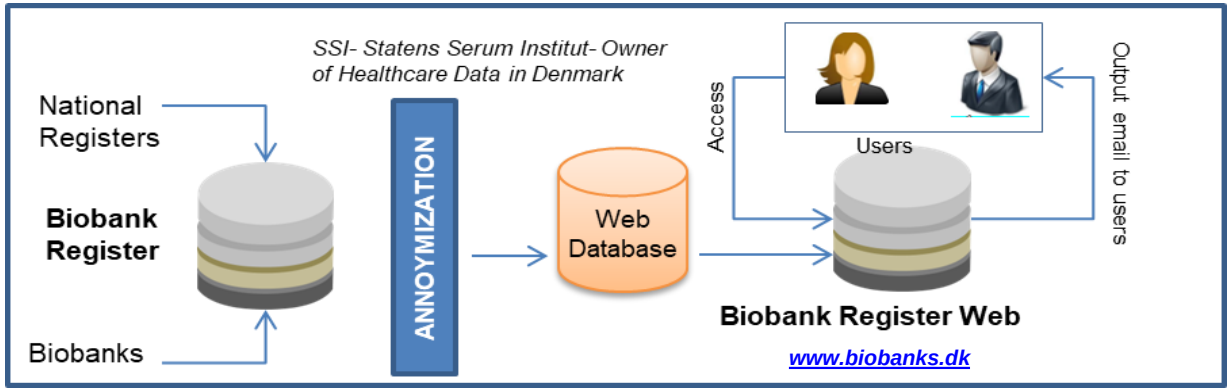
Danish National Biobank is the largest biobank in Denmark and also serves as a central portal for access to samples and information for the users

Danish National Biobank

Ministry of Science, Innovation, Higher Ed.	Novo Nordisk Foundation	Lundbeck Foundation

DANMARKS NATIONALE BIOBANK

Danish National Biobank- Biobank Register



- The **SSI institute** is responsible for all Healthcare Data in Denmark. SSI owns the **Danish National Biobank. DNB** was established with major financial support from the **Novo Nordisk Foundation** as well as assistance from **Lundbeck Foundation** and the **Ministry of Science, Innovation and Higher Education**
- DNB hosts the **Biobank register**. It is the platform for **linkage of data from Biobanks and National registers**. Biobank Webportal offers simplified access to users who can select the type of sample required by a set of criteria selected by the users. Users receive the output in the form of email
- Data may include **sensitive information** such as **Individual date of birth and PIN**, **diagnosis codes** assigned during hospitalization (ICD8/ICD10 codes), data about pathologies (SNOMED codes + pathology date), data about individual biologic materials (blood, tissue, etc.) including sample date

- The **Danish ELIXIR** Node focuses on **bioinformatics tool interoperability** and **integration** across workflows.
- DNB is also a part of **BBMRI-Large Prospective Cohorts** which is **pan-European population based cohort** study.

bbmri-lpc BBMRI – Large Prospective Cohorts

elixir DENMARK

Source: Frost and Sullivan Analysis, danishnationalbiobank.com

Biobank Initiatives

Highly evolved cross collaborative and well-funded projects, and with a focus on key therapeutic segments such as Stem Cells and Oncology, Denmarks also highlights the Precision Medicine potential

Key Growth Drivers

Strategic Partnerships/Clusters

Biobanks can actively participate in private or government initiated clusters that serve as hotspots for research, and collaboration in wide disease areas

Investments

Denmark has actively seen a culture of investments both by Private, Government agencies and not-for-profit foundations to promote research in healthcare

Policy and Vision

Precision Medicine applications are backed by a national strategy for implementation and funding by Government

Research and Therapeutic Focus

Key priority areas for precision medicine applications include protein research, Stem cells, companion diagnostics, genomic sequencing

Case Examples

- **National Danish Strategy for Personalized medicine** (2017-2020) will drive the overall strategy for precision medicine with focus on national infrastructure, data sharing guidelines, genome sequencing applications, patient data protection, and encouraging further research. Government will spend EUR 13.4 million. **RESEARCH2025** is a Government driven catalogue that identifies the **priority areas for research investments**
- ***GenomeDenmark's*** objective is to establish a platform with increased coordination, synergy and research infrastructure for genomics. It is a consortium of universities, hospitals and private firms. Partners such as hospitals contribute by providing access to biobanks and other applications and development tools
- **Danish National Genome center,** established in Copenhagen will act as a hub for integrating genomic data which will be utilized in precision medicine applications. The Government has set aside EUR 13.5 million (USD 14.2 million) for 2017-2020. Novo Nordisk will invest USD 150 million in next 4.5 years to support the National Genome Center
- **Life Sciences Clusters: Biopeople**, Denmark's Life Science Cluster is funded by the Government with a focus on in companion diagnostics, biomarkers, etc. through innovation and collaboration with stakeholders. **Copenhagen Bioscience Cluster**, was established by **Novo Nordisk** with a grant of more than EUR 853 million at University of Copenhagen. It promotes research and innovation by collaboration between acaden hospitals and industry. Focus areas include Stem Cells Research, Bio-sustainability, Protein Research
- **Innovation Fund Denmark (IFD)** is a Govt. agency that invests in innovative ideas and solutions. It invested EUR 23.4 million in health area with a focus on precision medicine applications. **Lundbeck Foundation** also provides funding for precision medicine applications such as in brain and nervous system diagnosis and treatment

Source: Frost and Sullivan Analysis, lif.dk,ufm.dk

Regulatory Scenario

There is no separate legislation for biobanking services and the activities are governed by the data processing act and approval from the research ethics committee

Danish Act on Processing of Personal Data

- Biobanks in Denmark are **subject to personal data legislation and data protection laws**, along with approval from a research **ethics committee (EC)** as there is no separate biobanking legislation in the country
- The **Data Processing Act (DPA)** is the main law governing how and when personal information is processed, and applicable to both electronic data processing as well as manual processing of data kept in a register
- The collection of human biological samples are also covered by the Act. Furthermore the Act also defines the Principle of Purpose which states that **collection of information be done for explicitly stated professional purposes**, and that any **subsequent processing** should be in **line with the originally stated purpose**
- Furthermore, if the biobank does include human biological material, an **approval from a research ethics committee** must be **obtained**.

Biobank legislation understood by examples

Use of identifiable HBM collected from patient in a research/clinical trial	Collection/Storage of identifiable HBM in biobank	Use of stored identifiable HBM	Use of collected or stored anonymous HBM
• Approval from Ethics Committee • Approval from Data Protection Agency • Approval from health authority (for clinical trials) • Destroy or anonymize HBM after closure	• Approval from DPA and guidelines for storage • EC approval for patient consent for identifiable HBM	• Approval from EC • Approval from DPA • Consult in the tissue	Anonymous HBM is not considered personal data and is not regulated by the approval from the DPA is not required. Research on anonymous HBM is exempted from EC approval if it meets certain criteria

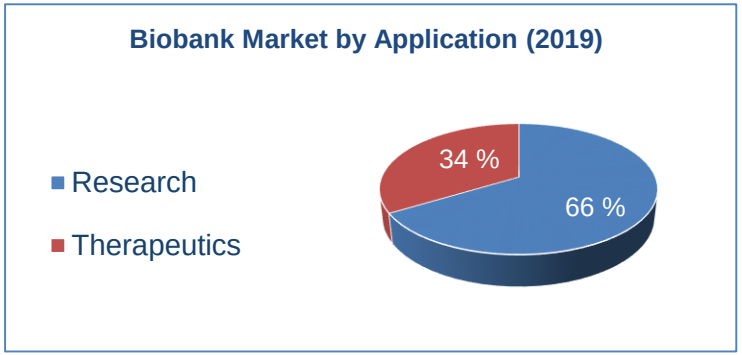
HBM- Human Biological Material

Source: Frost and Sullivan Analysis, lif.dk

Biobank Application trends

Highly sophisticated disease registries, investments in genomic and precision medicine initiatives and highly mature clinical research landscape would positively impact the biobanking sample applications

The total biobanking market was $919 million in 2019 growing at a CAGR of 4.3% in 2019-2026 to reach $1,235 million in 2026. Research segment is the highest contributor to the Denmark biobanking market and anticipated to reach $806 million by 2026 ($609.8 mn,2019) with a CAGR of 4.1% in 2019-2026. Therapeutic segment is likely to witness growth at a CAGR of 4.8% in the same period to reach $429 million by 2026 ($309.9 mn, 2019) .



Category	CAGR (2019-2026)
Research	4.1%
Therapeutics	4.8%

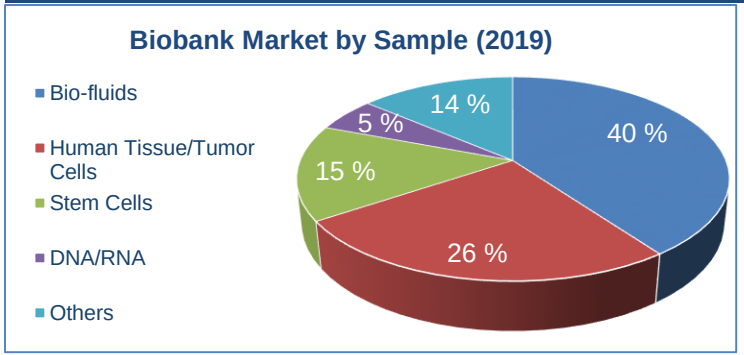
- **Denmark** has a robust infrastructure of data collection and storage in the form of disease registries
- As the data is linked through a personal identification number, the data from the disease registries is highly utilized in research applications. For example studies such as **Danish Twin Registry**, **Copenhagen City Heart Study**, **Copenhagen Breast Cancer Study**, etc.
- Research applications are also supported by an ecosystem of clusters/partnerships between academia, government agencies and private commercial companies, and investments from the stakeholders
- **Therapeutic applications** in Denmark are driven by a strong environment for clinical research applications. Denmark is the country with largest share of R&D investments in medical and health sciences
- **Initiatives in precision medicine applications** are at the center of various Government initiatives including a **national strategy for precision medicine**, **Genome Center development**, etc.
- Denmark is highly developed in terms of **clinical research** landscape. Extensive Patient data and registries, public private partnerships with national research centers on disease areas such as **Oncology, dermatology**, etc. and **active participation** of **pharmaceutical companies** favorably impact the therapeutic applications of the biospecimens in the biobank

Source: Frost and Sullivan Analysis, AMR Market Study

Biobank Sample Trends

Human Tissue cells and Stem cells are growth drivers for sample applications; Stem Cells Research is highly advanced in Denmark with strong backing industry partners (Novo Nordisk) and universities

Tissue Cells and Stem cell segment is at $234.5 million and $138.6 million in 2019 and register strongest growth to reach $349.7 million and $186.2 million by 2026 respectively. Biofluids sample types are the most commonly utilized specimens and likely to reach $469.8 million in 2026



Sample Type	CAGR (2019-2026)
Bio-Fluids	3.6%
Tissue Cells	5.9%
DNA/RNA	2.3%
Stem Cells	4.3%

- The increase in demand for biosamples is likely to be driven by human tissue/tumor cells and Stem Cells. Purity of the samples and physical conditions are critical for the tissue/stem cells samples to be utilized for biomedical research purposes
- **Human Tissue** cells applications on **Oncology** are the major drivers for the samples. Biobanks such as **Danish Cancer Biobank** and **Colorectal Cancer tissue biobank** focus specifically on the cancer research such as in **bladder cancer, prostate, colon cancer**, etc.
- **Samples** collected for neoplasm studies include **adenomas, adenocarcinomas, liver metastases, mucosa** and others such as blood. DNA/RNA isolation from samples is also done in the Biobanks for Oncology studies on case to case basis
- **Stem Cell Applications** have seen an increasing growth trend in Denmark. **Novo Nordisk Foundation Center for Stem Cell Biology**, DanStem is housed at University of Copenhagen and is a premier stem cell research institute focusing on developmental biology, embryonic development, oxygenesis through cell/drug based therapies especially in cancer and in diabetes
- **BrainStem** is a center of excellence in neurology across academia and industry especially with a strong platform for induced pluripotent stem cells **(iPSC) applications**

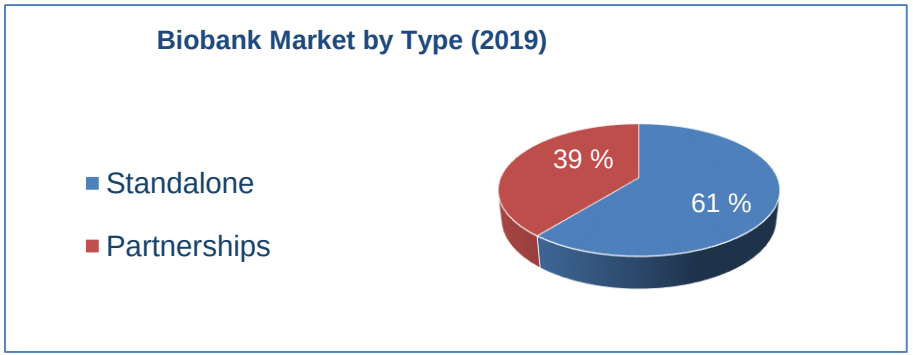
Source: Frost and Sullivan Analysis, AMR Market Study

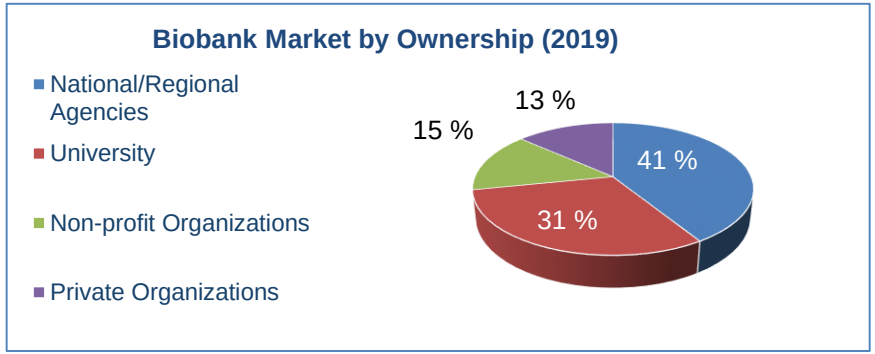
Biobank Other trends

Private organizations are likely to register the strongest growth given the increasing demand for biospecimen and data and a favorable environment for biobanking activities in Denmark

The partnership based biobanks are expected to register a growth of 4.8% in 2019-2026 and reach $501.8 million in 2026, currently at $360.5 million. Standalone segment is likely to grow by 4.0% in the same period

National/regional agencies hold the dominant share and expected to grow by 3.9% in 2019-2026 reaching $493.0 million. Private organizations are expected to grow at 5.3% in the same period





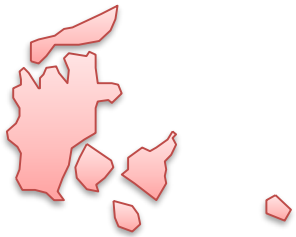
- The standalone biobanks protect the data from unauthorized access and sharing and participation through networks is limited in such biobanks. Partnership biobanks are likely to increase with the increasing need for sample and data sharing across biobanks. Danish National Biobank serves as an example wherein it acts as a national collaborator and facilitates sample and data sharing across biobanks
- Biobanks are being established by various national and regional agencies across the Denmark. Examples include National Danish Birth Cohort, National PKU Biobank, etc. Biobanks in Denmark are considered key research facilities for the universities/hospitals of which they are a part.

Source: Frost and Sullivan Analysis, AMR Market Study

Biobank Profiles

Biobank Profiles overview

There are a number of biobanks in Denmark with different therapeutic focus areas, however the Danish National Biobank serves as a major collaborator of samples across the country



Danish Rheuma Biobank

A large number of biobanks are present in Denmark with the Danish National Biobank being one of the largest in the country.

- The **Danish National Biobank** is the largest biobank owned by SSI, the institute which is responsible for all healthcare data in Denmark. It is also the center for the **Biobank Register** that serves as a platform providing access to samples for researchers
- **Patobank** is a nationwide database that contains data from **patho-anatomical studies** conducted at the **country's pathology departments.**
- **Bio and Genome Bank** Denmark works mostly on biomarker studies with the aim of strengthening the collaboration between biobanks and hospitals for better targeted treatment of patients. Currently Bio and Genome Bank Denmark consists of the **Danish Cancer Biobank**, **Danish Rheuma Biobank**, **Danish Genetic Biobank**, **Danish Blood Donor Biobank**, **Patobiobank**

Source: Frost and Sullivan Analysis, company websites

Biobank Profile

Overview

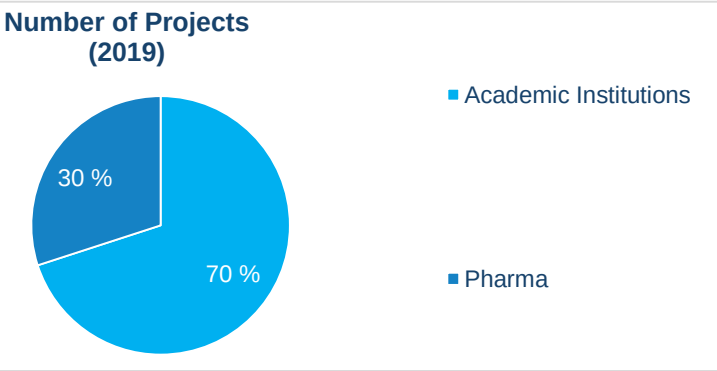
Bio and Genome Bank			
Location	Denmark	Established year	2010
Biobank type	Focus on both population and disease based studies		
Ownership	Non-Profit organization		
Brief overview	▪ Bio- and Genome Bank Denmark (RBGB) is a collection of biobanks in Denmark, which aims to provide an easy, transparent and safe entrance to biological material in Denmark. ▪ Today, RBGB consists of three biobanks: Danish Cancer Biobank (DCB), Danish Rheumatologic Biobank (DRB) and Danish Blood Donor Biobank (DBB) and is a national cooperation between public hospital departments which handle blood, bone marrow, tissue and other biological material		
Core area of specialization	▪ The Biobank is able to provide high quality biological samples to conduct research not only for the biobank itself, but also provide these samples to other hospitals and resources that are spread across Denmark. Prime focus is the field of personalized medicines		
Rationale for prioritizing	▪ RBGB Biobank specializes in companion diagnostics, genome sequencing and Oncology related projects		
Total number of samples	▪ NA		

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

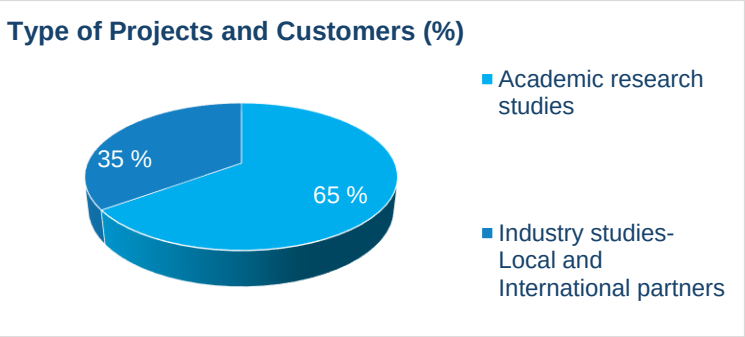
Customer Acquisition

Customer Types and Marketing

Biobank Customer Types



Biobank Customer Project Types



- RBGB Biobank has engaged in various partnerships with mainly Academics institution followed by Pharma companies. The key areas where RBGB Biobank has engaged with both academic and commercial clients include biomarker studies, genome sequencing applications and OMICS studies. However for oncology related projects, pharma is the major collaborating partner for RBGB Biobank. **University of Copenhagen is a key partner for RBGB Biobank for academic research studies**

- **Print media such as articles published in research magazines and brochures are the most common ways for RBGB Biobank to reach out to potential clientele followed by conferences and symposiums**. RBGB Biobank also considers social media outreach especially LinkedIn to publicize more about its services. **There is a dedicated team for marketing activities in RBGB Biobank and a separate annual budget for the marketing activities.**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

Biobank Engagement Model Alignment			
Model	**Adoption**		**Key End Users**
	Current	**Future**	
Research Provider			Academics, Pharma
Strategic Partnership			Academics

- RBGB Biobank adopts the **research provider model in order to target specific areas of research and can collaborate with specific pharma companies and academic institutes based on a pre-defined criteria for research topics across different disease areas**. The biobank adopts strategic partnership to collaborate with various academic institutes for a long-term basis for a particular project.

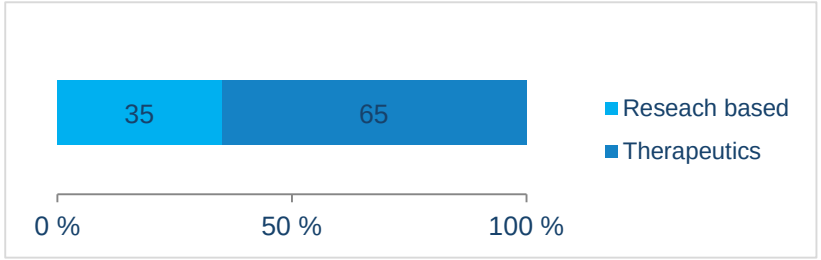
Low High

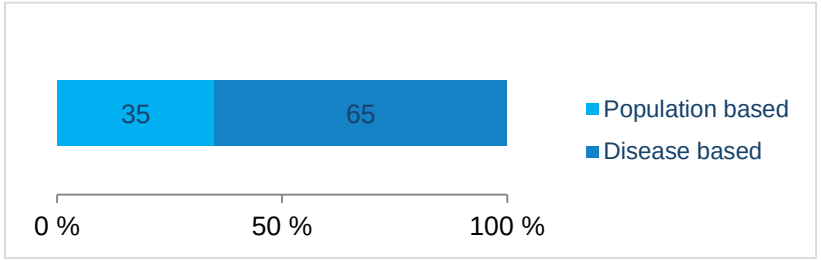
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

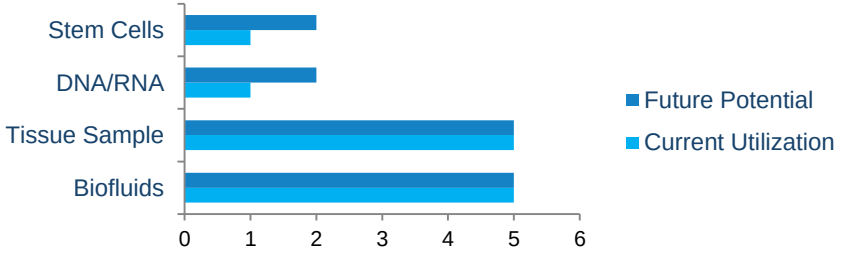
Service Segments

Share from total projects in % (2019)





Sample Utilization



- Major partners for RBGB are academic institutions a few pharmaceutical companies. For academics the major partner of RBGB Biobank is University of Copenhagen
- **Sample utilization of RBGB Biobank is high in particular for Tissue samples and Biofluids (mainly blood samples)**. Key focus area for RBGB Biobank where most of the projects are utilized is personalized medicine applications and Oncology studies

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

Biobank Application Area Alignment						
Application Area	**Key competency of your biobank**	**Biospecimens Utilized**	**Key End Users**	**Growth Potential**		**Growth Drivers/ Challenges for your biobank**
				Present	**Future**	
Companion Diagnostic	Biospecimen type	Cancer tissues and blood sample	Academics			Procurement of samples is challenging for these areas whereas the analysis of the data and insights generated for oncology and genomic sequencing are key growth drivers
Genomic Sequence	Biospecimen and Biodata type	Cancer tissues	Academics			
Oncology Clinical Development	Biospecimen type	Blood samples	Academics			
Real World Evidence	-	-	-	-	-	-
Digital Pathology	-	-	-	-	-	-

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Drug Development Value chain competency

Application type	Expertise (Scale)	Number of Studies	Key End Users
Target identification and validation		>10	Academics, Pharma
Lead identification and optimization			
Preclinical			
Phase I			
Phase II			
Phase III			
Phase IV (RWE studies, Post marketing, etc.)			

- The key therapy area for RBGB Biobank in drug development projects is Oncology.

Low High

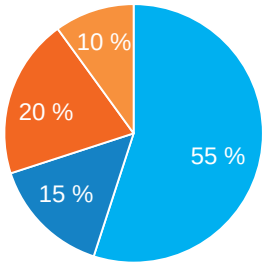
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Financial Sustainability

Biobank Funding Sources

Number of Projects (2019)



- Government/Non-Profit grants
- Fee recovered from biobank operations
- Internal funds
- Commercial partnerships

Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Cost Recovery Model			Academics, Pharma

- **RBGB Biobank does not consider financial sustainability as a major challenge** as it as they have efficiently worked towards improving **their customer outreach with the goal of reducing dependency on short term funding**.
- RBGB Biobank mainly **work for cost recovery model because they are a non-profit organization and try to charge minimum amount to the end-users** especially when dealing with other research institutes and **more for the commercial engagements with Pharma although in such a model, challenge is to arrive at a consensus price after negotiations and is dependent on the market availability of the samples as well**.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Sample Management

Sample Management	
Function	**Key Value Proposition**
Sample Collection	Large number of samples in order to conduct multiple kinds of research
Sample Processing and Storage	Liquid nitrogen storage, -80 freezers and -20 freezers
Sample Maintenance	Optimal storage equipment
Sample Retrieval	Set of guidelines and fully automated systems
Quality Control Procedures	Set guidelines and QC procedures

Biobank Cost Drivers

Cost Drivers

- **The key constituents of cost drivers are the collection of biospecimens especially highly specific cancer-related tissues that are comparatively difficult to procure**. Along with sample collection, storage of such specific samples for oncology requires top-most precision while storing them for which the RBGB Biobank has multiple equipment such as deep freezers, liquid nitrogen tanks and others.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (1/3)

Data Management Application Area				
Function	Key End User	Application Area	Adoption	
			Current	Future
Exogenous Data	-	-		
OMICS/Dx Data	Academics	Precision Medicine		
Clinical Data	Academics and Pharma	Companion Diagnostics		
Remote Care Data	-	-	-	-

Data Management	
Function	Key Value Proposition
Data Collection	AI based software and applications for data based services are utilized at the Biobank
Data Processing and Storage	
Data Analytics	
Data Sharing	

- **RBGB Biobank utilizes AI based applications as well array based sequencing techniques for data analysis**. RBGB Biobank is proficient in data based capabilities mainly for personalized medicine applications and **does not outsource any of the data based functions to the third party vendor.**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (2/3)

Data Security and Privacy	
Parameter	**Current Proficiency**
Compliance to data privacy (EU GDPR, etc.)	
Established policy guidelines	
Dedicated personnel or data security manager	
Adherence to the patient consent norms	

Data Access Framework	
Parameter	**Current Proficiency**
Open Access Model	No
Control Access Model	Yes
Tiered Access Model	No
Existence of Institutional review board (IRB) for biospecimens sharing	Yes
Privacy and confidentiality protection	Yes

- **RBGB Biobank has a dedicated IRB team which takes care of all the biospecimens** that are shared with the clients. Furthermore the access is controlled **in order to prevent any possibility of data breach while sharing the samples or information with the end-users**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

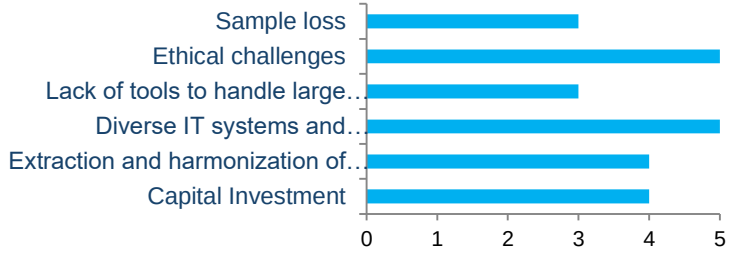
Operational Sustainability Focus- Data Management (3/3)

Digitization- One Stop Access		
Type of Access	Adoption	
	Current	Future
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease Registers		

Low High

Digitization- Key barriers

Key barriers



- RBGB Biobank **considers the use of virtual portal as an important concept so that the end-users are able to access both sample data and sample information for the better understanding of the types of samples and types of research that the biobank are conducting**.
- Further it is also expected that it will be **easier for the end-users to access any required information under one roof**. Although in its evolving stage, RBGB Biobank considers **digitization and one access as a significant feature in the biobanking activities**.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

Regulatory Scenario		
Model	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		-
Is the prevailing patient consent system efficient in biobanking activities		
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		

Collaborations

- **RBGB Biobank is not a part of any other regional or global network however it has participated in numerous local studies most prominent among them being the Copenhagen breast cancer study** which was conducted to decrease breast cancer mortality along with gaining insights regarding the disease-specific conditions.
- RBGB Biobank has also collaborated with Danish National Biobank (largest in Denmark) by which it is able to access data of various research studies and analytical reports for better data interpretation.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

Biobank Future Outlook	
Customer Acquisition	Academics and Pharma would remain the key customers in the future for RBGB Biobank followed by Biotech, Contract Services Organizations and healthtech to be the most potential customers in the future Bio and Genome bank considers to utilize strategic partnership, research based engagements, more prominently in the future with the end-users
Service Scope	Key focus area will be to deliver the high-quality samples especially biofluids and tissues. Focus will be to **partner with the Academics mainly for personalized medicines and oncology whereas pharma partnerships, though currently limited and of short term in nature, are likely to be evolve into longer duration projects.**
Financial Sustainability	Although financial sustainability is not a challenge for the Biobank, it will still focus on **improving campaigning strategies to decrease the dependency on short term funding,**
Operational Sustainability	RBGB Biobank will invest on advanced equipment mainly for sample management purposes and it will continue to **expand its sample pool especially since the samples have varied DNA/RNA makeup**. The biobank will continue its focus mainly on data analytics and processing services and expand the use of AI, array based sequencing for proper analysis of data
Social Sustainability and Collaborations	**RBGB Biobank will work on creating awareness to allay concerns about patient data breach and privacy**. It will also focus on collaborating with hospitals and universities and provide high quality sample data. The **biobank has no concrete plans to participate in an international network however it considers it useful.**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Profile

Overview

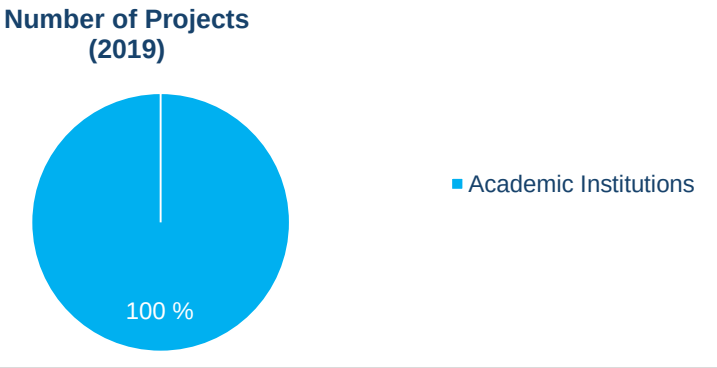
Danish Cancer Biobank			
Location	Denmark	Established year	2009
Biobank type	Disease based biobank		
Ownership	National Agency		
Brief overview	▪ The Danish Cancer Biobank (DCB) is a national collaboration between departments dealing with blood and tissue samples from cancer patients and contains data relating to these samples. ▪ The primary aim is to improve diagnostics and treatment of carcinomas and to boost Danish cancer research to the highest international level.		
Core area of specialization	▪ Core area of research is cancer and we work towards conducting the research for different types of cancer and it specializes in blood and tissue samples for the treatment of carcinomas.		
Rationale for prioritizing	▪ Danish Cancer Biobank is one of the major biobank in Denmark with specialization in Oncology		
Total number of samples	▪ In Thousands		

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

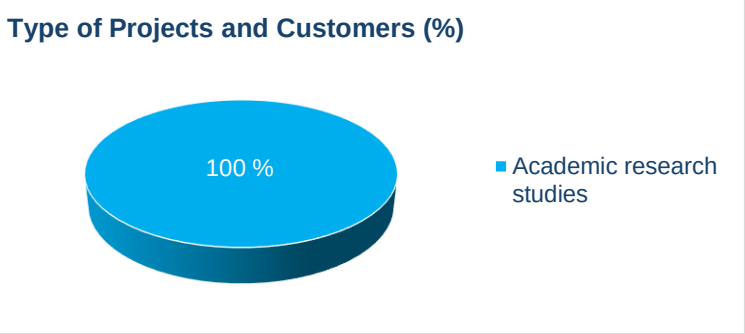
Customer Acquisition

Customer Types and Marketing

Biobank Customer Types



Biobank Customer Project Types



- Danish Cancer Biobank is customers are only in Academics and hospitals with the focus being cancer related studies with major partners **being Aalborg Hospital, Herlev Hospital, Naestved Hospital, Odense University Hospital, Copenhagen University hospital and Aarhus University Hospital**
- **Danish Cancer Biobank is not very active on major platforms such as print, electronic or social media as the focus is mainly to collaborate with hospitals and universities in Denmark** although it participates in cancer specific conferences in Denmark.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

Biobank Engagement Model Alignment			
Model	**Adoption**		**Key End Users**
	Current	**Future**	
Research Provider			Academics
Strategic partnership			Academics

- Dansk Cancer Biobank utilizes the research-provider model because the **Biobank deals only in oncology segment and therefore, it looks for specific research institutions with whom there is high level of research alignment**. The Biobank also engages in a **strategic partnership especially for long term projects** with multiple organizations using both sample and data.

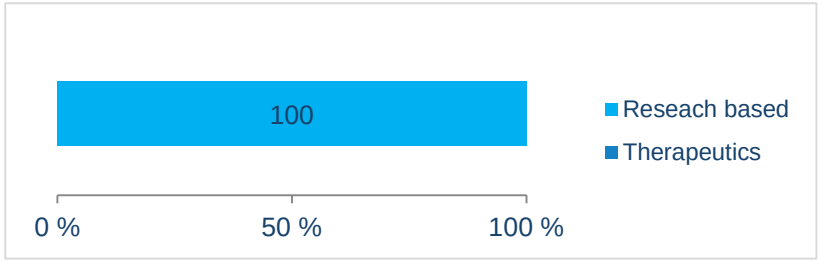
Low High

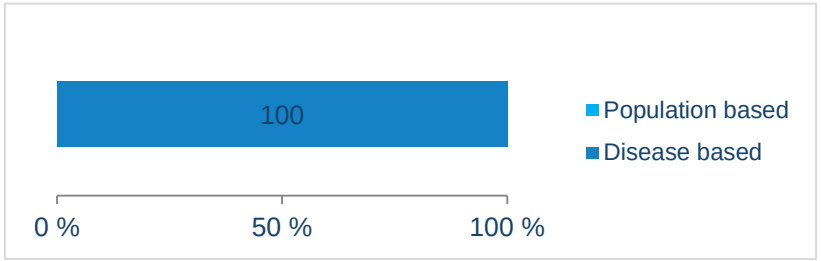
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

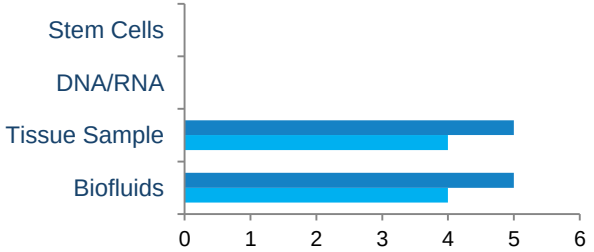
Service Segments

Share from total projects (%)





Sample Utilization



- Dansk Cancer Biobank only engages in disease based projects with universities and university hospitals in Denmark. As far as the sample utilization of the Dansk Cancer Biobank, it only uses blood samples and tissue samples, both for **Oncology projects. It does not envisage any further diversification of sample type.**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

Biobank Application Area Alignment						
Application Area	Key competency of your biobank	Biospecimens Utilized	Key End Users	Growth Potential		Growth Drivers/ Challenges for your biobank
				Present	Future	
Companion Diagnostic	-	-	-	-	-	-
Genomic Sequence	-		-	-	-	-
Oncology Clinical Development	Biospecimen type	Blood and tissue samples	Academics			Driver is the increasing number of oncology studies in the country and ease of linking patient data to the other sources.
Real World Evidence	-	-	-	-	-	-
Digital Pathology	-	-	-	-	-	-

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Drug Development Value chain competency

Application type	Expertise (Scale)	Number of Studies	Key End Users
Target identification and validation		4-5 studies	Academics
Lead identification and optimization			
Preclinical			
Phase I			
Phase II			
Phase III			
Phase IV (RWE studies, Post marketing, etc.)			

- Dansk Cancer Biobank has only **engaged in Oncology specific studies across the drug development value chain with academic institutions**

Low High

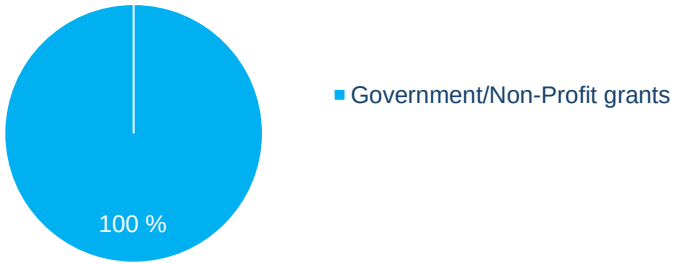
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Financial Sustainability

Biobank Funding Sources

Number of Projects (2019)



Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Fee for service			Academics

- Dansk Cancer Biobank does not consider financial sustainability as a challenge as it healthcare in Denmark is highly advanced and Government provides considerable support . It only works on the fee for service model since the prices of the services are pre-decided and there is little for negotiations with the end-users

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Sample Management

Sample Management	
Function	**Key Value Proposition**
Sample Collection	Collaboration with large number of hospitals for a wide variety of sample collection
Sample Processing and Storage	Cryopreservation of the samples and they are maintained in a highly controlled environment
Sample Maintenance	
Sample Retrieval	Approval from ethics committee or data protection authority
Quality Control Procedures	Established procedures

Biobank Cost Drivers

Cost Drivers

- Sample storage is a major cost driver for the Biobanks as the temperature control equipment for storing the samples, like freezers are expensive yet if not invested in, can hamper the quality of the sample. **Sample distribution and shipping can specifically be more costly** if the **samples are shipped within specified temperature requirement such as in liquid nitrogen containers**.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (1/3)

Data Management Application Area				
Function	Key End User	Application Area	Adoption	
			Current	Future
Exogenous Data				
OMICS/Dx Data				
Clinical Data	Academics	Oncology		
Remote Care Data				

Data Management	
Function	Key Value Proposition
Data Collection	Outsourced data based functions
Data Processing and Storage	
Data Analytics	
Data Sharing	

- While the Dansk Cancer Biobank deals in both samples and data, it outsources and different data based functions to a third party vendor. The focus is only on clinical data with application area in Oncology.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (2/3)

Data Security and Privacy	
Parameter	**Current Proficiency**
Compliance to data privacy (EU GDPR, etc.)	
Established policy guidelines	
Dedicated personnel or data security manager	
Adherence to the patient consent norms	

Data Access Framework	
Parameter	**Current Proficiency**
Open Access Model	No
Control Access Model	Yes
Tiered Access Model	No
Existence of Institutional review board (IRB) for biospecimens sharing	No
Privacy and confidentiality protection	No

- As far as the data access framework is concerned, the Dansk Cancer Biobank has a controlled access to the information and only those people can access the information that have all the credentials for it and are authorized to do so.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (3/3)

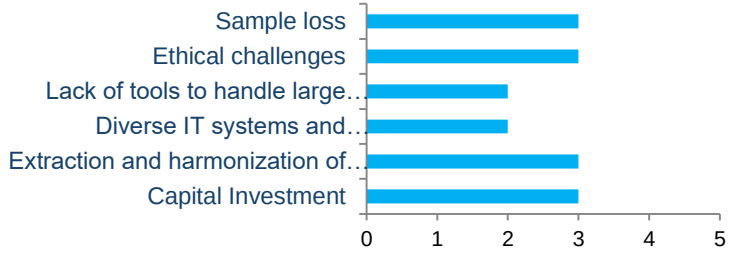
Dansk CancerBiobank
www.cancerbiobank.dk

Digitization- One Stop Access

Type of Access	Adoption	
	Current	Future
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease Registers		

Digitization- Key barriers

Key barriers



- Dansk Cancer Biobank considers **easy access to samples as a major advantage of virtual portals**. It will help the end-users to know more about the research activities that the biobank is involved and facilitate further collaborations too and similarly for the access of data, it will be easier for the end-users to understand the possible areas where the interpretation of data can be useful.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

Regulatory Scenario		
Model	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		-
Is the prevailing patient consent system efficient in biobanking activities		-
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		-

Collaborations

European Network of Cancer Registries

Danish Biobank Register

- **Danish Cancer Biobank considers laws and regulations for biobanking to be efficient both with respect to patient consent and data protection**. The Biobank has also collaborated with Danish Biobank register, and Danish National Biobank. For them, participation in such networks makes it easy to connect with other organizations and brings an ease in sample sharing.
- **The Biobank also believes that participation in such network can help in identifying the best practices and implement them locally. Dansk Cancer Biobank also collaborated with European Network of Cancer registries in 2018**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

Biobank Future Outlook	
Customer Acquisition	**Academics would remain the key customers in the future for the Danish Cancer Biobank and the focus will remain on Oncology specific studies**. Danish Cancer Biobank considers to utilize research based engagements, and strategic partnership more prominently in the future with the end-users and **does not plan to increase any marketing based activities as the focus area is academic institutions and hospitals**
Service Scope	Oncology related research will remain the key focus area for Danish Cancer biobank. It will expand its research based capabilities in oncology especially in diagnosis and treatment methods related studies and also increase the sample donor pool for both tissue samples and blood samples
Financial Sustainability	Financial sustainability is not a challenge for the Danish Cancer Biobank as it is entirely funded by the government. The biobank will focus on expanding its collaborations to include more hospitals and academic institutes for better sample utilization
Operational Sustainability	**Danish Cancer Biobank considers both samples and data services (especially collection of clinical data for oncology studies) as long term focus areas however expertise in sample collection and management will remain the key focus area**. Danish Cancer Biobank will aim to increase collaborations with hospitals so as to increase the sample pool with high degree of specificity while at the same time maintaining state of the art equipment for preservation of the purity of samples
Social Sustainability and Collaborations	Danish Cancer Biobank considers the current legislations appropriate for the biobanking activities and it does not foresee any ethical or legal concerns. The biobank key focus will remain on partnering with hospitals and universities in Denmark in the near future in order to develop its core capability in oncology related research.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Profile

Overview

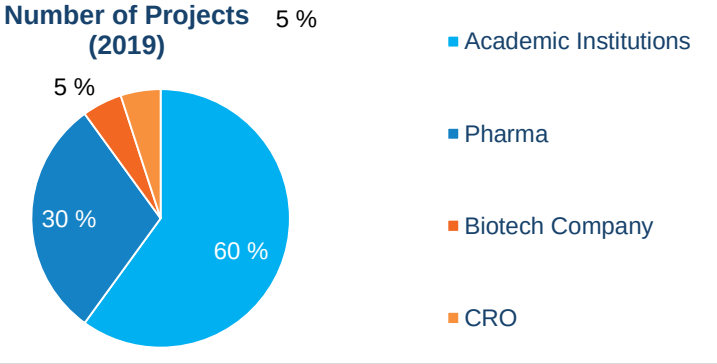
Danish National Biobank			
Location	Denmark	Established year	2012
Biobank type	Both population and disease based biobank		
Ownership	Government owned		
Brief overview	▪ Danish National Biobank is the largest biobank in Denmark and also serves as a central portal for access to samples and information for the users. ▪ SSI owns the Danish National Biobank. DNB was established with major financial support from the Novo Nordisk Foundation as well as assistance from Lundbeck Foundation and the Ministry of Science, Innovation and Higher Education		
Core area of specialization	▪ High proficiency in terms of handling samples, ensuring the storage of samples, getting the registration done for the samples and performing interpretation of data and outcomes from various research purposes across disease areas. It also offers vast array of biochemical and immunological assays, as well as DNA purification and genetic analysis.		
Rationale for prioritizing	▪ Largest biobank in Denmark and it specializes in Oncology, RWE studies and Digital Pathology projects		
Total number of samples	▪ In Millions		

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

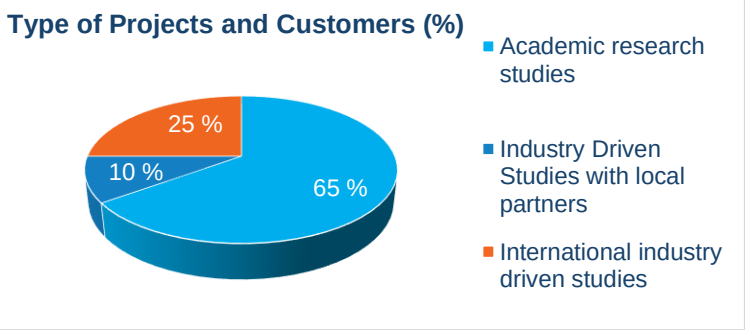
Customer Acquisition

Customer Types and Marketing

Biobank Customer Types



Biobank Customer Project Types



- DNB Biobank has a diverse set of customers including Academic institutions, Pharma, Biotech and CRO. Major partners include **University of Copenhagen, Copenhagen University Hospitals and Novo Nordisk.**
- **DNB Biobank customer outreach is evenly done through all major media types** such as conference presentations, where they interact with other organization to spread awareness regarding the Biobank services . **For print media it considers publications in the advertisement in university hospital magazines regarding its services and specializations**. **There is a dedicated team for marketing activities in DNB Biobank however no pre-defined budget but the team contributes to promotion activities**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

Biobank Engagement Model Alignment			
Model	**Adoption**		**Key End Users**
	Current	**Future**	
Data Owner			Academics
Strategic Partnership			Academics, Pharma, Biotech, CSO

- For the **data owner type model, the DNB Biobank has full ownership rights of the data and it is used generally with the academics where such requirement of data is very high**. **Strategic engagement is utilized for long term project engagements where both samples and data services are being used** and there are multiple areas of collaborations with the end-users

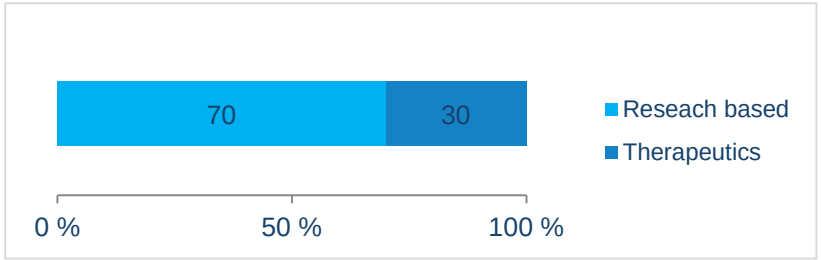
Low High

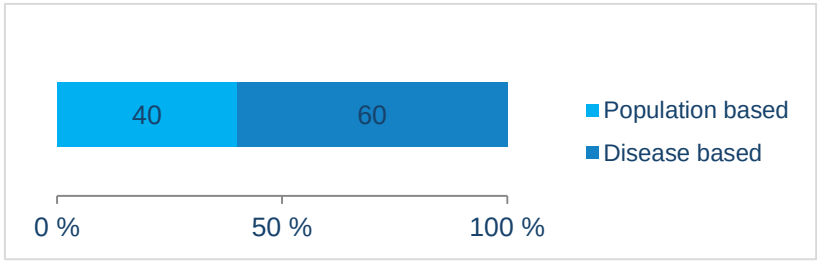
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

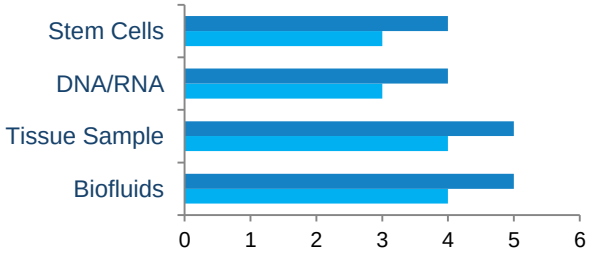
Service Segments

Share from total projects (%)





Sample Utilization



- DNB Biobank has **largely focused on research based studies in disease areas such as Oncology, OMICS based studies, PHM studies, translational health studies, and microbiome studies**. While the current sample utilization of DNB Biobank is higher in biofluids such as blood samples and Plasma, and tissue samples, this trend is likely to remain the same in the future years due to increase in the oncology and digital pathology applications. **DNA/RNA extracts are mainly utilized in rare disease studies, RWE studies as well as some digital pathology studies by the Biobanks**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

Biobank Application Area Alignment						
Application Area	Key competency of your biobank	Biospecimens Utilized	Key End Users	Growth Potential		Growth Drivers/ Challenges for your biobank
				Present	Future	
Companion Diagnostic	-	-	-	-	-	-
Genomic Sequence	-	-	-	-	-	-
Oncology Clinical Development	Biospecimen type	Tissue samples and blood	Academic, Pharma			Data for oncology related studies is not well documented at all times in biobanks which is a major challenge
Real World Evidence	Networking and collaborations	Blood, plasma and DNA/RNA extract	Academic, Pharma			Demand for epidemiological data is a key driver for RWE studies however it is challenging to manage large scale of data
Digital Pathology	Digitization and data integration	Blood, plasma and tissue	Academic, Pharma			Better analysis of disease conditions are by digital pathology is a main driver for such applications

Low High

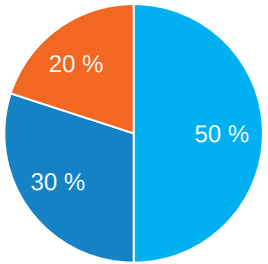
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Financial Sustainability

Biobank Funding Sources

Number of Projects (2019)



- Government/Non-Profit grants
- Fee recovered from biobank operations
- Others (Internal Funds, Private grants by charities, organizations, Commercial partnerships)

Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Fee for service			Academics, Pharma, Biotech, Clinical Diagnostics
Cost recovery model			

- The key factors that **impact the financial sustainability of the Biobank is the lack of defined business models and dependency of short term funding**. DNB Biobank plans to increase **long term partnerships with the end-users**. This will be based on **providing high quality samples to the end-users and also work with them on various platforms for convenient data access and sharing of sample and data**.

- DNB Biobank uses fee for service as well as cost recovery model mainly based on the type of project requirement. Generally the **cost-recovery model follows a small amount to be charged for the academic institutions while same services priced differently for commercial end-users**. In fee for service model the **DNB Biobank charges a pre-defined fee for its sample and services for the end-users based on the complexity and the requirements for the particular study**.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Sample Management

Sample Management	
Function	**Key Value Proposition**
Sample Collection	High degree of sample collection across the country
Sample Processing and Storage	Robotic system of aliquoting of samples
Sample Maintenance	Automated robots and freezers to store samples
Sample Retrieval	Existence of a research ethics committee which ensures to provide approval to only those projects when the review report is positive
Quality Control Procedures	Well established quality control procedures

Biobank Cost Drivers

- The key constituents of the cost drivers for the DNB Biobank include **procurement of specific samples such as for oncology, tumor tissues, etc. that are costly to procure, equipment such as freezers for sample storage**. **While Packaging and shipping as per the end-user requirement also contributes to the cost, data management software such as LIMS, etc. and other such technologies further inflate the costs for DNB Biobank**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (1/3)

Data Management Application Area				
Function	Key End User	Application Area	Adoption	
			Current	Future
Exogenous Data	Pharma, Academics	RWE studies		
OMICS/Dx Data	Pharma, Academics	Microbiome studies		
Clinical Data	Pharma, Academics, CSO, Biotech	Oncology		
Remote Care Data	Academics, Pharma	-		

Data Management	
Function	Key Value Proposition
Data Collection	LIMS system installed to manage data in the biobank. Moreover, there are barcodes labeling done to ensure the storage of sample data along with data of research projects.
Data Processing and Storage	
Data Analytics	
Data Sharing	

- The Danish National Biobank is the largest biobank owned by SSI, the institute which is responsible for all healthcare data in Denmark. **DNB Biobank is highly proficient in collecting all types of data** given that **Denmark has a high quality data collection system which dates back decades**. As all the **Danish citizens have a unique personal identification number, linkage between the nationwide registers and other data sources from the biobanks is feasible**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (2/3)

Data Security and Privacy	
Parameter	**Current Proficiency**
Compliance to data privacy (EU GDPR, etc.)	
Established policy guidelines	
Dedicated personnel or data security manager	
Adherence to the patient consent norms	

Data Access Framework	
Parameter	**Current Proficiency**
Open Access Model	No
Control Access Model	Yes
Tiered Access Model	Yes
Existence of Institutional review board (IRB) for biospecimens sharing	Yes
Privacy and confidentiality protection	Yes

- DNB Biobank has a research ethics committee for approval of different applications and samples from biobank. **The Biobank follows a controlled access model wherein it doesn't provide authorization to all the members due to security of data except to few selected members**. The access if provided based on consent and permissions allotted by the donor and the Biobank also has a data protection law to ensure the safety of data and sample related information.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

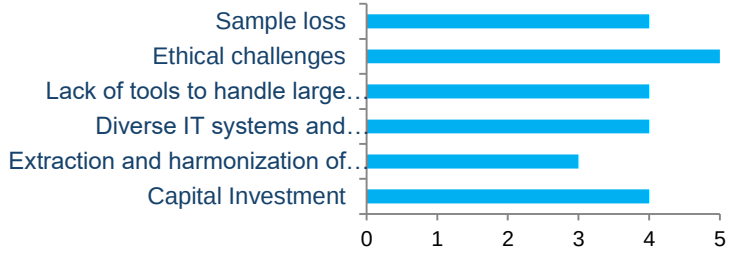
Operational Sustainability Focus- Data Management (3/3)

Digitization- One Stop Access

Type of Access	Adoption	
	Current	Future
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease Registers		

Digitization- Key barriers

Key barriers



- **DNB hosts the Biobank register. It is the platform for linkage of data from Biobanks and National registers**. **Biobank Web portal offers simplified access to users who can select the type of sample required by a set of criteria selected by the users. Users receive the output in the form of email**.
- Data may include **sensitive information** such as **Individual date of birth and PIN**, **diagnosis codes** assigned during hospitalization (ICD8/ICD10 codes), data about pathologies (SNOMED codes + pathology date), data about individual biologic materials (blood, tissue, etc.) including sample date

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

Regulatory Scenario		
Model	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		-
Is the prevailing patient consent system efficient in biobanking activities		-
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		-

Collaborations

bbmri-lpc
BBMRI – Large Prospective Cohorts

elixir DENMARK

Danish Biobank Register

- There is no separate legislation for biobanking services and the activities are governed by the data processing act and approval from the research ethics committee and the DNB Biobank considers the current laws and regulations sufficient in the biobanking activities
- The Danish ELIXIR Node focuses on bioinformatics tool interoperability and integration across workflows. **DNB is also a part of BBMRI-Large Prospective Cohorts which is pan-European population based cohort study.** The only advantage of being a part of such networks is the easy access to data of various samples and outcomes from various research studies. **DNB Biobank has a wide range of studies involved in its network ranging from cancer to twin registry study.**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

Biobank Future Outlook	
Customer Acquisition	DNB Biobank is looking forward to having more collaboration with the pharmaceutical companies, and the academic partnerships are expected to be the major customer type in the near future. It considers to utilize data owner and strategic partnership more prominently in the future with the end-users. **DNB Biobank has a dedicated team of marketing professionals and it plans to increase its marketing outreach mainly through exhibitor conferences with some portion also dedicated to print media such as brochures and social media outreach**
Service Scope	DNB Biobank **will shift its focus on causes of disease along with their treatment and prevention**. It will expand its partnerships with the Pharma companies especially in **genome sequencing applications, oncology and RWE studies**.
Financial Sustainability	Although the DNB Biobank is well funded by the Government, along with various private organizations, **it will seek to increase commercial partnerships especially with Pharma companies for long term strategic engagements**. DNB Biobank considers the cost recovery model and fee for service pricing model optimum for most of the engagements and will continue to utilize it for both commercial and academic partners
Operational Sustainability	DNB Biobank considers **both samples and data services (especially collection of OMICS/Dx and clinical data for RWE and oncology studies) as key focus areas**. It considers **one access to services as a future growth initiative mainly due to easy approach to access data as well as sample information**
Social Sustainability and Collaborations	DNB Biobank **will focus on establishing standard operating procedures especially while working in network partnerships to reduce the time spent in administrative activities**. Furthermore DNB will also focus on harmonization in terms of legal procedures for better collaboration. **DNB Biobank key areas of collaboration with hospitals and networks include large scale registry studies, with a major advantage being updated about the latest research and easy access to data**.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Sweden

Market Overview

Executive summary

Ecosystem

- Swedish Biobanking landscape is **highly developed** with a large number of biobanks managed through **regional biobank centers** that are located in **key areas of research activities** in Sweden
- Sweden is **ranked 2nd globally** in **innovation** 2019 by the Global Innovation Index

Regulatory Scenario

- **Swedish Biobank** Act regulates the biobanking activities in Sweden along with Ethical Review Act and the GDPR regulations.
- There has been **requests to the Government to update the Biobank Act**, most of the **provisions of which are outdated** and need to provide clearer **protection of privacy** and **strengthen medical research** in Sweden

Data Infrastructure

- Research and IT infrastructure is **well developed** in Sweden.
- Availability of **large number of registers**- population, disease, quality registers, etc. **linked through the personal identification number (PIN)** make Sweden a resource rich network

Initiatives

- **Total 450 biobanks** in Sweden (~250 governed by councils/universities and 200 are private)
- **Biobank Sweden** (formerly National Biobank Council and BBMRI.se) is the collaboration of the county councils/regions with hospitals and the universities to support the overall biobank infrastructure in Sweden

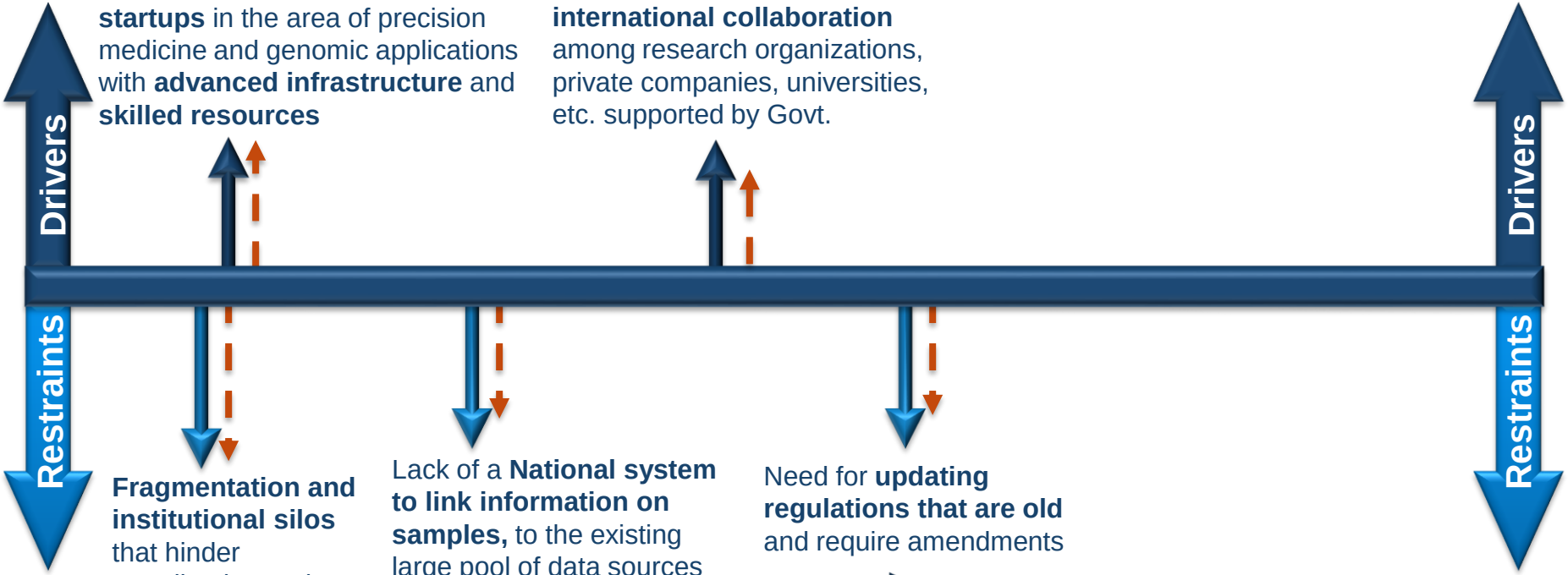
Market Analysis

- Research Applications form ~66% of the total biobanking market while 34% is for therapeutic based applications. While biofluids are the dominant market share holders for biospecimens, the **human tissue samples and stem cells samples are expected to grow by 6.8% and 5.2%** CAGR (2019-2026) respectively
- A **favorable ecosystem** and developed infrastructure **, large number of micro organizations**, and **universities acting as incubators** are some of the key highlights that set apart Sweden as a pioneer in **Precision Medicine applications** thus driving the market for biobanking activities. Some of the example include **Genomic Medicine Sweden (GMS)** as a national initiative of Genomics, **SciLifeLab** (partnership of 4 universities in Sweden) which acts as an accelerator for precision medicine applications

Source: Frost and Sullivan Analysis

Drivers and Barriers

Skilled resources, advanced biobanking infrastructure and Govt. support in health innovation are key drivers for biospecimen demand in Sweden



Source: Frost and Sullivan Analysis

Biobank Data Infrastructure

Availability of large number of registers and linkage to personal identification number (PIN) make Sweden a resource rich network in the Nordic region

Data Infrastructure

- Sweden has robust infrastructure for data in the form of registers that provide data from thousands of patients
- Registers can be divided into- public governing registers, quality registers in healthcare, biobanks and research generated data

Registerforskning.se

- **The Swedish Research Council (SRC)** - information about different registers, how data is requested and legislative information
- **Register Utilizer Tool (RUT)** – To enable efficient searching and matching of information on metadata in registers.

- **National Governing Register:** These include population, socio-economic and health data registers as well as population based surveys and studies
- **Research Database/Cohorts (Universities):** They are used for specific research projects sometimes even within different scientific disciplines. Examples include Prescribed Drugs Register, In-Patient Register, Swedish Cancer Registry, Cause of Death Register, etc.
- **National Quality Registers (County Councils/Regions):** There are 108 *National Quality Registers* under the country councils/regions and contain personal data regarding healthcare, such as diagnosis, treatment, and results of treatment.

- The Swedish ELIXIR Node contributes to the Human Protein Atlas (HPA) program
- Efforts of the Swedish ELIXIR node will focus on integration of HPA with other ELIXIR resources

Below mentioned components of the Swedish Biobanking system are based on the Personal Identification Number (PIN)

Data on lifestyle, diet, environment collected at time of sampling for population based studies

- Pathology labs storing samples submitted for pathology diagnosis over decades in Sweden
- Clinical Virology departments have stored serum samples with archiving times from 6 to 30 years

PKU registry has stored all the newborn samples (dried blood on filter paper) since 1974

Source: Frost and Sullivan Analysis, biobanksverige.se

Biobank Initiatives

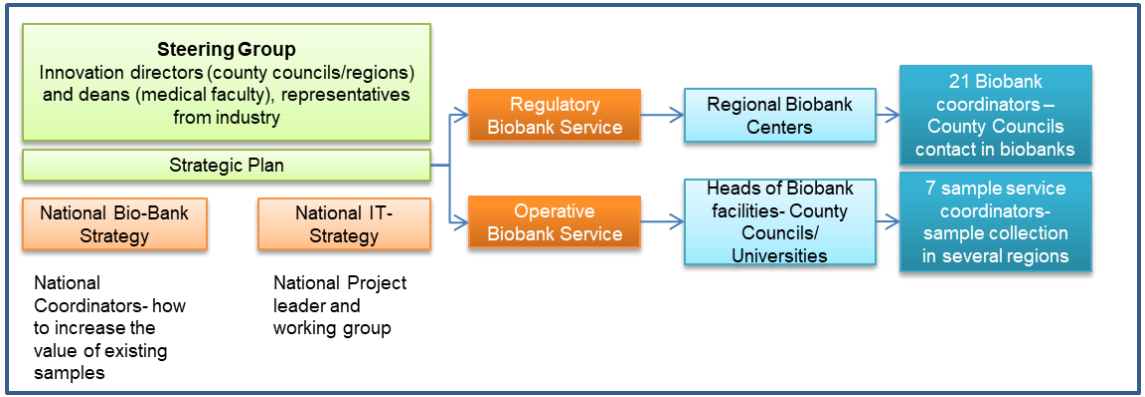
Biobank Sweden acts as a national collaborator for the biobanks and steers the biobanking activities

BIOBANK SVERIGE

Key Features

- Biobank Sweden (formerly National Biobank Council and BBMRI.se) is the collaborative body of the county councils/regions with hospitals and universities to support the overall biobank infrastructure in Sweden
- Established in 2018, Biobank Sweden is funded by the **Sweden Research Council (SRC)**

Biobank Sweden Service Organization



Goals

- **Long term sustainable** biobanking infrastructure
- Enabling **national, accessible, cost efficient**, and competitive collection which will secure the access of **high-quality samples**
- **Data security** of sample donors in accordance with **consent**

Strategic Plan

- **Regulatory Biobank Service**- Guidelines and advice on legislation, national principals, documents, instructions and guidelines, agreements, and applications for samples, sample access etc..
- **Operative Biobank Service**- Guidelines for collection logistics, sample processing and storage, DNA/RNA extraction, cryopreservation of cells etc. healthcare Integrated biobanks (SIB) a unique initiative that deals with liquid based sample biobanking services. Also includes e-referrals, needle to freezer time of less than 2 hours, high standardization, as well as a high focus on quality

Source: Frost and Sullivan Analysis, biobanksverige.se, swedenbio.se

Biobank Initiatives

A thriving ecosystem consisting of startups, established universities, pharmaceutical firms and well supported by national initiatives supports precision medicine applications in Sweden, OMICS being the focus

Key Growth Drivers

Commercial Partnerships

Active collaboration of pharmaceutical firms with universities/ startups in precision medicine applications

Policy and Vision

Multiple government run initiatives that support precision medicine research and applications

Genomics/OMICS focus

Focus on genomics, proteomics, metabolomics, etc. through national initiatives and partnerships

Technology

Innovative diagnostic and instrumentation platforms, bioinformatics, AI/ML used in precision medicine applications

Disruptive Innovation

Strong association of precision medicine startups with incubators and universities

Case Examples

- **SciLifeLab**, **an initiative of 4 Universities**, functions as an accelerator for genomic research and precision medicine applications. Research areas include OMICS, single cell biology, cell and molecular imaging, diagnostics, clinical research, etc.
- The projects are sequenced at the **National Genomics Infrastructure (NGI)** hosted at SciLifeLab. Projects include the **Swedish Genomes program** in the area of cancer, cohort based studies, Alzheimer disease, metabolism, etc.
- Genomic Medicine Sweden (GMS) is a **national initiative in genomics.** Objectives include increasing the harmonization of broad gene sequencing, and increasing patient participation in clinical trials. **GMS** received a funding of **SEK 43.8 million** from **VINNOVA,** the **Swedish Government funding agency.** The **Human Protein Atlas (HPA)** is a Swedish program to map all the human proteins in cells, tissues and organs using **integration of the various "-omics" technologies**
- **Pfizer R&D, Karolinska Institute and Olink Proteomics** for large scale studies of **plasma proteins**
- **Pfizer** also collaborated with **AMRA**, a company specializing in MRI image analysis, to assess fat and muscle measurements from **MRI images** through the UK Biobank registry
- **AZ** has partnered on a wide variety of precision medicine projects in Sweden .
- With **Pelago Bioscience** on **nano scale drug discovery projects**, with **SciLifeLab** to deliver **biomarkers** fit for clinical use

76 companies specializing in precision medicine

72% of the total companies are university spin-offs

74% have less than 50 employees

Source: Frost and Sullivan Analysis, swedenbio.se, company websites

Regulatory Scenario

The Swedish Biobank Act facilitates biobanking activities in Sweden and harmonizes the GDPR regulations

Swedish Biobank Act

- The Biobank activities in Sweden are governed by the Swedish Biobank in Medical care Act (2002), Ethical Review Act (2003), and the General Data Protection Regulation, GDPR (2016)
- The Swedish Biobank Act **regulates how the samples** taken in the Swedish biobanks can be **used for research or clinical trials**

Key Features

- For the samples to be used in research, an approval from the **Ethics Review Board** is required. The Ethical vetting also reviews whether the processing of **personal data is in accordance with GDPR regulations**
- The donor **must be informed** that the sample may be saved and **for what purpose**. Samples are **not to be used for purposes other than that covered** by prior information and consent **without the donor consenting** for the new purpose. Donor has **the right to withdraw consent** at any time
- Samples in the biobank are **coded and safely secured** so that there is no risk of samples getting destroyed or accessed by any unauthorized persons.

Amendments to the Biobank Act

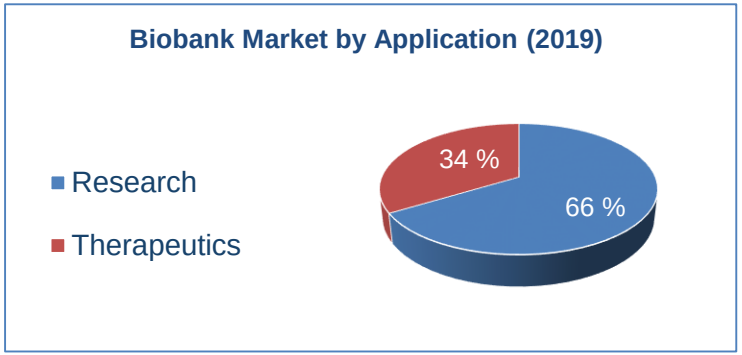
- From **January 2019**, an **exception** was introduced **for the samples** that are used in research but **not stored in the biobanks.** The exception means that the **Biobank Act will not apply to samples** that are intended for research and analyzed within six months and then destroyed
- However there have been **repeated requests to the Government to update the Biobank Act**, most of the **provisions of which are outdated** and need to provide clearer **protection of privacy** and **strengthen medical research** in Sweden.

Source: Frost and Sullivan Analysis, biobanksverige.se

Biobank Application trends

Genomic and precision medicine applications are likely to be the growth drivers in Sweden, well supported by national initiatives

The total biobanking market was $1,164 million in 2019 growing at a CAGR of 5.2% in 2019-2026 to reach $1,658 million in 2026. The Research segment is the highest contributor to the Swedish biobanking market and anticipated to reach $1,082 million by 2026 ($772.1 mn, 2019) with a CAGR of 4.9% in 2019-2026. The Therapeutic segment is likely to witness growth at a CAGR of 5.6% in the same period to reach $576 million by 2026 ($392.3 mn, 2019) .



Category	CAGR (2019-2026)
Research	4.9%
Therapeutics	5.6%

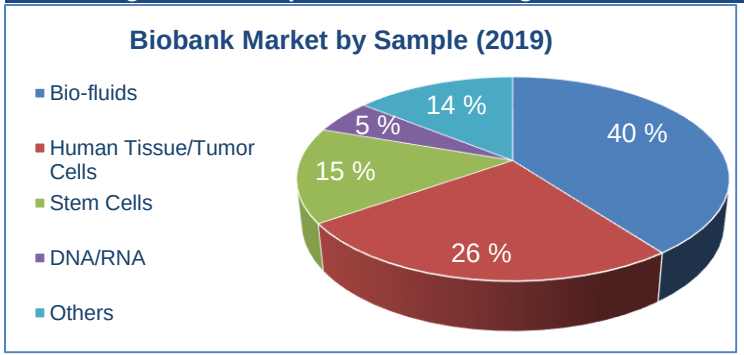
- Sweden has a robust infrastructure in health research (basic research to commercialization) with **investments from county councils**, universities, **research institutes**, etc. that support the research activities for the biobanks
- **Clinical Trials** involving novel therapeutic applications and the interest of both large pharmaceuticals and life sciences companies especially in precision medicine in Sweden are a driver for the therapy segment of the Biobank
- Research activities in Sweden are the main application for biobanking areas due to existence of infrastructure that comprises national level health research programs, research institutes, hospitals and trained staff
- Programs such as **Genomic Medicine Sweden** for instance collect samples from all Cancer patients and carry out the DNA analysis for cancer research purposes. Other research areas where biobanks are actively involved include **cardiovascular research, cytological research** such as in Cervical Cancer, PKU studies, etc.
- Therapeutic applications largely involve the clinical trials for instance in hematology studies, oncology, etc. **Top therapy areas** for drug development in general include **Oncology**, **CNS, Metabolism, GI, Cardiovascular, Pain, Sepsis.**

Source: Frost and Sullivan Analysis, AMR Market Study

Biobank Sample Trends

Tissue Cells and Stem Cells are expected to see heightened demand due to applications in key areas such as oncology, rare disease and biomarker studies

Bio-fluids segment was the highest contributor to the biobanking market, with $463 million in 2019 and is anticipated to reach $630 million by 2026, registering a CAGR of 4.5%. Stem Cells segment is anticipated to reach $249.9 million by 2026 at a CAGR of 5.2%. Human Tissue/Tumor Cells segment are expected to witness growth at a CAGR of 6.8% during the forecast period.



Sample Type	CAGR (2019-2026)
Bio-Fluids	4.5%
Tissue Cells	6.8%
DNA/RNA	3.1%
Stem Cells	5.2%

- Bio-fluids and human tissue samples are the most commonly used biospecimens. Bio-fluids such as blood, urine, saliva etc. have a plethora of applications in disease research, diagnostics, clinical research, etc.
- The increase in demand for biosamples is likely to be driven by **Human tissue/tumor cells and Stem Cells** applications. Purity of the samples and physical conditions are critical for the tissue/stem cells samples to be utilized for biomedical research purposes.
- Tissue samples have seen an increasing demand as a result of increasing therapeutic focus on **oncology** trials, **disease markers** based analysis and also in **rare diseases** segment such as **autoimmune diseases**, **inflammatory, rheumatology, urology**, etc.
- Stem Cell samples in Biobanks are also utilized especially in cord tissue and cord blood. Sweden has one of the largest and most experienced **private biobank, Cellaviva**, that is entirely focused on **stem cell biobanking**.
- DNA/RNA samples are extracted from a number of sources such as blood, tissues for many of the Biobanks in Sweden and especially RNA based analysis has provided insights in pathogenic mechanisms and diagnostic and prognostic information from such studies.

Source: Frost and Sullivan Analysis, AMR Market Study

Biobank Other trends

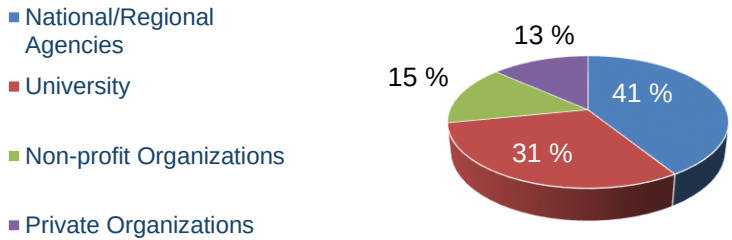
Private Biobanks especially with a focus on stem cell biospecimens are prevalent in Sweden specifically targeting oncology, and rare diseases therapy areas

The Partnership based biobanks are expected to register a growth of 5.6% in 2019-2026 and reach $674.9 million in 2026. The Standalone segment is likely to grow by 4.9% in the same period

Biobank Market by Type (2019)

National/regional agencies hold the dominant share and expected to grow by 4.7% in 2019-2026 reaching $661.5 million n by 2026. Private organizations are expected to grow by 6.2% in the same period

Biobank Market by Ownership (2019)



- Standalone biobanks tend to better secure data from unauthorized access and sharing, while participation through networks is limited in such biobanks. Partnership biobanks are likely to increase with the increasing need for sample and data sharing across biobanks such as the Uppsala Biobank which is one of the oldest biobanks in Sweden

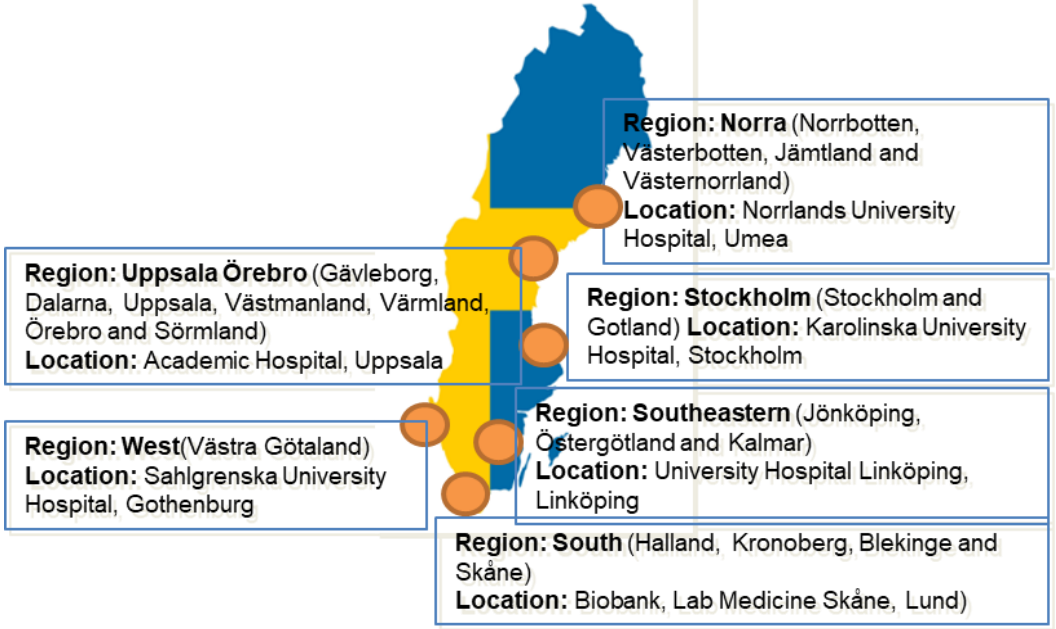
- Biobanks are being established by various national and regional agencies across Sweden. Examples include KI Biobank, PKU Biobank,etc. In addition to national and regional biobanks, private healthcare providers are also establishing biobanks in Sweden. Cellaviva is Sweden's first private biobank for stem cells from umbilical cord blood and tissue. Cellaviva is owned by NextCell Pharma AB and has been approved by Health and Social Care Inspectorate (IVO).

Source: Frost and Sullivan Analysis, AMR Market Study

Biobank Profiles

Biobank Overview

Biobanking activities in Sweden are managed by six regional biobank centers located at the key nodal points in health innovation



Landscape

- **6 Regional Biobank centers** in Sweden that serve as hubs
- Approximately **450 biobanks, majority of which (~250)** are managed by **county Councils and Universities**; ~16 million samples
- Rest of 200 biobanks, mainly comprise of **private organizations, laboratories**, etc.

Sample Collection

- **For Healthcare purpose:** samples are taken within the healthcare system everyday and stored in the biobanks. Used for diagnostics, treatment and follow-up. Information is stored in the LIMS which is linked to the patient record
- **For Research purpose:** samples are taken from specific academic trials, large prospective cohorts, and clinical trials (not stored within the country council/regional biobanks)
- **Newly collected samples:** samples collected for a specific academic or a pharmaceutical study

Source: Frost and Sullivan Analysis, biobanksverige.se

Biobank Profile

Overview

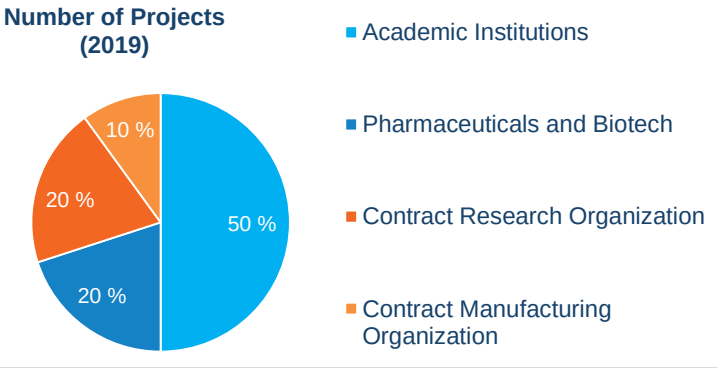
Biobank Vast profile			
Location	Sweden	Established year	2010
Biobank type	Focus on both population and disease based studies		
Ownership	University of Gothenburg and Sahlgrenska Academy		
Brief overview	▪ It is the regional biobank center for the Vastra Gotaland Region in Sweden ▪ Biobank West collaborates with the Core Facilities unit, which belongs to the Sahlgrenska Academy at the University of Gothenburg		
Core area of specialization	▪ Large sample collection especially the biofluids such as blood, saliva, sera, and urine. The Biobank also offers other types of samples such as DNA/RNA and tissue for therapeutic research ▪ A developed infrastructure which supports efficient sample storage. The Biobank have temperature controlled freezers which administers the low temperature sample collection.		
Rationale for prioritizing	▪ Biobank Vast is one of the Regional Biobank Centers (RBC) in Sweden and serves as a center for the Western region in Sweden. It has expertise in companion diagnostics, oncology, genome sequencing, RWE studies and digital pathology		
Total number of samples	▪ Approximately in the range of 15,000-20,000 samples		

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

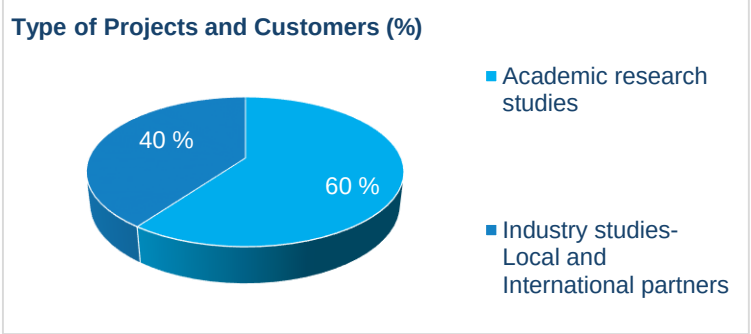
Customer Acquisition

Customer Types and Marketing

Biobank Customer Types



Biobank Customer Project Types



- Biobank Vast customers are Academic institutions and hospitals. Major partners include University of Gothenburg, Sahlgrenska institute and Eastern Hospital in Sweden which mainly work in research based projects with the Biobank. Average range of value for projects- both **Academics and industry studies is between 400K-600K USD annually**

- A large proportion of customer outreach is done through **conference presentations and network participation through consortiums**. Biobank Vast considers such outreach to be most optimum means of reaching out to both commercial and Academics clientele. There is a dedicated team for marketing activities in Biobank Vast and a **separate annual budget for the marketing activities (~2-3% of the total revenues**)

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

Biobank Engagement Model Alignment			
Model	Adoption		Key End Users
	Current	Future	
Research Provider			Academics, CSO
Strategic Partnership			Pharma, Biotech, CSO
Time and Material			Pharma, CSO

- Research provider model offers project based support by providing samples to carry out efficient therapeutic research on a specific research study be it therapy-specific or a biomarker research. **Strategic partnership is adopted for long-term benefits not only for one project, but for multiple studies with Pharma, Biotech and contract services organizations**. Time and Material model is adopted where the Biobank provide samples in different phases of the studies, like for clinical trials and this model has stringent timelines for delivery of samples to the end-users . Along with the other models listed above, Biobank Vast also sees potential for more engagements using data owner based models
- **There is no single preferred model** for Biobank Vast for engagements and **it depends upon duration of engagement, type of project, research outcomes, and the type of end-user** to finalize the engagement model
- Stringent delivery timelines of is a major challenge encountered by the Biobank which may be due to difficulty in obtaining timely patient consent. In such cases, the patients do not consider to donate samples due to lack of scientific knowledge which makes difficult to deliver the promised amount of specimens in a specific time

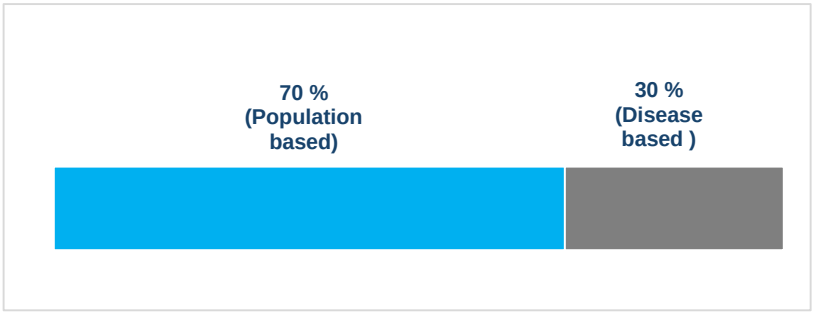
Low High

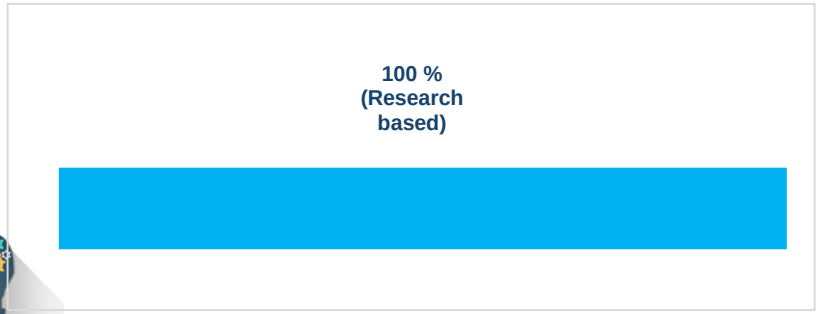
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

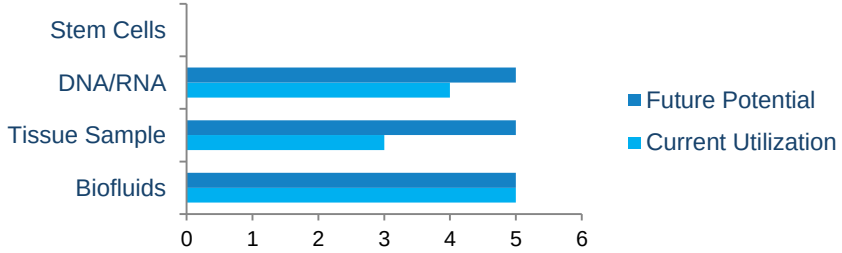
Service Segments

Share from total projects (2019) in %





Sample Utilization



- Major partners for Biobank Vast are academic institutions and hospitals in Sweden such as **University of Gothenburg, Sahlgrenska University Hospital and Eastern Hospital for research based projects using both healthy samples (population based studies) and disease samples.** Biobank Vast has also partnered with a few CROs
- Biobank Vast has engaged in various studies in **biomarker profiling, genome sequencing applications and oncology specific studies** where sample utilization of biofluids and tissue samples is high.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

Biobank Väst
VÄSTRA GÖTALANDSREGIONEN OCH GÖTEBORGS UNIVERSITET

Biobank Application Area Alignment						
Application Area	**Key competency of your biobank**	**Biospecimens Utilized**	**Key End Users**	**Growth Potential**		**Growth Drivers/ Challenges for your biobank**
				Present	**Future**	
Companion Diagnostic	Biospecimen type	Blood samples, saliva, urine, serum	Pharma, CSO, Diagnostics			The growth driver for all these areas is the Increasing demand for good quality samples which facilitates efficient research outcomes
Genomic Sequence	Biospecimen type	Blood samples, saliva, urine, serum	Academics Institution, CSO			
Oncology Clinical Development	Biospecimen type	Blood samples, saliva, urine, serum	Academics Institution, CSO, Pharma			
Real World Evidence	-	-	-	-	-	-
Digital Pathology	-	-	-	-	-	-

Low High

FROST & SULLIVAN

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Drug Development Value chain competency

Application type	Expertise (Scale)	Number of Studies	Key End Users
Target identification and validation		90-100 studies in total	Majority of the end-users are Academics institutions. Other end-users include pharma, CSO, Biotech
Lead identification and optimization			
Preclinical			
Phase I			
Phase II			
Phase III			
Phase IV (RWE studies, Post marketing, etc.)	-	-	-

- Biobank Vast has engaged with end-users on drug development value chain both in population based studies involving healthy donor samples as well as disease based studies, however % share of population based were comparatively more than the disease specific studies.
- Biobank Vast has been also a part of quite a few research studies and clinical research that take place in the University of Gothenburg and in the Gothenburg region as it is a regional biobank.

Low High

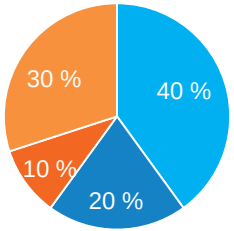
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Financial Sustainability

Biobank Funding Sources

Number of Projects (2019)



- Government/Non-Profit grants
- Fee recovered from biobank operations
- Internal Funds
- Commercial partnerships

Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Cost Recovery Model			Academics, CSO
Fee for service			Pharma, Biotech, CSO

- Biobank Vast considers **lack of defined business/pricing models and dependency on short term funding (Government/Non profit grants, etc.) to be key factors that impact financial sustainability**. In order to improve upon financial sustainability, Biobank Vast looks forward to improve biobanking sample management services, and expand the biospecimen portfolio, in order to have more efficient collaborations.

- In **the cost recovery model the end-user pays only a small amount of the total price of the services, that is the cost of the samples**, and the **rest is recovered from the government as they financially support the study**. This model is particularly adopted for the **government academic institutes and university hospitals** who are funded by the government to conduct the research. In the **fee for service model**, the **end-user is charged for the complete fee for the services they require**. Like for example, the private-funded studies are usually accomplished by the pharmaceutical and biotechnology industries, some private CROs and CMOs, who take the samples from the Biobank and it charges the entire fee for them

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Sample Management

Sample Management	
Function	**Key Value Proposition**
Sample Collection	Skilled resources, and sample collection capabilities
Sample Processing and Storage	Temperature controlled freezers , technology to meet quality compliance
Sample Maintenance	Robotic and automated systems
Sample Retrieval	Data management software, and automated systems
Quality Control Procedures	Operational guidelines and regulatory standards compliance for sample storage, and maintenance

Biobank Cost Drivers

Cost Drivers

- The key areas that constitute the cost drivers for Biobank Vast include utilization of **skilled resources to carry out sample collection**, **improved infrastructural set-up** in terms **of temperature controlled freezers, standardized storage capabilities, an IT system for standardized data management through digitized systems** with no manual labor, **shipping and distribution under standard conditions and regulations**, and **efficient means of distribution channels.**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (2/3)

Biobank Väst
VÄSTRA GÖTALANDSREGIONEN OCH GÖTEBORGS UNIVERSITET

Data Security and Privacy	
Parameter	**Current Proficiency**
Compliance to data privacy (EU GDPR, etc.)	
Established policy guidelines	
Dedicated personnel or data security manager	
Adherence to the patient consent norms	

Data Access Framework	
Parameter	**Current Proficiency**
Open Access Model	No
Control Access Model	Yes
Tiered Access Model	No
Existence of Institutional review board (IRB) for biospecimens sharing	Yes

- Biobank Vast **provides restricted access to data using common network BBMRI**, where the researchers can contact the Biobank if they require any particular sample for their research purpose using a common sample id. **Data sharing is not done through any public website or domain and the Biobank Vast follows strict guidelines set by IRB for biospecimen sharing.**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (3/3)

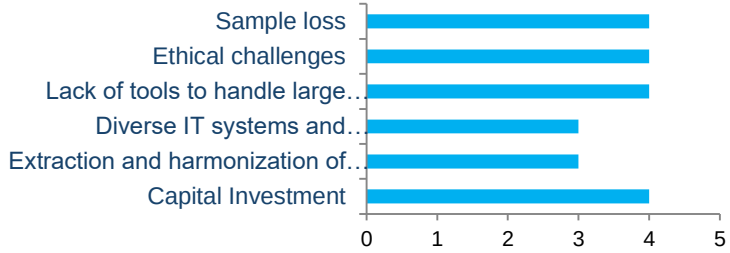
Biobank Väst
VÄSTRA GÖTALANDSREGIONEN OCH GÖTEBORGS UNIVERSITET

Digitization- One Stop Access

Type of Access	Adoption	
	Current	Future
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease Registers		

Digitization- Key barriers

Key barriers



- Online portals can be a convenient means to make sample information available through the data management software which are built in-house. Each sample has a unique ID and the information related to it can be accessed through the software by using the sample ID. **Linkage of data from the disease registers is not currently adopted but in near future, the Biobank expects to link the personal identification number of the patients to their sample information**
- End-users can connect and communicate with the Biobank through various digital platforms available on the website. However **digitization also poses barriers** especially in terms **of ethical challenges around data sharing and possibility of loss of sample information**. Biobank Vast is also focusing on investing on more advanced tools to handle large volumes of data that can be generated from information contained in its huge sample repository

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

Regulatory Scenario		
Model	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		-
Is the prevailing patient consent system efficient in biobanking activities		-
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		-

Network Participation

- Biobank Vast is a part of the national initiative Biobank Sweden, which connects various healthcare organizations, university hospitals, academic institutions and commercial industries that focus on clinical research and therapeutic research.
- Furthermore Biobank Vast is also a part of BBMRI-ERIC which gives the advantage of efficient flow of data and information between the regional and international biobanks through a common platform.
- **Network participation can enhance the market outreach for the Biobanks by becoming aware of project requirements of the end-users at an early stage**.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

Biobank Future Outlook	
Customer Acquisition	Academics would remain the key customers in the future. However Biobank Vast considers Pharma, and Contract services organization to be the most potential customers in the future followed by biotech Biobank Vast considers to utilize different engagement models such as strategic partnership, research provider, service provider and data owner model as per end-user requirements in the future
Service Scope	Biobank Vast considers high quality samples to be key sources of expertise in service capabilities. The focus is expected to remain on the tissue samples, DNA/RNA extract. Biobank Vast considers companion diagnostics, genome sequencing and oncology clinical development to be major areas of future applications
Financial Sustainability	Biobank vast will focus on expanding the biobanking services portfolio, and biospecimen portfolio in order for increased collaborations which will help the financial viability of the biobank. Fee for service and cost recovery pricing model will remain the focus of the biobanks in the future
Operational Sustainability	Biobank Vast will consider further improvement in sample management and handling services and investments in advanced equipment. The focus will remain on providing high quality biospecimens to the end-users for research. However the biobank, in the long term, will also seek to provide data services to the end-users for both commercial and research based purposes
Social Sustainability and Collaborations	Biobank Vast will consider expanding its collaborations with different networks with key drivers being exchange of samples and sharing of research data through a common platform.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Profile

Overview

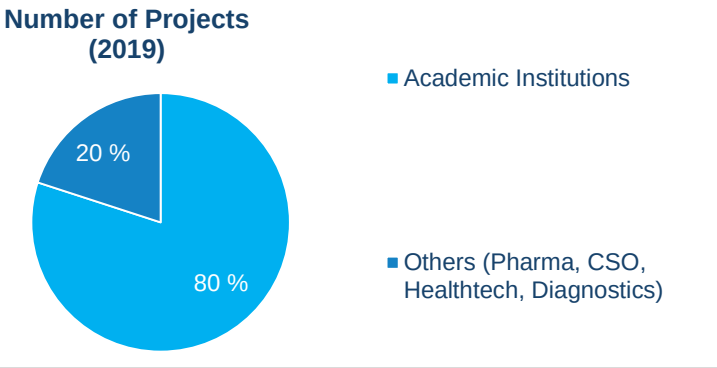
Uppsala Biobank profile			
Location	Sweden	Established year	2008
Biobank type	Focus on both population and disease based studies		
Ownership	Uppsala County Council and Uppsala University		
Brief overview	▪ Uppsala Biobank has a robust research infrastructure and is considered a center of excellence for biobank issues at Uppsala University and Uppsala Region ▪ Uppsala Biobank has two principals, the Uppsala Region, which is represented by the Academics Hospital and Uppsala University, represented by the medical faculty in the medical and pharmaceutical sciences		
Core area of specialization	▪ Biobank has an expertise in sample handling and their storage and provide the samples of highest quality to end-users. ▪ It also provides advisory support for biobanking operations and additional queries regarding the various application procedure as per the regulatory and ethical laws under the Swedish Biobank Act and other related information.		
Rationale for prioritizing	▪ Uppsala Biobank is one of the Regional Biobank Centers (RBC) in Sweden and serves as a center for the Uppsala region in Sweden. It is specialized in companion diagnostics, genome sequencing and Oncology		
Total number of samples	▪ In Thousands		

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

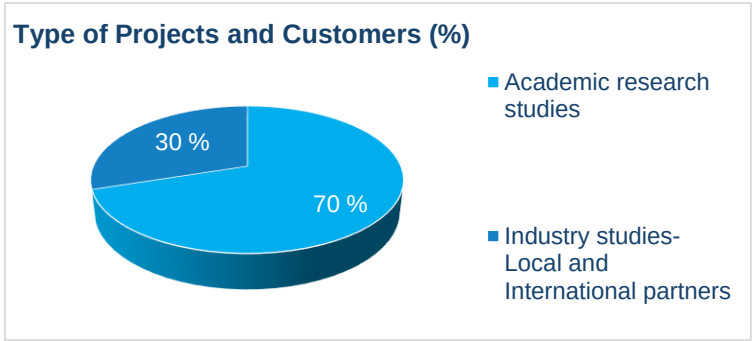
Customer Acquisition

Customer Types and Marketing

Biobank Customer Types



Biobank Customer Project Types



- **Conferences and symposiums are the most common ways for Uppsala bank to reach out to potential clientele** where the focus is to spread awareness related to the services provided in the biobank with an expectation to receive opportunities for collaboration and consents for sample donation.
- On an **average ~1% of the total revenues is dedicated for marketing activities and social media outreach is the focus of the Uppsala Biobank in the near future**
- Uppsala Biobank has engaged in various partnerships with both Academics and commercial institutions mainly in the areas of biomarker studies and genome sequencing studies. **Major partners include Karolinska Insitute, Uppsala University and AstraZeneca**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

Biobank Engagement Model Alignment			
Model	**Adoption**		**Key End Users**
	Current	**Future**	
Service Provider			All types
Research Provider			Academics
Strategic Partnership			Pharma, Biotech, Contract Services Organization, Healthcare technology

- **Service provider model providers both samples and data services to the end-users especially through data hubs**. In this model the researchers can access data from the online system and can also manage the orders and sample requirements efficiently.
- **Strategic partnership is basically adopted for long-term engagements with the end-users that may last for 3-4 years or more**. The end users can ask for any kind of sample or data as per the requirement of individual project. **Research provider model is mainly used for providing data for specific projects in a particular domain**. For instance if the end-user **is engaged in a oncology specific study and needs information or data related to its ongoing study**, then the Uppsala Biobank can provide this information to the end-users.
- Ensuring privacy and security of patient's data along with other confidential research project data at times becomes difficult in the engagements along with challenges around harmonization and synchronization while working with the end-users.

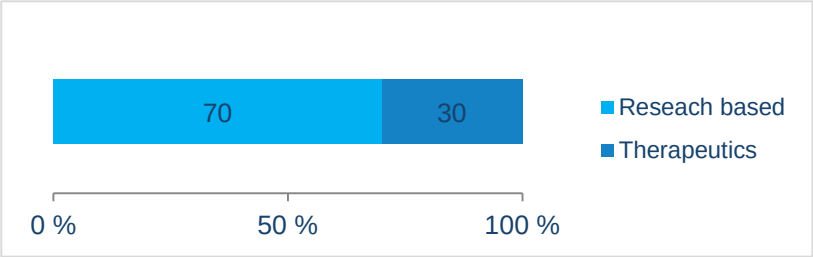
Low High

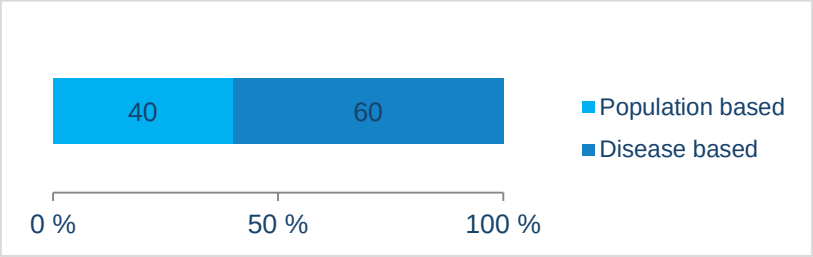
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

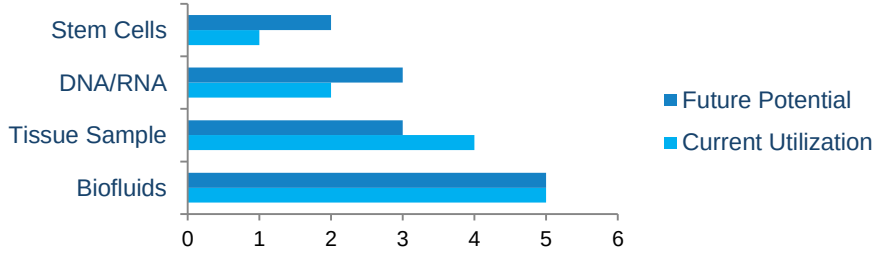
Service Segments

Share from total projects in % (2019)





Sample Utilization



- Major partners for Uppsala Biobank for different projects (research and therapeutics) are **Karolinska Institute and Uppsala University. AstraZeneca has also partnered with Uppsala Biobank for several of its projects**.
- Uppsala University has engaged in various studies in **biomarker profiling, genome sequencing applications and oncology specific studies** where sample utilization of biofluids such as blood samples, saliva and urine and tissue samples is high. However Uppsala Biobank would focus more on DNA/RNA extracts in the future as per its research requirements. **Uppsala university also collaborates with Umea University for higher sample utilization especially in oncology studies**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

Uppsala Biobank

Biobank Application Area Alignment						
Application Area	**Key competency of your biobank**	**Biospecimens Utilized**	**Key End Users**	**Growth Potential**		**Growth Drivers/ Challenges for your biobank**
				Present	**Future**	
Companion Diagnostic	Biospecimen type	Tissue samples	Pharma			Precision medicine applications are a growth driver for the companion diagnostics. However lack of skilled resources, and operational management is challenging
Genomic Sequence	Biospecimen type	Tissue samples	Academics			NGS applications are a growth driver but it's a complex and a lengthy process with skilled resources requirement
Oncology Clinical Development	Biospecimen type	Blood samples	Academics, Pharma			Diagnostic applications in oncology are a key driver whereas differences in study types in pre-clinical and clinical are a major challenge
Real World Evidence	-	-	-	-	-	-
Digital Pathology	-	-	-	-	-	-

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Drug Development Value chain competency

Application type	Expertise (Scale)	Number of Studies	Key End Users
Target identification and validation		Multiple number of studies	Pharma and Academics institutions
Lead identification and optimization			
Preclinical			
Phase I			
Phase II			
Phase III			
Phase IV (RWE studies, Post marketing, etc.)			

- Uppsala Biobank has engaged with end-users on drug development value chain mainly in therapy areas of **Oncology, and precision medicine applications for both academic and pharma end-users**.

Low High

FROST & SULLIVAN

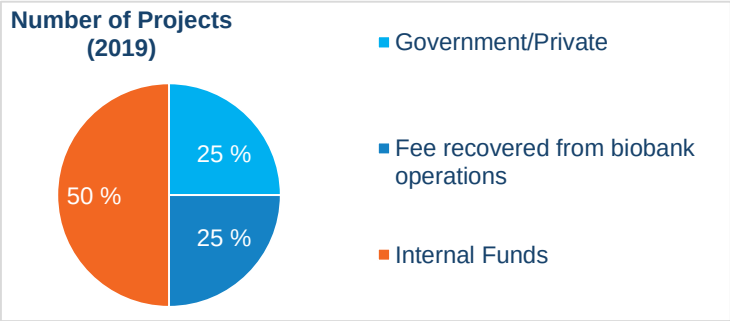
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Financial Sustainability

Uppsala Biobank

Biobank Funding Sources



Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Cost Recovery Model			Academics
Fee for service			Pharma

- **Uppsala Biobank considers lack of defined business/pricing models and dependency on short term funding (Government/Non profit grants, etc.) to be key factors that impact financial sustainability followed by lack of sufficient commercial partnerships** . In order to improve upon financial sustainability, Uppsala Biobank is working on the **awareness campaigns to reach out to the majority of the industries in terms of collaboration and association with leading research-based organizations to dispense better quality of samples** and also expand the vertical of sample collection as per the market requirements for research domain.
- In **the cost recovery model the Uppsala Biobank provides subsidy to the academic institutions only for samples**. In this type the Biobank **charge fees for the transportation and storage of the samples**. However, the academic institution and government research organizations receive subsidy on the overall price than the pharmaceutical industries and biotech companies who look for quality of samples and don't expect any price reduction. For the fee-for service model, the end-user is charged based on the sample and data services provided

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Sample Management

Sample Management	
Function	**Key Value Proposition**
Sample Collection	Sample ordering and collection by integrated biobanking services
Sample Processing and Storage	Automated processing
Sample Maintenance	High end equipment
Sample Retrieval	Internal committee for examining and approval of sample retrieval
Quality Control Procedures	Integrated biobanking services for better QC procedures

Biobank Cost Drivers

Cost Drivers

- The key areas that constitute the cost drivers for Uppsala Biobank include several direct and indirect costs such as spending on **blood sample collection tube, 2D-coded microtubes and additional cost for DNA preservation and cell separation methods**. Furthermore other constituents of cost drivers include **temperature controlled freezers for sample storage, robots for automated processing**. On **certain occasions samples require dry ice and liquid nitrogen to pack the samples and transport them to the destination, along with paraffin wax blocks which is also a cost driver**. The investment into Laboratory Information Management System to store data ensuring privacy and security also necessitates high investment .

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (2/3)

Data Security and Privacy	
Parameter	**Current Proficiency**
Compliance to data privacy (EU GDPR, etc.)	
Established policy guidelines	
Dedicated personnel or data security manager	
Adherence to the patient consent norms	

Data Access Framework	
Parameter	**Current Proficiency**
Open Access Model	No
Control Access Model	Yes
Tiered Access Model	Yes
Existence of Institutional review board (IRB) for biospecimens sharing	Yes
Privacy and Confidentiality protections	Yes

- Uppsala Biobank provides limited access to samples as it strictly adheres to GDPR regulations and have strict policies within Sweden which require a controlled access model. However on **certain occasions the very confidential data obtained from research studies is only provided if special authorization or permission is received from the relevant authorities**. **Uppsala Biobank has Regional Ethical Review Board to consider ethical factors for dispersing samples for research purposes.**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (3/3)

Uppsala Biobank

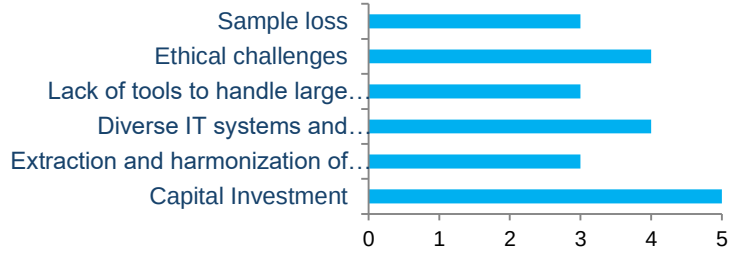
Digitization- One Stop Access

Type of Access	Adoption	
	Current	Future
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease Registers		

Low High

Digitization- Key barriers

Key barriers



- Using the virtual portals, the end-users can easily have knowledge about the types of samples available in the biobank. This way as per the study requirements, the end users can target the appropriate biobanks without in less time. This has the potential to make the entire procedure of accessing the biospecimen and data easily in a single platform.
- Although there are significant advantages to virtual portals for providing access, **Uppsala Biobank also considers the possibility of ethical issues arising from sharing and access of data such as data breaches and diverse IT systems and compatibility issues between biobank platforms and end-user platforms to be the most significant barriers along with high investments**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

Uppsala Biobank

Regulatory Scenario		
Regulatory Attributes	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		Prevailing regulations in Sweden for biobanking practices need to be lenient
Is the prevailing patient consent system efficient in biobanking activities		Procedure to take consent is very long and tedious. Due to extreme regulatory restrictions, the patient's generally don't prefer to donate samples. Better clarity in terms of the regulatory framework.
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		Need for lenient laws that deal with data protection

Collaborations

BBMRI-ERIC®

BIOBANK SVERIGE

SWEDEHEART

conception

SCAPIS
A unique research project with the aim of predicting and preventing cardiovascular and pulmonary disease.

Uppsala Longitudinal Study of Adult Men (ULSAM)

- Uppsala University has participated in several studies such as SCAPIS, ULSAM cohort, U-CAN studies. In one such study SCAPIS (Swedish Cardiopulmonary Bioimage Study), the main aim of the study was to select 30,000 random subjects of age group 50 to 64 and collect their samples. The study was based on an objective of prevention and treatment of cardiopulmonary disease and cardiovascular. The major challenge encountered in such studies which involves participation of multiple organizations is effective coordination among the members
- **Network participation is a key enabler for Uppsala Biobank to develop better clinical associations from different experiments conducted at different times. This further strengthens the research potential and rigor for the Biobank in its ongoing research studies**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

Biobank Future Outlook	
Customer Acquisition	Academics would remain the key customers in the future. However Uppsala Biobank considers Pharma, and Biotech to be the most potential customers in the future followed by diagnostics and contract services organizations Uppsala Biobank **considers to utilize service and research based engagements more prominently** in the future followed by strategic partnership with the end-users
Service Scope	Uppsala Biobank considers **high quality samples to be key sources of expertise in service capabilities**. The focus is expected to remain on the biofluids however Uppsala Biobank will focus more on the projects involving DNA/RNA extract. Uppsala Biobank considers companion diagnostics, genome sequencing and oncology clinical development to be major areas of future applications
Financial Sustainability	Uppsala Biobank will focus on increasing commercial partnerships and collaboration with leading research based organizations for high quality samples. It will also work on awareness campaigns to reach out to potential target clients. **Fee for service and cost recovery pricing model will remain the focus of the biobank in the future**
Operational Sustainability	Uppsala Biobank **focus on further improving the integrated biobanking services by which it can order samples from the hospitals with which it has collaborations**. The focus will remain on providing high quality biospecimen and advanced equipment for storage and handling
Social Sustainability and Collaborations	Uppsala Biobank has a sharp focus on ensuring the ethical concerns are met by following the guidelines such as Ethical review act, law of data protection, GDPR, etc. The biobank is also likely to streamline the process in the future as there are multiple steps and procedures which make the process lengthy and complex.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Profile

Overview

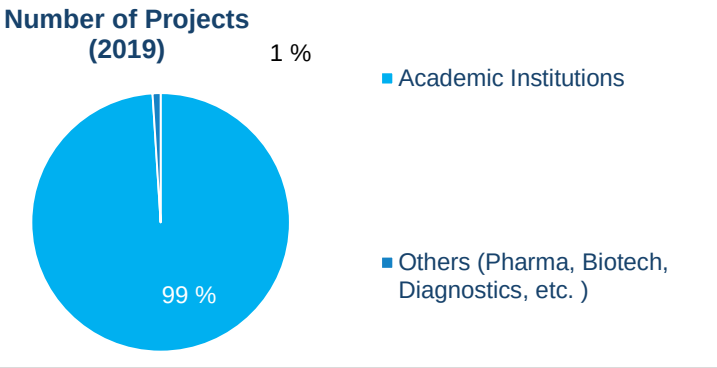
KI Biobank			
Location	Sweden	Established year	2004
Biobank type	Focus on both population and disease based studies		
Ownership	University Owned- (Karolinska University)		
Brief overview	▪ KI Biobank has been established with financial support from the Wallenberg Foundation. ▪ The aim is to build up a non-commercial resource for collection, handling and storage of human biosamples to be used in molecular and genetic research in Sweden .		
Core area of specialization	▪ Biobank areas of specialization include sample handling, storage preparation and retrieval. There is another specialty for DNA extraction from blood and saliva, which it provides for research domains like Next Generation Sequencing and genotyping. ▪ It has also started to provide advice for different stages of the research study. This refers to providing guidance for the application procedure, consent forms and a number of other information-related to the samples. This is done so that the organizations can reach our biobank for any kind of counseling required before starting with any research in any domain.		
Rationale for prioritizing	▪ KI Biobank is one of the largest biobanks in Sweden. It specializes in genome sequencing projects, RWE studies and Oncology clinical development		
Total number of samples	▪ ~10 million		

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

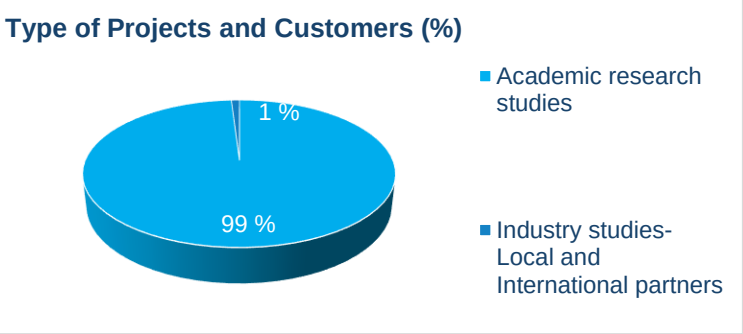
Customer Acquisition

Customer Types and Marketing

Biobank Customer Types



Biobank Customer Project Types



- KI Biobank has engaged in various partnerships with mainly Academics institution most prominently in the areas of genome sequencing, oncology studies and RWE studies. Major partners include Karolinska Insitute, and Stockholm's County Council and the **total value of the projects conducted in 2019 was around 10-14 million SEK with academic partners studies, wheras 1-2 million SEK with industry partners**
- **Conferences and symposiums and print media such as articles published in research magazines and journals are the most common ways for KI Biobank to reach out to potential clientele** where the focus is to spread awareness related to the sample collection and research done in the in the biobank
- **There is a dedicated team for marketing activities in KI Biobank** however it **considers focus is not too sales driven** due to its non-profit nature of activities

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

Biobank Engagement Model Alignment			
Model	**Adoption**		**Key End Users**
	Current	**Future**	
Service Provider			Aademics, Pharma, Biotech, CSO, Healthtech
Strategic Partnership			

- KI Biobank utilizes the **service provider model for short term engagements** with the end-users and the level of services are fixed whereas the **strategic partnership is mainly employed for projects with a longer duration** and there is flexibility in terms of requirements of the end-users.
- **Strategic partnerships encourages greater collaboration between the biobank and the end-users in terms of common research areas and research objectives for both biobank and the end-user**

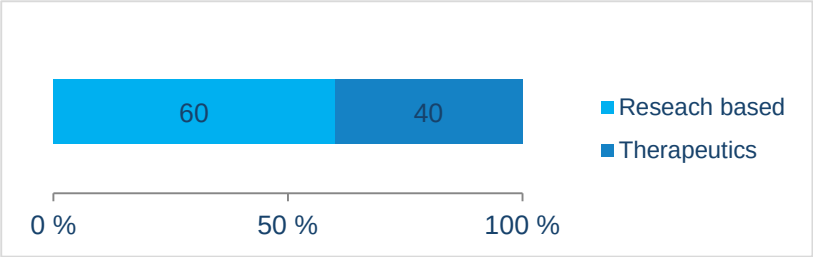
Low High

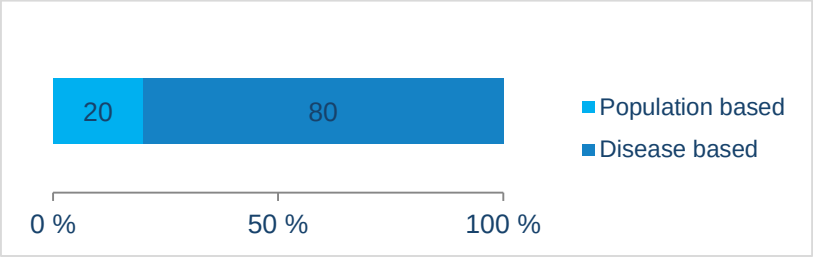
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

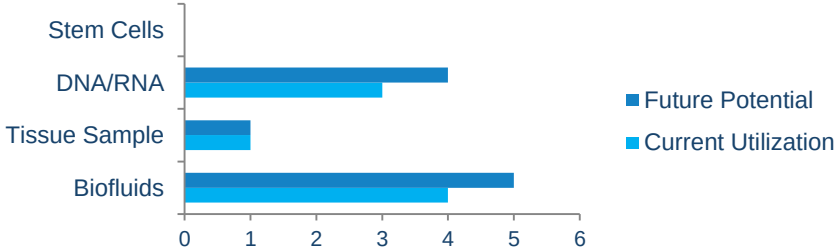
Service Segments

Share from total projects (%)





Sample Utilization



- KI Biobank specializes in **disease based studies** with academic institutes in the areas of genome sequencing applications, Oncology and RWE studies with partners such as Karolinska Institute and Stockholm Country Council. **On an average the value of such studies in the past 1 year for KI Biobank has been in the range of 8-10 million SEK**
- KI Biobank has engaged in various studies in wide range of application areas where sample utilization is high. Especially the usage of DNA extracts, blood samples and plasma is utilized the most by the KI Biobank in a wide range of application areas including oncology, RWE studies, gene therapy studies, PHM studies, and Microbiome studies. Tissue samples are primarily used for OMICS based studies.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

Biobank Application Area Alignment						
Application Area	Key competency of your biobank	Biospecimens Utilized	Key End Users	Growth Potential		Growth Drivers/ Challenges for your biobank
				Present	Future	
Companion Diagnostic	-	-		-	-	-
Genomic Sequence	Biospecimen type	DNA extracts and biofluid	Academics			Interpretation of laws such as GDPR is challenging. Also cost of services in the genome sequencing projects is a challenge
Oncology Clinical Development	Biospecimen type	DNA extracts and biofluid	Academics			Oncology is a key driver due to increased demand for number of research projects.
Real World Evidence	Biospecimen type	DNA extracts and biofluid	Academics			RWE studies have grown in prominence due to its utilization in drug effectiveness studies
Digital Pathology	-	-	-	-	-	-

Low High

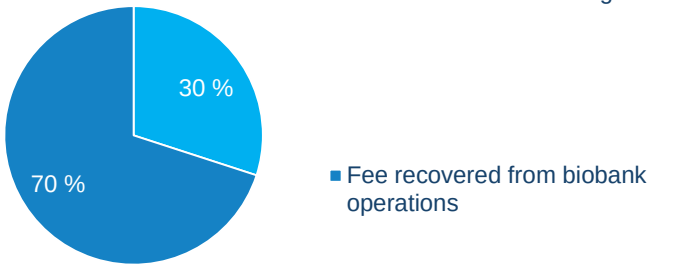
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Financial Sustainability

Biobank Funding Sources

Number of Projects (2019)



Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Cost Recovery Model	■	■	Academics, Pharma, Biotech, CSO, Healthtech, Diagnostics
Fee for service	■	■	

- KI Biobank **considers lack of commercial partnerships as a key factor that impacts the financial sustainability** as most of the funds are received in the form of non-profit grants and fee recovered from the existing projects. KI **Biobanks plans to tap more pharmaceutical companies as our customers because these organizations are ready to make huge investments for samples with good quality and have well defined pricing models to engage with these end-users**
- KI biobank utilizes the **cost recovery model by charging minimum amount to the researchers and academic institutions for carrying out the research** using the biobank services however this **model is difficult since majority of customers for KI Biobank are public sector organizations with lesser funds to invest** on the sample services. For rest of the engagements the KI Biobank utilizes the fee for service model where the end-users are charged appropriately for the services undertaken

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Sample Management

Sample Management	
Function	**Key Value Proposition**
Sample Collection	Various tests done prior to collecting the samples and then samples undergo various filters in order for the selection of the best quality sample
Sample Processing and Storage	Freezers and automated robots for storage of samples
Sample Maintenance	Freezers with alert system and system to trace each sample in order to prevent samples from any damage.
Sample Retrieval	A different committee which proof-reads the request application to ensure the samples are only provided within the limits of guidelines.
Quality Control Procedures	LIMS and proper staff trained for regular maintenance of samples at different intervals.

Biobank Cost Drivers

Cost Drivers

- The key areas that constitute the cost drivers for KI Biobank include **various screening tests to determine the quality of samples**. Furthermore additional costs are contributed by **maintenance and usage of automated freezers and other equipment** with optimum storage conditions like liquid nitrogen or dry ice, and the **transportation and shipping costs**.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (1/3)

Data Management Application Area				
Function	Key End User	Application Area	Adoption	
			Current	Future
Exogenous Data	Academics	RWE studies		
OMICS/Dx Data	-	-	-	-
Clinical Data	-	-	-	-
Remote Care Data	-	-	-	-

Data Management	
Function	Key Value Proposition
Data Collection	Automated robots and LIMS system which ensures management of huge amount of data will full-efficiency and quick mode with lesser chances of developing any errors
Data Processing and Storage	
Data Analytics	
Data Sharing	

- KI Biobanks major application is RWE studies where it utilizes the exogenous data. It considers this as a promising feature even in the future based on increasing demand for RWE studies. Although the **current studies is mainly for academic partners, KI Biobank looks forward to utilize this capabilities to work on drug development projects in the future for Pharma companies especially in the late phases**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (2/3)

Data Security and Privacy	
Parameter	**Current Proficiency**
Compliance to data privacy (EU GDPR, etc.)	
Established policy guidelines	
Dedicated personnel or data security manager	
Adherence to the patient consent norms	

Data Access Framework	
Parameter	**Current Proficiency**
Open Access Model	No
Control Access Model	Yes
Tiered Access Model	Yes
Existence of Institutional review board (IRB) for biospecimens sharing	Yes
Privacy and confidentiality protections	Yes

- **KI Biobank has Institutional review board which grants ethical permission for usage of samples for any research purpose**. Furthermore the **Biobank has multiple filters for access to the data**. Depending **upon the kind of consent provided, the permission is provided to only selective group of people for accessing information regarding any sample**.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (3/3)

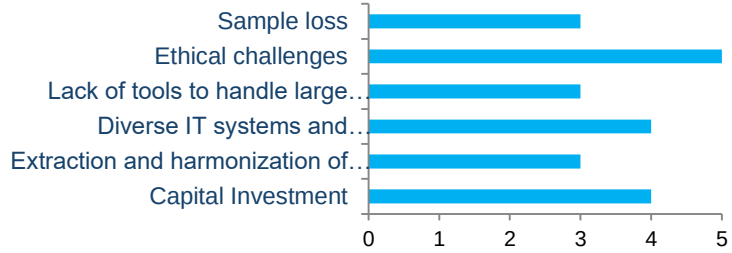
Digitization- One Stop Access

Type of Access	Adoption	
	Current	Future
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease Registers		

Low High

Digitization- Key barriers

Key barriers



- KI Biobank considers the **idea of having online portals related to the concept of having virtual biobanks**. With the help of such a **service, KI Biobank considers that it will be comparatively easy to gain access to samples and data without seeking additional permission from different authorities**.
- **The future potential of such portals is beneficial, however, due to the strict regulatory framework, this type of digitization is difficult to implement within the biobanks in Sweden**. In addition to this, diverse IT systems, high capital investment, etc. are other key barriers to introduce such a system functional in the Biobanks.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

Regulatory Scenario		
Model	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		Regulations can be less complicated in order to have clarity in terms of understanding the guidelines.
Is the prevailing patient consent system efficient in biobanking activities		Need to have less restrictions in terms of consent.
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		-

Collaborations

- KI Biobank is part of the Biobank Sweden network at the national level and it is one of the extensions of BBMRI with support from the Swedish Council.
- **KI Biobank considers such participation in networks or collaborations to be helpful in developing synchronization and uniformity in various operational protocols in terms of sample collection, storage and getting consent for sample donation**.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

Biobank Future Outlook	
Customer Acquisition	Academics would remain the key customers in the future. However KI Biobank considers Pharma followed by Biotech, Contract Services Organizations and healthcare technology to be the most potential customers in the future KI Biobank considers to utilize strategic partnership and service based engagements more prominently in the future with the end-users
Service Scope	KI Biobank will mainly **focus on RWE studies, Oncology and genome sequencing applications** and the utilization of DNA/RNA extracts and the biofluid is expected to increase.
Financial Sustainability	KI Biobank will focus on increasing commercial partnerships and collaboration and improve infrastructure in near future for better sample management. Fee for service and cost recovery pricing model will remain the focus of the biobank in the future
Operational Sustainability	KI Biobank will focus on improving sample quality and variety and also improve on providing data services to the partners. It **considers one access and the concept of virtual biobank as a major driver for data and sample access**
Social Sustainability and Collaborations	KI Biobank considers the participation of networks as highly beneficial and will continue to work with different partners especially Biobank Sweden and the Swedish Council.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Profile

Overview

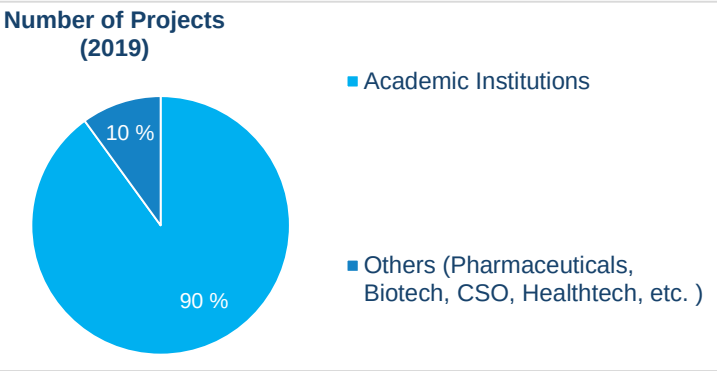
Stockholm's Medical Biobank profile			
Location	Sweden	Established year	2014
Biobank type	Focus on both population and disease based studies		
Ownership	Operations are placed under the board of Karolinska University Hospital		
Brief overview	▪ Stockholm's Medical Biobank (SMB) and the Regional Biobank Center Stockholm-Gotland (RBC Stockholm) have a regional healthcare assignment for biobanking within the Stockholm region		
Core area of specialization	▪ Good quality samples for academic research organizations and the main area of interest is cancer-related research studies. SMB also provides consultancy services to the end-users.		
Rationale for prioritizing	▪ SMB is one of the Regional Biobank Centers (RBC) in Sweden and serves as a center for the Stockholm region. Although it provides services in all the applications areas, oncology is its key competency		
Total number of samples	▪ ~0.5 million samples		

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

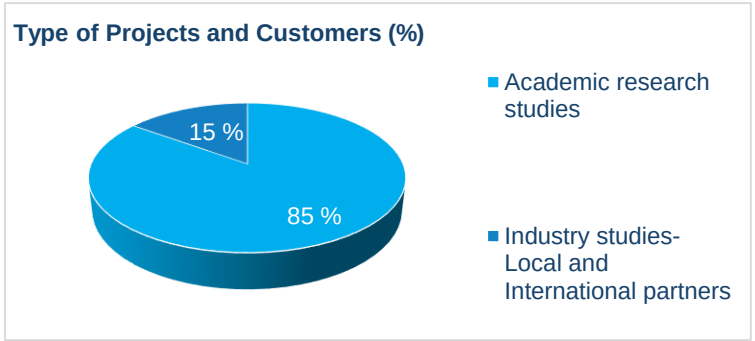
Customer Acquisition

Customer Types and Marketing

Biobank Customer Types



Biobank Customer Project Types



- SMB customers are chiefly in Academics and hospitals. Major partners include Karolinska University and Karolinska University Hospital in Sweden which are the source of research based projects. **The total value of the projects conducted in 2019 was approximately 10 million SEK**.
- SMB customer outreach is mainly through **conference presentations and print media**. It **considers to invest more into marketing in order reach out to the end-users and increase awareness of the services the biobank provides.**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

Biobank Engagement Model Alignment			
Model	Adoption		Key End Users
	Current	Future	
Strategic Partnership			Academic, Pharma, Biotech, CSO, Healthtech, etc.

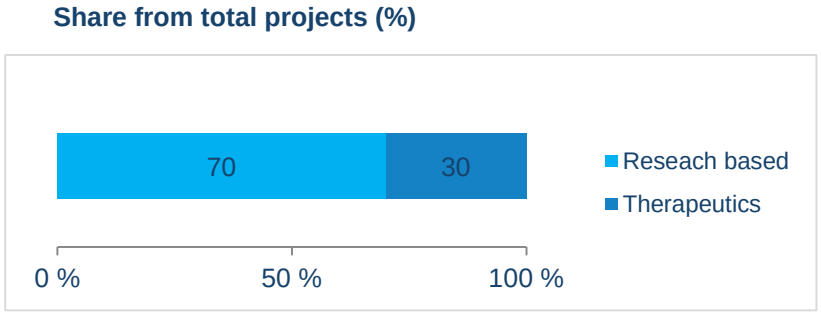
- **SMB only follows a strategic partnership model with all its end-users**. The main features are the **sharing of resources and scientific expertise for research objectives, between the two parties**. This model is chosen by the SMB Biobank for business collaborations with the academic institutions or the commercial industries are for a longer term and both samples and services are provided.

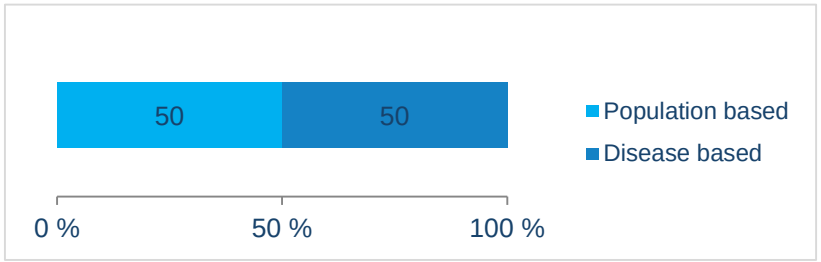
Low High

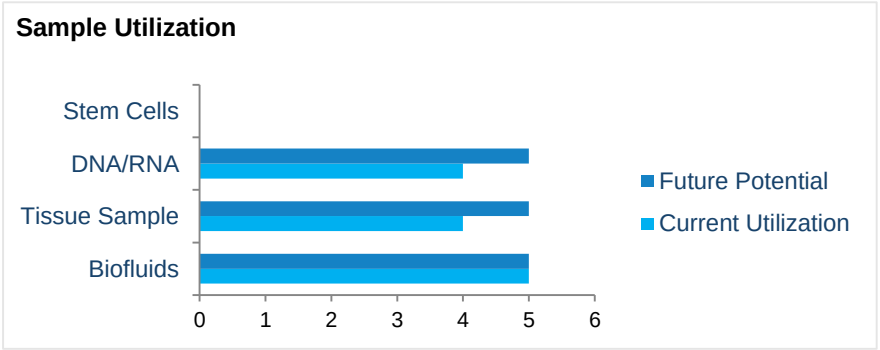
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Service Segments





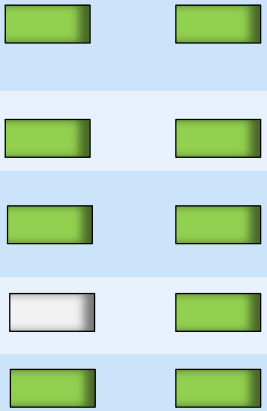


- Major partners for SMB are academic institutions and hospitals in Sweden such as Karolinska University and Karolinska University Hospital for both healthy samples (population based studies) and disease samples. **The average value of the total studies conducted by SMB in 2019 was approximately 12 million SEK**.
- SMB Biobank has a healthy sample utilization especially for biofluids such as blood samples and plasma, tissue samples and DNA extract. The future sample utilization is high for the tissue sample and DNA **extract mainly because of the growth potential by areas such as OMICS studies, gene therapy applications and rare disease studies**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

Biobank Application Area Alignment					
Application Area	**Key competency of your biobank**	**Biospecimens Utilized**	**Key End Users**	**Growth Potential**	**Growth Drivers/ Challenges for your biobank**
				Present / **Future**	
Companion Diagnostic	Biospecimen type	Blood, Tissue samples, DNA extract	Academics, Pharma		The major growth driver for all these areas is the increasing amount of research conducted which creates high sample demand. However the procuring of samples is difficult and to get the consent of the patients is not easy
Genomic Sequence					
Oncology Clinical Development					
Real World Evidence					
Digital Pathology					

Low High

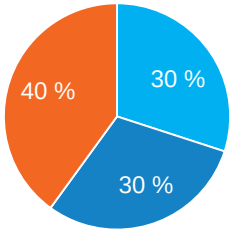
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Financial Sustainability

Biobank Funding Sources

% Share of total funds (2019)



- Government/Non-Profit grants
- Fee recovered from biobank operations
- Others (Internal Funds, Commerical partnerships, etc.)

Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Cost Recovery Model			Academics, Pharma, Healthtech, CSO

- **SMB considers lack of defined business/pricing models and dependency on short term funding (Government/Non profit grants, etc.) to be key factors that impact financial sustainability**. In order to improve upon financial sustainability, SMB looks forward to **improve biobanking sample management services and collaborate with more commercial partners in order to increase the financial viability**.
- SMB utilizes only the cost recovery model in which it charges a minimal fee for the service as it follows a policy of non-profit model, and only costs are recovered from the end-users

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

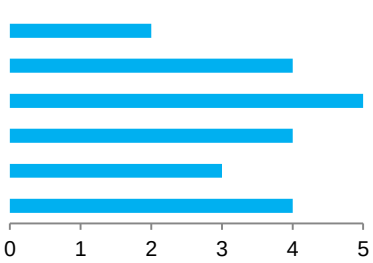
Biobank Sustainability

Operational Sustainability Focus- Sample Management

Sample Management	
Function	**Key Value Proposition**
Sample Collection	Infrastructural support in terms of technical platforms or the storage capabilities for the sample handling like, having a sufficient number of freezers to handle the samples efficiently
Sample Processing and Storage	
Sample Maintenance	
Sample Retrieval	
Quality Control Procedures	

Biobank Cost Drivers

Cost Drivers



- Labor
- Data storage and management
- Sample distribution and shipping
- Sample processing and management
- Sample storage facilities
- Sample collection

- The key areas that constitute the cost drivers for SMB include **utilization of skilled resources to carry out sample collection, efficient storage capabilities in terms of freezers, advanced IT platforms, sample distribution** and shipping involves optimized process for distribution as per requirement and labor costs as well.

Low High

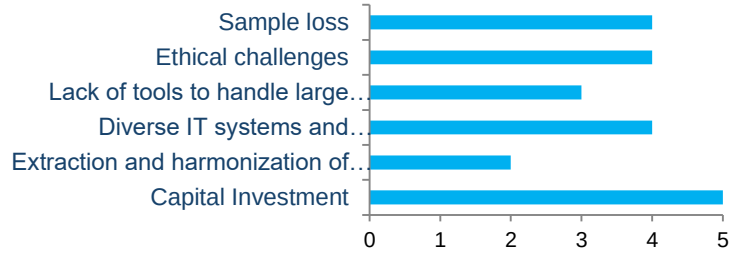
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (3/3)

Digitization- Key barriers

Key barriers



- **SMB Biobank has not embarked upon digitization initiatives** due to barriers which affect the digitization initiatives with the major ones being **high capital investments followed by sample loss, diverse IT systems, and ethical challenges**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

Regulatory Scenario		
Model	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		There is a need for a national platform where patient related information can be shared nationally among various biobanks connected in the network and should also be accessible to the researchers. Government can also look into providing awareness campaigns and programs that would improve the patient awareness and increase the patient consent broadly.
Is the prevailing patient consent system efficient in biobanking activities		
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		

Network Participation

Swedish Research Council

BIOBANK SVERIGE

gms

- SMB considers **interpretation of laws as a major challenge in the current regulatory framework**, since the different interpretations by patients sometimes leads to difficulty in obtaining consent. Thus there is a need for more clarity and awareness for better understanding and interpretation of laws.
- SMB is a part of the Biobank Sweden, the national initiative of Sweden for Biobanking. Furthermore it has also participated in **Genomics Medicine Sweden (GMS) which is a study to enhance the research domain in precision medicine and to develop therapeutic treatments for the critical medical ailments using genetic mechanisms**. Participation in such networks contributes to the growth of the biobanking activities at both the national and the individual scale as it facilitates sharing of knowledge as well as experiences with researchers

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

Biobank Future Outlook	
Customer Acquisition	Academics would remain the most prominent customers in the future. However SMB also considers Pharma, Contract services organizations, Biotech, etc. to be the potential customers in the future SMB **considers to utilize only strategic partnership as its key source of engagement** in the future with the end-users
Service Scope	**SMB considers long term engagement for research trials in Oncology as its major focus area in the future.** It sees potential to increase the utilization of tissue samples and DNA/RNA extracts for all its major applications in the future. SMB will try to cover all major application areas such as biomarkers, genome sequencing, RWE studies, as well as its core area of Oncology in the future.
Financial Sustainability	SMB will focus on **expanding the biobanking services portfolio and increasing the number of commercial engagements as a part of its program to attain financial sustainability in its operations**. However its preferred model of **pricing will remain as the cost recovery model**
Operational Sustainability	SMB considers **sample based services as its long term focus of engagement with the end-users**. It will continue to improve upon the current infrastructure around sample storage capabilities and technical platforms
Social Sustainability and Collaborations	**SMB considers the need to improve the current legislations to enhance the patient participation and consent**. Engagement in awareness programs to improve the patient understanding will also facilitate better participation in studies. SMB will also keep working with the national and international networks for growing its biobanking activities

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

UK

Market Overview

Executive summary

Ecosystem

- The Biobanking ecosystem in UK is **highly developed** with a large number of biobanks broadly classified in disease based or population based cohorts
- UK Biobank is considered to be the benchmark in global best practices

Regulatory Scenario

- There are multiple laws that deal with the biobanking activities. The Human Tissue Act deals with regulation of samples and Data Protection Act with implementation of GDPR regulations and regulation of data processing
- The UK Biobank has in addition developed a broad ethics and governance framework to further review and monitor its activities

Data Infrastructure

- Biobanks in the UK have a robust **IT infrastructure** and **standard practices for data sharing are further improving**.
- UK is a member of multiple regional/global initiatives to improve upon current levels of harmonization of data. Ex- ELIXIR UK, P3G, BBMRI-ERIC

Initiatives

- UK Biobank has demonstrated high level of **expertise in large scale sample collection**, a large **variety of sample data**, **multiple levels of collaboration** with **partners both commercial and academia**.
- **UK Tissue Directory** is the **UK's register** of **sample collections** covering multiple diseases. The focus is to make tissue and data collections easier to find and **access** through a **freely accessible online directory**.

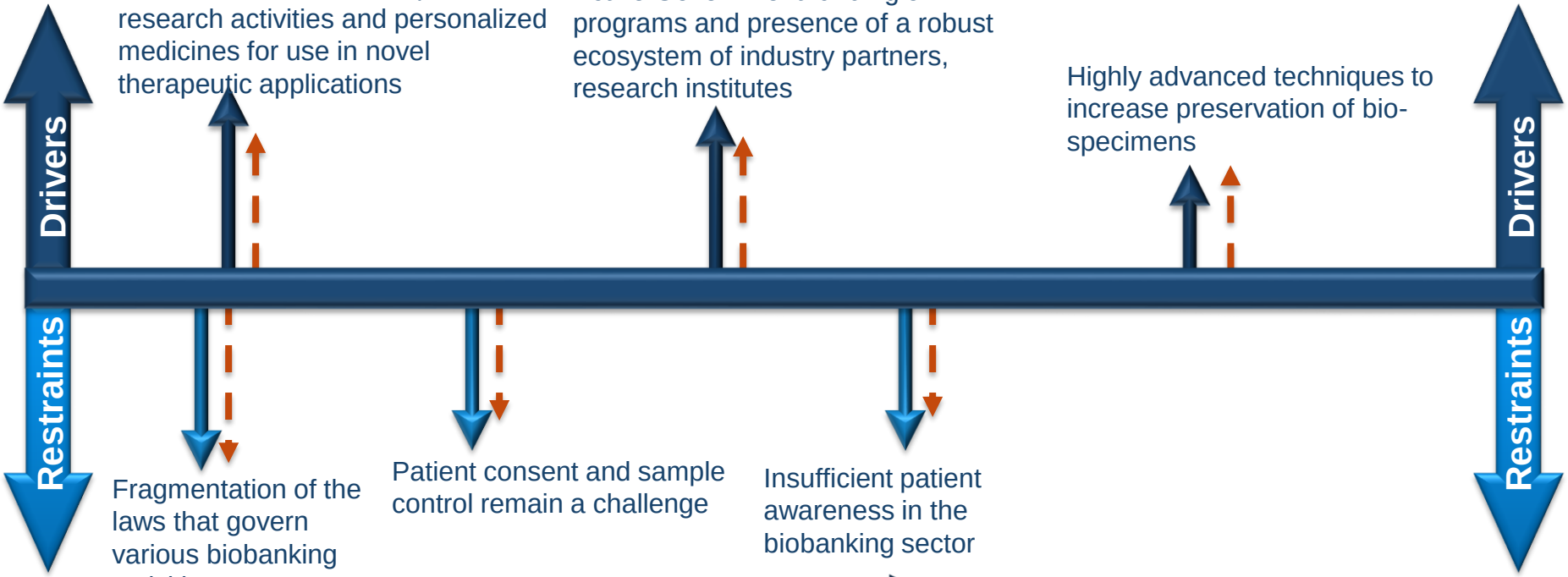
Market Analysis

- Research Applications form ~66% of the total biobanking market while 34% is for therapeutic based applications. While biofluids are the dominant market share holders for biospecimens, the **human tissue samples and stem cells** samples are expected to grow by **2.2% and 1.9%** CAGR (2019-2026) respectively. **Medical research** in the UK continues to flourish with strong collaborative efforts of the government, charities and industry with key areas being **rare diseases, mental health, genomic medicine, blood cancer, etc.**
- **UK has a highly developed** ecosystem consisting of research institutes, companies, etc. , **commercial partnerships** between govt. agencies and private organizations, and **diversified sources of funding** including charitable organizations, industry partners, Government agencies, etc. are some of the major enablers for market growth. Some of the examples of such collaborations include **100,000 Genome Project**, **Cancer Research UK Stratified Medicine Program**, etc.

Source: Frost and Sullivan Analysis

Drivers and Barriers

Increase in disease specific research activities and active Govt. support are key drivers for biospecimen demand



Source: Frost and Sullivan Analysis

Biobank Data infrastructure

Linkage of patient data to health registries is gradually increasing for the biobanks. UK is a member of multiple regional/global initiatives to improve upon current levels of harmonization of data

- **Linking biobanks to EHR** allows the researchers to monitor health outcomes and connect them t o biological, genetic and behavioral factors or treatments
  - **UK Cohort Studies**- **Linked to at least one source of medical records**. Patients must give consent to allow the linking of biobank data to existing and future records
  - **Disease Biobanks**- **Have begun to link patient's data to health registries**. This can assist in tracing the progress of disease in individuals' whose data is being tested and also improve diagnosis
  - The majority of biobanks have not been able to incorporate data from primary care records held by general. Access to such data however can improve the understanding of conditions that are usually treated in primary care settings such as mental health, diabetes, etc.
- Some of the biobanks do not have sufficiently large samples to produce statistically significant results. **Data sharing** capabilities **between biobanks**, however has **is improving** although **barriers** exist in terms of **ethical and legal challenges**, **interoperability**, **different governance structures**, etc.

- **ELIXIR UK** is the UK node of ELIXIR that brings together **18 organizations in the UK** to collaborate on the **bioinformatics services** and **computational biology**
- The UK node assists the life science research by providing training and services in **data handling** and establish standard approaches for **analyzing, storing and exchange of data**
- **P3G is a global consortium** established in 2007, which aims to develop and manage inter-disciplinary collaboration between biobanks to compare and merge a range of datasets and analyses from already published studies. It also aims to harmonize future epidemiological projects in genomics
- **BBMRI-ERIC** is a European research infrastructure for biobanking. It brings together all the major stakeholders – researchers, biobanks, industry and patients – to boost biomedical research. The scope of services offered range from **online tools and software** solutions to **quality management services** and support with **Ethical, Legal and Societal issues**. UK joined in 2015 and nominated UKCRC as the National Node. Focus areas for **UK BBMRI** include **discoverability of tissue and data collections**, **harmonization of data and storage** across stakeholders, **increased stakeholder engagement** and links with other European and **international biobanking initiatives**

Source: Frost and Sullivan Analysis, elixiruknode.org

Biobank Initiatives

Precision Medicine applications with wide therapeutic focus in Genomics, Oncology etc., a highly developed ecosystem, partnerships and funding are growth enablers for the UK market

Key Growth Drivers

Developed Ecosystem

The UK has a large and highly developed ecosystem of Govt. based initiatives, industry partners.

Policy and Vision

Government supports large scale programs in precision medicine applications in various therapeutic areas

Broad Therapeutic Applications

The UK has dedicated biobanks/research centers that specialize in various therapeutic areas such as Oncology, Rare Disease, Stem Cells, Neuro-generative disorders, etc.

Commercial Partnerships

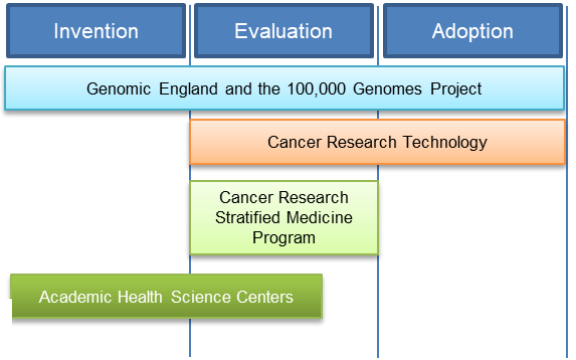
Commercial partnerships between industry partners and Govt./University based programs are a regular feature in the UK

Diverse Funding Streams

The UK has comparatively diversified sources of funding including charitable organizations, industry partners, Government agencies, etc.

Case Examples

- There are **over 400 infrastructure assets** for precision medicine in the UK that are categorized by type of infrastructure facility, or by the type of disease or by the type of pathway. Precision Medicine Applications in UK are classified as the **invention** of the precision medicine interventions, **evaluation** of their clinical validity and **adoption** into the healthcare system.
- The **100,000 Genome Project** involved Whole Genome sequencing from NHS patients with rare disease, plus their families and cancer patients. Launched in 2013, the project reached its halfway milestone in 2018, with sequenced genomes of **8,000 cancer patients, 42,000 patients with rare diseases,** funded by the NHS and National Institute of Health Research



- The **Cancer Research UK Stratified Medicine Programme** is a collaborative initiative to undertake large volume genetic testing within the UK, aiming to test around 9,000 patients across the UK in a 2-year period. The program is **supported by the Government and industry (AstraZeneca, Pfizer, etc.)** and diagnostic and IT companies

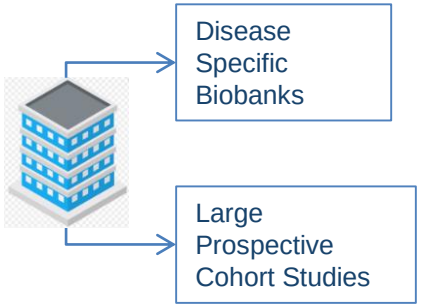
Precision Medicine Ecosystem

FROST & SULLIVAN

Source: Frost and Sullivan Analysis, genomicsengland.co.uk

Biobank Initiatives

UK has a large number of biobanks that are either disease specific or support large cohort studies that are a part of regional and international networks



Large Prospective Cohort Studies

- Large prospective Cohort studies engage with the population in order to monitor who develops what diseases and when
- The information is linked with the biological and lifestyle characteristics (such as biomarkers or genetic factors) with risk of developing a wide range of diseases
- Participation of tens of thousands of people is common in these studies and examples include the **UK Biobank Study, Twins UK,** etc.

Disease Specific Biobanks

- These biobanks are disease focused, generally restricted to specific type of disease under study
- The focus in on the causes of disease and effectiveness of treatments. Examples include **CCLG Biobank, CIGMR, MCRC Biobank**, etc.

- UK Tissue Directory is the UK's register of sample collection covering multiple diseases. The focus is to make tissue and data collections easier to find and access through a freely accessible online directory.

TISSUE DIRECTORY AND COORDINATION CENTRE

UK CLINICAL RESEARCH COLLABORATION

- The objectives of the UKCRC are
  - **SUPPORTING RESEARCH:** Making tissue and data collections easier to find and access through a freely accessible online UKCRC Tissue Directory
  - **IMPROVING SYSTEMS:** Developing standards and consensus on the collection and storage of tissues and data across academia, the NHS and industry so they can be more widely used across projects
  - **IMPROVING POLICY:** Working with people and organizations to promote best practice in sample collection, governance and public engagement
  - **ENGAGING BEYOND THE UK:** Connecting the UK with European and other international biobanking initiatives such as BBMRI-ERIC, by being the UK National Node (BBMRI.uk).

Source: Frost and Sullivan Analysis, biobankinguk.org

Regulatory Scenario

There is no single piece of legislation that governs the biobanking activities in UK; The Human Tissue Act deals with regulation of samples and the Data Protection Act implements the GDPR regulations and personal data processing

The laws that deal with the biobanking activities in the UK are fragmented. While the Human Tissue Act deals with regulation of the samples, the Data Protection Act oversees the data processing and implemented the GDPR. The UK Biobank has in addition a broad ethics and governance framework to further review and monitor its activities

Human Tissue Act

- **Unlike Finland** there is **no single piece of legislation** that deals with biobanking activities in the UK
- The **Human Tissue Act** regulates the removal, storage, use and disposal of **human tissues**. The **data protection legislation** provides for processing of data for research purposes without consent in certain circumstances, the Human tissue act holds the appropriate consent of individuals as a striking feature
- The Data protection Act **implements the GDPR** and regulates the processing of personal data in research purposes

UK Biobank

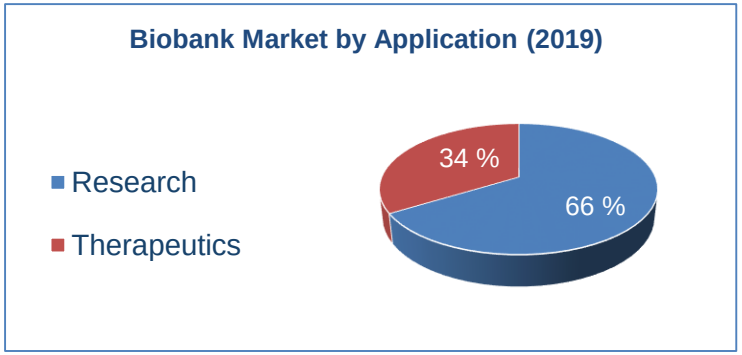
- The **Ethics and Governance Framework (EGF**) is intended to provide a foundation for trust by publicly specifying the standards to which UK Biobank is managed. This included nature of participation of volunteers, principles which govern access to resources by researchers, and the overall management and accountability of UK Biobank towards society. An **Ethical Governance Council (EGC)** was also formed to act as an independent guardian of the EGF.
- However, over a period of years as the UK Biobank matured in its operations, the EGC was dissolved. The EGC was then replaced by a new **Ethics Advisory Committee** as the EGC felt that its oversight role would be more effectively discharged by better integration within UK Biobank as an advisory committee of the UK Biobank Board.

Source: Frost and Sullivan Analysis, ncbi.nlm

Biobank Application Trends

Novel therapeutic innovations in disease areas such as Cancer, Cell and Gene Therapies, etc. are likely to boost demand especially in the therapeutic segment of biobank services

The total biobank market will reach $2,272.5 million in 2019 with research contributing approximately ~66% of the total revenues generated and anticipated to reach $1638.1 million by 2026 with a CAGR of 1.2% in 2019-2026. The Therapeutic segment is likely to witness growth at a CAGR of 1.9% in the same period.



Category	CAGR (2019-2026)
Research	1.2%
Therapeutics	1.9%

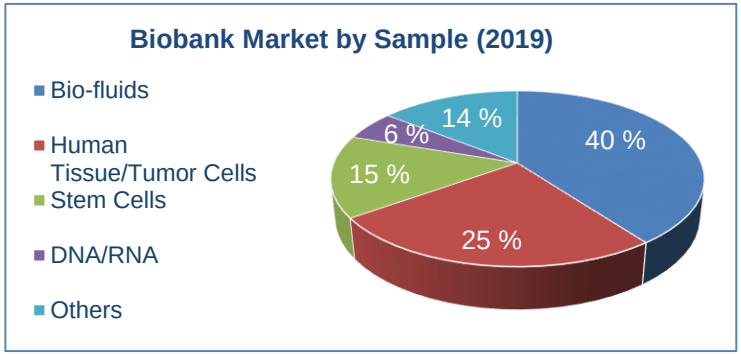
- **Medical research** in the UK continues to flourish with strong collaborative efforts of the Government, charities and industry. Some of the **key future areas** highlighted by Medical Research Council include **brain injuries in newborn, rare diseases, mental health, genomic medicine, blood cancer**, etc.
- The Government is aggressively investing financially and scientifically into this market segment for better clinical and translational research. For example the Manchester Cancer Research Centre has provided large quantities of biological samples for cancer research purposes.
- A large number of **research institutes utilize samples** for their ongoing research studies which are either commercial or academic in nature. For instance **Cancer UK** has projects that span from imaging, clinical development to drug discovery. It is currently supporting **a total of 30 drugs in pre-clinical** and clinical development, **3 drugs in phase II/III trials** and **8 already on the market**
- **Cell Gene and Tissue Therapeutics (CCGTT)** based in UK incorporates the UCL/RFH Biobank that stores both non-therapeutic and therapeutic research **samples for research and clinical trials** especially in the **areas of regenerative medicine applications**

Source: Frost and Sullivan Analysis, AMR Market Study

Biobank Sample Trends

Growth will be driven by Stem Cells and Tissue cells in UK Biobanks with novel therapeutic applications especially in oncology, rare diseases and pluripotent stem cell applications in clinical studies

Bio-fluids are the top sample contributors (by revenue) to the UK biobank market and likely to reach $904.7 million in 2019. Highest growth is expected to be in the human tissue/tumor cell category with an anticipated CAGR of 2.2% in 2019-2026, followed by Stem Cells with a CAGR of 1.9% in the same period to reach 670.8 million and 392.0 million respectively in 2026



Category	CAGR (2019-2026)
Bio-Fluids	0.9%
Tissue Cells	2.2%
DNA/RNA	0.5%
Stem Cells	1.9%

- Since the biobanking ecosystem is highly mature in the UK in terms of number of biobanks, large number of therapy areas etc., demand for all types of samples is expected to increase in the next few years
- Bio-fluids such as blood, serum, urine, etc. are regularly collected and form the major portion of the sample due to convenience in access and collection and utility across a large number of areas
- **Stem Cells and Human tissues** are expected to register strongest growth with the increasing applications in cell therapies and chronic and rare disease segment such as in cancer, autoimmune diseases, etc.
- **Tissue samples** present enormous growth opportunities largely due to their applications **in cancer research and diagnosis** however standardization and consistency is essential in terms of sample quality and data. The UK has specialized biobanks for cancer which largely collect tissue samples. Some of the examples include **UCL Human Tissue Biobank**, **Wales Cancer Bank**, etc.
- **Stem cell biobanks** have seen both commercial and academic engagements, especially with the potential of induced pluripotent stem cells **(iPS) applications** in clinical studies and regenerative medicines. Examples include **Cambridge Blood and Stem Cell Biobank**, **UK Stem Cell Biobank**

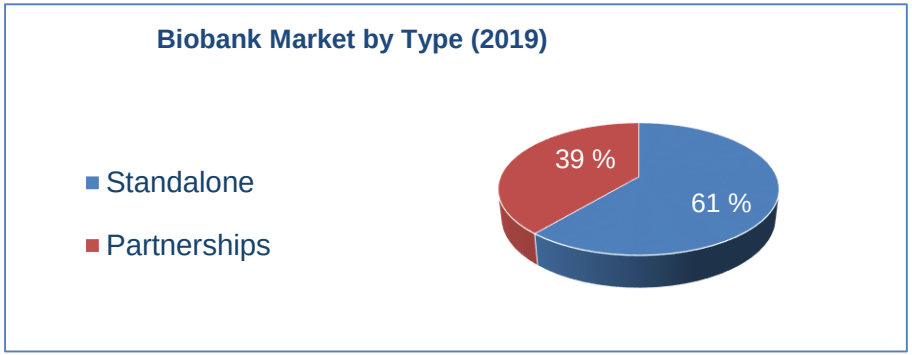
Source: Frost and Sullivan Analysis, AMR Market Study

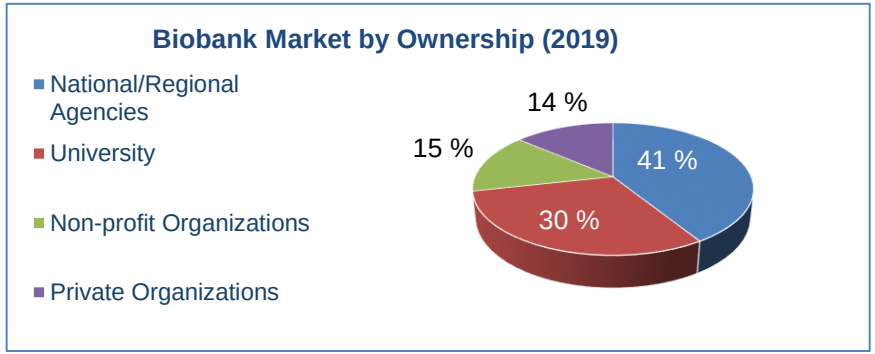
Biobank Other trends

Private organizations with biobanking services are also expected to grow given the increasing demand in samples and sample data applications

The partnership based biobank models are expected to register a growth of 2.1% in 2019-2026 and reach $1,020 million in 2026 ($882.9 mn, 2019). The Standalone segment is likely to grow by 1.0% in the same period

National/regional agencies hold the dominant share and expected to grow by 1.0% in 2019-2026 reaching $1,002 million in 2026 ($934.8 mn, 2019). Private organizations are expected to grow at 2.4% in the same period





- Partnership biobanks are likely to increase with the expansion of network based biospecimen sharing and its widespread applications. For example UK Biobank has a large number of partnerships with regional and global organizations for biobanking services
- Biobanks are being established by various national and regional agencies across the UK. Examples include Wales Cancer Biobank, UK Stem cell Biobank, etc. The Private Biobanking category although small is likely to grow with the widening scope of biobanking activities and partnerships. Biovault is the private human tissue bank in the UK. In 2017, GlaxoSmithKline invested in genetic research to generate genetic sequencing data from UK biobanks.

Source: Frost and Sullivan Analysis, AMR Market Study

Biobank Profiles

Biobank Overview

Biobanks in the UK are highly developed and offer services in specialized therapeutic areas such as cancer, gene therapy applications. The UK Biobank sector is considered a global benchmark

UK Biobank is an **international health resource in the UK** with the aim to improve the prevention, diagnosis and treatment of a wide range of serious and life-threatening diseases- including cancer, heart disease, stroke, diabetes, arthritis, osteoporosis, eye disorders, depression and forms of dementia with a base of 500,000 volunteers in the age group of 40-69. UK Biobank is considered to be a **global benchmark for biobanking services**

- **CIGMR Biobank** supports a number of Manchester-led collaborative research projects requiring large numbers of biological samples for analysis . also works closely with NHS health partners within the Manchester Academic Health Science Centre (MAHSC) in the area of sample management
- The **CCLG Tissue Bank** is the UK's **largest** unique collection of **tumour, DNA** and other **tissue samples from childhood cancer patients**.
- **MCRC Biobank** has been set-up to collect human samples from **cancer patients** in the Greater Manchester area. The Biobank collects tissue, blood and other samples from patients who are undergoing an operation or procedure for a confirmed or suspected diagnosis of cancer.
- **UCL Biobank** focuses on tissue collection and the main aim of developing Biobanking at UCL is to maximize the value of data and biospecimen repositories across all areas.

Source: Frost and Sullivan Analysis, company websites

Biobank Profile

Overview

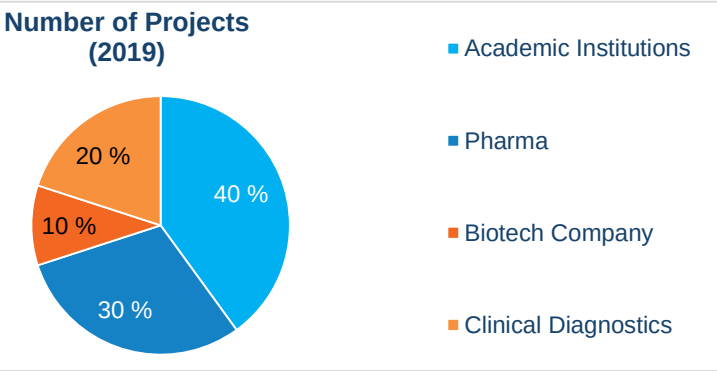
UK Biobank			
Location	UK	Established year	2006
Biobank type	Both population and disease based biobank		
Ownership	Established by the Wellcome trust charity, British heart foundation, cancer research UK, etc. It is also supported by National health services		
Brief overview	▪ UK Biobank is an international health resource in the UK with the aim to improve the prevention, diagnosis and treatment of a wide range of serious and life-threatening diseases.		
Core area of specialization	▪ Largest blood research-based biobank in the world. We work on the objective to improve the diagnosis and treatment of different life-threatening diseases which includes diabetes, cancer and depression. A dedicated team of scientists and other technical staff that are indulged in the sample collection processing as well as in the data processing		
Rationale for prioritizing	▪ One of the global benchmark in Biobanks across the world. It specially focuses on companion diagnostics (biomarker studies), genome sequencing projects and Oncology studies.		
Total number of samples	▪ In Millions		

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

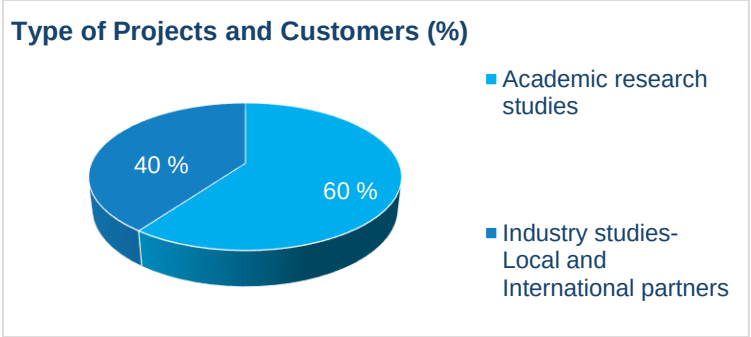
Customer Acquisition

Customer Types and Marketing

Biobank Customer Types



Biobank Customer Project Types



- UK Biobank has engaged in various partnerships with mainly commercial partners such as Pharma, Biotech, as well as academics. The key areas where UK Biobank has engaged with partners are mainly population based studies with both academics and industry studies.UK Biobank genome study is a benchmark in global biobanking practices
- Biomarker studies across different disease areas such as oncology, neurlogy, etc. genome sequencing applications, digital pathology studies, and regenerative medicine applications are the major focus areas of collaboration of UK Biobank with its partners. **Partners such as Amgen, GSK, AstraZeneca, Regeneron Pharmaceuticals, etc. and academic partners such as Bristol University, King's College, etc.**
- UK Biobank is one of the few biobanks in the world which is highly active across different media types such as social media, International conferences and symposiums, etc. **There is a dedicated marketing team with a fixed budget that takes care of outreach activities for the UK Biobank**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

Biobank Engagement Model Alignment

Model	Adoption		Key End Users
	Current	Future	
Research Provider			Academics, Pharma, Biotech, Clinical Diagnostics
Strategic Partnership			Academics, Biotech, Clinical Diagnostics
Service Provider			Pharma, Biotech, Clinical Diagnostics

- For the service provider model, the UK Biobank provides all type of services to the end-users like data processing and analytical tools. In this model, it acts as a one-stop-shop and fulfill all the requirement of the end-users and for the **research provider model, the end-users utilize the data and research of UK Biobank for their individual studies or in their drug development program**. **Strategic engagement model is mainly used for long term project engagements for both samples and data**.

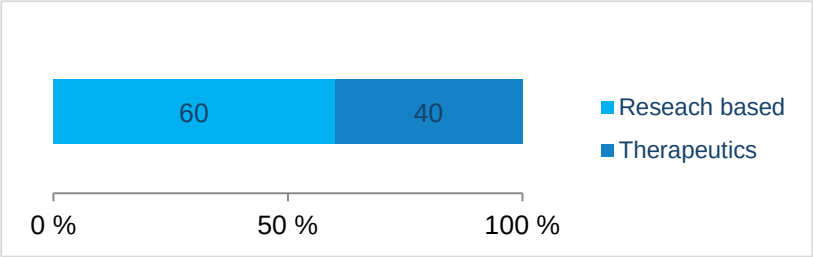
Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

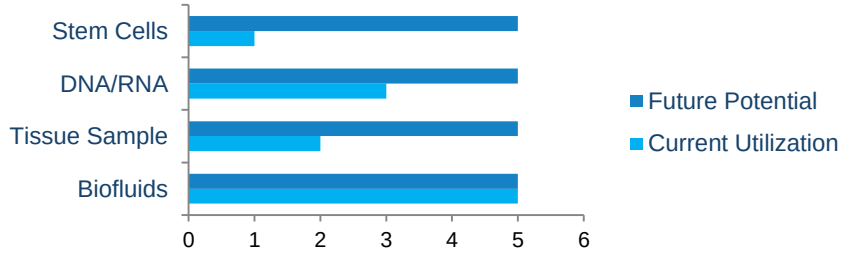
Service Scope

Service Segments

Share from total projects (%)



Sample Utilization



- A fairly large portion of UK Biobank is into population based studies using the healthy samples. For **research based studies, end-users include University of Bristol, King's College of London, etc. whereas for therapeutic based studies, partners include the likes of GSK and Regeneron, Amgen and AstraZeneca**

- Although UK Biobank current utilization of Biofluids is the highest consisting mainly of blood samples, urine, and saliva, it will focus on gaining the competency on other sample types such as tissues, stem cells, RNA/DNA,etc. The key focus areas are likely to remain as biomarker studies, Oncology, Genome sequencing studies and rare diseases studies.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

Biobank Application Area Alignment						
Application Area	**Key competency of your biobank**	**Biospecimens Utilized**	**Key End Users**	**Growth Potential**		**Growth Drivers/ Challenges for your biobank**
				Present	**Future**	
Companion Diagnostic	Biospecimen and Biodata	Blood, saliva, urine	Pharma			Improving patient response by diagnostic studies is a key growth driver however the studies are lengthy and challenging
Genomic Sequence	Biodata	Blood, saliva, urine	Pharma			Increase in demand from the pharmaceutical companies for genomic studies acts as growth driver, however analysis of data is difficult
Oncology Clinical Development	Biospecimen type and Biodata	Blood, saliva, urine	Pharma, Academics			Increasing number of drugs in the pipeline for the companies is a key driver for oncology related studies, however the biggest challenge is maintaining sample quality
Real World Evidence	-	-	-	-	-	-
Digital Pathology	-	-	-	-	-	-

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Drug Development Value chain competency

Application type	Expertise (Scale)	Number of Studies	Key End Users
Target identification and validation		Large number of studies. Difficult to give a approximate number	Pharma
Lead identification and optimization			
Preclinical			
Phase I			
Phase II			
Phase III			
Phase IV (RWE studies, Post marketing, etc.)			

- For any of the clinical development projects, **UK Biobank has adopted a highly standardized approach**. The s**cientific team first evaluates the request of the samples and then the ethical team provides the samples to the end-users**. There are cases where they provide sample analysis and share the data when the sample count is low. UK Biobank also provides data as a service to our researchers for numerous studies. Apart from the UK biobank projects, there are number of studies in rare diseases of which UK Biobank is a part.
- UK Biobank does not focus on a single therapeutic area and it considers the request from the end-users for samples based on the project demand.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Financial Sustainability

Biobank Funding Sources

Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Fee for service			Academics, Pharma, Biotech, Clinical Diagnostics

- There are multiple funding partners for UK Biobank such as **Wellcome Trust, Department of Health (DoH), Medical Research Council (MRC), Cancer Research UK, Diabetes Research UK** and so on.
- The funding is either a core funding for sample storage and management and an additional funding for support to any project based requirement. For instance, the **MRC has allocated a core funding of £29.4m (2010-2022), while it provided £18.9m for establishing & delivering an MRI imaging study of 100,000 participants**
- UK Biobank **does not consider financial sustainability as a challenge to its operations as it is well funded by the donors**. However it admits that there are factors such as **insufficient commercial partnerships, and well defined pricing as key factors that impact financial sustainability for any biobank.**
- UK Biobank has only utilized fee for services based model for all its end-users. **Fee for samples and data is priced differently and is also based on the type of project requirement. UK Biobank also includes an initial registration cost to the end-users as well.**

Biobank Sustainability

Operational Sustainability Focus- Sample Management

Sample Management	
Function	**Key Value Proposition**
Sample Collection	Highly skilled people dedicated for sample collection activities
Sample Processing and Storage	Centrifuge, autoclave and other equipment for the sample storage as well as for the processing. Cryopreservation is used for maintenance
Sample Maintenance	
Sample Retrieval	Well established guidelines and procedures for sample retrieval
Quality Control Procedures	Established procedures

Biobank Cost Drivers

- Major constituents of the cost drivers for the UK Biobank include **skilled resources for sample collection and processing, cost of freezers and cryopreservation**. As far as the data storage and management costs, it is the software and a dedicated team to manage all the data related problems which adds to the cost burden for the Biobank.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (1/3)

Data Management Application Area				
Function	Key End User	Application Area	Adoption	
			Current	Future
Exogenous Data	Pharma, Academics	Genome sequencing		
OMICS/Dx Data	Pharma, Academics	Companion diagnostic and Genome sequencing		
Clinical Data	Pharma, Academics	Oncology and companion diagnostics		
Remote Care Data	-	-	-	-

Data Management	
Function	Key Value Proposition
Data Collection	Large number of data sets approx. of 500,000 individuals
Data Processing and Storage	Specialized tools and software for easier data processing and storage
Data Analytics	A dedicated team for data analytics and data sharing with other partners
Data Sharing	

- UK Biobank has extensive sources of data that it manages and it utilizes them across a large number of studies be it research or therapeutic based. All the data related functions are used in-house and UK Biobank generally utilizes LIMS and barcoding based systems for data management and tracing of samples respectively.
- The biobank has also established portals based on the type of data, for instance **UK Biobank Axiom Array content summary provides an overview of the content of the UK Biobank Axiom Array (which comprises 820,967 genetic markers). For genetic data, UK Biobank has a portal from which information about genotypes, exome sequences, whole genome sequences can be derived.**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (2/3)

Data Security and Privacy	
Parameter	**Current Proficiency**
Compliance to data privacy (EU GDPR, etc.)	
Established policy guidelines	
Dedicated personnel or data security manager	
Adherence to the patient consent norms	

Data Access Framework	
Parameter	**Current Proficiency**
Open Access Model	No
Control Access Model	Yes
Tiered Access Model	No
Existence of Institutional review board (IRB) for biospecimens sharing	Yes
Privacy and confidentiality protection	Yes

- UK Biobank has an **established IRB team that takes care of all the samples and data request that it receives from the end-users**. Furthermore only if the access if granted then the user can be allowed to utilize the sample data. UK Biobank has its own set of guidelines in order to prevent any breach of the data and maintain confidentiality and privacy.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

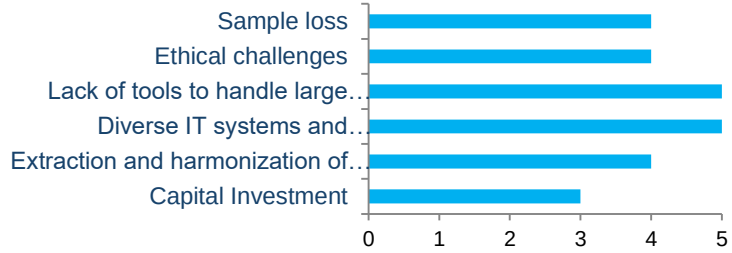
Operational Sustainability Focus- Data Management (3/3)

Digitization- One Stop Access

Type of Access	Adoption	
	Current	Future
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease Registers		

Digitization- Key barriers

Key barriers



- UK Biobank has been one of the pioneers in the biobanking services and it has utilized the available data to make it useful and accessible through portals and virtual access. **The portal can have a direct access link wherein the end-users can easily connect to the Biobank and send queries for any sample or data type.** Furthermore the **direct contact enables the end-users to approach the research team thus effectively minimizing the time lag between query initiation and closure**. While the UK Biobank has robust offerings of data through portals, it will focus on further improvising upon the features and the details in order to reduce turn around time and increase productivity.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

Regulatory Scenario		
Model	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		-
Is the prevailing patient consent system efficient in biobanking activities		To increase trust building measures for the donors to remove their concerns around patient consent
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		-

Collaborations

P3G PUBLIC POPULATION PROJECT IN GENOMICS AND SOCIETY

BBMRI Biobanking and Biomolecular Resources Research Infrastructure

- Obtaining Patient consent is a challenge for the UK Biobank due to the large population enrollment. Other challenges include data analysis of large volumes of datasets and its conversion from raw form to a more user-friendly format. UK Biobank adheres to all the relevant norms and laws such as Research Governance Frameworks of England, Governance Arrangements and Supplementary Operational Guidelines for NHS Research Ethics Committee and the GDPR guidelines very strictly.

- **UK Biobank is a partner to several networks which include BBMRI, P3G**, etc. By participation in such networks a biobank can easily work with different other biobanks and can share as well as can extract the required data. Apart from this, **it also helps in collaboration among biobanks for the joint studies**. There are some government-funded studies, where different biobanks work together to accomplish the goals.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

Biobank Future Outlook	
Customer Acquisition	UK Biobank focus will continue to be on working across wide customer types including academics and commercial partners such as **Pharma, Biotech, Clinical Diagnostics, CSOs, and Healthcare technology in that order**. It considers to utilize **service provider, research based engagements and strategic partnership more prominently in the future with the end-users**.
Service Scope	UK Biobank **will focus on understanding the role of genetics in the lifestyle of the patient**. It will **expand its partnerships with the Pharma companies especially in diagnostic studies, and genome sequencing applications in chronic disease like heart disease, cancer, stroke and other life-threatening diseases.**
Financial Sustainability	Although the UK Biobank is well funded by the agencies, i**t will seek to increase commercial partnerships especially with Pharma in drug development projects**. UK Biobank considers the fee for service pricing model optimum for most of the engagements and will continue to utilize it for both commercial and academic partners
Operational Sustainability	UK Biobank considers **both samples and data services (especially collection of exogenous data for lifestyle studies) as key focus areas**. UK Biobank considers one access to services as a future growth initiative and major features being efficient access to sample information and sample data
Social Sustainability and Collaborations	**UK Biobank considers patient consent for sample donation as a major challenge and it will focus on initiatives and awareness programs that enunciate the benefits associated with the biobanks and address concerns of the donors**. It will also consider collaborating with external organizations as a key means to become aware of the requirements of the end-users, capabilities of the other biobanks and access to new-technologies

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Profile

Overview

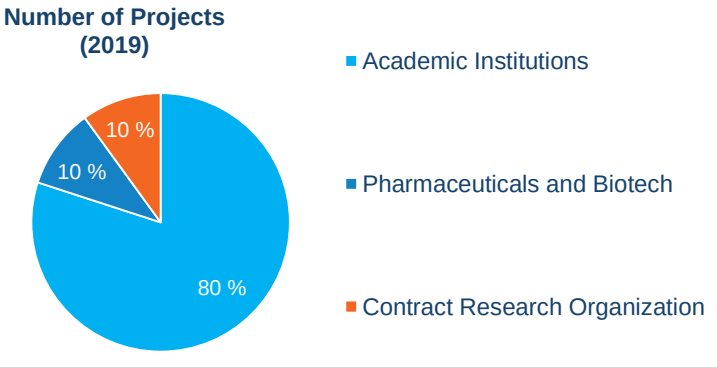
CIGMR Biobank			
Location	UK	Established year	2001
Biobank type	Focus on both population and disease based studies		
Ownership	University Manchester		
Brief overview	▪ CIGMR Biobank supports a number of Manchester-led collaborative research projects. It also works closely with NHS health partners within the Manchester Academic Health Science Centre (MAHSC) in the area of sample management and has established shared sample tracking and quality assurance (ISO 9001:2008) systems with Salford Royal NHS Foundation Trust.		
Core area of specialization	▪ Large scale sample collection and collaboration is mainly with academic research institutes. As far as the core specialization area, the Biobank works mainly in the field of biomedical research in population health and genetics		
Rationale for prioritizing	▪ CIGMR Biobank specializes in biomarker based studies, genome sequencing projects and Oncology and has considerable experience in biobanking services in UK		
Total number of samples	▪ ~60,000 samples		

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

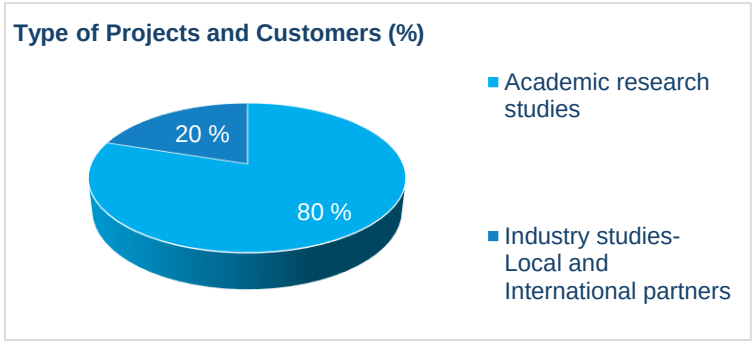
Customer Acquisition

Customer Types and Marketing

Biobank Customer Types



Biobank Customer Project Types



- Majority of CIGMR Biobank customers are in Academics. Major partners include **The University of Manchester, Salford Royal NHS Foundation Trust and Manchester Mental Health and Social Care Trust** for its research based projects. **CIGMR Biobank has also partnered with AstraZeneca for its industry based studies**
- Although CIGMR Biobank is active across all major marketing avenues including **print media, social media and participation in conferences and networks**. **There is a dedicated team for marketing activities in CIGMR Biobank and a separate annual budget for the marketing activities**.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

Biobank Engagement Model Alignment			
Model	Adoption		Key End Users
	Current	Future	
Strategic Partnership			Academic, Pharma, and CSO

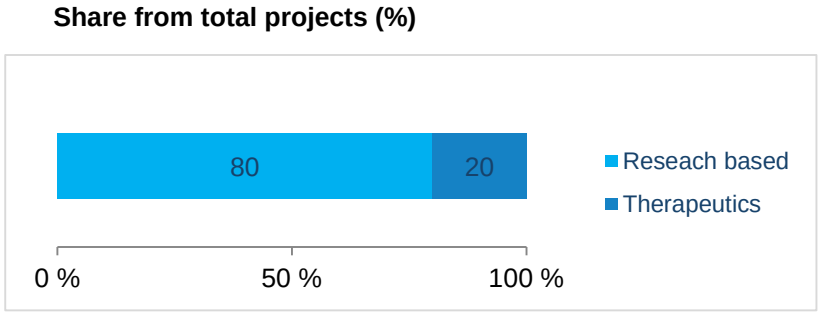
- In the strategic partnership model the **CIGMR Biobank and the company collaborates for long term, such as for a period of 4-5 years and the services utilized are mainly for samples and data**. CIGMR Biobank **only engages in long term partnerships through this model** and it has well defined terms and conditions.

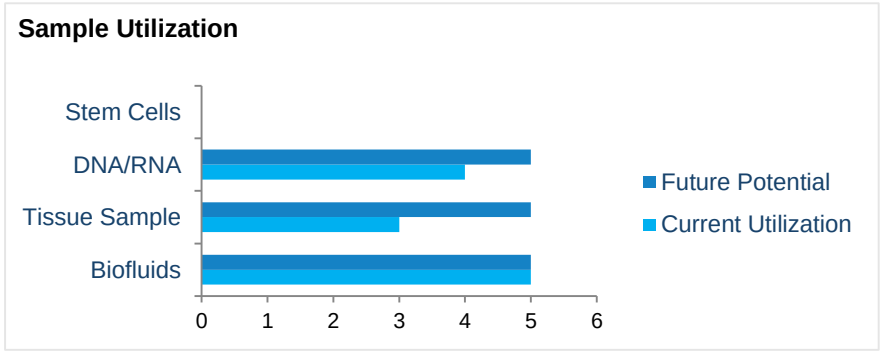
Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Service Segments





- Major partners for CIGMR Biobank include **The University of Manchester, Salford Royal NHS Foundation Trust, University Hospital of South Manchester and The Christie Hospital NHS Foundation Trust research** based projects using both healthy samples (population based studies) and disease samples. **CIGMR Biobank has also partnered with AstraZeneca for therapeutic based engagements**.
- Sample utilization of the biofluids is high for CIGMR Biobank mainly due to the utilization of blood, saliva, serum, in biomarker studies and genome sequencing applications. which are expected to increase in the future for the biobank. CIGMR Biobank has utilized tissue samples and the DNA extracts mainly for oncology, rare disease studies and OMICS studies.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

Biobank Application Area Alignment						
Application Area	**Key competency of your biobank**	**Biospecimens Utilized**	**Key End Users**	**Growth Potential**		**Growth Drivers/ Challenges for your biobank**
				Present	**Future**	
Companion Diagnostic	Biospecimen type	Blood, saliva, serum	Pharma, Academics			Growth driver for the biobank is the variety of samples that it provides for biomarker studies
Genomic Sequence	Biospecimen type	Blood, DNA, RNA	Pharma, Academics			Analysis of the large scale data involved in genome sequencing studies is a cumbersome task for the biobank
Oncology Clinical Development	Biospecimen type	Tissue, DNA, RNA	Pharma, Academics			Growth driver for the biobank is the demand for the specific cancer tissues that are utilized in such studies. Storage, however, presents a challenge
Real World Evidence	-	-	-	-	-	-
Digital Pathology	-	-	-	-	-	-

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Drug Development Value chain competency

Application type	Expertise (Scale)	Number of Studies	Key End Users
Target identification and validation		2-3	Pharma
Lead identification and optimization		3	Pharma
Preclinical		4	Pharma
Phase I	-	-	-
Phase II		-	-
Phase III	-	-	-
Phase IV (RWE studies, Post marketing, etc.)	-	-	-

- **CIGMR Biobank has worked on oncology based projects for target identification and lead optimization**. In one of the projects for the Pharma, it worked on collecting Anemia blood samples to extract DNA which was used in the diagnosis of leukemia.

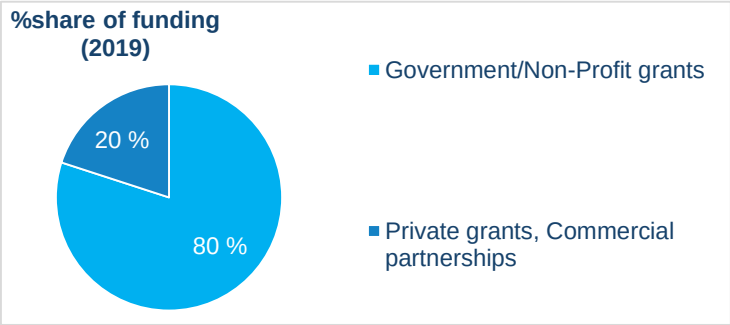
Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Financial Sustainability

Biobank Funding Sources



Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Fee for service			Academic, Pharma,CSO

- **CIGMR considers insufficient commercial partnerships and lack of defined business/pricing models as key factors that influence the financial sustainability of the biobank** . It will focus on increasing the partnerships and collaborating with the pharma companies with defined pricing for services
- **CIGMR Biobank applies a fee for service model to all its end-users where they charge a pre-decided fee for the samples and services provided**. The fee is decided by multiple factors including the complexity of study, type of biospecimen used, research outcomes, etc.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Sample Management

Sample Management	
Function	**Key Value Proposition**
Sample Collection	Skilled resources, regular training programs,
Sample Processing and Storage	PSS Magtration System 8Lx robotic work station which is highly advanced and used for sample processing
Sample Maintenance	Storage at optimum temperatures
Sample Retrieval	Well-developed policies for the sample collection, storage as well as for the sample retrieval
Quality Control Procedures	Standard operating procedures to maintain quality of samples

Biobank Cost Drivers

- The key areas that constitute the cost drivers for CIGMR Biobank include **skilled staff and a variety of equipment**, **use of different types of freezers such as -20, -80 degree, etc., automated tools for sample processing and management, and specialized software or IT systems**.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (1/3)

Data Management Application Area				
Function	Key End User	Application Area	Adoption	
			Current	Future
Exogenous Data	Pharma, CSO	Genome sequence		
OMICS/Dx Data	Pharma, CSO, Academic	Oncology		
Clinical Data	Pharma, CSO, Academic	Oncology, Genome sequence		
Remote Care Data	-	-	-	-

Data Management	
Function	Key Value Proposition
Data Collection	LIMS platform
Data Processing and Storage	LIMS platform
Data Analytics	LIMS platform
Data Sharing	LIMS platform

- While the data collection, processing and storage is done by the CIGMR Biobank, data analytics and sharing is done by outsourcing it to a third party vendor. CIGMR Biobank uses LIMS data management program which is customized and also robotic instruments that enable to achieve 100% accuracy in data based services for the Biobank

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (2/3)

Data Security and Privacy	
Parameter	**Current Proficiency**
Compliance to data privacy (EU GDPR, etc.)	
Established policy guidelines	
Dedicated personnel or data security manager	
Adherence to the patient consent norms	

Data Access Framework	
Parameter	**Current Proficiency**
Open Access Model	No
Control Access Model	Yes
Tiered Access Model	No
Existence of Institutional review board (IRB) for biospecimens sharing	No
Privacy and confidentiality protections	Yes

- CIGMR Biobank has a highly restricted access to samples and data and it could only be accessed from registered users.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (3/3)

CIGMR Biobank

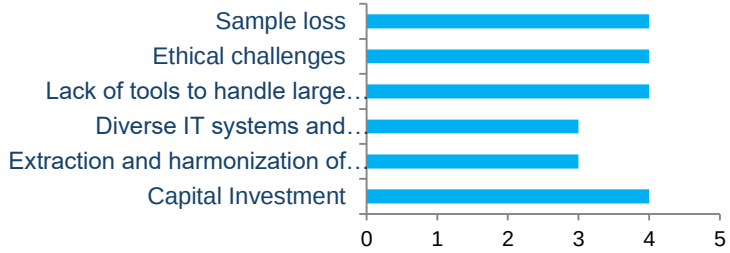
Digitization- One Stop Access

Type of Access	Adoption	
	Current	Future
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease Registers		

Low High

Digitization- Key barriers

Key barriers



- **Access to sample information is the key enabler for the virtual portals which can help the researchers get access to sample information and data**. The **portal can also help the Biobank to reach out to end-users more effectively**. It will also act as a centralized source of query handling and thus reduce turnaround time for the end-users

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

Regulatory Scenario		
Activities	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		-
Is the prevailing patient consent system efficient in biobanking activities		-
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		-

Network Participation

- CIGMR Biobank considers the **current laws and regulations to be proficient for the Biobanking activities**.
- CIGMR Biobank is involved in multiple associations such as Motor Neurone Disease Association, Arthritis Research UK, EU and Innovative Medicines Initiative, BBMRI and UKCRC Tissue Directory. **Participation in these associations help them to know more about the new upcoming information and it also allows to get access to the data which is not available for the biobanks who are not a part of it.**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

Biobank Future Outlook	
Customer Acquisition	For CIGMR Biobank, academics, Pharma and Contract services organizations will be the key potential customers in the future. **Disease based studies will be in focus for Pharma and Academics while with CSOs CIGMR Biobank will collaborate with both disease and population based studies.** CIGMR Biobank will **continue its focus on strategic partnerships in the future to engage with the end-users**
Service Scope	CIGMR Biobank will focus on increasing the sample utilization for tissue and DNA/RNA extracts. The application area focus will likely to be on biomarker studies, genome sequencing and oncology research.
Financial Sustainability	CIGMR Biobank **does not consider financial sustainability as a major challenge as it is supported by the Medical Research Council**. However the Biobank **will strive to increase its commercial partnerships in order to improve the brand reputation of the biobank and the financial condition as well**. It will also work on having well defined pricing models in order to have transparency while working with the commercial partners
Operational Sustainability	CIGMR Biobank has both sample and data based capabilities and it will look forward to **further improve its capabilities especially in collection of exogenous data and clinical data.**
Social Sustainability and Collaborations	CIGMR Biobank will **focus on improving upon patient awareness by organizing camps, etc. so that the patients realize the benefits of sample donation and it will look forward to further increase its participation in networks**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

USA

Market Overview

Executive summary

Ecosystem

- Large number of Biobanks exist in a highly fragmented ecosystem in the US
- Biobanks are a part of many national/global networks. Researchers can get information about biospecimens in specific research areas through these resources.

Regulatory Scenario

- The regulations governing the biobank activities in the US are fragmented with **HIPAA rules, Common rule and Federal/State laws** being applicable as per conditions
- Laws in the US also do not directly address the international sharing of data by the US entities outside of the **EU-US Safe Harbor Agreement**, that applies to receipt of data by US entities from EU countries

Data Infrastructure

- Biobanks have **evolving IT infrastructure** to support **standardization of procedures** and workflows. Cancer Human Biobank (part of National Cancer Institute) is a case in point in standardization of workflows

Initiatives

- A large number of biobanks operate in the US. Some of them focus on niche therapeutic areas such as cancer, stem cells while others are broad in terms of biospecimen collection and research. Examples include All of US Research Program, Cancer Human Biobank, Coriell Institute, etc.

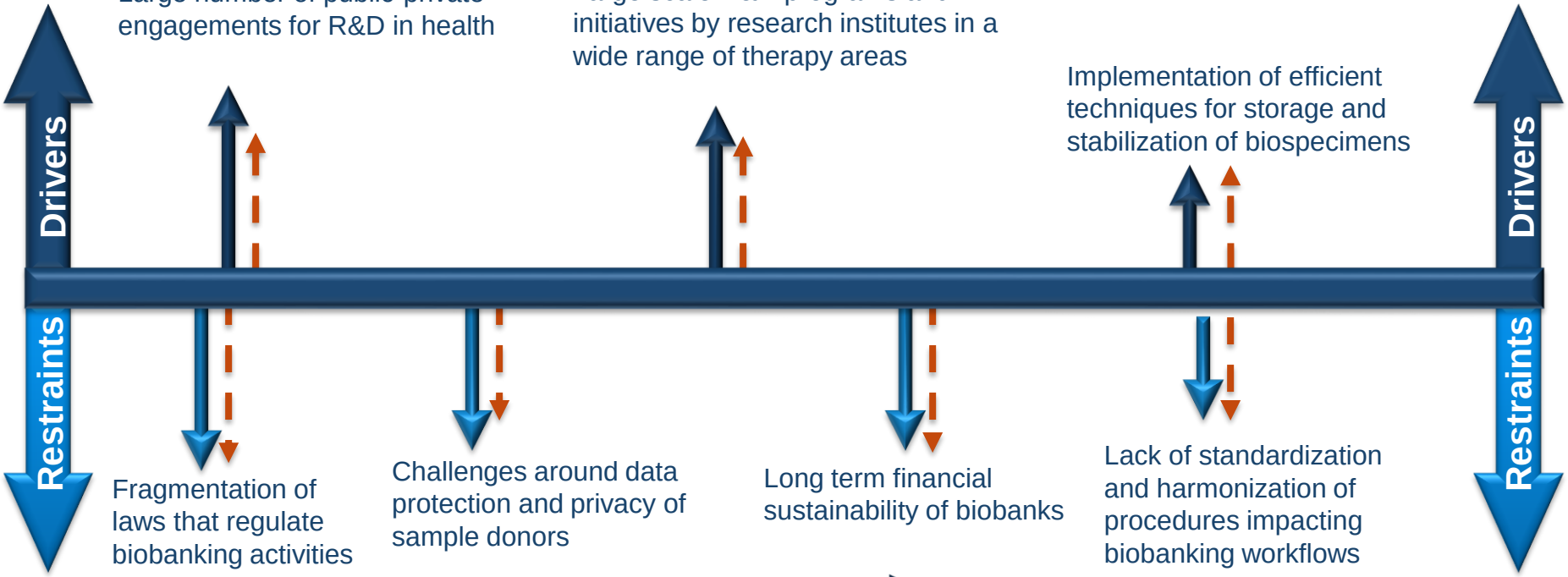
Market Analysis

- Research Applications form ~67% of the total biobanking market while 33% is for therapeutic based applications. While biofluids are the dominant market share holders for biospecimens, the **human tissue samples and stem cells samples are expected to grow by 6% and 4.4%** CAGR (2019-2026) respectively
- Large number of programs aimed at **expanding precision medicine applications** are ongoing in the US. The **Precision Medicine Initiative (PMI)** by the **US Government** was launched in 2016 with a short term focus on **oncology applications** and long term expansion of the program to cover **other health areas**. Another key stakeholder for the Precision Medicine Initiative, is the **National Cancer Institute (NCI)** that has supported precision medicine research through a **large number of studies and centers of excellence**.

Source: Frost and Sullivan Analysis

Drivers and Barriers

Large scale R&D initiatives in wide therapy areas and public-private partnerships are major growth drivers



Source: Frost and Sullivan Analysis

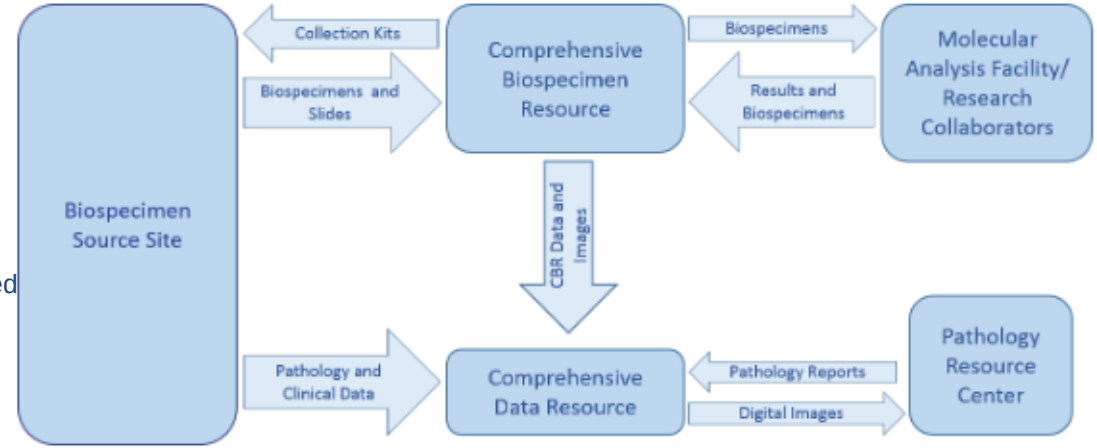
Biobank Data Infrastructure

Biobanks have evolving data infrastructure to support standardization of procedures and workflows. Cancer Human Biobank (part of National Cancer Institute) is a case in point in standardization of workflows

- There are a large number of biobanks in the United States which are largely associated with universities and Government institutes along with certain private organizations offering biobanking services
- The harmonization and standardization procedures in the US Biobanks have been slow to adopt given a large number of factors such as standards for informed consent, preservation, storage, rights management, material transfer agreements, classifications and other such factors.
- The Cancer Human Biobank- caHUB (previously known as The US National Cancer Biobank) was the pioneer to introduce standard operating procedures in Biobanking services an effort to streamline the process workflow

- **Biospecimen Source Sites (BSS):** organizations, such as academic medical centers, rapid autopsy centers, and organ procurement organizations that acquire and ship biospecimens
- **Comprehensive Biospecimen Resource (CBR)**: a centralized site that assembles collection and shipping kits, receives biospecimens from the BSS for processing and storage
- **Comprehensive Data Resource (CDR):** a centralized data storage facility that obtains patient and biospecimen data from BSS and other program sites that handle and analyze samples.
- **Pathology Resource Center (PRC):** a network of board certified pathologists who review H&E sections from collected tissue biospecimens to confirm patient diagnosis and provide tissue quality metrics.
- **Molecular Analysis Facilities (MAFs):** carry out molecular analysis on collected biospecimens.

Process Flow and IT Infrastructure (caHUB)



Biobank Initiatives

World class Research Institutes and large public private partnerships in novel therapy applications are expected to act as key growth drivers in the US

Key Growth Drivers

Public-Private Partnerships

Large number of programs and initiatives are a result of public-private partnerships between private organizations and research institutes

World-Class Research Ecosystem

USA has some of the highly recognized and top universities and research institutes that engage in cutting edge research

Policy and Vision

The Government has initiated several national initiatives with long term vision to impact health positively

Research and Therapeutic Focus

Key priority areas include novel applications in oncology, regenerative medicines, etc.

Case Examples

- The **Precision Medicine Initiative** is a long term endeavor of the US Government that was launched in 2016 by President Obama with a budgetary allocation of $215 million. **Short term** goals of the initiative involve **expanding precision medicine in the area of cancer** research. The **long-term** goals of the Precision Medicine Initiative focus on bringing precision medicine to **all areas of health and healthcare** on a large scale. The initiative would adhere to privacy protection and review regulatory modernization to facilitate innovation .

- As a key stakeholder for the Precision Medicine Initiative, the **National Cancer Institute (NCI)** has supported precision medicine research through a large number of studies and centers of excellence. These include **NCI Translational and Therapeutic Studies** for **targeted therapeutics**, **NCI Genomics and Cancer Biology** Research for high-throughput techniques to **identify mutations in DNA/RNA, proteins**, **NCI Immunology and Immunotherapy** Research for **immunotherapy studies**, both extramural and intramural, **NCI Cancer Imaging** Research for **latest diagnostics tools** for oncologists, etc.

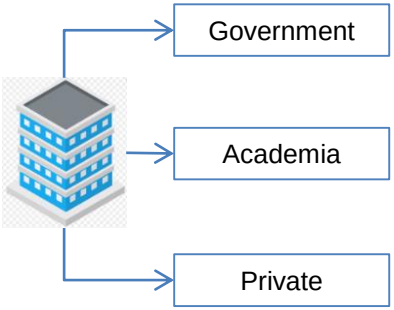
- **All of the US Research Programs** are a component of the Precision Medicine Initiative. The program aims to collect health and wellness data from 1 million or more Americans with the goal to advance precision medicine. Besides this, the program aims to become the nation's largest and most diverse research cohort with plans to oversample communities that are underrepresented in past research activities

- Furthermore, there are a **large number of research institutes and initiatives** in **Gene therapy and Stem cell** applications such as **Cure Sickle Cell initiative** by the NIH, **National Human Genome Research Institute**, **public-private partnership by Harvard-MIT** in gene therapy, **IQVIA- CIRM** (California Institute for Regenerative Medicine) partnership, etc.

Source: Frost and Sullivan Analysis, ord.harvard.edu

Biobank Initiatives

Biobanks are a part of many national/global networks. Researchers can get information about biospecimens in specific research areas through these resources.



- Biobank market in the USA is fragmented with a large number of biobanks functional in the country. On a **broad level** the Biobanks can be classified as either **Government, Academia or private**.
- Some of the biobanks are **actively supported by Government departments or agencies**. For example National Cancer Institute supports tissue based resources/networks such as **Specialized Programs of Research Excellence** (SPORE), **NCI Cooperative Group Human Tissue Resources** (CHTN), the **Early Detection Research Network** (EDRN), etc.
- A large number of Biobanks are instituted within universities with collaboration and funding from the Government agencies. For example Duke University Breast SPORE, **University of Mississippi Medical Center (UMMC)** Biobank, University of Pittsburg Medical Center- **Health Sciences Tissue Bank (HSTB)**, etc.
- **Private organizations** also provide biospecimens for research. Some of them include **Centogene AG**, which provides biobanking facilities especially in rare disease research, **ProMedDx** provides biospecimens and related services which are individualized, and offer precise treatments in the U.S.

Biobanks in the US are a part of **several national and international resources** that provide information about biospecimen availability and research focus of the network. Some of the major networks/resources are highlighted below:

Examples of Biobank Resources in the US

NIH National Cancer Institute Specimen Resource Locator
Coriell Institute for Medical Research
AATB American Association of Tissue Banks
NIH National Heart, Lung, and Blood Institute
emerge network Electronic Medical Records and Genomics
CHTN Cooperative Human Tissue Network
isber-irl
GTEx Portal
NIH National Institute of Neurological Disorders and Stroke
NIH National Institute on Aging
NIH National Institute of Diabetes and Digestive and Kidney Diseases

Source: Frost and Sullivan Analysis, specimens.cancer.gov

Regulatory Scenario

The regulations governing biobank activities in the US are fragmented with HIPAA rules, and Federal/State laws applicable to the biobanks on a case by case basis

Biobanking Laws and Regulations

- Privacy of the individual is protected as per **the HIPAA rules** and Federal Policy for Protection of Human Subjects. The rules are not unique to biobanking based research and are not applicable to every biobank or biobank based research.
- **Common Rule (CFR title 45 part 46)** also applies to human subjects and includes requirements for Institutional Review Board (IRB) review and informed consent from the participants. Other Federal/State laws are also applicable to the biobanking services and research
- Laws in the US also do not directly address the international sharing of data by the US entities outside of the **EU-US Safe Harbour Agreement**, that applies to receipt of data by US entities from EU countries

HIPAA and Biobanking

- **Who does HIPAA regulate**: Covered entities, Health plans, healthcare clearinghouses, and healthcare providers. A Biobank is part of an institution that provides health care and stores and transmits medical records electronically. Therefore, the Biobank is a covered entity according to the statute.
- **What does HIPAA regulate**: Protected health information, also known as individually identifiable health information. Biobanks collect samples that have the information related to the past, present, or future medical status of a specific person and contains information sufficient to identify the person

Case Study

MAYO CLINIC

Mitochondrial Disease Biobank

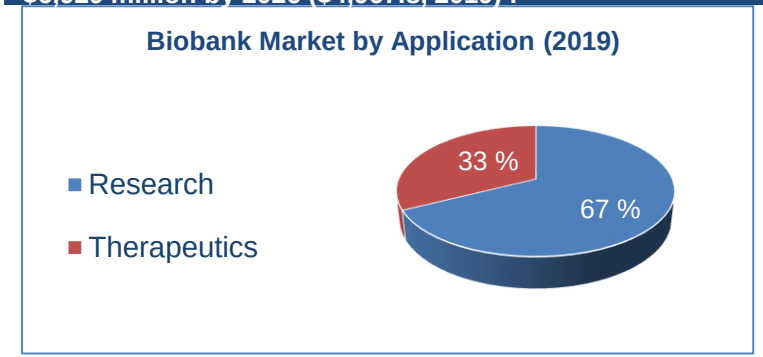
Case example in the Biobank	Does HIPAA apply	Comments
A woman agrees to join a BB study, requests to send an enrollment form for herself and her sister	No	Both demographic and medical information must be shared for falling under HIPAA rules
A man sends a mail regarding his struggle with mitochondrial disease and attaches list of family members with details about symptoms and diagnosis, names and address	Yes	Demographic and medical information is shared hence will fall under the purview of HIPAA rules
A woman requests enrollment information for herself and asymptomatic son. Provides his contact number	Unclear	HIPAA can only apply if there is information that relates to past, present, future medical condition

Source: Frost and Sullivan Analysis, mayo.edu

Biobank Application trends

Globally recognized institutes with broad research areas and novel treatment applications such as digital pathology, imaging studies etc, are expected to boost biopecimen demand in the US

The total biobanking market stands at $15,285 million in 2019 and growing at a CAGR of 4.4% in 2019-2026 to reach $20,653 million by 2026. The Research segment is the highest contributor to the biobanking market and anticipated to reach $13,724 million by 2026 ($10,317.7 million, 2019) with a CAGR of 4.2% in 2019-2026. The Therapeutic segment is likely to witness growth at a CAGR of 4.9% in the same period to reach $6,929 million by 2026 ($4,967.8, 2019) .



Category	CAGR (2019-2026)
Research	4.2%
Therapeutics	4.9%

Research applications growth

- Research applications are likely to dominate Biospecimen utilization due to highly diverse research areas which are well supported by the Government.
- **National Institute of Health (NIH)** is a global pioneer in research applications and engages in multidisciplinary research through various specialized centers such as the National Cancer Institute, National Institute for Aging, National Institute for Diabetes and Kidney, etc. Such research centers are major drivers for the utilization of biospecimens across applications

Therapeutic Applications growth

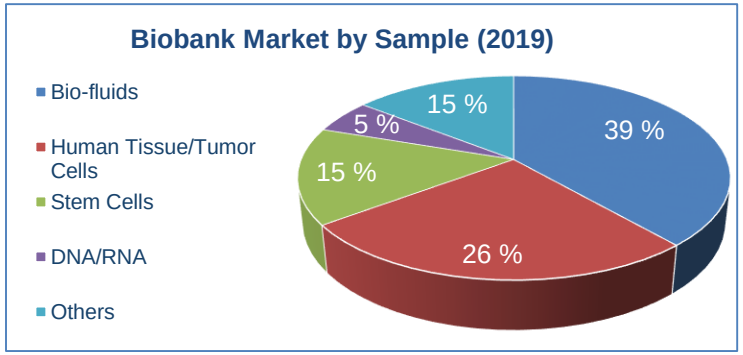
- Therapeutic applications for the biospecimens has seen growth largely due to treatment innovations especially in cell-based therapeutics and precision medicine applications
- Novel therapeutic applications especially in i**mmuno-oncology, companion diagnostic and molecular diagnostics applications**, etc. are further likely to boost biospecimen demand.
- Commercial applications of digital pathology in **pre-clinical pathology/imaging** that have lately seen greater activity from Pharma, Medical Devices and academia are further expected to boost biospecimen demand for such studies

Source: Frost and Sullivan Analysis, AMR Market Study

Biobank Sample Trends

While Biofluids remain the dominant category, demand from the Human Tissue samples and Stem cells are expected to increase due to applications in gene therapy, pluripotent cell lines, etc.

Bio-fluids segment was the highest contributor to the biobanking market, with $6,077 million in 2019 and is anticipated to reach $7,850.2 million by 2026, registering a CAGR of 3.7%. Stem Cells segment is anticipated to reach $3,112 million by 2026 at a CAGR of 4.4%. Human Tissue/Tumor Cells segment are expected to witness growth at a CAGR of 6.0%, during the forecast period.



Sample Type	CAGR (2019-2026)
Bio-Fluids	3.7%
Tissue Cells	6.0%
DNA/RNA	2.3%
Stem Cells	4.4%

- Biofluids such as blood, urine, saliva, are the most common forms of samples collected in studies and its widespread applications
- **Human tissues and Stem cells** remain the top growth samples for biobanking applications
- Large number of applications of **human tissue** are prevalent in the US research institutes especially in areas such as **Cell- biology, Microbiome research, Oncology therapeutic applications**, etc.
- Human tissue specimens have been increasingly applied in targeted therapies such as **HER-2** which made use of the human tissue samples to detect breast cancer, and has been expanded to **other forms of cancer.**
- Furthermore research programs such as **CHTN, SPORE programs**, and private organizations such as bioserve, etc. serve as major centers for **tissue samples storage** besides other sample types.
- **Stem cell samples** are also increasingly utilized by the research institutes in different application areas such as **regenerative medicine, gene therapy treatments, iPSC**. Several research institutes such as the National Institute for Biomedical Imaging and Bioengineering, etc., organizations such as International Society for Stem Cell Research, and **private companies such as Reprocell, Bioserve, ATCC**, etc. routinely utilize stem cells for research

Source: Frost and Sullivan Analysis, AMR Market Study

Biobank Other trends

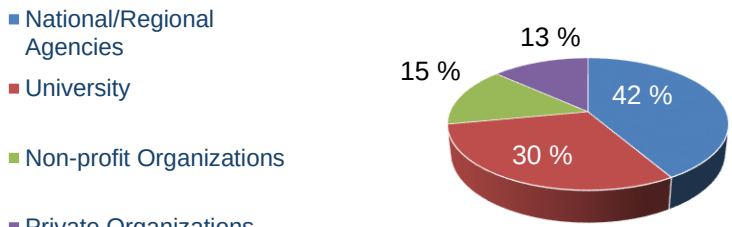
Private organizations are likely to grow further with the widening scope of biobanking activities and advanced data analytics capabilities.

Partnership based biobanks are expected to register a growth of 4.7% in 2019-2026 and reach $8,264 million in 2026 ($6,129 million, 2019). The Standalone segment is likely to grow by 4.2% in the same period

Biobank Market by Type (2019)

National/regional agencies hold the dominant share and expected to grow by 3.9% in 2019-2026 reaching $8,326 million in 2026 ($6,351.1 million, 2019). Private organizations are expected to grow at 5.4% in the same period

Biobank Market by Ownership (2019)



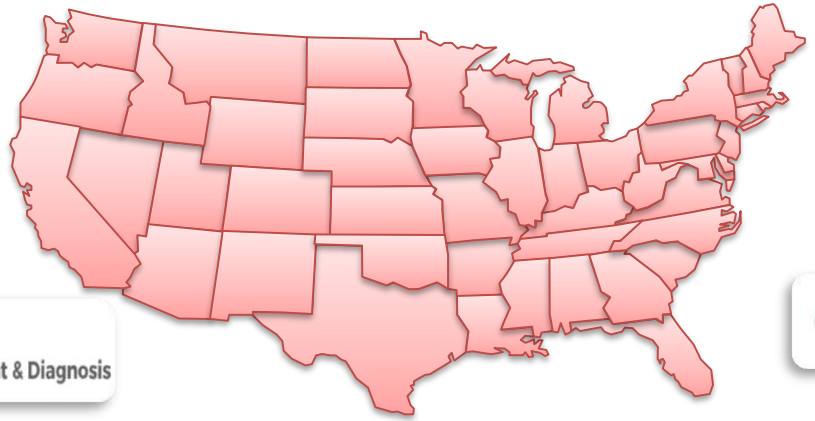
- Partnership based biobanks in the US such as the All for US program, caHUB, etc. are likely to grow further given the increasing demand for biospecimens for research purposes and participation in network based activities
- Biobanks are being established by various national and regional agencies across the U.S. Examples include UMMC Biobank, Duke BRPC Durham, etc. Private Biobanking category although small is likely to grow with the widening scope of biobanking activities and increase of data sharing and analysis capabilities

Source: Frost and Sullivan Analysis, AMR Market Study

Biobank Profiles

Biobank Overview

A large number of biobanks operate in the US with some having a focus on a specific therapy such as cancer and others on wide range of therapeutic applications



A large number of biobanks exist in the United States; some of them focus on niche therapeutic areas such as cancer, stem cells while others are broad in terms of biospecimen collection and research.

- **All of US Research Program**- This program is a part of the NIH initiative to advance Precision Medicine applications and the goal is to collect more than a million samples from people across the country through a wide range of sources such as health surveys, EHRs, etc.
- **National Cancer Institute**- NCI has supported a large number of initiatives that involve biospecimens for cancer research purposes. Some of the initiatives include Cancer Human Biobank (caHUB), Cancer Moonshot Biobank, Genotype-Tissue Expression (GTEx) Biobank, etc.
- **The AIDS and Cancer Specimen Resource** (ACSR) biorepository includes biospecimens from persons with HIV/AIDS who have been diagnosed with a wide spectrum of HIV/AIDS-related diseases, particularly cancers, pre and post-HAART.
- Established in 2008, the **Coriell Stem Cell Biobank** has developed core capabilities to maintain, characterize, bank, and distribute important stem cell resources provide scientists to bank their pluripotent stem cell lines, and to develop in-house induced pluripotent stem cell (iPSC) lines for distribution to researchers.
- The **University of Mississippi Medical Center (UMMC)** established the UMMC Biobank to support translational and clinical research in addition to serving as the tissue bank core of the Cancer Center and Research Institute.

Source: Frost and Sullivan Analysis, company websites

Biobank Profile

Overview

Kaiser Permanente Research Bank			
Location	USA	Established year	2000
Biobank type	Focus on both population and disease based studies		
Ownership	Kaiser Permanente		
Brief overview	▪ Kaiser Permanente Research Bank is the second largest biobank in the US. ▪ It provides an exceptional opportunity to enable research studies related to the prevention, diagnosis and treatment of disease.		
Core area of specialization	▪ Prime focus is to assist the end-users for precision medicine applications by providing high quality samples. KP Research Biobank also has partnerships in order to provide samples that are not available in-house from the partners		
Rationale for prioritizing	▪ KP Research Biobank is the second largest biobank in the US and has extensive research capabilities in genome sequencing, oncology, reproductive health, chronic disease and specialty diseases		
Total number of samples	▪ ~1.5 million		

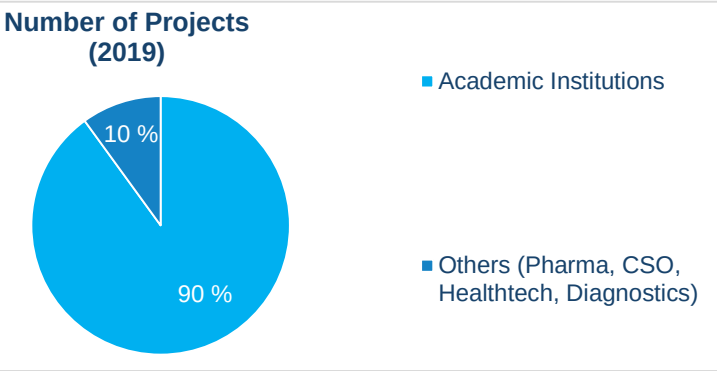
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

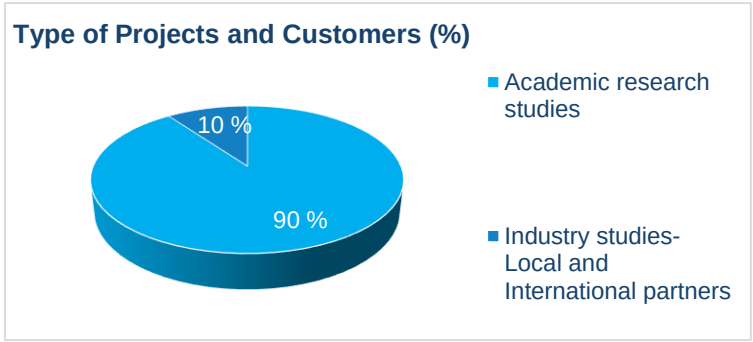
Customer Types and Marketing

KAISER PERMANENTE® RESEARCH BANK

Biobank Customer Types



Biobank Customer Project Types



- Majority of the KP Research Biobank customers are academic institutions. Major partners include **University of California San Francisco, Stanford University School of Medicine, University of California Berkeley and Kaiser Medical Group**. which are the source of research based projects. **Average range of value for projects- both Academics and industry studies is between 1-2 million USD per project**.
- KP Research Biobank **customer outreach is primarily through conferences or medical universities magazines in order to spread awareness regarding biobank activities**.
- **On an average ~2-3% of the total revenues is dedicated for marketing activities of KP Research biobank**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

KAISER PERMANENTE® RESEARCH BANK

Biobank Engagement Model Alignment

Model	Adoption		Key End Users
	Current	Future	
Research Provider			Academics, Pharma, Biotech, Contract Services Organization, Diagnostics
Strategic Partnership			

- KP Research biobank follows the **service provider model mainly for short term engagements** with the end-users for both samples and data based services. Such model effectively utilizes the resources of the Biobank based on the end-user requirement. **Strategic partnerhsip model is preferred by the KP Research Biobank for long term engagements with the end-users**. Here the partnership is **not just for a single project and there is more flexibility in terms of fulfilling the requirement of end-users for both samples and services**

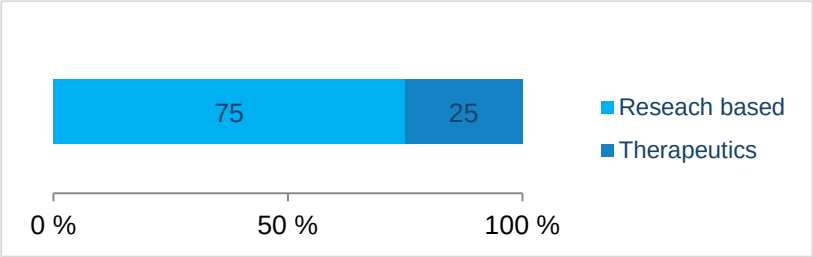
Low High

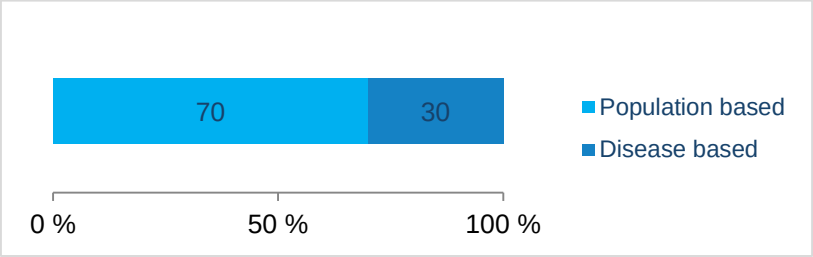
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

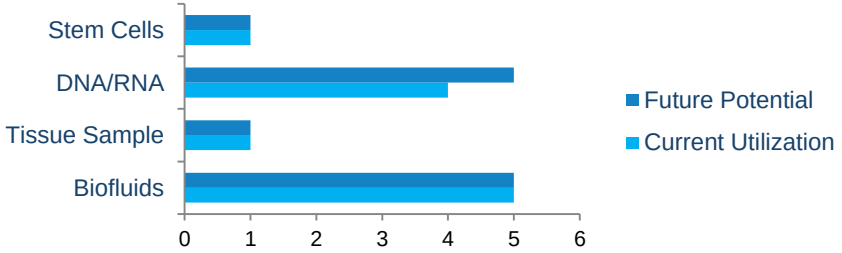
Service Segments

Share from total projects in % (2019)





Sample Utilization



- The research based studies are a majority for KP research Biobank and the average value for such studies is approximately 2-3 million USD whereas for **projects with diseased samples are used, it is approximately 1.5 million USD.**
- KP Research Biobank has engaged in various studies in **genome sequencing applications, oncology studies, rare disease studies, OMICS studies, Population Health management studies and translational studies**. The sample utilization of biofluids such as blood and serum and DNA extracts is high for such studies.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

KAISER PERMANENTE® RESEARCH BANK

Biobank Application Area Alignment						
Application Area	**Key competency of your biobank**	**Biospecimens Utilized**	**Key End Users**	**Growth Potential**		**Growth Drivers/ Challenges for your biobank**
				Present	**Future**	
Companion Diagnostics	-	-	-	-	-	-
Genomic Sequence	Biospecimen type	DNA extract, blood and serum	Academics			Applications in rare disease and oncology therapies are growth drivers, however high investment in equipment for the process
Oncology Clinical Development	Biospecimen type	Blood samples	Academics, Pharma, Biotech			Oncology innovative therapies will remain the growth drivers, whereas there are **challenges around patient identity concerns**
Real World Evidence	-	-	-	-	-	-
Digital Pathology	-	-	-	-	-	-

Low High

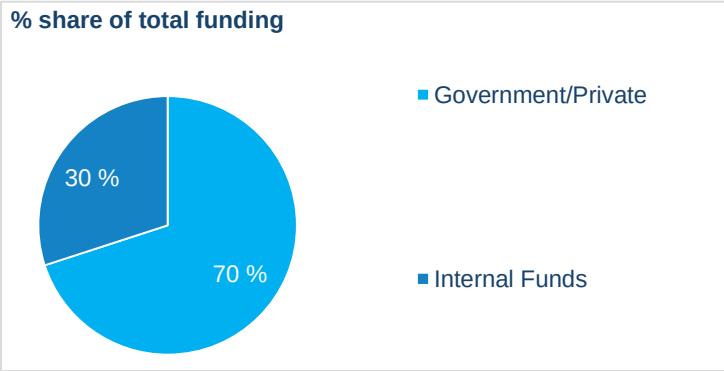
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Financial Sustainability

KAISER PERMANENTE® RESEARCH BANK

Biobank Funding Sources



Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Cost Recovery Model			Academics, Pharma, Biotech, CSO, Diagnostics

- **KP Research Biobank considers dependency on short term funding (Government/Non profit grants, etc.) as a key factor that impacts financial sustainability followed by lack of defined business models**. In order to improve upon financial sustainability, KP Research Biobank is **trying to ensure the quality of biospecimens that it provides to the end-users so that there is increase in investing grants by the end-users.**
- In the **cost recovery model the KP Research Biobank tends to charge the pharmaceutical companies comparatively more than the academic institutions as they have enough budget to invest on the samples that they purchase**.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Sample Management

KAISER PERMANENTE® RESEARCH BANK

Sample Management	
Function	**Key Value Proposition**
Sample Collection	Automated robotic systems, freezers and LIMS software act as key value proposition for the biobank
Sample Processing and Storage	
Sample Maintenance	
Sample Retrieval	
Quality Control Procedures	

Biobank Cost Drivers

Cost Drivers

- The key areas that constitute the cost drivers for KP Research **include the use of robots for sample aliquoting**. **The shipping of samples in paraffin boxes, or dry ice or other conditions as per the requirement also acts as a cost driver** along with LIMS data system for data storage and management which requires high investments from the Biobanks.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (1/3)

KAISER PERMANENTE® RESEARCH BANK

Data Management Application Area				
Function	Key End User	Application Area	Adoption	
			Current	Future
Exogenous Data	Academics, Pharma	Oncology		
OMICS/Dx Data	Academics, Pharma	Oncology, Genome Sequencing		
Clinical Data	Academics, Pharma	Oncology, Genome Sequencing		
Remote Care Data	-	-	-	-

Data Management	
Function	Key Value Proposition
Data Collection	LIMS software for all data management applications along with automated robots
Data Processing and Storage	
Data Analytics	
Data Sharing	

- Although KP Research Biobank collects exogenous, OMICS/Dx and Clinical data extensively for its processes, the **Biobank outsources data analytics capabilities to a third party vendor which specializes in data analysis solutions.**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (2/3)

KAISER PERMANENTE® RESEARCH BANK

Data Security and Privacy	
Parameter	**Current Proficiency**
Compliance to data privacy (EU GDPR, etc.)	
Established policy guidelines	
Dedicated personnel or data security manager	
Adherence to the patient consent norms	

Data Access Framework	
Parameter	**Current Proficiency**
Open Access Model	No
Control Access Model	Yes
Tiered Access Model	Yes
Existence of Institutional review board (IRB) for biospecimens sharing	Yes

- KP Research Biobank has **Kaiser Permanente Institutional Review Board** to review all the research projects and based on the on the type of consent provided by the donor, it provides authorizations for data access. KP research biobank follows the guidelines of **Federal Policy for Protection of Human Subjects to ensure privacy and security of data**.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (3/3)

KAISER PERMANENTE® RESEARCH BANK

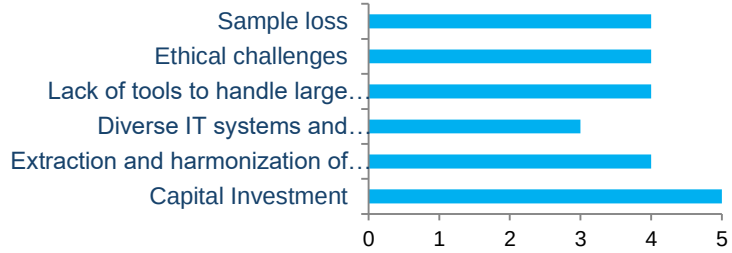
Digitization- One Stop Access

Type of Access	Adoption	
	Current	Future
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease Registers		

Low High

Digitization- Key barriers

Key barriers



- KP Research Biobank considers the use of **virtual portal as an efficient means to access data of the samples required for any particular** research project. It can be done by observing the sample list available online and user guidelines to access data. D**ata from disease registers helps in performing comparative analysis of the results that is obtained from the research studies on treatment of various diseases.**
- KP Research Biobank considers **sample loss during sharing, ethical issues and harmonization and extraction of data to be the key barriers for digitization**. Investment into such systems is a high cost activity for the KP Research Biobank

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

KAISER PERMANENTE® RESEARCH BANK

Regulatory Scenario		
Model	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		-
Is the prevailing patient consent system efficient in biobanking activities		-
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		-

Collaborations

Addiction Research Network

CRN RESEARCH NETWORK

NAACCORD

Mental Health Research Network

MHRN Mental Health Research Network

- Some of the networks that KP Research Bank is a part of are Cancer Research Network, Addiction research Network, CREST, Mental Health Research Network. **The advantages include easy exchange of data and samples between research organizations.**
- Moreover, the **network helps in getting knowledge and updates about the advancements and developments in various research domains**. **However coordination among various organizations involved in such networks is a major challenge encountered by the Biobank**.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

Biobank Future Outlook	
Customer Acquisition	Academics would remain the key customers in the future. However KP Research Biobank considers **Pharma, Biotech, CSOs to be the most potential customers in the future** KP Research Biobank considers to utilize **strategic partnership and research based engagements more prominently in the future with the end-users**
Service Scope	KP research Biobank considers high quality samples to be key sources of expertise in service capabilities. The focus is **expected to remain on the biofluids however the Biobank will strengthen its capabilities especially on the projects involving DNA/RNA extract**. KP Research Biobank considers Genome sequencing and Oncology clinical development to be major areas of future applications
Financial Sustainability	**KP Research Biobank will primarily focus on working with the commercial clients on the cost recovery model** in order to receive appropriate amount for the quality of biospecimens provided.
Operational Sustainability	KP Research Biobank will focus on further **improving sample variety and quality. The biobank also considers the one access as a potential means for sharing data easily with the end-users**. The KP Research Biobank has a consistent focus on improving the data based services for the end-users
Social Sustainability and Collaborations	KP Research Biobank considers the application of laws in the biobanking to be sufficient to ensure transparency and ethics in the research activities. **The biobank is currently a member of multiple consortiums and is expected to further collaborate with external partners in order for easy exchange of data and samples between research organizations**.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Profile

Overview

NATIONAL CANCER INSTITUTE
DCTD Division of Cancer Treatment & Diagnosis

National Cancer Institute Biobank			
Location	USA	Established year	2009
Biobank type	Focus on both population and disease based studies		
Ownership	National Agency (National Cancer Institute)		
Brief overview	▪ NCI started its biorepository with the establishment of US National Cancer Human Biobank, caHUB mainly for storing biospecimens for cancer research purposes.		
Core area of specialization	▪ The Biobank has a dedicated team of research scientists that actively participate in the cancer research projects. Also, the key area of research is oncology for which we have different type of tissues sample collections within the biobank.		
Rationale for prioritizing	▪ NCI Biobank is one of the largest biobanks in the world especially in Oncology and it offers services across all application areas in digital pathology, genome sequencing, RWE studies and companion diagnostics		
Total number of samples	▪ ~5-8 million		

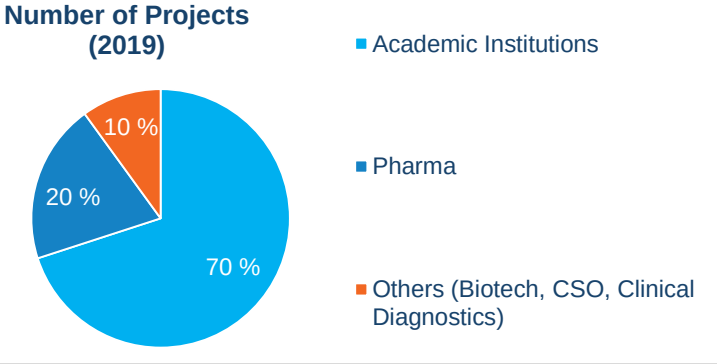
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

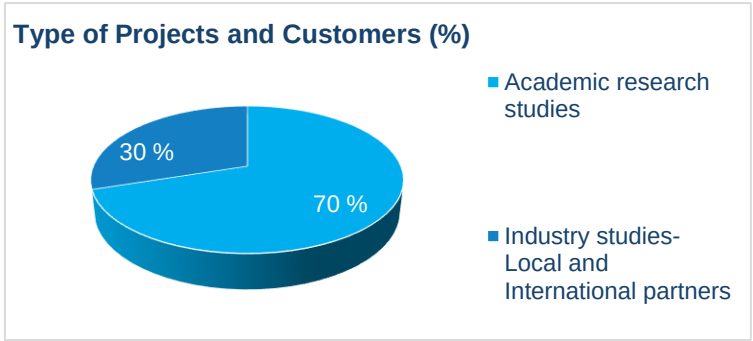
Customer Types and Marketing

NATIONAL CANCER INSTITUTE
DCTD Division of Cancer Treatment & Diagnosis

Biobank Customer Types



Biobank Customer Project Types



- NCI Biobank has engaged in various partnerships with mainly Academics institution followed by Pharma companies. The collaboration with commercial partners is mainly in OMICS based studies. Major partners for NCI Biobank include National Children Hospital, University of Zurich and commercial partners such as AstraZeneca and Amgen
- The commercial value of the projects for both academics and industry based studies can vary between $100K to as high as $8-10 million per project.
- Conferences and symposiums and print media such as articles published in research magazines are the most common ways for NCI Biobank to reach out to potential clientele. NCI Biobank also considers social media outreach significant to sharing he updates about its sample collections to the clients.
- There is a dedicated team for marketing activities in NCI Biobank and a separate annual budget for the marketing activities.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

NATIONAL CANCER INSTITUTE
DCTD Division of Cancer Treatment & Diagnosis

Biobank Engagement Model Alignment

Model	Adoption		Key End Users
	Current	Future	
Research Provider			Aademics, Pharma, Biotech, CSO, Healthtech
Strategic Partnership			
Build Operate Transfer			

- NCI adopts **research provider model as the end-users are able to fully utilize the expertise of the NCI Biobank and its resources in oncology specific research**.
- The NCI Biobank prefers the strategic partnership model when projects that the **Biobank is working upon are mostly long term projects and customers with which the Biobank has a partnership earlier**. NCI Biobank is willing to expand into more engagement types such as data based model, time and material model, etc. in the future with the end-users

Low High

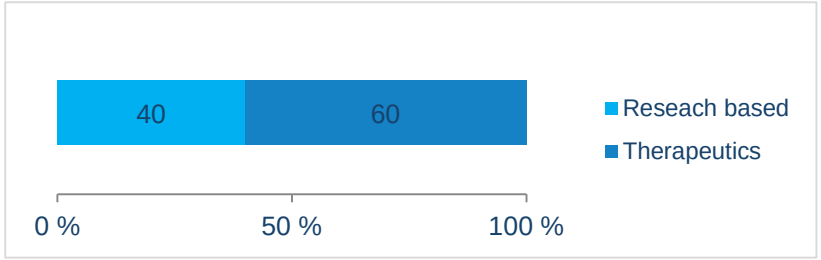
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

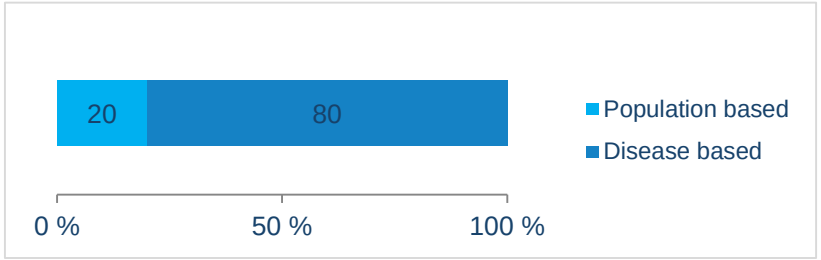
Service Scope

Service Segments

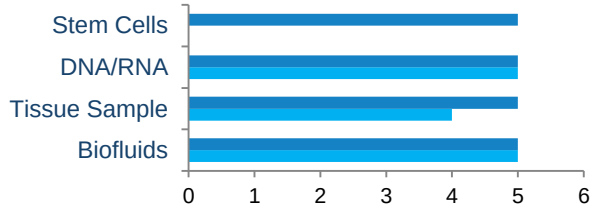
NATIONAL CANCER INSTITUTE
DCTD Division of Cancer Treatment & Diagnosis

Share from total projects in % (2019)





Sample Utilization



- NCI Biobank are largely involved in disease based studies with the end-users. The cost of the projects varies as some projects carried out for a shorten span of time that lasts for 2-3 months while there are other projects that run for years. **The minimum cost for the project would be around $100K and the maximum cost can be as high as 8 million USD**.
- NCI Biobank has partnered with **The Ohio State University for both disease and population-based research**. It has also partnered with **the University of Alabama at Birmingham and the University of Virginia**.
- NCI Biobank has a high rate of sample utilization for Biofluids such as blood, plasma and tissue samples as well DNA/RNA extracts. **While the tissue samples have been utilized for genome sequencing applications, Oncology, digital pathology, OMICS studies, DNA/RNA extract have been used across several translational studies by NCI Biobank**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

NATIONAL CANCER INSTITUTE
DCTD Division of Cancer Treatment & Diagnosis

Biobank Application Area Alignment						
Application Area	Key competency of your biobank	Biospecimens Utilized	Key End Users	Growth Potential		Growth Drivers/ Challenges for your biobank
				Present	Future	
Companion Diagnostic	Biospecimen type	Bio fluids like Blood and plasma	Academics			Challenge is around smoother adoption of the new technology
Genomic Sequence	Biospecimen and Biodata type	Tissue samples	Academics			Challenge is the usage of new technology and there are new genes that are added in the panel which makes the genome sequencing lengthy.
Oncology Clinical Development	Biospecimen type	Tumour tissue samples	Academics			On-going research activities are the key driver
Real World Evidence	Biodata type	Blood	Academics			Obtaining minority population is the biggest challenge
Digital Pathology	Biospecimen type	Tissue specimen	Academics			The key driver is the enhanced accuracy in the specimen analysis using digital pathology

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

NATIONAL CANCER INSTITUTE
DCTD Division of Cancer Treatment & Diagnosis

Drug Development Value chain competency

Application type	Expertise (Scale)	Number of Studies	Key End Users
Target identification and validation		20-30	Academics, Pharma
Lead identification and optimization			Academics
Preclinical			Pharma
Phase I			Pharma
Phase II			Pharma
Phase III			Pharma
Phase IV (RWE studies, Post marketing, etc.)			Academics, Pharma

- **Most of the drug development studies of NCI Biobank have been disease based** while a small portion are based on population samples in the area of **Oncology for instance in B-Cell lymphoma, breast cancer studies**, etc.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

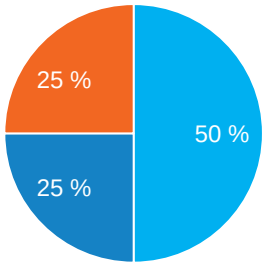
Biobank Sustainability

NATIONAL CANCER INSTITUTE
DCTD Division of Cancer Treatment & Diagnosis

Financial Sustainability

Biobank Funding Sources

Number of Projects (2019)



- Government/Non-Profit grants
- Fee recovered from biobank operations
- Commercial Partnerships

Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Cost Recovery Model			Academics, Pharma, Biotech, CSO, Healthtech, Diagnostics

- NCI Biobank has a healthy mix of commercial and academic partnerships as well as sufficient grants from the Government.
- Irrespective of the end-user the NCI **Biobank utilizes the cost-recovery model, where subsidized fee is applicable for the academic based projects whereas the commercial engagements are priced higher.**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Sample Management

NATIONAL CANCER INSTITUTE
DCTD Division of Cancer Treatment & Diagnosis

Sample Management	
Function	**Key Value Proposition**
Sample Collection	A dedicated team for sample collection that is responsible for visiting different clinical trial sites as well hospitals and collect samples after gaining the patient consent
Sample Processing and Storage	Automated tissue processing unit and a top-line technology along with a robotic arm attached to the instrument
Sample Maintenance	Liquid Nitrogen cylinders and the robotic arms helps in taking out the samples from the nitrogen cylinder
Sample Retrieval	
Quality Control Procedures	Medidata Rave System

Biobank Cost Drivers

Cost Drivers

- NCI Biobank considers **sample collection a critical cost driver due to the collection of specific biospecimens in oncology based studies.**
- Furthermore other drivers of cost include storage and maintenance costs of different samples at appropriate conditions, automated tools for sample processing. **Shipping and distribution costs also add to the total cost burden as sometimes the research sites are far away from the biobank and it needs to be ensured that the samples are delivered without getting hampered**.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

NATIONAL CANCER INSTITUTE
DCTD Division of Cancer Treatment & Diagnosis

Operational Sustainability Focus- Data Management (1/3)

Data Management Application Area

Function	Key End User	Application Area	Adoption	
			Current	Future
Exogenous Data	Pharma	Population based studies		
OMICS/Dx Data	Pharma and Academics	Companion Diagnostics, Oncology and Genome sequencing		
Clinical Data	Pharma and Academics	Companion Diagnostics		
Remote Care Data	Pharma	Stress related studies and population based studies		

Data Management

Function	Key Value Proposition
Data Collection	Outsourced
Data Processing and Storage	Specialized software for data processing and management
Data Analytics	Dedicated team for data analytics
Data Sharing	Outsourced

- NCI **Biobank has an expertise in data based projects to the end-users and it has a robust repository of major data types** including exogenous data, OMICS/Dx data, Clinical Data and remote care data. NCI Biobank utilizes different data processing tools such as LIMS, etc. for effectively managing samples and associated data.
- **It also possesses RFID and Barcode system that helps in the logistics and to overcome the challenge associated with the identification and tracking of the samples**.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (2/3)

NATIONAL CANCER INSTITUTE
DCTD Division of Cancer Treatment & Diagnosis

Data Security and Privacy	
Parameter	**Current Proficiency**
Compliance to data privacy (EU GDPR, etc.)	
Established policy guidelines	
Dedicated personnel or data security manager	
Adherence to the patient consent norms	

Data Access Framework	
Parameter	**Current Proficiency**
Open Access Model	No
Control Access Model	Yes
Tiered Access Model	No
Existence of Institutional review board (IRB) for biospecimens sharing	Yes
Privacy and Confidentiality protections	Yes

- NCI Biobank has strict regulations to get access to the data. **It has a data committee team that takes care of all the data access related queries**. The Biobank adheres to all the requisite norms that relate to data protection as **HIPAA rules, Common Rule and EU-US Safe Harbor agreement** that applies to receipt of data by US entities from EU countries.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

NATIONAL CANCER INSTITUTE
DCTD Division of Cancer Treatment & Diagnosis

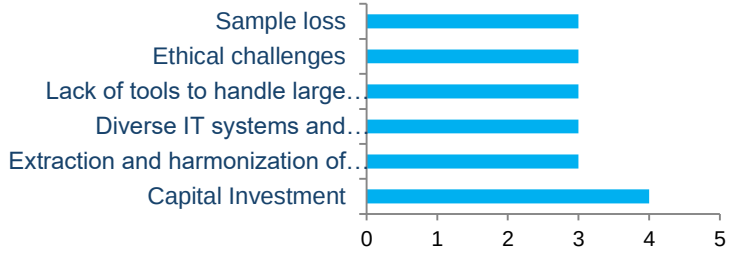
Operational Sustainability Focus- Data Management (3/3)

Digitization- One Stop Access

Type of Access	Adoption	
	Current	Future
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease Registers		

Digitization- Key barriers

Key barriers



- NCI Biobank has a **dedicated centralized team that helps the researchers as well as the pharma companies, to get the access of the data available on the portal**. The **end-users can communicate through an email to the Biobank regarding any type of queries regarding the sample requirement**. NCI Biobank considers the **virtual portal as a quick and efficient way of transferring the information between the biobank and the end-user**.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

NATIONAL CANCER INSTITUTE
DCTD Division of Cancer Treatment & Diagnosis

Regulatory Scenario		
Model	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		Highly fragmented laws and guidelines and less support for the biobanks by the Government
Is the prevailing patient consent system efficient in biobanking activities		
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		

Collaborations

NIH

CHTN COOPERATIVE HUMAN TISSUE NETWORK

isber-irl

BBMRI Biobanking and Biomolecular Resources Research Infrastructure

- The laws that regulate the Biobanking activities in the US are not governed by a single framework but managed by multiple rules such as **HIPAA rules** and Federal Policy for Protection of Human Subjects. **Common Rule (CFR title 45 part 46)** also applies to human subjects and includes requirements for Institutional Review Board (IRB) review and informed consent from the participants. Laws in the US also do not directly address the international sharing of data by the US entities outside of the **EU-US Safe Harbour Agreement**,
- NCI Biobank is **also a part of many global networks such as BBMRI, CHTN, ISBER**, etc. It considers such participation as beneficial to obtaining **all the information about the data related to different aspects of biobanking research. Apart from this, the other benefit of being a part of the network is that the Biobank can get updates of all the new upcoming technologies**.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

NATIONAL CANCER INSTITUTE
DCTD Division of Cancer Treatment & Diagnosis

Biobank Future Outlook	
Customer Acquisition	NCI Biobank does not have any specific emphasis on customer type and it considers all of them, namely academics, Pharma, Biotech, Contract Services Organizations and healthcare technology to offer great opportunities NCI Biobank considers to utilize strategic partnership, research based engagements, and build operate transfer model more prominently in the future with the end-users as compared to any other models
Service Scope	Key focus area will be to deliver the high-quality samples like biofluids, tissues and DNA, RNA extract and ensure the providing sample management and data services across all application areas namely companion diagnostics, digital pathology, RWE studies, genome sequencing and oncology based projects
Financial Sustainability	NCI Biobank is looking to expand **its capabilities especially in oncology clinical development projects for both government funded and commercial studies. The focus would be to work on projects with long term funding potential**
Operational Sustainability	NCI Biobank will invest on advanced equipment mainly for sample management purposes. The biobank will continue **its focus primarily on data analytics and processing services and considers one access service portal as a quick and efficient means of sharing information with the partners**
Social Sustainability and Collaborations	NCI Biobank will continue to advance its collaborations that can help in precision medicine applications and knowledge sharing. **Such partnerships are considered useful by the NCI Biobank as researchers can easily obtain the data through a simple request rather than approaching individual biobanks**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Profile

Overview

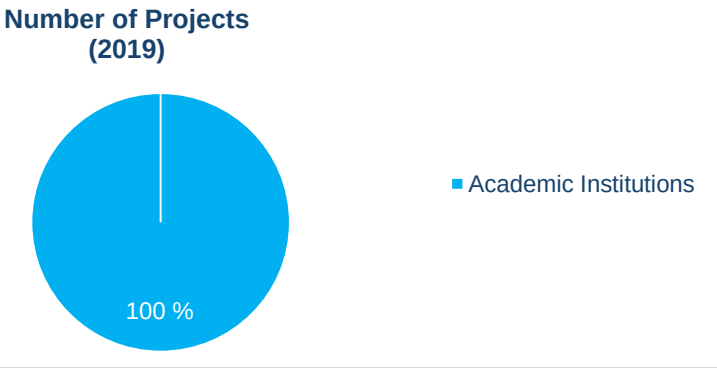
UMMC Biobank			
Location	USA	Established year	2011
Biobank type	Both disease and population based		
Ownership	University owned (University of Mississippi Medical Center)		
Brief overview	▪ UMMC Biobank supports translational and clinical research in addition to serving as the tissue bank core of the Cancer Center and Research Institute.		
Core area of specialization	▪ Core areas of research are cancer-related surgery specimens, transplants, gastrointestinal surgery specimens, congenital heart disease related specimens and HIV related samples. These are the main areas of research for which it collects different samples like blood, serum, plasma, white blood cells, tumour cells and normal tissues.		
Rationale for prioritizing	▪ UMMC Biobank is one of the major biobank with large experience in cancer related studies and specializes in application areas namely companion diagnostics, genome sequencing , besides its focus on Oncology studies		
Total number of samples	▪ In Thousands		

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

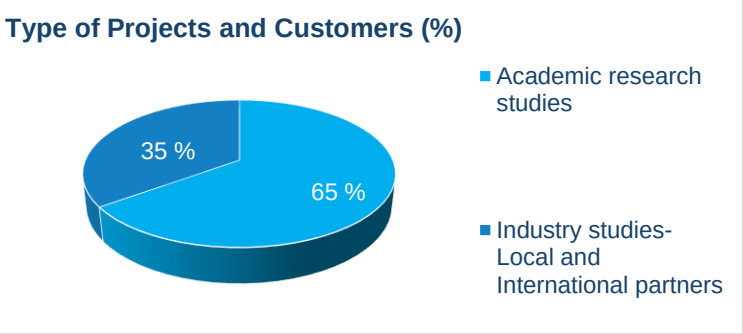
Customer Acquisition

Customer Types and Marketing

Biobank Customer Types



Biobank Customer Project Types



- Currently the UMMC Biobank partners only with academics however it considers to have more with the commercial collaborations in the future. For a **small portion of the projects, the UMMC Biobank has collaborated indirectly in industry based projects. The major areas of research based partnerships are biomarker based studies, next generation sequencing projects and oncology studies**.
- UMMC Biobank **customer outreach is mainly through research articles in various newsletters, conferences and symposiums** and it doesn't believe social media to be an appropriate means of sharing information about research activities. **There is no dedicated team for marketing activities in UMMC Biobank currently but it does plan to have one in the near future.**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

Biobank Engagement Model Alignment			
Model	**Adoption**		**Key End Users**
	Current	**Future**	
Research Provider			Academics
Strategic partnership			Academics

- For the research provider model, the UMMC Biobank has collaborated with different academic institutes for multiple projects although the terms and conditions of the projects are made for individual projects.
- The model for **Strategic partnership is with the end-users for a longer period of time be it an academic research study, or partnership with academic for a clinical trial.**

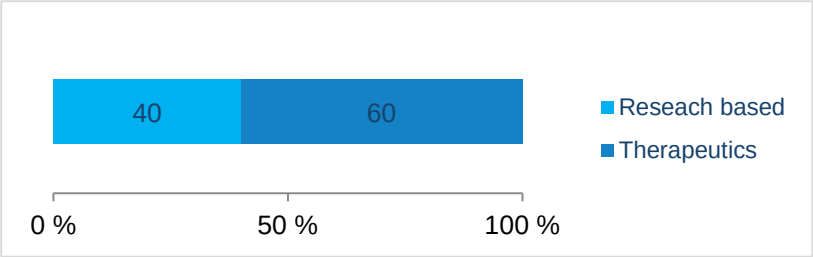
Low High

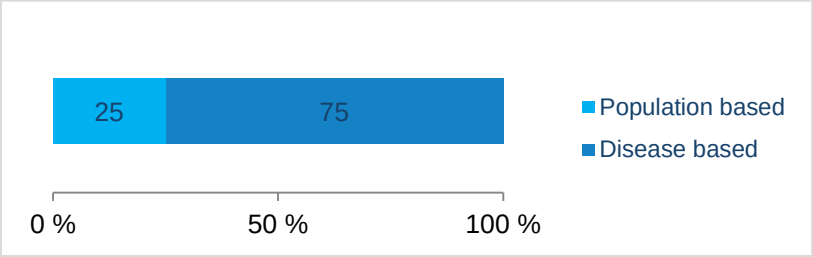
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

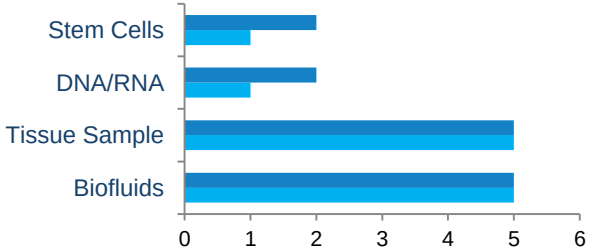
Service Segments

Share from total projects (%)





Sample Utilization



- UMMC Biobank has only collaborated with Academic institutes for its projects and **it looks forward to increase its infrastructure (working space, sample collection, etc.) so that they can work with the industry partners more**.
- Sample utilization for UMMC Biobank has been into blood samples, plasma and tissue samples. **Tissue samples are highly utilized in Oncology and translational research studies whereas blood and plasma samples are utilized in OMICS, genome sequencing applications, and biomarker based studies.**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

Biobank Application Area Alignment						
Application Area	**Key competency of your biobank**	**Biospecimens Utilized**	**Key End Users**	**Growth Potential**		**Growth Drivers/ Challenges for your biobank**
				Present	**Future**	
Companion Diagnostic	Biospecimen type	Biofluids like blood and plasma and Tissue samples				Major growth driver is that it offers complete diagnosis and biomarker profiling with a better approach. Challenge is that it is difficult to get appropriate samples for the purpose of diagnosis.
Genomic Sequence	Digitization, Biodata type and data integration	Biofluids like blood and plasma	Academics, Pharma, Biotech			Driver is the cost-effective NGS applications but challenge is to procure large number of samples
Oncology Clinical Development	Biospecimen type and infrastructure	Tissue samples	Academics, Pharma			Research in novel therapies is a major driver for oncology studies whereas procuring specific samples for studies is a challenge
Real World Evidence	-	-	-	-	-	-
Digital Pathology	-	-	-	-	-	-

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Drug Development Value chain competency

Application type	Expertise (Scale)	Number of Studies	Key End Users
Target identification and validation		~10	Academics
Lead identification and optimization			
Preclinical			
Phase I			
Phase II			
Phase III			
Phase IV (RWE studies, Post marketing, etc.)			

- UMMC Biobank has partnered with Academics as a part of the drug development studies across various phases. The key therapy areas where the Biobank has worked include **Oncology, GI and Congenital Heart Disease, for example in Oncology the UMMC Biobank has participated in several pre-clinical studies.**
- For **target identification and lead optimization studies it is mainly providing relevant samples which fit the research objectives whereas in lead optimization, UMMC Biobank was mainly involved in sorting the samples as per the demand of the project**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Financial Sustainability

Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Fee for service			Academics

- While UMMC Biobank has not disclosed the sources of funding for its operations, it does not consider financial sustainability as a major challenge. However the **Biobank does consider using an efficient pricing model in order to generate profits on the operations and as of now it has utilized mainly fee for service based model wherein it offers a fixed price for samples and services to the end-users**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Sample Management

Sample Management	
Function	**Key Value Proposition**
Sample Collection	Collection of samples of blood, plasma, serum, tumour tissues and normal tissues.
Sample Processing and Storage	-80 freezers, -20 freezers, cryostats and temperature management systems
Sample Maintenance	cold and ambient temperature centrifuges and BSL-II cabinets
Sample Retrieval	Set of guidelines presented to the donors for easier retrieval of samples
Quality Control Procedures	Own quality procedures

Biobank Cost Drivers

- UMMC **Biobank considers the use of specific tissue samples in projects as a major cost driver**. Additional cost is spent on the **procurement of deep freezers and nitrogen tanks for the storage of samples** and on the distribution of the samples in different geographies.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (1/3)

Data Management Application Area				
Function	Key End User	Application Area	Adoption	
			Current	Future
Exogenous Data	Academics	Cardiovascular based studies		
OMICS/Dx Data	Academics	Oncology, Gastrointestinal and Congenital Heart Disease		
Clinical Data	Academics			
Remote Care Data	Academics	Oncology		

Data Management	
Function	Key Value Proposition
Data Collection	AI based programs are utilized for data collection and analytical procedures
Data Processing and Storage	
Data Analytics	
Data Sharing	

- UMMC Biobank has got specialized capabilities in data management and collection. UMMC Biobank does not outsource any of the data management functions to the third party **vendor and has got AI based and highly advanced technological capabilities to carry out data analysis on multiple data types such as exogenous, OMICS and Clinical data**.
- **UMMC Biobank patient consent allows access to historical and future clinical data through the electronic health record (EHR) to facilitate in-depth translational research**.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (2/3)

Data Security and Privacy	
Parameter	**Current Proficiency**
Compliance to data privacy (EU GDPR, etc.)	
Established policy guidelines	
Dedicated personnel or data security manager	
Adherence to the patient consent norms	

Data Access Framework	
Parameter	**Current Proficiency**
Open Access Model	No
Control Access Model	No
Tiered Access Model	No
Existence of Institutional review board (IRB) for biospecimens sharing	Yes
Privacy and confidentiality protection	Yes

- **UMMC Biobank has an internal review board** that looks after all the research that is being conducted and ensures that the biobanking activities, both sample and data management and sharing is happening within a set legal and ethical framework. The Biobank has developed **internal protocols for maintaining the privacy and confidentiality so that there is no data breach and the data is not easily accessed by anyone**.

Low High

Source: Frost and Sullivan Analysis, AMR Market Study

Biobank Sustainability

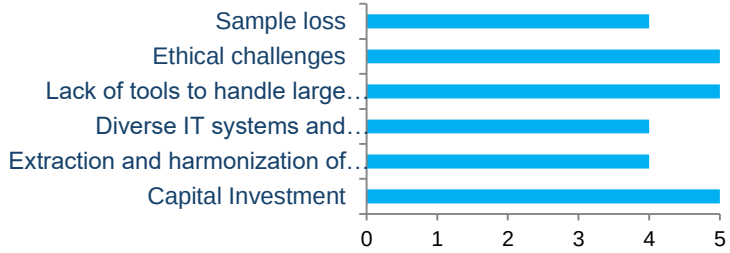
Operational Sustainability Focus- Data Management (3/3)

Digitization- One Stop Access

Type of Access	Adoption	
	Current	Future
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease Registers		

Digitization- Key barriers

Key barriers



- UMMC Biobank **considers access to sample information as an important feature in the virtual portals** in order to reach **out to as many customers as possible to make them aware about the type of research that the Biobank is conducting.**
- **Sample data access is also an important feature** so that the **end-user can assess the relevance of the data to their own research priorities** and accordingly utilize the same from the biobank.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

Regulatory Scenario		
Model	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		Present laws should be modified for better data protection and better sample collection and increase trust in the donors
Is the prevailing patient consent system efficient in biobanking activities		Process should become more efficient and easier
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		Scope for improvement in order to prevent data breaches or data sharing

Collaborations

- UMMC Biobank considers **patient consent in terms of privacy of information and withdrawal of samples as major challenges** since on many occasions people are concerned about their privacy and not ready to share their details. In other cases patients express dissatisfaction with the clauses that are mentioned in the document of privacy for sample collection.
- UMMC Biobank has **partnered in various studies and it is also a part of many networks**. **It considers joining such network an advantage as the Biobank is updated for most of the international trends**. In terms of joint studies and common platform, there is an **added advantage for the researcher as one can apply to the association as whole rather than individual members for requesting specimens and to collaborate on a mutually beneficial study.**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

Biobank Future Outlook	
Customer Acquisition	Academics would remain the key customers in the future for UMMC Biobank followed by Pharma, CSO and biotech. Both population and disease based studies will continue to be the focus in the future UMMC Biobank considers to utilize research based engagements, and strategic partnership more prominently in the future with the end-users
Service Scope	**Oncology, transplants, gastrointestinal related research and congenital heart disease related research will be the key focus areas for UMMC Biobank in the future**. UMMC Biobank will also expand its sample variety to include more number of DNA/RNA extracts and stem cells based samples
Financial Sustainability	In order to increase financial viability, **the UMMC Biobank will focus more on long term funding projects with a longer consistent revenue stream**. UMMC Biobank considers the **fee for service based pricing engagements** as an optimum means to negotiate with the end-users for its projects and likely to continue it in the future.
Operational Sustainability	UMMC Biobank considers **both samples and data services as long term engagements**. It will expand its focus more on DNA/RNA extracts and stem cells samples in the future engagements along with increasing current utilization biofluids such as blood samples and tissue samples
Social Sustainability and Collaborations	UMMC Biobank **will further its awareness programs in order to allay fears among the sample donors regarding confidentiality and protection of samples and data**. UMMC Biobank will focus on increasing its **participation in networks that are aligned with its project objectives** as it considers them a good platform to connect with potential partners and know more about the recent trends in the research areas which the network represents

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Profile

Overview

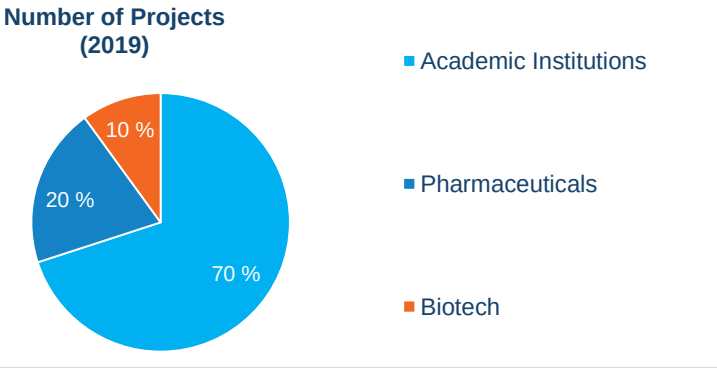
Biome Biobank			
Location	USA	Established year	2007
Biobank type	Focus on both population and disease based studies		
Ownership	University owned (Mount Sinai, Icahn School of Medicine)		
Brief overview	▪ Mount Sinai is driving innovation in the data-driven and gene-based individualization of health care. More than 33,000 patients throughout the Mount Sinai Health System have signed up for innovative genomic research through BioMe.		
Core area of specialization	▪ Expertise involves the processing and storage of large numbers of samples preserved with good quality. Core area of specialization, I think that would be personalized medicine		
Rationale for prioritizing	▪ Biome Biobank specializes in precision medicine applications in the US and has its services across application areas of companion diagnostic, genome sequencing, Oncology, RWE studies, and Digital Pathology		
Total number of samples	▪ 500-800K		

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

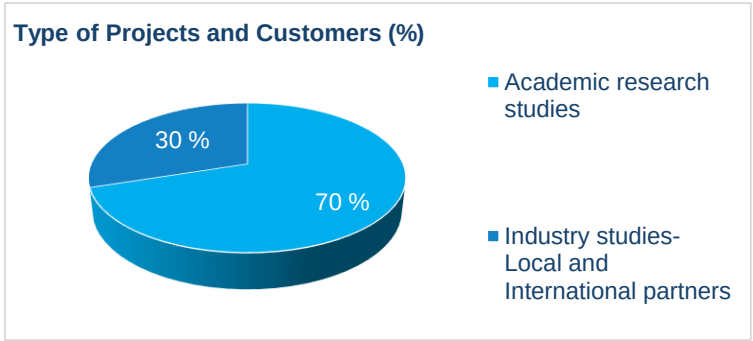
Customer Acquisition

Customer Types and Marketing

Biobank Customer Types



Biobank Customer Project Types



- Biome customers are a good mix of academic and commercial partners for its studies. **For academic research studies, Biome has collaborated with University Of Colorado, University Of California, Johns Hopkins University, Stanford University, New York Genome Centre, whereas for industry studies it has partnered with Mount Sinai Health System, Seam 4, Roche, Merck, J&J, and Novartis**

- Biome customer outreach is through **conference presentations and symposiums** and in terms of printing media, it is through brochures. Biome doesn't have a dedicated marketing budget although **the maximum expenditure is around $10,000-15,000 per year for marketing activities**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

Biobank Engagement Model Alignment			
Model	Adoption		Key End Users
	Current	Future	
Data Owner			Academics, Pharma, Biotech
Strategic Partnership			Academics, Pharma, Biotech

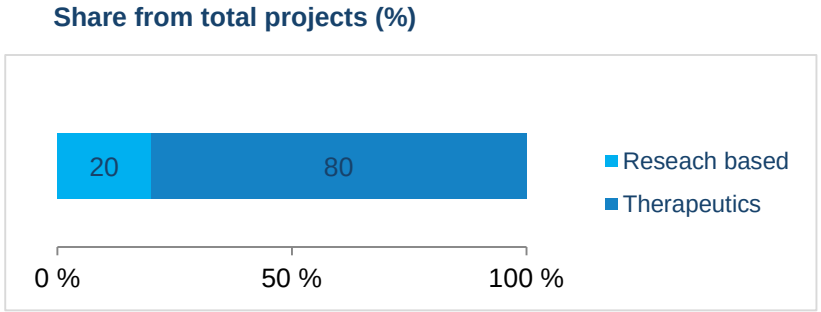
- **The data owner model makes Biome the sole owner of the data that is provided and the end-users are allowed to access the data after requisite permissions from the Biobank**. For strategic partnership, **the end-users work in collaboration with the biobank for samples and data required for various research domains**. So, they either work for specific research purpose or to get access to various other data related to specific research domain.
- In the data owner model, there **are challenges in terms of security, privacy of the data as the end-users utilize the data for the research purposes**. Furthermore ownership of samples is a quite conflicting issue in case of joint ventures.

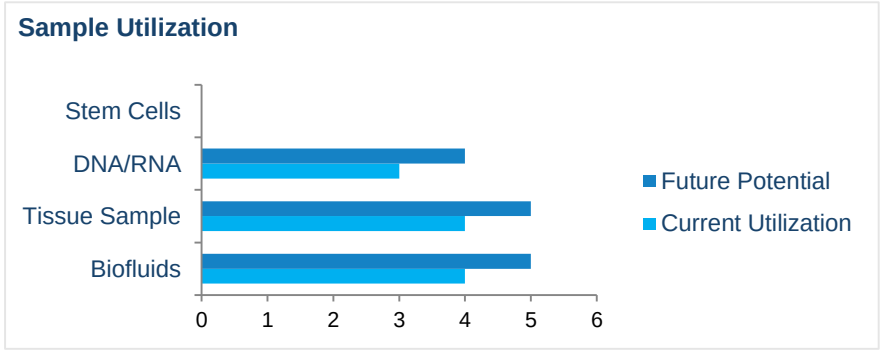
Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Service Segments





- Biome Biobank has worked with a large number of both commercial and academic partners. The collaborations have covered all application areas such as biomarker profiling, genome sequencing, oncology, RWE studies, rare disease studies, etc.
- It mainly makes use of blood samples, tissue samples and DNA/RNA studies and considers their utilization to increase in the future as the **Biome biobank has plans to expand its service offerings especially through the Bio*Me* resource which is mainly for biomedical and genetic research**.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

Icahn School of Medicine at Mount Sinai

Biobank Application Area Alignment						
Application Area	Key competency of your biobank	Biospecimens Utilized	Key End Users	Growth Potential		Growth Drivers/ Challenges for your biobank
				Present	Future	
Companion Diagnostic	Digitization and data integration	Blood samples, serum and tisues	Pharma, Academics			High quality standards of samples as well as storage facilities, big data capabilities and Biome biobank is the one of the few EHR-linked biorepository
Genomic Sequence	Digitization and data integration	Blood samples, serum and tisues	Pharma, Academics			
Oncology Clinical Development	Digitization and data integration	Blood samples, serum and tisues	Pharma, Academics			
Real World Evidence	Digitization and data integration	Blood samples, serum and tisues	Pharma, Academics			
Digital Pathology	Digitization and data integration	Blood samples, serum and tisues	Pharma, Academics			

Low High

FROST & SULLIVAN

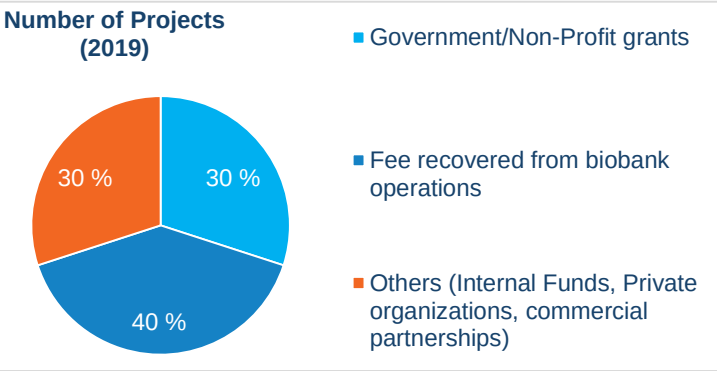
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Financial Sustainability

Icahn School of Medicine at Mount Sinai

Biobank Funding Sources



Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Cost Recovery Model			Academics, CSO
Fee for service			Pharma, Biotech, CSO

- **Dependency on short term funds acts as a major constituent of a weak financial sustainability for Biome Biobank**. It is working on plans involving more stakeholder participation and areas where more funds can be generated.
- **In the cost recovery model the end-user pays only a small amount of the total price of the services**. This model is particularly adopted for the government academic institutes and also some of the contract services organizations. In the **fee for service model, the end-user is charged for the amount for the services they utilize from collection of samples till transportation of samples to the required destination. Any additional cost is not applied by the Biome Biobank**.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Sample Management

Sample Management	
Function	**Key Value Proposition**
Sample Collection	High quality sample collection by proper tests, etc.
Sample Processing and Storage	Sample aliquoting of samples along with cryopreservation method for preservation of samples in the biobank
Sample Maintenance	Well trained staffs who keeps a track on all the samples. It also has alarm freezers which alerts in terms of cases where there are chances of damage of samples
Sample Retrieval	separate application procedure where the researchers provide their requests for various purposes
Quality Control Procedures	Quality control department which makes frequent visits to ensure the samples are maintained in proper format and it also keeps a regular check with the LIMS system on the types of samples that are stored.

Biobank Cost Drivers

Cost Drivers

- Major constituents of the cost drivers for Biome Biobank include **pathological tests before collection of samples , freezers and other equipment like nitrogen gas cylinders** involved for maintenance of samples, and software that are used for managing the data related top the samples

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (1/3)

Icahn School of Medicine at Mount Sinai

Data Management Application Area				
Function	Key End User	Application Area	Adoption	
			Current	Future
Exogenous Data	Academics, Pharma	RWE studies, epidemiology studies		
OMICS/Dx Data	Academics, Pharma, CSO	Oncology studies		
Clinical Data	Academics, Pharma, CSO, Biotech	Biomarkers, etc.		
Remote Care Data	-	-	-	-

Data Management	
Function	Key Value Proposition
Data Collection	LIMS data management system to manage data, perform comparative analysis of data to calculate future predictions in few research projects efficiently. system also helps in collecting a lot of information related to the various research purpose and provide to various organizations as per their needs in a quick and efficient manner without any error or accuracy issues.
Data Processing and Storage	
Data Analytics	
Data Sharing	

- Biome Biobank has **robust capabilities in data based applications especially around personalized medicines and genomics in areas such as gene discovery, system biology, topic modeling, phenome wide association studies, pleiotropy**, etc. where the utilization of different set of data types is high. The Biome Biobank will further **improve its data capabilities such as linking the electronic clinical records to the sample data and explore more richness of the clinical data derived**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (2/3)

Icahn School of Medicine at Mount Sinai

Data Security and Privacy	
Parameter	**Current Proficiency**
Compliance to data privacy (EU GDPR, etc.)	
Established policy guidelines	
Dedicated personnel or data security manager	
Adherence to the patient consent norms	

Data Access Framework	
Parameter	**Current Proficiency**
Open Access Model	No
Control Access Model	Yes
Tiered Access Model	No
Existence of Institutional review board (IRB) for biospecimens sharing	Yes

- Biome Biobank has institutional review boards, restrictive authorization along with laws to maintain privacy and security of information and provide access only to authorized members. Different types of **filters and inclusion/exclusion criteria are put to avoid intrusion by any third party without due permissions.**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (3/3)

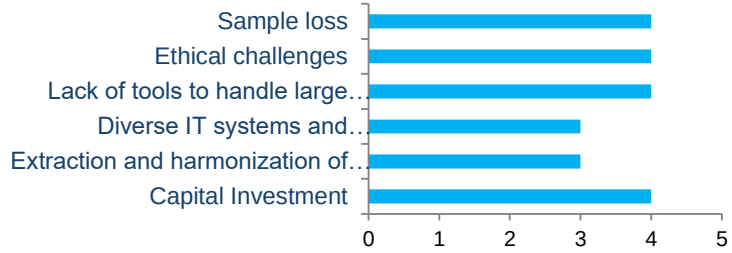
Icahn School of Medicine at Mount Sinai

Digitization- One Stop Access

Type of Access	Adoption	
	Current	Future
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease Registers		

Digitization- Key barriers

Key barriers



- Access to sample information will remain the prime focus for any online portal to work upon. Further **Biome Biobank has developed a tool called Bio*Me* which is a unique EHR-linked bio and data repository that performs unrestricted patient enrollment** (non-selective in terms of gender, race, ethnicity, age, medical condition, or disease status).
- This can help in developing a cohort unmatched in ethnic, socio-economic, and medical diversity and ready to be tapped for the broadest variety of biomedical and genetic research. It is a promising tool and expected to play a major role in commercial engagements with the end-users in the future.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

Icahn School of Medicine at Mount Sinai

Regulatory Scenario		
Model	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		-
Is the prevailing patient consent system efficient in biobanking activities		-
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		-

Network Participation

IGNITE Implementing GeNomics In pracTicE

isber

eMERGE network
ELECTRONIC MEDICAL RECORDS AND GENOMICS

- Biome Biobank considers the laws as sufficient that deal with ethical and legal aspects of samples and data for biobanking services in the US.
- Furthermore the **Biome Biobank is a part of Implementing Genomics in Practice (IGNITE) network that provides a platform for access to genomic information as well as exploring methods for effective implementation, dissemination and sustainability in various clinical settings**. The main purpose of this network is to spread data across the networks so that other researchers can access the conclusions of various research projects as well.
- **eMERGE is a national network organized and funded by the National Human Genome Research Institute (NHGRI) that combines DNA biorepositories with electronic medical record (EMR) systems for large scale, high-throughput genetic research** in support of implementing genomic medicine.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

Biobank Future Outlook	
Customer Acquisition	Academics would remain the key customers in the future. However Biome Biobank considers partnering with major commercial companies in the future such as Pharma, Biotech, Contract Services organizations, Diagnostics, etc. especially in genome based projects Biome Biobank considers to use only data owner and strategic partnership model, prominently the former with the end-users
Service Scope	Biome Biobank considers high quality samples to be key sources of expertise in service capabilities. The focus is expected to remain on the tissue samples, DNA/RNA extract, and biofluids such as blood, serum, and tissue samples. etc. **Biome Biobank has extensive applications in wide variety of research areas such as population genetics, genomic medicines, biomarkers**, etc. and is expected to further increase its capabilities
Financial Sustainability	Biome Biobank will focus on increasing its revenues through the partnerships both commercial and academic. It will **look to engage more efficiently through better pricing models such as fee for service, etc. with the clients in order to improve the margins**
Operational Sustainability	Biome Biobank will continue towards improving the infrastructure for sample and data services. It has taken initiatives such as developing **Bio*Me* tool and Bioserve- a genomics research portal mainly for improving sample access and information on research programs for the end-users**
Social Sustainability and Collaborations	Biome Biobank is **already a member of many organizations focusing on genomics as it would look to increase its expertise by collaborating for easier access to samples and data** and updated with modern trends in the personalized medicines category

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Profile

Overview

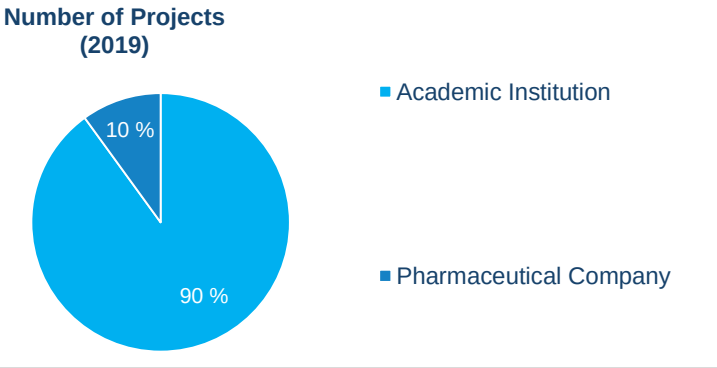
All of US			
Location	USA	Established year	2007
Biobank type	Focus on both population and disease based studies		
Ownership	Government (National Institute of Health)		
Brief overview	▪ All of Us is a research program in USA that aims to further the objectives of Precision Medicine Initiative by the NIH. All of US has a goal of enrolling 1 million or more participants that will also reflect the diversity of the population. It is building a database for the information collected in order to assist researchers across different disease areas		
Core area of specialization	▪ The core focus of the All of Us study is into precision medicine research. All of Us collects many types of data, including data from surveys, electronic health records, and blood and urine tests.		
Rationale for prioritizing	▪ It is one of the largest of its kind study in the US and specially focusing on genomic sequencing applications in precision medicine research		
Total number of samples	▪ ~200,000-300,000 till date		

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

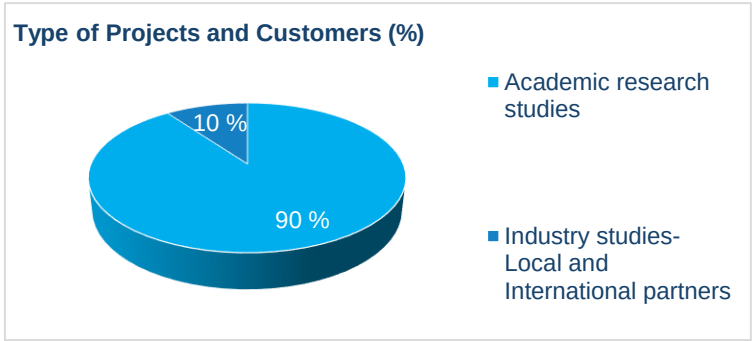
Customer Acquisition

Customer Types and Marketing

Biobank Customer Types



Biobank Customer Project Types



- All of Us is the largest study program in the US and it has chiefly collaborated with academic partners namely Stanford University, Johns Hopkins University, University of Texas Health Science Center at Houston.
- All of Us customer outreach is mainly through **conference presentations and social media outreach**. Since the number of enrollments are high, **such outreach makes it easier to put regular updates, and requests for the donors to be a part of the study**. **Conferences play a major role in dissemination of information to tap more customers** and showcase the capabilities of the Biobank. **There is a dedicated marketing team in the All of Us Biobank which focuses on promotion and customer acquisition strategies**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

Biobank Engagement Model Alignment			
Model	Adoption		Key End Users
	Current	Future	
Data Owner			Academic, Pharma
Strategic Partnership			Academics, Pharma

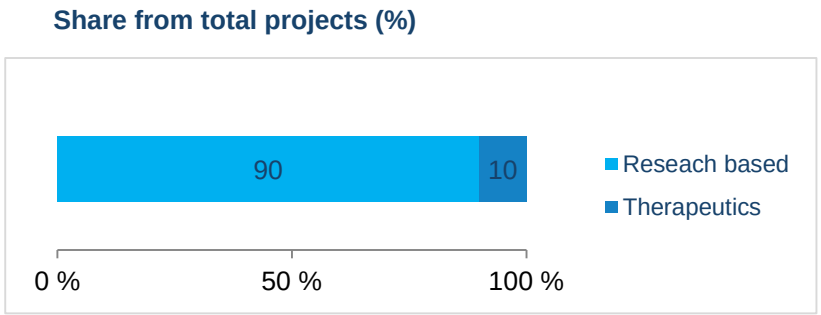
- For the data owner model, the All of Us Biobank focuses on the need and data requirements of the organizations especially in specific research areas. **Strategic partnership is generally utilized where samples are provided on a continuous basis for a longer duration to either academic or industrial partners**

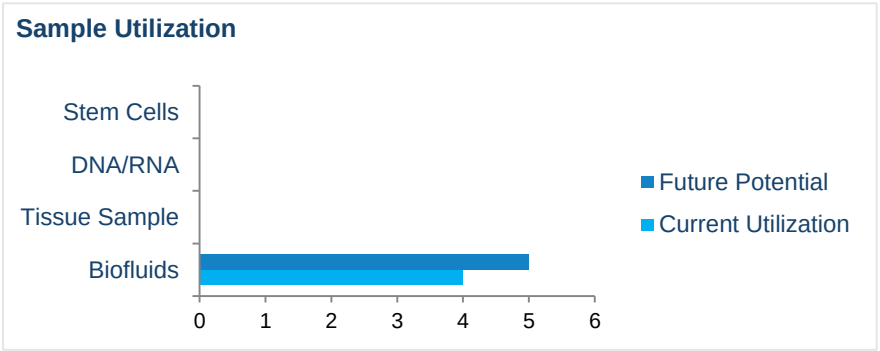
Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Service Segments





- Major partners for All of Us research program are **Brigham and Women's Hospital, Massachusetts General Hospital, Newton-Wellesley Hospital, Stanford University, Johns Hopkins University, University of Texas Health Science Center at Houston**. The cost approximately lies between 2**00 to 220 million USD for both the segments.**
- Sample utilization of the biofluids for All of Us consists of blood, urine, serum, etc. which is utilized in **Genome sequencing applications, Oncology, and regenerative medicine applications**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

Biobank Application Area Alignment						
Application Area	**Key competency of your biobank**	**Biospecimens Utilized**	**Key End Users**	**Growth Potential**		**Growth Drivers/ Challenges for your biobank**
				Present	**Future**	
Companion Diagnostic	-	-	-	-	-	-
Genomic Sequence	Biodata Type	Blood samples				Increase in demand for clinical diagnostics and drug development in the research domain are the growth drivers for this particular segment. Skilled resources is a major challenge
Oncology Clinical Development	Biospecimen and Biodata type	Blood samples	Pharma, Academics			Occurrence of various types of chronic, critical and rare type of cancers and the need to identify their treatment in the research domain has driven research in oncology sector. working with variety of assays particularly for genomics and histological studies is another challenge
Real World Evidence	-	-	-	-	-	-
Digital Pathology	-	-	-	-	-	-

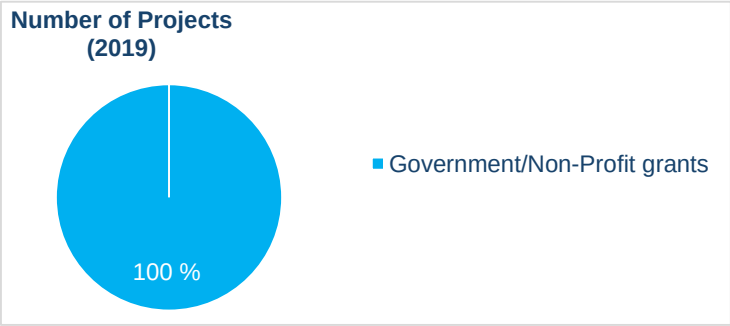
Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Financial Sustainability

Biobank Funding Sources



Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Fee for service			Academic, Pharma

- All of Us research program **does not see financial sustainability as a challenge as it is fully funded by the Government.** All of Us Study is the next step of the Precision Medicine Initiative that was constituted in 2015 by the NIH.
- **In the fee for service model, the Biobank charges appropriate fee in order to recover the cost for storage, collection and transportation of the biopsecimen**. Since the biobank is well funded by the Government, such a pricing model does not pose a major challenge to its operations, yet it believes there is a scope of improving the terms and conditions of the pricing in order to receive gains

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Sample Management

Sample Management	
Function	**Key Value Proposition**
Sample Collection	Samples collected are assayed to generate biological data related to the sample
Sample Processing and Storage	Cryopreservation for storage of samples for a longer term and to maintain quality. Automated freezers, easyBlood assay for hands-free blood fractionation and buffy coat transfer. LabElite DeCapper for automated tube decapping.
Sample Maintenance	Freezers for maintenance and staff to look after the process
Sample Retrieval	Separate application procedure with stated objectives in order to retrieve the samples
Quality Control Procedures	Secured cloud computing systems to provide individual protection against personal data security. LIMS system for proper tracking

Biobank Cost Drivers

Cost Drivers

- The key areas that constitute the cost drivers for All of Us Biobank include the **screening and pathological tests while collection of the samples, and transportation charges for dispensing of the samples**. The process requires the samples to be well packaged with paraffin blocks, nitrogen and dry ice. Technology platforms for storage and analysis of data also constitute a major portion of the costs incurred

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (1/3)

Data Management Application Area				
Function	Key End User	Application Area	Adoption	
			Current	Future
Exogenous Data	Academics, Pharma	Population Health Management		
OMICS/Dx Data	Academics, Pharma	Genome Sequencing		
Clinical Data	Academics, Pharma	Oncology		
Remote Care Data	Academics, Pharma	Population Health Management		

Data Management	
Function	Key Value Proposition
Data Collection	LIMS and EHR for collection of data
Data Processing and Storage	LIMS
Data Analytics	LIMS
Data Sharing	LIMS

- Since the All of Us program has **highly diverse sources of data collection and a large target population, it has proficiency of data collection of all different types**. Such data is highly utilized in areas such as Oncology, Genome Sequencing, PHM for research purposes.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (2/3)

Data Security and Privacy	
Parameter	**Current Proficiency**
Compliance to data privacy (EU GDPR, etc.)	
Established policy guidelines	
Dedicated personnel or data security manager	
Adherence to the patient consent norms	

Data Access Framework	
Parameter	**Current Proficiency**
Open Access Model	No
Control Access Model	Yes
Tiered Access Model	Yes
Existence of Institutional review board (IRB) for biospecimens sharing	Yes
Privacy and confidentiality protections	Yes

- All of Us Biobank has an IRB which takes care of operational protocol and the type of consent provided by the donor. All of Us Biobank restricts authorization for filtered access of data to selective personnel and there is two tier access, one is for the public and the other for registered users

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

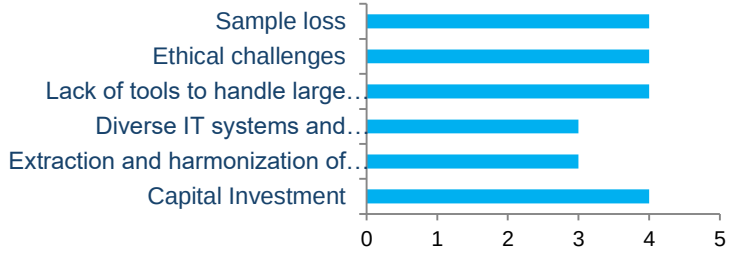
Operational Sustainability Focus- Data Management (3/3)

Digitization- One Stop Access

Type of Access	Adoption	
	Current	Future
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease Registers		

Digitization- Key barriers

Key barriers



- All of Us Biobank considers **digitization and one stop access as a key feature in making the samples and data available for the researchers**. **Current levels of digitization is low in All of Us Biobank and expected to improve in the future**. All of Us Biobank **considers centralized access as a key feature that provides access to researchers to a broad set of samples and gives flexibility to retain best standard controls for sharing of samples**. With the data from the disease registers, researchers can find the data for specific diseases and biosamples for their interest of disease

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

Regulatory Scenario		
Features	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		-
Is the prevailing patient consent system efficient in biobanking activities		-
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		-

Network Participation

- As the All of Us program began only two years back, it will take some time to evaluate if the regulatory features pose any significant barriers or there is a need for improvement. **All of Us program has partnered with NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development** for precision medicine. **The institute research focuses on understanding the biology of human development and reproduction. It also conducts research in reproductive, perinatal and pediatric health.**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

Biobank Future Outlook	
Customer Acquisition	Academics and Pharma will remain the key customers for All of Us Biobank. The research focus is likely to be on genome sequencing, Oncology, and regenerative medicines applications All of Us Biobank considers to utilize data owner and strategic partnership extensively in the future with the end-users
Service Scope	All of Us Biobank has a highly specific focus on biofluids such as blood, urine, saliva among others. Biobank will also focus on expanding its data as a service capabilities to provide large datasets to the end-users for research purposes
Financial Sustainability	All of Us Biobank , does not foresee any challenge to maintain the financial sustainability for its operations as it will continue to leverage the funds provided by the Government
Operational Sustainability	All of Us Biobank has highly sophisticated sample storage and management infrastructure and is likely to continue as the sample collection increases towards the target levels of 1 million. Furthermore All of Us Biobank will focus on collection and analysis of the data types and provide data as a service to its end-users.
Social Sustainability and Collaborations	All of Us Biobank has only participated with NIHCHD for research purposes and it considers such partnership valuable due to access and sharing of relevant data through such partnerships.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Additional Biobank Profiles

Biobank Profile

Overview

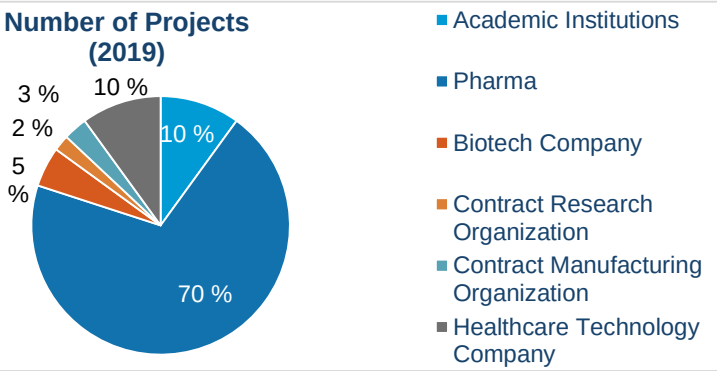
Decode Genetics			
Location	Iceland	Established year	1996
Biobank type	Population based biobank		
Ownership	Private Ownership (Amgen)		
Brief overview	▪ Decode is a global leader in analyzing and understanding the human genome. ▪ Decode has discovered key genetic risk factors for dozens of common diseases ranging from cardiovascular disease to cancer.		
Core area of specialization	▪ Biobank has been working in the field of genome sequencing for more than 20 years now. The Biobank also focuses on digitalizing the Icelandic genealogical records, creating an extensive database to trace the ancestry of the population, making it the most unique collection of biobank data, in the world.		
Rationale for prioritizing	▪ Decode Genetics specializes in genome sequencing projects, however it does offer capabilities in Oncology and biomarker identification		
Total number of samples	▪ NA		

Source: Frost and Sullivan Analysis, AMR Market Study

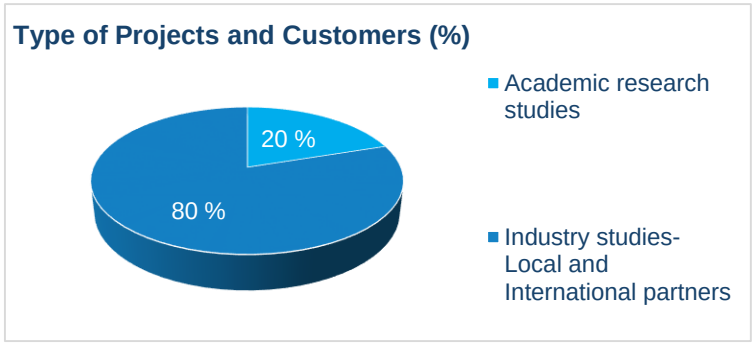
Customer Acquisition

Customer Types and Marketing

Biobank Customer Types



Biobank Customer Project Types



- Decode Genetics has engaged in various partnerships commercial partners such as Pharma, Biotech, etc. The key areas where Decode genetics has engaged with commercial clients include **genome sequencing projects, oncology studies, rare disease projects, and OMICS studies.**
- For Decode genetics, **the focus is on population based studies with both academic and commercial partners**, with major ones being **Somalogic, Wellcome Sanger institute and also the studies commissioned by the parent firm, Amgen**
- **International Conferences and symposiums** are the key sources for Decode genetics to publicize information regarding their services and capabilities. **Decode genetics also considers social media outreach as a significant means to reach out to potential clientele**. **There is a dedicated team for marketing activities in Decode genetics which is often supported by Amgen's marketing team.**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

Biobank Engagement Model Alignment

Model	Adoption		Key End Users
	Current	Future	
Research Provider			Academics
Service Provider			Pharma, Biotech, Diagnostics, CSO
Data Owner			CSO

- Decode genetics works on different engagement models with the end-users. **With commercial partners, the company mainly engages in service based partnership** where it provides them **services related to genome sequencing as well as already sequenced genome data on request**.
- In case of a **data owner model, which the company has mainly partnered with some institutions where they are only allowed access to data, which is necessary for their project**. The **ownership of the data stays with Decode genetics** and the end-users are **only granted temporary access to the data during the project timeline**.
- Research provider model has mainly been utilized **for the academics who can request for collaboration for any particular research**

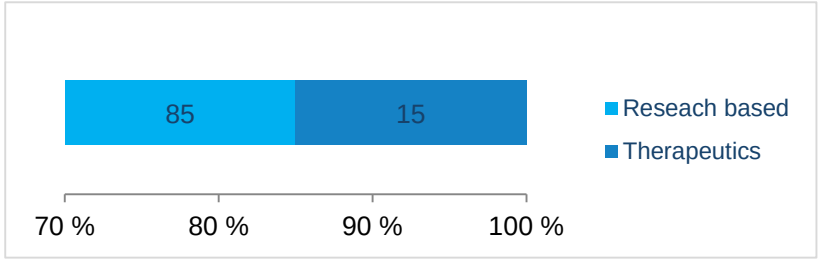
Low High

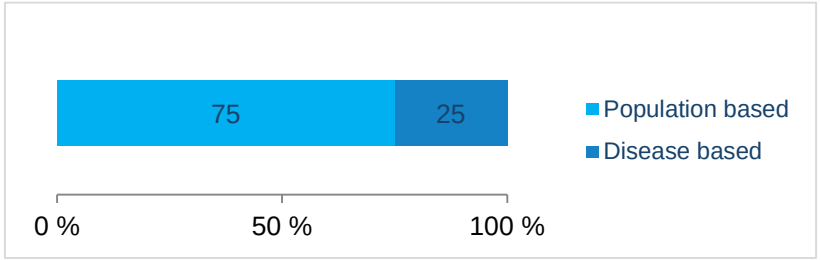
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

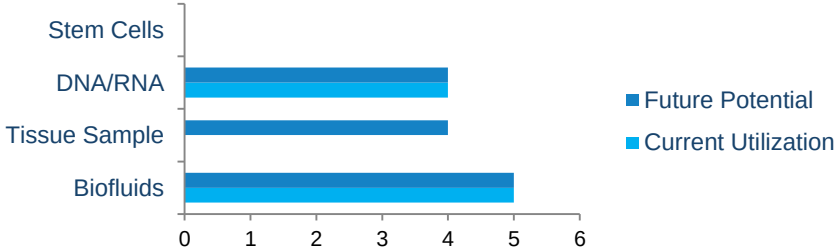
Service Segments

Share from total projects in % (2019)





Sample Utilization



- Major partners for Decode genetics are **UK Biobank, EU-AIMS and Somalogic for genome based studies**. As far as **disease based studies are concerned, Decode genetics has partnered with Intermountain Healthcare, an integrated healthcare delivery network, to research on the link between the genes and the common diseases.**
- Decode genetics main sample utilization is of blood samples, DNA/RNA extracts and for majority of its studies across different **project types such as exclusively sequenced genetic maps, whole genome sequences, oncology projects**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

Biobank Application Area Alignment						
Application Area	Key competency of your biobank	Biospecimens Utilized	Key End Users	Growth Potential		Growth Drivers/ Challenges for your biobank
				Present	Future	
Companion Diagnostic	-	-	-	-	-	-
Genomic Sequence	Digitization, Biodata type and data integration	Blood samples	Academics, Pharma, Biotech			Technological capabilities for sequencing are the main driver whereas obtaining patient consent for second round of sample collection is a challenge
Oncology Clinical Development	Biospecimen type and infrastructure	Blood samples	Academics, Pharma			Biomarker identification for novel therapies is a major driver for oncology studies
Real World Evidence	-	-	-	-	-	-
Digital Pathology	-	-	-	-	-	-

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Drug Development Value chain competency

Application type	Expertise (Scale)	Number of Studies	Key End Users
Target identification and validation		2-3	Pharma, Biotech
Lead identification and optimization			
Preclinical			
Phase I			
Phase II			
Phase III			
Phase IV (RWE studies, Post marketing, etc.)			

- Decode genetics has experience across different drug development phases and **key projects have been biomarker identification for oncogene such as BRCA2**, **identification of tumour biomarkers in blood**, and **mutation variants associated with the urinary biomarkers (Target and Lead)**, **drug for treatment of atherosclerosis**, in phase 1 of clinical trials, in phase 2 product for the treatment of asthma, and a phase 3 trial for prevention of coronary artery disease.
- Key therapy areas have been **cardiology, pulmonary disorders and oncology**.

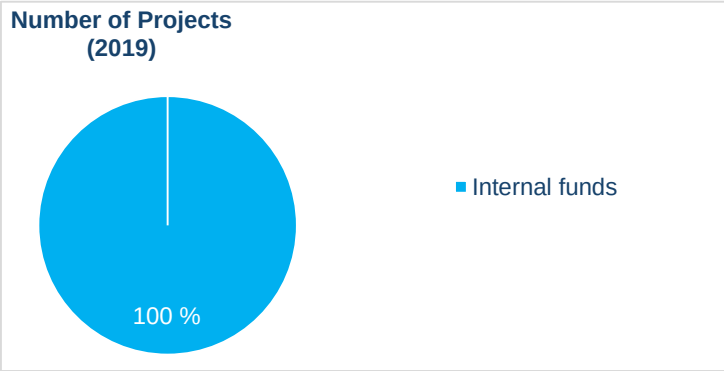
Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Financial Sustainability

Biobank Funding Sources



Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Fee for service			Academics, Pharma, Biotech, CSO, Healthtech

- Decode **genetics does not consider financial sustainability a challenge since the parent company, Amgen provides the financial support in all research activities**.
- It employs fee for service type of agreement with the end-users as it considers this model quite convenient in terms of the returns received and negotiations with the end-users. The fee for service model is by which, the end-users pay for the bio samples and the data that is supplied to them. **The cost is only based on the samples and their delivery.**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Sample Management

Sample Management	
Function	**Key Value Proposition**
Sample Collection	Large scale sample collection from Icelandic population and skilled staff
Sample Processing and Storage	State of the art cryopreservation unit
Sample Maintenance	Optimal conditions for cryovials and cryopreservation equipment
Sample Retrieval	Set of guidelines and fully automated systems
Quality Control Procedures	CLIA certified laboratory

Biobank Cost Drivers

- The key constituents for the cost drivers for Decode genetics are **sample processing and management** as the samples have to be kept at an optimum temperature since they are heat labile and the cost of biospecimen itself is high.
- The cost is further increased during their storage and transport. **Data storage and management also acts as a cost driver** as it involves **maintenance as well as management of the data associated with the samples which also includes genealogical documents**.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (1/3)

Data Management Application Area				
Function	Key End User	Application Area	Adoption	
			Current	Future
Exogenous Data	-	-		
OMICS/Dx Data	Academics, Pharma	Oncology, Neurology and Cardiovascular		
Clinical Data	-	-	-	-
Remote Care Data	-	-	-	-

Data Management	
Function	Key Value Proposition
Data Collection	-
Data Processing and Storage	Illumina data sequencing array chips, BamQC
Data Analytics	Graphtyper, BamHash, PopSTR
Data Sharing	-

- Decode genetics has state of the art technology for its data management services and the tools utilized in data processes include TwoFish, an encryption algorithm used to encrypt data during collection, Illumina, used in processing, and Pseudonymization, used while sharing of data.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (2/3)

Data Security and Privacy	
Parameter	**Current Proficiency**
Compliance to data privacy (EU GDPR, etc.)	
Established policy guidelines	
Dedicated personnel or data security manager	
Adherence to the patient consent norms	

Data Access Framework	
Parameter	**Current Proficiency**
Open Access Model	No
Control Access Model	Yes
Tiered Access Model	Yes
Existence of Institutional review board (IRB) for biospecimens sharing	Yes
Privacy and confidentiality protection	Yes

- Decode genetics has **an internal review board and according to the mandate, it checks all the samples to ensure quality collection**. Furthermore it uses the **controlled model to ensure safe transfer of data, in which there are also layers or tiers of access** mainly to ensure data confidentiality and privacy.
- **Depending on the type of consent provided**, **the company can also determine whether to destroy the biosample or not**.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

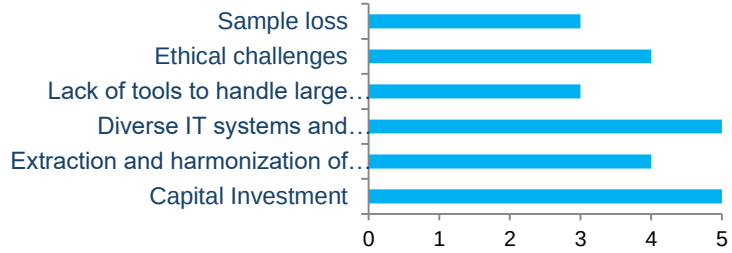
Operational Sustainability Focus- Data Management (3/3)

Digitization- One Stop Access

Type of Access	Adoption	
	Current	Future
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease Registers		

Digitization- Key barriers

Key barriers



- Decode genetics considers the use of virtual portals to be highly beneficial to the end-users. Furthermore **the end-users prefer those portals that have a direct login to take them to the relevant information suggested and avoid the display of non-essential information**.
- Decode genetics provides the service to the end-users partners with a different web portal and login details. This enables them to access the sample data and the biorepository information from any place, in a secured way.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

Regulatory Scenario		
Feature	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		Data confidentiality procedures
Is the prevailing patient consent system efficient in biobanking activities		
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		

Collaborations

EU-AIMS Autism Research in Europe

Intermountain® Healthcare

- Decode genetics considers the prevailing laws and regulations appropriate except the need for improving data confidentiality procedures especially because the firm deals with high level of patient classified data related to patient's whole genetic make-up
- **Decode genetics is not a part of any international network** however it has collaborated with major biobanks and organizations such as UK Biobank, EU-AIMS, Intermountain Healthcare Network. Currently they are also **involved in a study called HerediGene, which is a population based study with a collaboration with Intermountain Healthcare Network**. Its **objective is to develop clear connections between the diseases and its genetic predisposition.** The main motivation of the stakeholder was to avail our gene sequencing expertise to analyze the genome of the Utah-based patients.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

Biobank Future Outlook	
Customer Acquisition	Pharma and Biotech would remain the key customers in the future for Decode genetics followed by Academics and CSOs in the future. Focus would be more on population based studies **Decode genetics considers to utilize research based engagements, data owner and the service provider** model more prominently in the future with the end-users
Service Scope	**Genotyping, genome sequencing and gene mapping services will be the key focus areas for Decode genetics in the future**. Decode genetics will also expand its sample variety to include more number of tissue samples especially for oncology related projects.
Financial Sustainability	Decode genetics is internally funded by the parent company, Amgen hence **does not see financial sustainability as a challenge**. However **it will focus on reducing the effect of the major cost drivers such as sample processing and management**
Operational Sustainability	Decode genetics has state of the art facilities for sample storage and management and **its future outlook would be to increase sample utilization for all the major categories**. Decode genetics has all the data processing facilities in house and it is **expected to further expand on OMICS data analysis for the genome sequencing projects**
Social Sustainability and Collaborations	Decode genetics being a private organization is **not a part of major network or collaboration and does not consider it as a high priority activity in the future**. However the **biobank will increase its involvement in large scale population based studies both regional and international in gene sequencing areas**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Profile

Overview

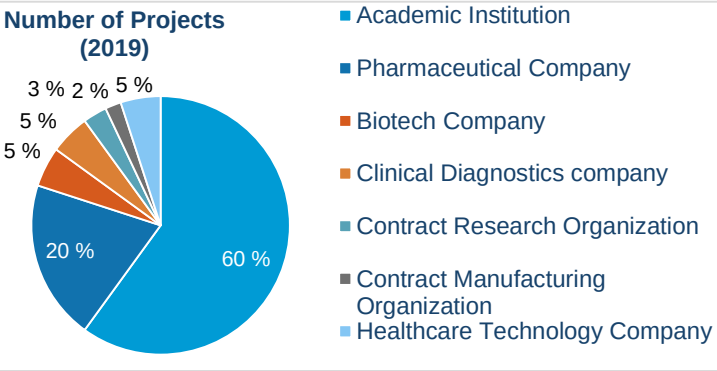
Biobank Graz profile			
Location	Austria	Established year	2007
Biobank type	Focus on both population and disease based studies		
Ownership	Medical University of Graz		
Brief overview	▪ It was established as publicly funded, non-profit central research facility of Medical University of Graz, Austria. With its broad informed consent, Biobank Graz distributes samples worldwide to ethically and scientifically approved research projects from academia, industry, and cooperative studies in biomedical sciences. It is considered to be a central hub for biomedical research		
Core area of specialization	▪ Biobank specializes in disease specific collections of samples, which is sourced from Austrian population, without a bias. It has a substantial variety of collection, we can cater to all the research demands, be it population-based, cohort-based, longitudinal or even disease specific. The therapeutic areas are oncology, cardiovascular, pulmonology and even dermatological research.		
Rationale for prioritizing	▪ Biobank Graz is among the world's biggest biobanks and its expertise is in biomarker development, oncology and digital pathology		
Total number of samples	▪ ~15-18 million samples		

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

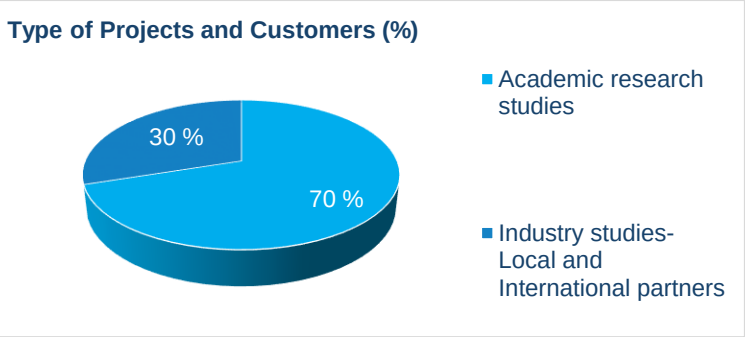
Customer Acquisition

Customer Types and Marketing

Biobank Customer Types



Biobank Customer Project Types



- Biobank Graz is the biggest biobank in the world and rightly so, **it has a diverse category of end-users for the projects**. Although the academic based studies still form the majority of the portion of the total projects, **Biobank Graz has mainly engaged with pharma and diagnostic companies for the industry based studies.**

- Biobank Graz customer outreach **is mainly through conference presentations print media advertising such as brochures, research articles in magazines**, etc. . As the services involve patient samples, data and other information that involves confidentiality and privacy, Biobank Graz does not consider social media as an optimum outreach platform . **There is a dedicated team for marketing activities in Biobank Graz and a separate annual budget for the marketing activities.**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

Biobank Engagement Model Alignment			
Model	Adoption		Key End Users
	Current	Future	
Research Provider			Academic, Biotech
Data Owner			Pharma, Diagnostics, CSO, Healthtech

- For the **data owner model, Biobank Graz has the total ownership of the data and the end-user is granted permissions to access the data which also requires some additional fee**. Since this model has demonstrated transparency and clear transactions, it is highly preferred by Biobank Graz with mainly **Pharma, Diagnostics, CSO, Healthtech where the requirement of data based services is high**.

- **Biobank Graz has also participated in the research provider model**, where the end-user mainly academic and the biotech companies collaborate with the Biobank and the main **feature of the engagement is that it is customized as per the type of research study and the area of the research study.**

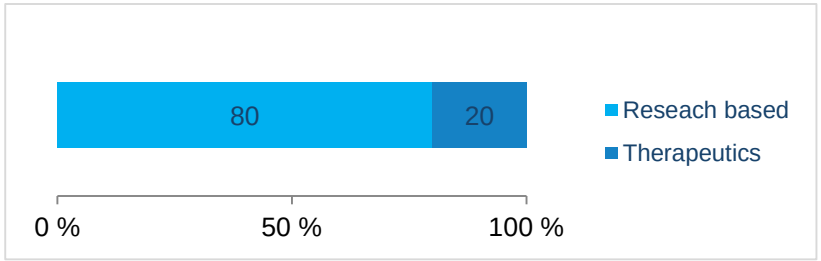
Low High

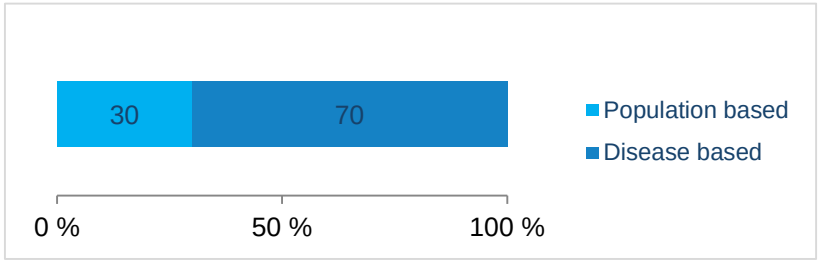
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

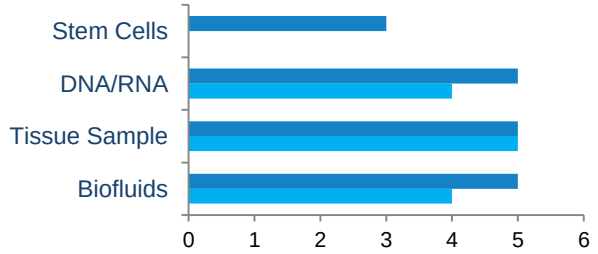
Service Segments

Share from total projects (%)





Sample Utilization



- Major partners for Biobank Graz **for research based projects are universities and research hospitals** like **Centre for Medical Research** whereas for therapeutic studies, it is pharma and diagnostics end-usrs.

- Sample utilization of the biofluids is high for Biobank Graz mainly due to the utilization of blood, urine, serum, sputum, in biomarker studies, digital pathology application, gene therapy applications and rare disease studies which are expected to increase in the future for the biobank. **CIGMR Biobank has utilized tissue samples and the DNA extracts mainly for oncology studies, translational research studies**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

Biobank Application Area Alignment						
Application Area	**Key competency of your biobank**	**Biospecimens Utilized**	**Key End Users**	**Growth Potential**		**Growth Drivers/ Challenges for your biobank**
				Present	**Future**	
Companion Diagnostic	Biospecimen type	Tissues, blood, urine, sputum	Diagnostics			Growth drivers for the biomarker based tests are the availability of large samples for testing although the challenge faced by the biobank is that they are too specific sometimes
Genomic Sequence	-	-	-	-	-	-
Oncology Clinical Development	Biospecimen type	Tissues, blood, serum, plasma	Pharma, Academics			In Oncology also the high demand for specific cancer tissue biospecimen is a growth driver however maintaining the purity of the samples is challenging
Real World Evidence	-	-	-	-	-	-
Digital Pathology	Biospecimen type	Blood, serum, plasma	Pharma, Academics			Increase in demand for sample types in TMA tests, are driving growth while rendering images for all the samples is a challenging task

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Drug Development Value chain competency

Application type	Expertise (Scale)	Number of Studies	Key End Users
Target identification and validation		Confidential	Pharma
Lead identification and optimization		Confidential	Pharma
Preclinical		Confidential	Pharma
Phase I		-	-
Phase II		-	-
Phase III		-	-
Phase IV (RWE studies, Post marketing, etc.)		-	-

- Biobank Graz has primarily worked in the **target identification and lead optimization projects along with preclinical studies**. The major clinical areas are oncology, cardiovascular and haematology based research.

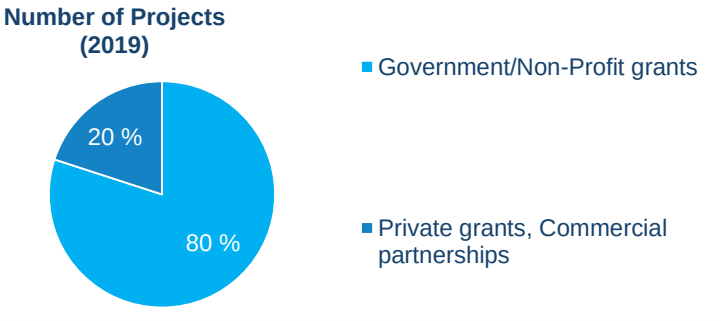
Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Financial Sustainability

Biobank Funding Sources



Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Fee for service			Academic, Pharma, Biotech, Diagnostics, CSO, Healthtech

- Biobank Graz **does not consider financial sustainability a challenge for running the operations as they consider the grants received sufficient for their biobanking operations**.
- Biobank Graz employs a **fee for service model for all its end-users**. Through this model, the Biobank ensures that the end-users pay for the samples. The main aim of this type of model is to assist medical research in diseases, hence Biobank Graz tries to work with a large number of end-users with the fee for service model. **Thus, the volumes of project helps them to recover the cost of the daily operations for Biobank Graz.**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Sample Management

Sample Management	
Function	**Key Value Proposition**
Sample Collection	Highly isolated Austrian population samples- both healthy and disease based
Sample Processing and Storage	FFPE tissue slides and blocks, and snap frozen samples are stored at appropriate temperature for long term storage
Sample Maintenance	Automated systems to avoid any degradation and aliquoting to minimize human error
Sample Retrieval	Automated robotic system for sample handling, and Micronics's tube scanning and data management system. CEN/TS quality standards for sample retrieval.
Quality Control Procedures	A full time operational temperature control system with 2D-barcode labels, FFPE sample handling systems and semi-automated cryopreservation units.

Biobank Cost Drivers

Cost Drivers

- The key areas that constitute the cost drivers for Biobank Graz include the sample collection methods as the Biobank has a huge sample repository, the storage of samples with specifications and temperature control that increases the cost of storage, robotic systems for sample management, and shipping costs.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (1/3)

Data Management Application Area				
Function	Key End User	Application Area	Adoption	
			Current	Future
Exogenous Data	-	-	-	
OMICS/Dx Data	-	-	-	
Clinical Data	Academics, Pharma	Oncology		
Remote Care Data	-	-	-	-

Data Management	
Function	Key Value Proposition
Data Collection	
Data Processing and Storage	
Data Analytics	
Data Sharing	

- While Biobank Graz utilizes the Clinical data mainly for oncology specific projects, it only provides biosample related data which is collected and stored in house. **It does not provide data as a service separately to the end-users.**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (2/3)

Data Security and Privacy	
Parameter	**Current Proficiency**
Compliance to data privacy (EU GDPR, etc.)	
Established policy guidelines	
Dedicated personnel or data security manager	
Adherence to the patient consent norms	

Data Access Framework	
Parameter	**Current Proficiency**
Open Access Model	No
Control Access Model	Yes
Tiered Access Model	No
Existence of Institutional review board (IRB) for biospecimens sharing	Yes
Privacy and confidentiality protections	Yes

- Biobank Graz has an **Approval as well as an Ethics committee** and it **does not provide an open access mainly due to the highly confidential nature of the clinical data being used**. The access is controlled to only authorized users. **The biobank has also incorporated the practice of destroying the sample which are meant for only one-time usage.**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (3/3)

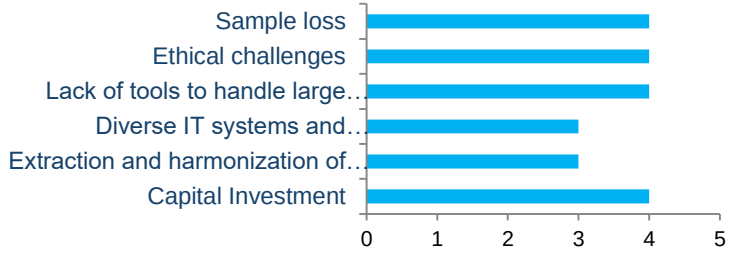
Digitization- One Stop Access

Type of Access	Adoption	
	Current	Future
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease Registers		

Low High

Digitization- Key barriers

Key barriers



- **Biobank Graz provides sample information through the BBMRI portal, whereas for sample data it is only provided through a written research proposal which needs to be approved from the Ethics Committee**. Biobank Graz does not have an online portal for access yet it considers this as a **potential opportunity especially because the end-users can get information about the collaborations and samples.**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

Regulatory Scenario		
Model	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		-
Is the prevailing patient consent system efficient in biobanking activities		-
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		-

Network Participation

- Biobank Graz Biobank considers the current laws and regulations to be proficient for Biobanking activities.
- Biobank Graz is a partner of multiple initiatives mainly **BBMRI, ISBER, ESBB through the Medical University of Graz. It has also participated in public programs like Horizon2020 and Competence Centres for Excellent Technologies or the COMET**.
- Biobank Graz considers such participation in national/international networks as a key to facilitate collaboration, data sharing, approvals and also contributing positively to the reputation of the biobank

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

Biobank Future Outlook	
Customer Acquisition	Academics and Pharma will remain the key customers for Biobank Graz followed by Biotech, CSO and others. The research focus is likely to be on oncology studies, biomarker discovery and personalized medicine **Biobank Graz considers to utilize data owner and research based model extensively in the future** with the end-users
Service Scope	Biobank Graz will focus on increasing the sample utilization mainly for tissue samples and on the stem cells samples. The application area focus will likely to be **on biomarker studies, genome sequencing applications, digital pathology, gene therapy applications**, etc.
Financial Sustainability	Biobank Graz, does not foresee any challenge to maintain the financial sustainability for its operations as it will continue to leverage its internal funds and its commercial and academic partnerships
Operational Sustainability	Biobank Graz **mainly focuses on sample related services to the customers and does not utilize data based services for them although it is likely to keep its focus on the clinical data in the future**. For sample related infrastructure Biobank Graz will continue to enhance its capabilities for sample processing and management
Social Sustainability and Collaborations	Biobank Graz considers **participation in networks to be highly advantageous not only in terms of ease of access to information and knowledge sharing but also as a credible parameter for the reputation of the biobank**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Profile

Overview

International Agency for Research on Cancer

World Health Organization

IARC Biobank			
Location	France	Established year	2010
Biobank type	Focus on both population and disease based studies		
Ownership	Government funded (approximately 60% of its budget is provided by IARC Participating States through the regular budget)		
Brief overview	▪ The IARC Biobank (IBB) is one of the largest, most varied and richest International collections of samples in the world. ▪ A major role of IARC is to promote scientific cooperation.		
Core area of specialization	▪ Biobank has an expertise in research domain particularly in cancer. It is involved in projects which revolve around the development and evolution in terms of diagnosis and treatment of cancer. ▪ It collects samples from a varied range of cancer patients with proper screening and pathological tests conducted to provide appropriate quality of samples to other organizations working in collaboration with the biobank. .		
Rationale for prioritizing	▪ IARC Biobank is one of the world's largest biobank. It specializes in Oncology but provides proficient services across areas including digital pathology, companion diagnostics, genome sequencing, and RWE studies		
Total number of samples	▪ ~7 million		

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

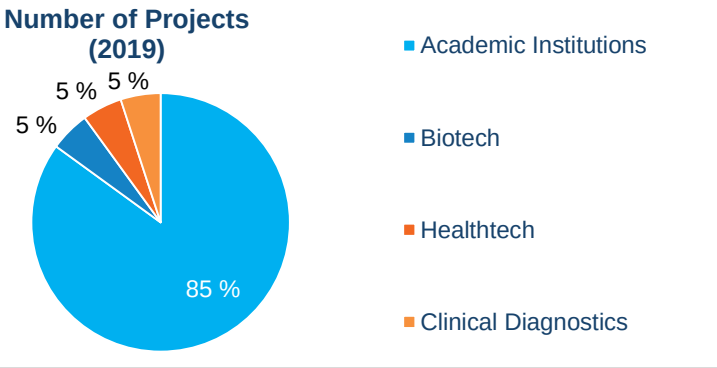
Customer Acquisition

Customer Types and Marketing

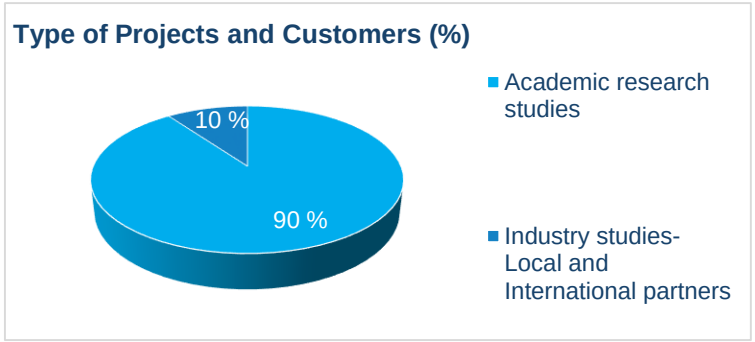
International Agency for Research on Cancer

World Health Organization

Biobank Customer Types



Biobank Customer Project Types



- IARC Biobank has a wide range of customers across Academics and commercial institutions. **Major partners include Vrije University in Brussels and Shanghai Jiao tong University, National Health Agency in France, University College London and Karolinska Institute which are the source of research based projects**.
- IARC Biobank **customer outreach is primarily through brochures which it utilizes during the conferences in order to spread awareness regarding the activities of the biobank**. IARC Biobank **has a team for marketing which works towards promoting the biobank** and spreading awareness regarding the services that it provides.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Customer Acquisition

Engagement Model

International Agency for Research on Cancer

World Health Organization

Biobank Engagement Model Alignment

Model	Adoption		Key End Users
	Current	Future	
Data Owner			Biotech
Time and material			Healthtech
Strategic Partnership			Academics

- IARC Biobank prefers the **data owner model for data based services and in this engagement, LIMS based system has online control access** which is provided to the end-users. Based on the level of authorization, the access is provided to filtered type of data that is required by the other party for research purpose. S**trategic partnership is mainly used for long term project engagements especially when the end-user has established long term association with the Biobank and there are regular project based requirements**. Time and material model is preferred for short term engagements with the end-users with a pre-defined requirement for sample and data with tight timelines

- **Strategic partnership involves long term commitment in terms of sample delivery and maintaining quality**, whereas in case of time and material model, stringent timelines pose a challenge to IARC Biobank especially while working with international partners.

Low High

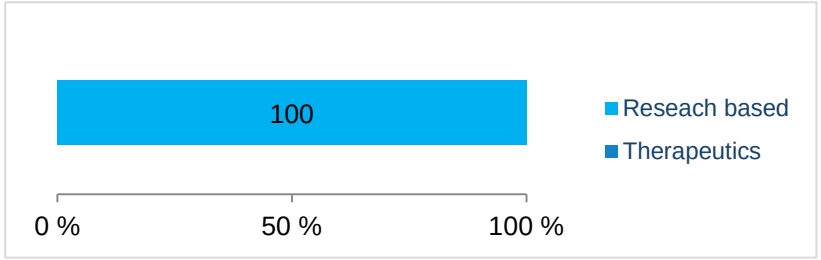
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

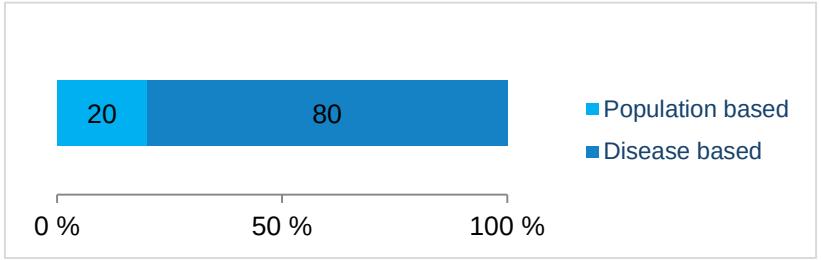
Service Scope

Service Segments

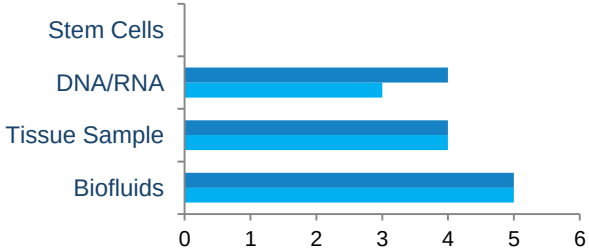
International Agency for Research on Cancer
World Health Organization

Share from total projects (%)





Sample Utilization



- Major partners for IARC Biobank for different projects **(mainly disease based studies) are John Hopkins University and Imperial College London**. IARC Biobank has engaged only in research based studies in oncology with major partners being **National Health Agency (France), University College, London, and Karolinska Institute**
- IARC Biobank has engaged in various studies in wide range of application areas where sample utilization is high. **IARC Biobank has utilized biofluids (plasma, urine) for biomarker studies, biofluids (serum, plasma), tissue samples and DNA for genome sequencing applications, and tissue samples for oncology studies**.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Service Scope

Application Area Matrix

International Agency for Research on Cancer
World Health Organization

Biobank Application Area Alignment

Application Area	Key competency of your biobank	Biospecimens Utilized	Key End Users	Growth Potential		Growth Drivers/ Challenges for your biobank
				Present	Future	
Companion Diagnostic	Biospecimen type	Biofluids such as Plasma, Urine, DNA extracts, and tissue samples	Academics			Precision medicine applications are a growth driver for the companion diagnostics especially in oncology. However lack of skilled resources, and operational management is challenging
Genomic Sequence	Biospecimen type	DNA, Tissue samples and biofluids	Academics			Human genomics applications with novel discoveries in the segment is a growth driver. Harnessing of big data is expected to be a key challenge
Oncology Clinical Development	Biospecimen type	Tissue Sample	Academics, Diagnostics			Precision medicine applications is a key driver and the purity and specificity of samples is a key challenge
Real World Evidence	Biospecimen type	Tissue samples and plasma	Academics, CSOs			Demand of samples for RWE studies is growing especially for research organizations
Digital Pathology	Data integration and digitization	Tissue samples	Academics			Technical skills is a major challenge

Low High

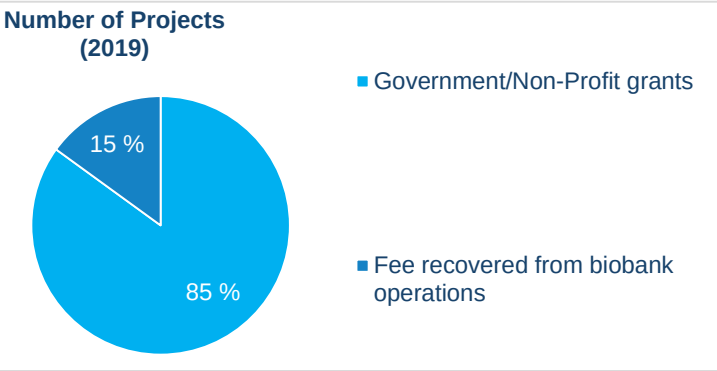
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Financial Sustainability

International Agency for Research on Cancer
World Health Organization

Biobank Funding Sources



Biobank Pricing Model Alignment

Model	Adoption		End-user
	Current	Future	
Cost Recovery Model			Academics
Fee for service			Academics
Dynamic Pricing			Academics, Biotech, healthcare tech
Milestone based pricing			Academics

- IARC Biobank considers **lack of defined pricing models, dependency on short term funding as key factors that impact financial sustainability of its operations**. The biobank is now working towards **having a change in the format of pricing model and looking to utilize additional charges on the biospecimens and also implement different models such as fee for service, dynamic and milestone based pricing as per requirements**.

- Currently for the **cost recovery model, the biobank charges a subsidized amount to the end-users such as academics** whereas in fee for service model, the biobank charges amount for the services utilized by the end-users. On few occasions when the **biobank utilizes the milestone based model, they payment is received by the biobank only after agreed milestones are achieved whereas in dynamic based pricing, the sample pricing is done based on market demand of the samples**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Sample Management

International Agency for Research on Cancer

World Health Organization

Sample Management	
Function	**Key Value Proposition**
Sample Collection	Sample collection from across the globe
Sample Processing and Storage	Cryopreservation, DNA aliquoting,
Sample Maintenance	Remote monitoring and access to samples for better maintenance
Sample Retrieval	Digital pathology and LIMS
Quality Control Procedures	Blood fractionation robot unit, robotic storage with optimum conditions available, freezers and LIMS system

Biobank Cost Drivers

Cost Drivers

- The key areas that constitute the cost drivers for IARC Biobank **include performance of screening tests as a part of sample collection, and fixed costs such as liquid nitrogen tanks and freezers**. Furthermore a lot of time is spent on processing the samples for storage purpose as there is labeling of samples appropriate storage conditions. **Transportation is another factor which can be expensive** as packing of the biospecimens in the paraffin blocks or other storage conditions such as dry ice or liquid nitrogen. **Investments into data management and storage software such as LIMS also acts as a key cost driver**.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (1/3)

International Agency for Research on Cancer

World Health Organization

Data Management Application Area				
Function	Key End User	Application Area	Adoption	
			Current	Future
Exogenous Data	Academics	RWE		
OMICS/Dx Data	Academics, Healthtech	Genomics		
Clinical Data	Academics	RWE		
Remote Care Data	-	-	-	-

- IARC Biobank utilizes exogenous data, OMICS/Dx data and Clinical data mainly for Academics and Healthtech end-users. **Sample collection and analysis is the key area of competency for the IARC biobank** and it utilizes data based services such as analysis, collection and storage, etc. on a need basis for the end-users in collaboration with the third party vendors

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (2/3)

International Agency for Research on Cancer

World Health Organization

Data Security and Privacy	
Parameter	**Current Proficiency**
Compliance to data privacy (EU GDPR, etc.)	
Established policy guidelines	
Dedicated personnel or data security manager	
Adherence to the patient consent norms	

Data Access Framework	
Parameter	**Current Proficiency**
Open Access Model	-
Control Access Model	Yes
Tiered Access Model	Yes
Existence of Institutional review board (IRB) for biospecimens sharing	Yes
Privacy and confidentiality protections	Yes

- IARC Biobank collects samples from across the world through different ways and it has an **Institutional Review Board** to make sure that the samples have been collected according to the permissions and within the parameters.
- **The access is provided only to particular group of people for reference purpose**. This measure also helps to maintain regulatory transparency and the biobank can evaluate the risk of releasing data to the respondents. **The biobank follows the GDPR regulations and it ensures to maintain privacy and security of the data by putting a certain amount of restrictions in terms of sharing data with the organizations**

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Operational Sustainability Focus- Data Management (3/3)

International Agency for Research on Cancer

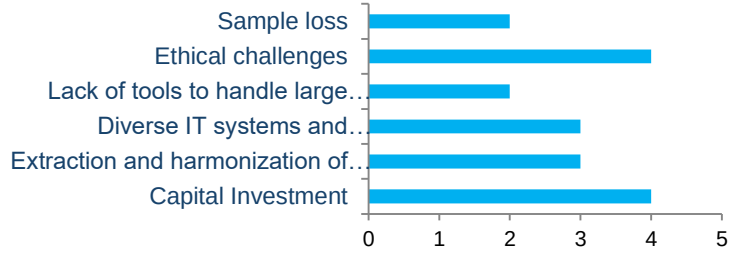
World Health Organization

Digitization- One Stop Access

Type of Access	Adoption	
	Current	Future
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease Registers		

Digitization- Key barriers

Key barriers



- The use of virtual portal is beneficial to get the access of the information easily. Such portals contain all the information related to the samples and the researchers can easily find the data specific to their requirement. Furthermore **centralized access feature provides a single point of contact and it becomes easier to handle multiple requests that are received by the Biobank through a single mode of interaction**.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biobank Sustainability

Social Sustainability and Collaborations

International Agency for Research on Cancer

World Health Organization

Regulatory Scenario		
Model	**Current Proficiency**	**Areas of improvement**
Are the prevailing laws/regulations efficient for the biobanking practices in your country		There are no laws specifically to ensure regulation within the biobanking sector. There is a need to have rules and guidelines within the biobank to ensure that certain limits are maintained for efficient functioning of biobanking activities
Is the prevailing patient consent system efficient in biobanking activities		-
Are the prevailing laws that deal with data protection and privacy efficient in biobanking activities		-

Collaborations

cohorte CONSTANCES

ARCH

AGRICOH: A Consortium of Agricultural Cohort Studies

BCNET Biobank and Cohort Building Network

- Participation in a network can help organizations can exchange the required set of data required for comparative analysis across any application areas. **IARC has participated in number of collaborations, both national and at international levels**. There is **AGRICOH, CONSTANCES and E3N cohort studies** in France. Talking about CONSTANCE, the main objective was to support various epidemiologic research considering the population for the cohort study. **The challenges involved in collaborations is the coordination and management of data at such large level and ensuring proper communication between the organizations involved in the study**.

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Future Outlook

Biobank Future Outlook

International Agency for Research on Cancer

World Health Organization

Biobank Future Outlook	
Customer Acquisition	Academics would remain the key customers in the future. However IARC Biobank considers Biotech, Diagnostics and healthcare technology to be the most potential customers in the future IARC Biobank considers to utilize strategic partnership and data owner based engagements more prominently in the future with the end-users
Service Scope	IARC Biobank will mainly focus on oncology related projects and diagnosis and the utilization of tissue samples, DNA/RNA extracts expected to increase. IARC Biobank will keep its focus on all the application areas namely companion diagnostics, genome sequencing, oncology, RWE studies and digital pathology
Financial Sustainability	IARC Biobank will focus **on increasing commercial partnerships and collaboration with leading research based organizations for high quality samples**. It will also work on awareness campaigns to reach out to potential target clients. **Cost recovery model is the most preferred model for IARC Biobank in the future followed by fee for service, dynamic pricing and milestone based pricing**
Operational Sustainability	While both sample and data based services will be the key focus for the IARC Biobank, clinical data will be highly utilized by it in the future. **IARC Biobank will look to further streamline operational flow of the sample value chain in terms of remote access to samples especially while shipping to international locations**
Social Sustainability and Collaborations	IARC Biobank will continue to maintain strict compliance to the guidelines especially the GDPR regulations and also the WHO guidelines as they are engaged in working across international locations and partners.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Growth Opportunities Analysis

Introduction

The Times that are Changing…Need for a Precision Health Eco-system

Economically Unsustainable
Current healthcare and human services industries

Treatment Decisions
Gap in accuracy

Evidence-Based Medicine
<50% is actually evidence-based

Chronic and Aging Populations
Require more care

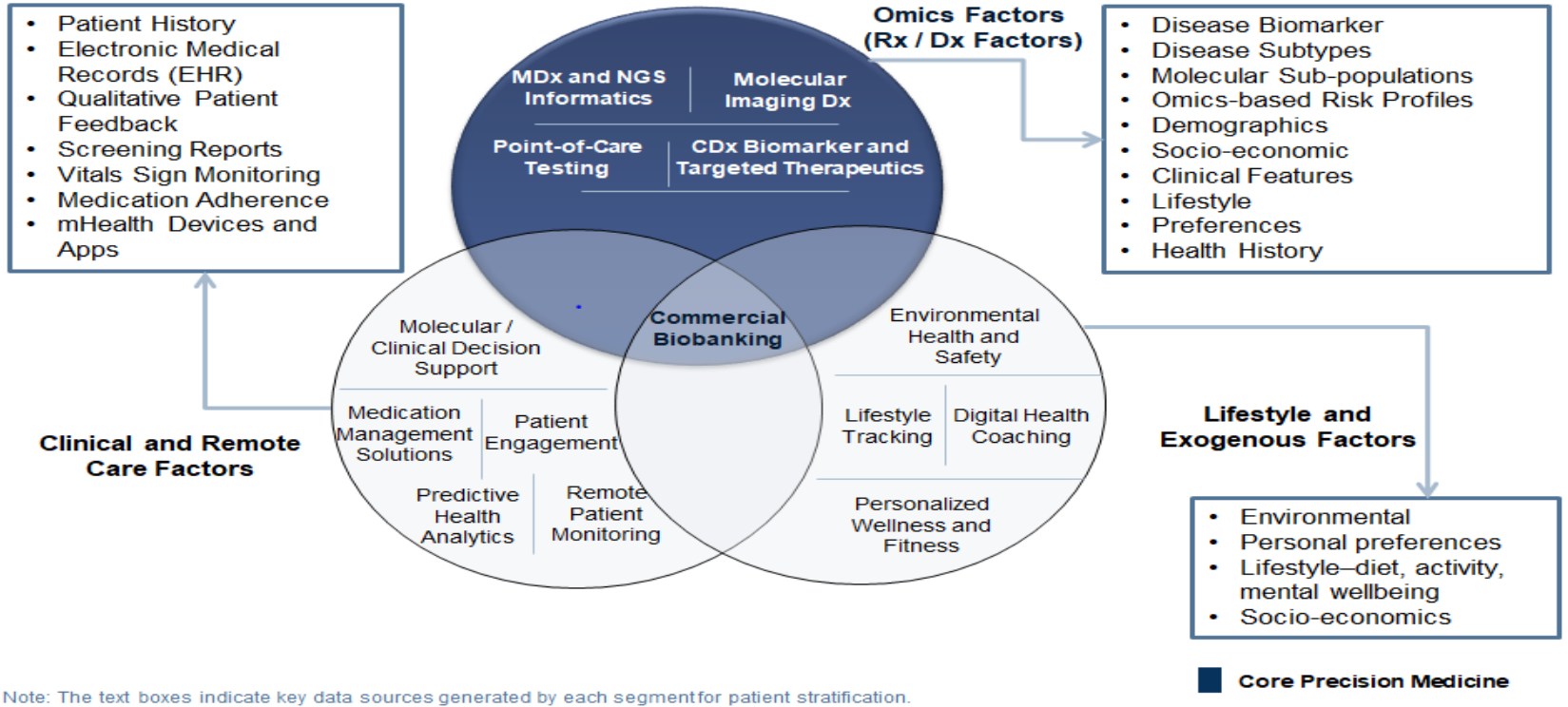
Health Spending
Disconnect with outcomes

The problem is one of precision and productivity, not of diseases, gadgets or healthcare

Now the new vision of healthcare is about Precision-based Predictive, Preventive and Participatory care models promoting social and financial inclusion.

Introduction

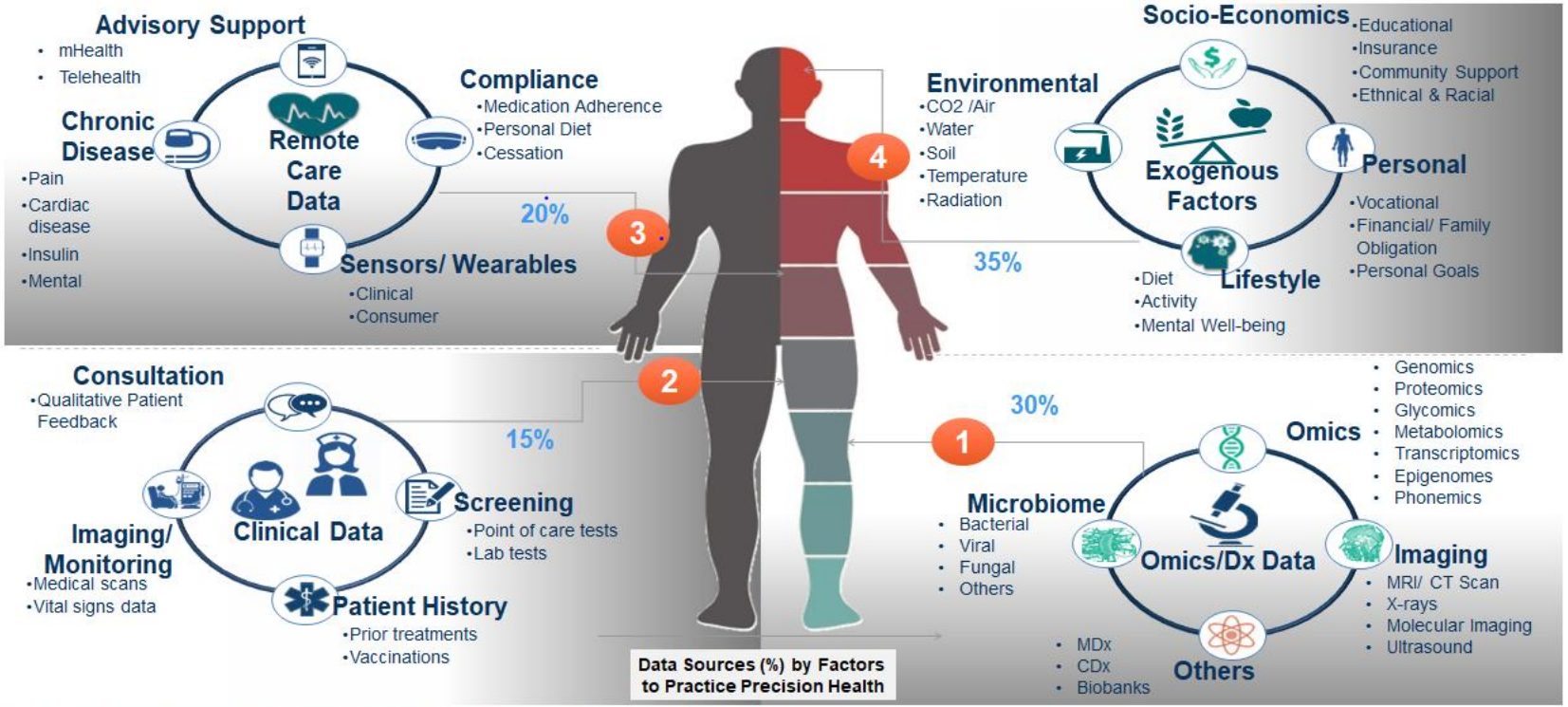
The role of Biobanks in the future of precision medicine is to provide clinical research support that translates into bedside diagnostics and treatments, and advances research technologies into clinical applications



Note: The text boxes indicate key data sources generated by each segment for patient stratification.

Introduction

The Sole Purpose of Samples is to Produce Biodata Enabling Patient Stratification for Precision Medicine



Note: Each data sources are not mutually exclusive to individual factors and are not exhaustive in nature.

Biobanking Solutions for Patient Stratification

Sustainable supply of high-quality and well-annotated tissue samples will be central to the practice of precision medicine

Healthy Individuals/ Patients

Types Human Samples

- Blood
- Serum
- Mouth swabs
- Plasma
- Urine
- Tissue (Cryo-preserved)
- Tumor Cells
- Nucleic acid
- Medical History
- Lifestyle Information

Biobanks

Major Activities

- Sample Collection
- Transportation
- Sample processing
- Sample Storage and Archiving
- Analysis, Reporting and Billing

Major Technologies

- LIMS
- Automated Compound Storage and Sample Management Systems
- Automated Liquid Handling Systems and Robotics

Patient Stratification

Major Applications

- Disease Biomarker
- Disease Subtypes
- Molecular sub-populations
- Risk Profiles
- Demographics
- Socio-economic
- Clinical Features
- Lifestyle
- Preferences
- Health History

Precision Medicine

Biomarker Diagnostic

Therapy (Rx + Dx = CDx)

Role of Biobanks in Targeted Therapy Development

Biobank Types: By Design and Scientific Targets

Disease-specific Biobanks

- Contain biospecimens collected specific to a disease type or health condition.
- Disease-specific exposure studies for biomarker discovery and companion diagnostic validation.

Residual Tissue / Pathology Biobanks

- Biological material removed during the course of diagnosis or treatment.
- Diverse tissue specimens generally collected and cryopreserved are used for developing personalized medical treatment strategies.

Longitudinal or Population Biobanks

- Collected from recruit participants from a specified general population.
- Biomarker discovery and long-term linkage studies between biospecimens and health data for disease susceptibility within a given population.

Role of Biobanks in Targeted Therapy Development Value Chain

- Investigation of molecular mechanism of specific diseases, establishment of human disease relevance with population-based cohorts for identification of genetic risk factors
- Tissue bank for investigation of target expression in diseases and non-affected organs and validation of human disease relevance of animal models

Target Selection and Drug Development → **Lead Optimization and Preclinical**

Research and Discovery

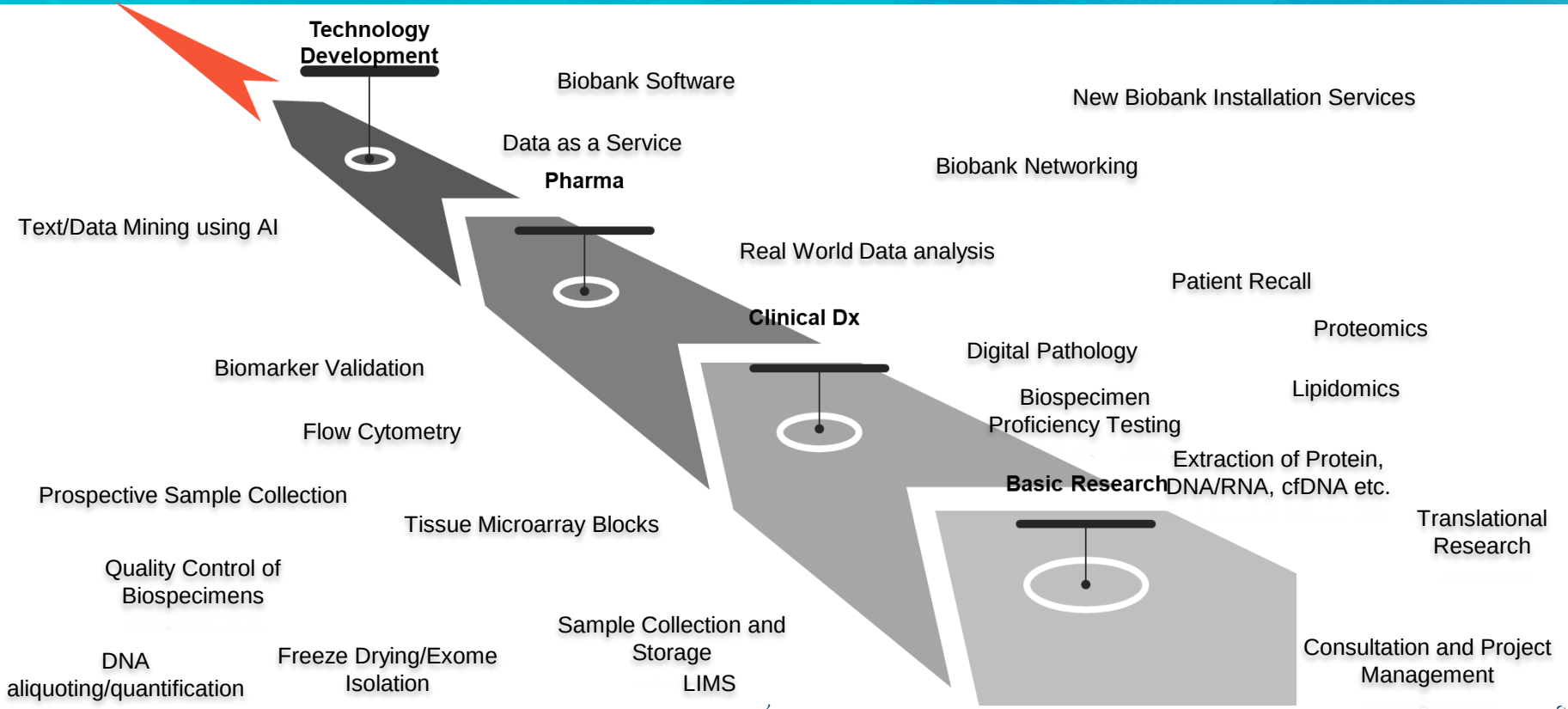
- Tissue banks to investigate target expression in large patient cohorts to support the design of clinical trials
- Archived tissues, cells and body fluids for biomarker discovery control cohorts
- Biospecimens collected in clinical trials for biomarker validation in companion diagnostic development

Phase I → **Phase II** → **Phase III**

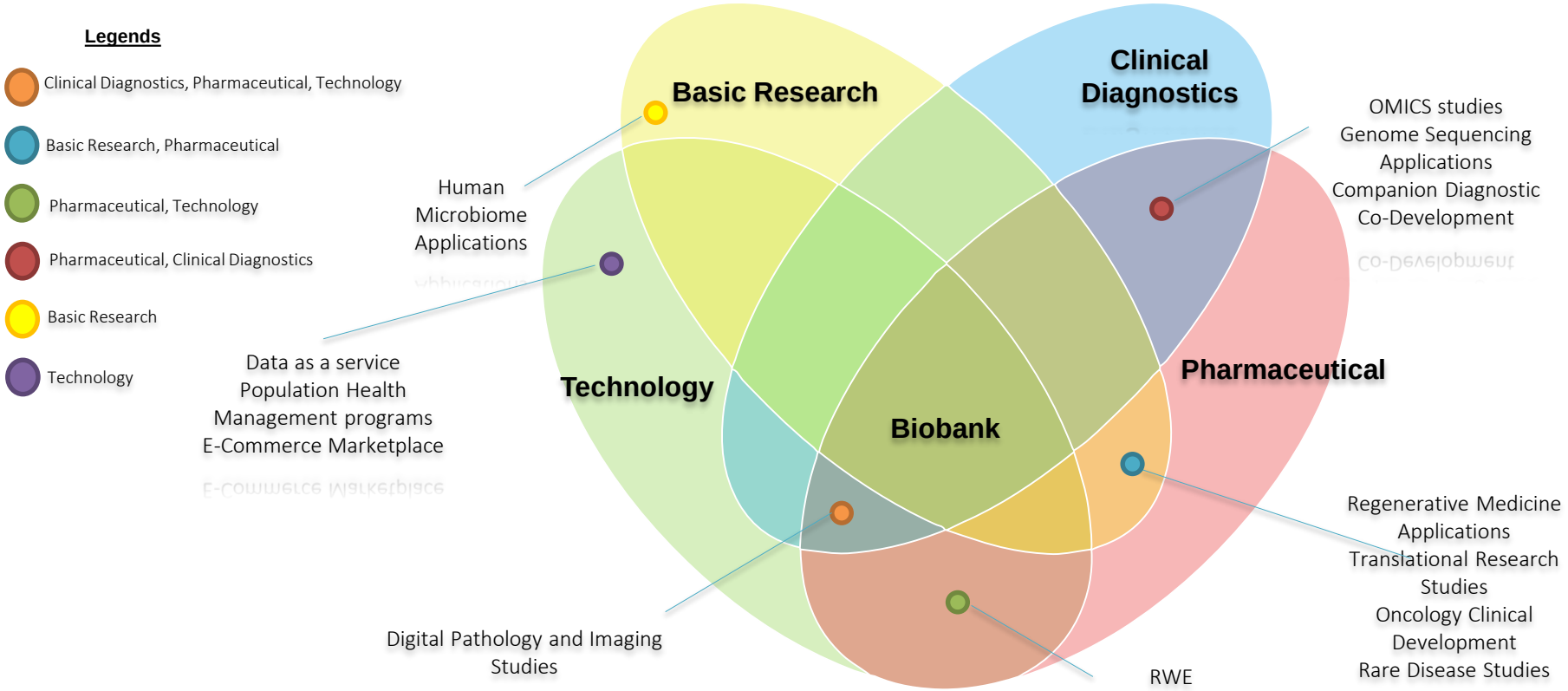
Clinical Development

Service Category Map

Biobank Services Category Map: Basic Research (Disease mechanisms, Functional studies), Clinical Diagnostics (Assay development, Genetic testing), Pharmaceuticals (Develop therapeutics, Drug target discovery) and Technology Development (New platforms & pipelines, Standards & validation)



Growth Opportunity Matrix



Source: Frost & Sullivan

Key Growth Opportunities

Evolving focus areas driving future growth for the Biobanks (1/4)

Companion Diagnostics Co-Development

- By 2025, targeted therapeutics focus shift beyond oncology toward infectious, CNS, and cardiovascular diseases.
- Predictive biomarkers for various diseases will be a sensational area for future investment and growth.

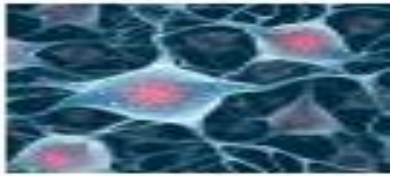
Large-Scale Genome Sequencing Projects

- NGS-as-a-service a dominant business model to make genomic data actionable in precision medicine practice.
- Emerging liquid biopsy and point-of-care testing technologies will start to compete against established NGS space for precision diagnostics.

OMICS Studies

- Pharmacogenomics, Proteomics and Metabolomics based research in predictive biomarkers, transcription studies, metabolite profiling, etc.
- Use of longitudinal data in genomics and proteomics studies.

Regenerative Medicine Applications

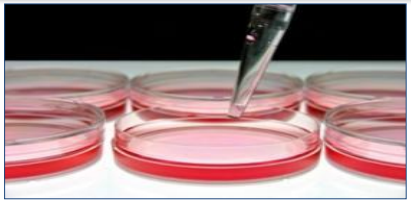


- Regenerative Medicines would see Cell & Gene Therapy applications
- Key areas for biobanks include iPSC (induced pluripotent Stem Cells) standardization, cell-line creation, gene editing, etc.

Key Growth Opportunities

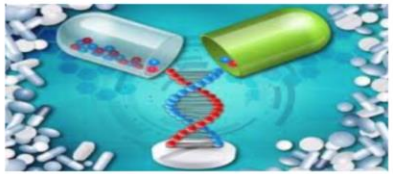
Evolving focus areas driving future growth for the Biobanks (2/4)

Rare Disease R&D



- Rare diseases are a clinically heterogeneous group of about 7,000 disorders which are mostly genetic in origin.
- The European Commission (EC) has prioritized rare diseases in recent health and research programs.

Oncology Clinical Development



- Immuno-oncology therapies are key application area in the oncology therapeutic category.
- DNA barcoding, molecular/integrative nomenclature in genome sequencing projects, testing on multitude of species, adding new barcoding markers are utilized by Cancer Biobanks.

Data-as-a-service

- Lifestyle, Exogenous, demographic, patient records, etc. are some of the key sources of biodata.
- Tailored information on lifestyle and behavioral-based health risks data have a white space opportunity to provide patient risk classification solutions to make precision medicine a holistic approach.

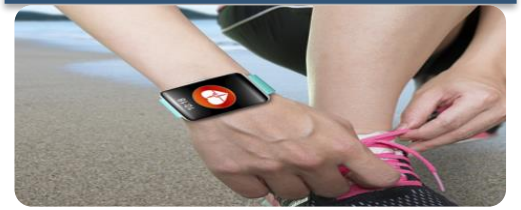
Human Microbiome Research

- Microbiome research explores the relationship between microbiota and their human hosts.
- Biobanking applications both in microbiome companion diagnostics and cancer immunotherapies.

Key Growth Opportunities

Evolving focus areas driving future growth for the Biobanks (3/4)

Population Health Management



- Customized intervention based on the patient's primary conditions and potential risk profiles to drive positive outcomes.
- PHM can be used by health systems to streamline outcomes of their entire patient population.
- Global trend towards value based reimbursement and patient centered care for improved clinical outcomes.

Digital Pathology and Imaging Services

- Biobank network or hub based models providing online access to high-quality samples and images globally with advanced data management and informatics solutions will be the key differentiator for the future success of both commercial and public biobanks.

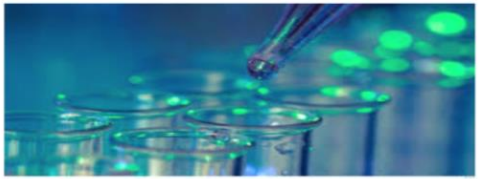
Real World Evidence Studies

- Clinical patient data that is generated in health care outside clinical trials.
- Real world data is increasingly utilized in influencing healthcare decision making, regulatory assessment, clinical practice and policy.
- Population sample data plays a major role in RWE studies for cost-effectiveness, disease burden, diagnostics, etc.

Key Growth Opportunities

Evolving focus areas driving future growth for the Biobanks (4/4)

Translational Research



- Disease areas such as cancer, cardiology, neurological disorders, etc. have been some of the key areas in translational research and system biology.
- System Biology platform: data generation, data curation, machine learning, modeling via AI will be key differentiator.

E-Commerce Marketplace

- E-commerce marketplace is an online platform where biospecimens and data can be shared easily and efficiently across stakeholders, countries as per requirement.
- A novel growth area for biobanks to increase sample utilization and attract potential engagement opportunities.

Companion Diagnostics Co-Development

The biomarkers directly driving precision medicine better known as companion diagnostics are mostly based on in vitro assays of biopsy material

The global companion diagnostics market is expected to reach $8.1 billion by 2023 with a CAGR of 21.2% between 2017-2023. By therapeutic area the oncology segment is expected to account for highest growth rate

Role of Biobanks

- **Identification of Biomarkers**
  - Biopecimen research has been instrumental in identification and validation of biomarker development.
  - **Quality** of the biopecimen and **reliability of the sample data** is critical for the biobanks to offer services in biomarker validation
  - Identification of biomarkers associated with disease conditions such as **cancer, cardiovascular disease, and neurological disorders**, etc. can be helpful in early **diagnosis and prevention**

Interreg North-West Europe Codex4SMEs

Companion Diagnostics expedited for SMEs is EU funded project to e**xpedite the development** of the SMEs' products in the field of CDx.

biobank uk
Improving the health of future generations

UK Biobank has measured a wide range of biochemical markers from blood and urine samples from all the 500,000 participants.

- **Both Population and Hospital Biobanks** can leverage large sample collection, centralized access to samples, and optimal standards of stored biospecimens for enhancing their role in the CDx.
- Most common sample types include **biofluids** such as **blood, serum, saliva, urine**, etc. to **tissue samples**
- CDx offers a range of customers for the biobanks who could be end-users such as **Pharmaceutical firms** or partners in the value chain such **as CROs, biolabs**, etc.

THL Biobank

Source: Frost & Sullivan: Companion Diagnostics Report, ncbi.nlm.nih.gov

Large Scale Genome Sequencing Projects

Genome Sequencing is the process through which the complete DNA sequence of the organism's genome is derived and thus turned into usable data

The European next generation genome sequencing services market is forecast to grow at a CAGR of 15.4% from 2016 to 2023 to reach $605.0 million by 2023. Bioinformatics and application based services to provide competitive edge

Role of Biobanks

- **Whole Genome Sequencing** is a key area for the Biobanks and with the onset of advanced techniques in genetics, sequencing enables **sharing of the detailed genome data** with the researchers
- Biobanks can play a major role in genome sequencing projects due to the **large sample availability and variety**
- Biobanking genome sequencing applications could act as a potential tool for contributing to the understanding of **disease mechanism** and **genetic and environmental determinants** for diseases such as diabetes, schizophrenia, etc.

biobank uk – Improving the health of future generations; gsk; wellcome; J&J; UK Research and Innovation; AMGEN; AstraZeneca; deCODE genetics

- WGS project initiated in September 2019 with the total funding of **£200m.**
- The end result of the project – expected in 2023 – will be a **genetic information storehouse** linked to **comprehensive clinical characterization**, with **de-identified samples**

- Genome sequencing offers opportunity for both **disease and population biobanks** as the genome projects are highly dependent on **large quantity of samples** and **data cohorts** especially the **purity of the DNA samples**
- Biobanks owned by the **Research institutes/University or national/regional agencies** have advantage in terms of an inherent **research ecosystem and efficient data access mechanisms**
- Genome Sequencing studies offer huge potential for the biobanks to **collaborate with the pharmaceutical firms** for **targeted therapies** that have **greater commercialization potential**

HELSINGIN BIOPANKKI / HELSINGFORS BIOBANK / HELSINKI BIOBANK

THL Biobank

Source: Frost & Sullivan: Europe NGS market forecast, proclinical.com

OMICS Studies

OMICS studies have a wide range of applications such as in screening and diagnosis, and key areas include pharmacogenomics, proteomics and metabolomics

The market for single cell genomics and proteomics is projected to reach a size of$1.3 billion by 2022. Shift in customer types (CROs, etc.), preference towards higher throughput solutions, need for simpler workflows and lowering costs are key drivers.

Role of Biobanks

- The use of **longitudinal data** from the provided by the **biobanks enables a large number of gene variants** (often at the **genome-wide** level) which is useful for such studies for the clinical and scientific communities in genomics and proteomics
- **Standardized methods** in proteomics and genomics studies especially for **sample processing is highly critical**
- Metabolites are small and unstable molecules hence **proper sample handling** and **processing at the biobanks** is crucial for **reducing variability** and **integrity** of the experimental data

GenomeQuébec

Genome Biobank, Quebec has an entire division- **Center for Advanced Proteomics Analysis** (CAPA) dedicated to providing state of the art proteomics services

DANMARKS NATIONALE BIOBANK

Danish National Biobanks uses state of the art technologies for **metabolomics and proteomics**.

biobank uk
Improving the health of future generations

Nightingale

UK Biobank partnered with Nightingale Health to analyze **metabolomic markers** using **NMR** based metabolite platform of Nightingale

- Biobanks with **a large variety of samples (biofluids, tissues, etc.**) with and **advanced sample processing** would be key to seize the growth in the OMICS segment
- Biobanks can seize the opportunities in the segment especially in the **research projects by universities**, such as in the area of **chronic diseases** which are a big driver for the OMICS studies.

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Source: Frost & Sullivan: Genomics and Proteomics Report, ncbi.nlm.nih.gov

Regenerative Medicine Applications

Regenerative Medicines play a significant role in treatment of chronic diseases. Gene Therapy applications have further enhanced the landscape of regenerative medicines

The market for regenerative medicine, one of the fastest growing segments in the biotechnology industry, is estimated to reach $67.5 billion by 2020 recording a compound annual growth rate (CAGR) of 22%..

Role of Biobanks

- Key areas of the Biobanks include iPSC (induced **pluripotent Stem Cells**) standardization**, cell-line creation, gene editing, etc.**
- Collection of **samples** done at **early age** is helpful so that the cells can be ready for optimal use for therapy at any time in the future
- **Cord blood samples, bone marrow**, **adipose tissue** are the major sources of stem cells that play a **central role** in regenerative medicine research globally

The recent launch of **Novartis' Kymriah** and **Gilead's Yescarta** is a case in point for the rising research activities around novel **cell therapies**. Following their footsteps, bluebird bio (Bluebird)is showing positive results for its upcoming **gene therapy LentiGlobin™**, which recently received accelerated assessment by the Committee for Medicinal Products for Human Use(CHMP) and the European Medicines Agency (EMA) for sickle cell disease.

xintela Pfizer AstraZeneca GE Healthcare

Sweden has funded a **SEK 48 million project** to establish **CAMP cell and gene therapy research center**

UCL

The **Gene Therapy Biobank** is based at **UCL Institute of Child Health** to facilitate the development of gene and **cell therapies for children** with rare inherited diseases

- **Stem Cell Biobanks** are most likely to be the drivers for the C&G therapy applications
- This is likely to be a promising area in terms of both **research and therapeutic applications** for the biobanks in the future especially for **partnership with pharmaceutical firms** with applications of **gene therapies** ever expanding.
- **Oncology** remains the most common therapy area explored within the category and hence **Biobanks with oncology focus** can also look to seize the growth opportunity in the segment

FHRB Biobank

AURIA BIOBANK

Source: Frost & Sullivan: Global Regenerative Market, ncbi.nlm.nih.gov

Rare Disease R&D

Rare diseases are a clinically heterogeneous group of about 7,000 disorders which are mostly genetic in origin. The European Commission (EC) has prioritized rare diseases in recent health and research

There are nearly 560 candidates in clinical development for the treatment of rare diseases. Approximately 80% of rare diseases are caused by genetic defects. Rare diseases having gain-of-function mutation and late onset are more likely to have a treatment option

Role of Biobanks

- Even small collections or individual samples might be precious for research for rare diseases as it is **difficult to obtain adequate number** of **desired samples due to low prevalence**
- **Storage and distribution of samples** would be a key role offered by Biobanks with large collection of samples
- **Transnational Collaboration** and **data harmonization** of the samples are the key challenges in rare disease research which Biobanks can attempt to address

Rare Diseases examples

- Cystic Fibrosis
- Muscular Dystrophy
- Spina Bifida
- Haemophilia

Rare Diseases in Finland
Nonketotic hyperglycemia, Usher Syndrome, AGU, Nonketotic hyperglycemia, Retinoschisis, etc.

EuroBioBank

EuroBioBank is a unique network of biobanks that **stores and distributes DNA**, cell and tissue samples for rare disease research. The network consists of **25 RD biobanks** located in 11 countries including **9 European countries** (France, Germany, Hungary, Malta, Slovenia, Spain, UK, Turkey) and Israel and Canada. There are more than 150,000 samples available across the network

- **Disease Biobanks** are poised to be the drivers in the **rare disease category** especially in research based applications
- **Biobanks with unadulterated and isolated data** pool are most likely to be of invaluable source of rare disease research
- **Biobank networks** are likely to be cornerstone of a robust rare disease program as the rare diseases are defined by their low prevalence which implies there are constraints and limitations for collecting a critical mass
- Primary sample types that the Bioabanks can offer **include tissue samples, DNA/RNA, cell lines**, and **biofluids** such as **serum**.

BIOBANK of Eastern Finland

Source: Frost & Sullivan: Rare Disease study, eurobiobank

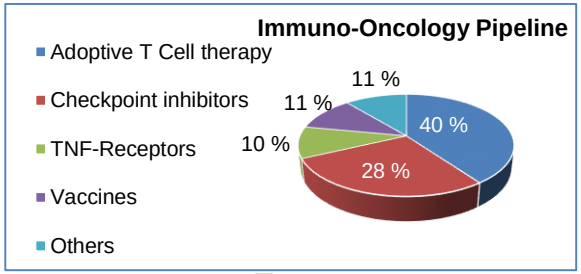
Oncology Clinical Development

With a high disease burden, oncology is a key focus area for innovative therapies globally both in terms of research and therapeutic applications

Immuno-oncology therapies are key application area in the oncology therapeutic category. The overall market for such therapies is expected to reach a revenue of $3.9 billion in 2022

Role of Biobanks

- Oncology is one of the major areas where biobanks can facilitate research into new diagnostic tests and therapeutic approaches
- Patient information on specific symptom, epidemiological data, environmental-occupational factors, lifestyle, societal data and histological cancer characteristics are registered
- DNA barcoding, molecular/integrative nomenclature in genome sequencing projects, testing on multitude of species, adding new barcoding markers are utilized by Cancer Biobanks
- Studies include various **genetic and molecular studies** that include **genotype-phenotype correlations**, cross-sectional, case control and cohort studies



Cancer Biobanks Examples

NCTB

MANCHESTER CANCER RESEARCH CENTRE

Victorian Cancer Biobank

TEXAS CANCER RESEARCH BIOBANK

- Oncology is the key disease area for the Biobanks both in terms of **research and therapeutic applications**.
- **Hospital Biobanks** with a large repository of **tissue samples are the key players**.
- Bioabanks can explore opportunities to strengthen the capabilities in this sample segment in terms of **sample collection, processing and technology** to act as a **one stop destination for research institutes** and **pharmaceutical firms** alike for oncology studies.
- **Diagnostics is a key service capability** and Biobanks can aim to strengthen the same to seize opportunity in this disease segment

AURIA BIOBANK

Source: Frost & Sullivan: Global Immuno-Oncology Market, nctb.com,

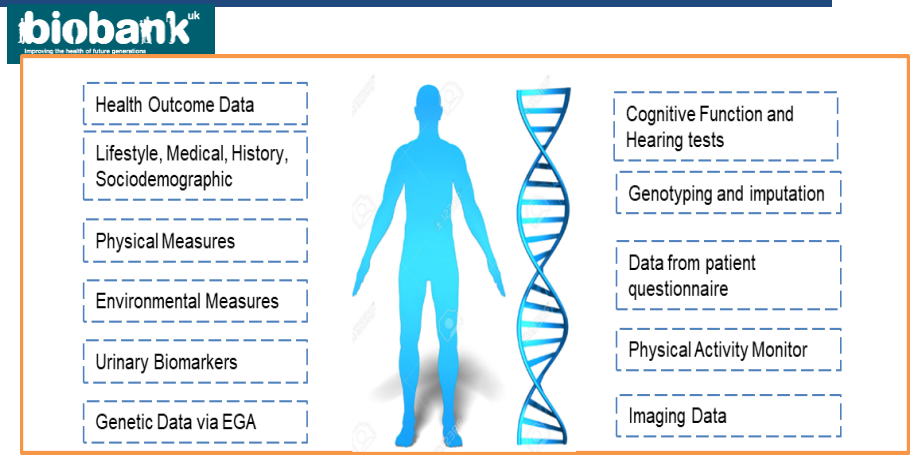
Data-as-a-service

Utilization of sample data as a service offering is a key opportunity for the Biobanks globally

Data as a service is a key application area with the explosion if data generation along with advanced computing technologies and platforms. Interoperability and meaningful use remain the major objectives of data based services

Role of Biobanks

- Sample collection is the key service capabilities of the Biobanks however sample data holds the key to future applications across segments
- Large amount of patient data from the sample is routinely collected by the biobanks. The type of data could include lifestyle data, patient information, demographic data, etc
  - Data collection is from a **wide variety of sources**
  - Data collection is **controlled, audited and standardized** that complies with **international standards**
  - Data is stored in a **highly secure Core Repository**



- **Lifestyle data, Sample Data, Patient data, etc.** from large variety of sources such as samples, tests, devices, etc. and **subsequent harmonization** would be a key to biobanks growth in this category.
- One example is **Patient recall** which is a major opportunity for the biobanks as with the availability of large amount of annotated data, patient recall process is simplified especially for patient recruitment in clinical trials. Biobanks have to **explore right business models** to appropriately **monetize the data**
- All types of Biobanks are poised to seize growth in this segment however the **virtual biobanks** core strength is in providing data to providers

Source: Frost & Sullivan Analysis, ukiobank.ac.uk

Human Microbiome Research

Microbiome research explores the relationship between **microbiota and their human hosts.**

The human microbiome market is expected was estimated to be $4.48 billion in 2018 and likely to grow to $6.08 billion by 2023

Role of Biobanks

- **Biobanks** have a role to play in microbiome research with **microbiota sample collection and utilization** in research.
- There are also possibilities that **association** between **microbiota and cancer** include prostate infections, and inflammation.
- Further the research studies point out **that gut microbiota influences human metabolic** and other functions

UK Biobank **partnered** with National Cancer Institute in **September 2019**. Project to determine **associations of oral and gut microbiome**-related exposures with **cancer risk and mortality.**Focus on better understanding of mechanisms underlying microbiome-disease associations.

Integrated Biobank of Luxembourg (IBBL) is involved in a number of **national research projects** on the **microbiome**, in close collaboration with all major biomedical research and healthcare actors in Luxembourg.

- Biobanks with collection of **Gut based microbiota samples** would be key to seize the opportunity in this potential growth segment .
- Human Microbiota presents potential growth opportunities for biobanking applications both in precision medicine **(through microbiome companion diagnostics) and cancer immunotherapies**.
- Customer types relevant for biobanks collaboration include **biotech companies, pharmaceutical and diagnostics firms**.

Source: Frost & Sullivan: Human Microbiome Market, biobank.lu

Population Health Management

Population Health Management segment is growing , largely due to its objectives to improve clinical and financial outcomes for the population and focus on value based care reimbursement model

Population Health Management market in the US was estimated to be $3.1 billion in 2018 and expected to grow to $7.7 billion by 2023

Role of Biobanks

- Biobanks offer **opportunity** in terms of **large sample data collection and population cohort data.**
- **Healthcare Data lakes** allows for **effective cross data analysis** and incorporates **all internal data sources** and **trusted external sources** for mining and **analysis** by **clinical departments, business analysts, and data science teams**.

CRLB (Canada) supports a **large number of population health studies** of the affiliated Population Health Research Institute.

UK Biobank partnered with **UT Health, USA** for a **computational biomarker study** for retinal vasculature in 2018. The objectives of the study state that **prompt recognition of cardiovascular disease** with a **technology scalable to population health** can be **facilitated by the applications of the study**

- **Population Biobanks** are especially poised to make use of the enormous growth potential that the PHM offers. However PHM programs have seen a focus towards **chronic disease** hence **disease biobanks** that can provide sample data of individuals with diseases
- The strength of the biobanks in terms of large **volumes of lifestyle, demographic data, population cohorts** along with other sources such as **registries** would be a key driver.
- **EHR companies** can be the prime target partners for the Biobank in this growing segment.

Source: Frost and Sullivan: US Population Health management, phri.ca

Digital Pathology and Imaging Services

Digital Pathology applications and imaging in biomarker and diagnostics have seen rapid advances in disease diagnosis procedures

The adoption of digital pathology systems is destined to gradually increase year on year with the Hospitals and Diagnostic Labs likely to the be largest adapters of digital pathology over the next decade.

Role of Biobanks

- **Increasing demand** of pathology tests for all **major sample types** (~5% increase year-on-year)
- **Increasing need** for **digital workflow** and technology for **biospecimen assessment** in pathology cases
- Digital information technologies offer the possibility to **track the entire life cycle of a biosample**
- **Codes** established by organizations such as ISBER such as SPREC or bar-coded collections can be used for reliable documentation
- **Quality Measurement of samples and integration** of data from varied sources is likely to be simplified by the digital applications

Helsinki biobank partnership with Fimmic for its **Aiforia Cloud Solution** provides a **unique one access service** using tissue sample collections and **deep learning AI-based image analysis** of Aiforia

EIT Health is a network of best-in-class health innovators backed by the EU.The **Digital Sandbox Program** supports SMEs in developing relevant products and services by working with **biobanks**, sample holders and quality registers in Europe.

IBBL Biobank utilizes digital technologies and AI in **Whole Slide imaging** and enhanced the process of collaboration and consultation among clinicians and pathologists, and analysis of the data

- Biobanks can partner with an **increasingly growing customer segment** that includes **pharmaceuticals, biotech companies, medical diagnostics and academic and government institutions**.
- **Whole Slide imaging, Image Analysis** are some of the **key application areas for** enhanced **disease diagnosis and predictive markers**
- Both **population and disease biobanks** can seize enormous opportunities either with **academic or commercial partners.**

Source: Frost and Sullivan: Digital Pathology market, eithealth.eu

RWE studies

Real world data is increasingly utilized in influencing healthcare decision making, regulatory assessment, clinical practice and policy.

The RWE market has witnessed a number of partnership and acquisition activities as companies aim to improve their technical expertise. The focus areas in RWE solutions include use of OMICS data, cloud computing, real time diagnostics, among others.

Role of Biobanks

- **Areas where biobanks have experience in real world evidence studies include** disease burden , use of healthcare resources, Diagnostics of rare diseases, treatment lines, mortality studies, characteristics of patient subgroups, Regional differences and treatment practices,cost-effectiveness
- The type of data sources may include **Biobank Sample data**, **population based cohorts**, **clinical and disease registry data**, **claims data and surveys**, **genomic data**

KI collaborated with Janssen to for a real world evidence study using the comprehensive data from **Swedish registries** and research expertise of KI in Sweden. The focus research areas include- **Depression, B-cell malignancies, Prostate Cancer, Psoriasis**

UK Biobank partnered with **Oxford University** for modeling dementia risk in real-world clinical and population data **in September 2019.** Using this RWD data, the study would calculate risk scores mid-life to accurately predict those who have a high possibility of developing dementia in later life

- The growing significance of **RWE studies** and the **large data assets of the Hospital Biobanks especially longitudinal patient data** makes a recipe for success in terms of collaboration with commercial partners for RWE studies.
- RWE is a growth opportunity in **research besides product development and commercialization in R&D value chain**.
- There is likely to be an **increased demand from the large pharmaceutical firms in RWE** with more focus on RWD on **product approvals**.
- Biobanks can facilitate RWE service engagements especially by improving **data harmonization and centralization of access**

Source: Frost and Sullivan Analysis, medaffcon.fi, medegine.fi

Translational Research

Translational Research is dedicated to improving health outcomes that address critical medical needs applying knowledge from basic biology and clinical research

The area of translational research is likely to continue its focus on wide areas within healthcare including biomedical engineering, diagnostics, biomarker responses, etc.

Role of Biobanks

- Some of the application areas of the biospecimen utilization include DNA linkage studies for complex disorders, Predictive and Prognostic Biomarker discovery, population based epidemiological studies, association studies using SNP, pharmacogenetic studies in drug discovery, etc.

EuroBioBank

BBMRI
Better Biology Makes Reality Interesting

- GenomeEUtwin Study
- NUGENOB (Nutrient-Gene Interactions in Human Obesity
- PHOEBE (Harmonization of Epidemiological Banks in EU)

IBCSG
International Breast Cancer Study Group

IBCSG Biobank (Switzerland) offers translational research in Breast Cancer. Its network includes partners across 50 counties and 6 continents

Cedars Sinai

Cedar-Sinai (USA) offers core biobanking and translational research services including DNA purification, histology, imaging and microscopy

- **Disease Biobanks** with large number of **biospecimens and centralized access** can make use of the opportunity in the translational research through **biobank networks, sample exchange platforms and uniformity in sample quality and exchange rules**.
- Translation research offers scope for sample utilization of different types such as **tissues, DNA extracts**, etc. are utilized in wide areas of research including **system biology research, oncology, neurology spanning from basic to patient oriented research.**
- **Research based applications** is the core area for translational research where the biobanks can actively collaborate with **national and international research institutions** that have expertise in wide areas within translational research

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HELSINGFORS BIOBANK
HELSINKI BIOBANK

Finnish Clinical Biobank Tampere

Source: Frost and Sullivan Analysis, ibcsg.org,cedars-sinai.org

E-Commerce Marketplace

E-commerce marketplace is an online platform connecting the vendors and buyers for products and services

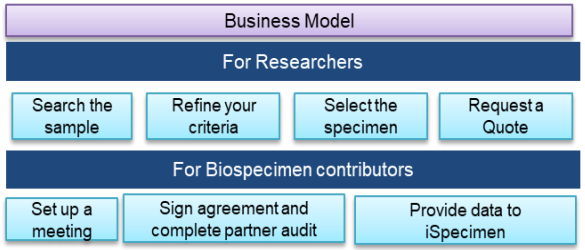
As per a recent study by a large investment banking firm, healthcare industry is prepared to spend $32 billion on e-commerce and web services given the industry growth and convenient access to consumers

Role of Biobanks

- iSpecimen is a firm based in United States. It was founded by a team of pathologists who utilized technology and processes to allow samples distribution and sharing
- iSpecimen acts as a **biospecimen marketplace** that **connects** life science researchers who need human biospecimen with the billions of specimens available in healthcare organizations worldwide
- **Ensuring sample availability** in **a timely manner** is the key **critical need** that e-commerce marketplace can solve in biobanking

https://www.ispecimen.com/

Sample types include whole blood, plasma, serum, urine, stool, CSF, Liquid Cytology, Sputum, buffy coats, FFPE, Frozen tissues



Other services include Compliance management, Contract Management, Site Selection and Management, Specimen Collection, processing and shipping, Custom Study Design

UK Tissue Directory is the UK's register of sample collections covering multiple diseases. The focus is to make tissue and data collections easier to find and access through a freely accessible online directory.

https://biobankinguk.org/

- Biobanks are yet to mature in e-commerce services however with **evolution of technology and enhanced patient protection measures**, this promises a **novel growth area for biobanks** to increase **sample utilization** and attract potential engagement opportunities with international customers.
- **Compliance to laws and regulations** in **data and sample sharing** however would be crucial to such engagements

Source: Frost and Sullivan Analysis, iispecimen.com, biobankinguk.org

End User Assessment

End User Executive Summary

FROST & SULLIVAN

Although sample quality is non-negotiable, Pharma prioritizes good scientific record and accreditation as key measures to select Biobanks for partnerships. Partnerships for novel targeted therapies and…

1

- **Novel targeted therapies for Neuro-generative diseases, Oncology, Cardiovascular** and **Genome sequencing applications** are key focus areas for the **Pharma in the longer term**. **Short term utilization of biospecimen is utilized in biomarker studies and target validation for specific disease conditions**
- While novel therapeutic applications in Oncology will remain the driver for sample utilization, Pharma considers robust genomic data and highly characterized samples for research as key requirements
- **Pharma considers the virtual access to portals as an attractive means to access genomic and clinical data**. Ease of access and enhanced data security are most desirable attributes for one stop access

2

- Pharma considers **large population base and expertise along with the good record of publications** as key to understanding the biobank's service alignment and capabilities in order to match their project specific requirements.
- **Accreditation and partnerships** are the key factors that are considered by the Pharma as a measure of reliability and authenticity for the Biobank.
- **Quality of samples remains a non-negotiable factor for the Pharma** as it is a key to their R&D processes and outcomes

Source: Frost and Sullivan Analysis

… genomic applications are long term whereas biomarker studies are utilized by Pharma for short term engagements. Pharma prefers to enter into strategic collaboration with Biobanks for long term…

3

- **Strategic collaboration is preferred by the Pharma** as it is more **flexible in its terms and conditions for sample and data services and a good fit for long duration projects in targeted therapies, drug development**
- **Data rent model is for data based partnerships** wherein **the research provider model is for short term projects** where research support from the Biobank is required in a disease area
- **Value based pricing is the preferred pricing model because the price of samples and data are determined as per a set of criteria** such as quality of samples, timely availability, and rarity of the samples. Pharma also works on fee for service and milestone based payment model
- For Pharma, **there is an involvement of the scientific, commercial and the procurement team** in the entire process of selecting the biobank, however the chief decision makers are head of R&D and head of Procurement
- **Print media such as brochures, newsletters are most prominent sources of information about the vendors**. Closing a deal with the partners is challenging due to lack of single contacts, multiple procedures and approvals and legal bottlenecks that delay the process and make it less efficient

FinnGen

Population cohorts

Broad Consent

- **FinnGen** study is a key attribute for the Pharma to look forward for working with the Finnish Biobanks, along with Population cohorts and broad consent
- Through such a large scale study as FinnGen, **Pharma can also look to participate in smaller genome sequencing projects, patient selection and disease specific research in Oncology, Neurology,**

Source: Frost and Sullivan Analysis

…projects. One Stop access to data is emerging to be a key attractive attribute for Pharma due to increasing data utilization and ease of access to data

Pharma

Key Research Areas

Precision Medicine
- Genome Sequencing

Pharmacotherapy
- Oncology
- Neuro-generative diseases
- Target validation studies

Research driven data
- OMICS Data
- Clinical Data
- Exogenous data

Targeted Therapies development | **Genomic Applications** | **Biomarkers**

Sample demand

Virtual Access to Portal

Biofluids | **Tissue** | **DNA/ RNA** | **Stem Cell**

Pharma preference for Online Portal is HIGH

Information on Biobanks

Pharma Engagement

Shortlisting and Selection

Scientific record | **Accreditation** | **Population Base** | **Data Integration /Privacy**

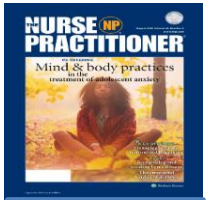
Terms of Engagement

Strategic Engagement | **Value Based pricing** | **Research Provider** | **Fee for service** | **Data Rent** | **Data Rent**

Biobank

Head of R&D
Head of Procurement

Conferences and symposiums



Newsletters, Articles in Journals

Source: Frost and Sullivan Analysis

In addition to good scientific record and accreditation, expertise in a therapeutic area is a significant feature to attract Biotech for a partnership. Such expertise is a strategic fit with the Biotech who…

1

- Biotech utilize the samples and services from the Biobanks based on their therapeutic focus. However with the **increasing research into gene therapy applications and oncology, the Biotech consider genomic sequencing as major area for collaboration**
- Key targeted therapies include **hormone therapies, signal transduction inhibitors, gene expression modulators, immunotherapies, and cancer vaccines**
- **Biotech engage comparatively less for data based partnerships** as their **prime requirement is to procure highly specific samples for disease areas** in order to meet research demand for that specialty. Thus virtual access to portal for data is not a key attractive attribute for the Biotech

2

- **High quality samples, good scientific record, accreditation from recognized organization and expertise** in a therapy or disease area are key selection criteria for biotech
- Samples with high purity and optimum storage conditions play a key role in analysis and results for genomic/disease based studies which are the key focus areas for the biotech
- In order to prevent the violation of local regulations, biotech consider **regulatory support from the biobanks as an essential service**. Biotech consider good scientific record as a credible measure of their ability to engage in complex disease based projects

Source: Frost and Sullivan Analysis

… prefer to procure highly specific biospecimen for early stage clinical and discovery projects for a specific therapy such as NASH, Oncology, Hematology and Neurology or for genome based projects.

3

- Biotech prefer strategic engagement model for **longer duration projects such as genome based studies**. This type of engagement offers **joint efforts by the skilled resources of the Biotech and the Biobank to achieve outcomes**.
- For projects where the **timelines are short and requirements are based on a specific therapy area for a shorter duration**, Biotech considers to enter into **a service based partnership**
- **Value based pricing is the preferred pricing model for Biotech** as there is **right pricing achieved for the samples which is determined by market demand, availability of the samples, competitor prices and sample characteristics**. Biotech have also engaged in dynamic pricing, fee for service pricing and milestone based payment
- For Biotech, there is an involvement of the scientific, and the procurement team in the entire process of selecting the biobank, however the **chief decision makers are head of R&D and head of Procurement**
- **Conference and Exhibitor presentations are the most prominent places for Biotech to seek information about the vendors**. Biotech consider the kick off of the deal to be a challenging exercise as its difficult to find the right contact and visibility of the biobanks is low

FinnGen

Population Base

Biobank Act

- Biotech consider the **FinnGen study and a large population base** as key attractive attributes as it has the potential to make the sample and data access easily available to them for research. As the Biotech are largely involved in early stage discovery projects, convenient sample donation by the donors is also a strong attribute, due to **highly regulated Biobank Act**
- Furthermore, the digital capabilities in the Finnish ecosystem especially **high interoperability of the EHR and clinical record of the patients** is also rated highly by the biotech companies

Source: Frost and Sullivan Analysis

For Biotech procurement of samples is a key requirement due to niche therapeutic or specialty based focus. Data based partnerships are not a priority for Biotech

Biotech

Key Research Areas

Precision Medicine
- Genome Sequencing

Pharmacotherapy
- Pre-Clinical and Early Phase
- Pharmacokinetics
- Efficacy studies

Research driven data
- OMICS Data
- Clinical Data

Genomic Applications | Biomarkers | Targeted Therapies

Sample demand

Virtual Access to Portal

Biofluids | Tissue | DNA/ RNA | Stem Cell

Biotech preference for Online Portal is LOW

Information on Biobanks

Biotech Engagement

Terms of Engagement

Strategic Engagement | Value Based pricing

Service Provider | Fee for service

Shortlisting and Selection

Scientific record | Accreditation

Therapeutic Expertise | Data Integration /Privacy

Biobank

Head of R&D
Head of Procurement

Conferences and symposiums

Promotional Mails, Newsletters

Source: Frost and Sullivan Analysis

Healthtech partnership with Biobanks is heavily skewed towards high utilization of data services and samples for diagnostics, immunoassay studies, biomarkers, and sequencing applications. This makes...

1

- **Cancer diagnostics is a key utilization area for the healthcare tech companies** in all types of services largely d**ue to increasing prevalence of oncology, constant technology interventions in diagnostics , and increasing demand for effective screening tests for cancer**
- Healthtech companies **are highly proficient on using technology in their core offerings, hence there exists immense scope for data based partnerships with the biobanks with focus on Clinical, OMICS/DX and Exogenous data**

2

- **Sample quality and variety, good scientific record and accreditation and ease of data integration with the systems** are key selection criteria for healthtech
- Since data is a key enabler for healthtech firms, data privacy measures, efficient sharing of data, easier integration, and better communication are major factors that the healthtech look for in a partner
- Healthtech engage in multiple project types such as omics, real world studies, microbiome studies, etc. **hence the sample variety is a strong selection factor for the healthtech**

Source: Frost and Sullivan Analysis

… data capabilities such as online access, integration with systems, sample integrity, among the key attributes for the Biobanks. Healthtech partner with the vendors exclusively for data using data rent…

3

- Healthtech also **prefers to enter into a strategic engagement model for a longer duration projects** such as in Genome based projects of long duration, Oncology. **This partnership may also include other partners as a part of a larger pooled study**
- Data rent model is used for projects with shorter durations where samples are not essential. It could be in RWE studies, diagnostics, OMICS studies, etc.
- **There is no single preferred model for the healthtech** and they engage in **value based pricing, bundled payment, fee for service and revenue sharing mode**l. Value based pricing entails sample availability and its utilization in research studies, and bundled payment is used when a single price is charged for a set of pooled services which may include both sample and data based services. **Revenue sharing model is also utilized especially when the outcome of study is significant to end-user and in that case revenue is shared based on a %**.
- For Healthtech, there is an involvement of the scientific, procurement, diagnostics and the commercial team in the entire process of selecting the biobank, however the **chief decision makers are Head of R&D, Head of Procurement and Head of Diagnostic**
- **Conferences and journal articles are the most prominent places for the healthtech to seek information about the vendors.** Closing a deal with the partner is challenging due to involvement of owner institutions in the process and lesser flexibility of the biobanks on sample prices

FinnGen

Population Base

Broad Consent

- **Data based capabilities are key focus areas for the healthtech firms** to partner with the biobanks hence it considers FinnGen study and a large population base to be major attributes for the Finnish Biobanks.
- Broad consent makes it further more easier to obtain samples from donors thus enabling large patient samples for studies

Source: Frost and Sullivan Analysis

…model where temporary access to data is granted. Healthech engages in a variety of pricing models based on the type of sample and data utilized and market demand for such samples and data.

Healthtech

- Genomic Applications
- Diagnostic Studies
- Biomarker studies

Sample demand

- Tissue
- Biofluids
- DNA/ RNA
- Stem Cell

Key Research Areas

Precision Medicine

- Genome Sequencing
- Biomarker profiling
- IVD studies for cancer
- Microbiome analysis
- Immunology assay studies

Research driven data

- OMICS Data
- Clinical Data
- Exogenous Data
- Remote Care Data

Virtual Access to Portal

Healthtech preference for Online Portal is HIGH

Information on Biobanks

Healthech Engagement

Shortlisting and Selection

- Population base
- Accreditation
- Scientific Record
- Data Integration /Privacy

Biobank

Head of Diagnostics
Head of R&D
Head of Procurement

Conferences and symposiums

Promotional Mails, Newsletters

Terms of Engagement

- Strategic Engagement
- Data Rent
- Fee for service
- Value based
- Revenue sharing
- Bundled payment

Source: Frost and Sullivan Analysis

Being a third party vendor to Pharma clients CSOs focus on sample variety (DNA/RNA extracts, tissue, biofluids), regulatory expertise, and good scientific record as key attributes in a biobank

1

- **Oncology specific research applications, epigenetics and genome analysis and utilization of DNA/RNA extracts** are key application areas for the Contract Services Organizations (CRO, CMO)
- CSOs have **data based partnerships on a need basis** as per the project requirements as **they prefer to carry out research and data analysis on the samples in-house for the clients they work**

2

- For the CSOs the focus is on the clinical research outcomes on the projects that they work on for the pharma, hence a biobank with **good scientific record, regulatory compliance to guidelines and expertise in therapy assists in the CSOs end objectives**
- As the CSOs engage in multi-center studies globally, regulatory support by the biobanks in the country of presence is an additional benefit to the CSOs as a part of their engagement

Source: Frost and Sullivan Analysis

Since the project timelines are critical for CSO and dependent on their partnership with the Pharma, CSOs tend to adopt a more flexible engagement with Biobanks in order to deal with dynamic…

3

- **Strategic collaboration** is preferred by the CSOs due to its **offering more flexibility in terms of the length of the projects and delivery, modification of procedures and service requirements**.
- **Fee for service model is preferred by the contract services organizations as it has simple to execute and offers more flexibility in terms of pricing for the samples**. Milestone based model is also an attractive pricing model for the CSO as they are engaged with the Pharma in achieving set milestones in a timely manner
- For CSO, there is an involvement of the scientific, procurement, clinical operations, finance and the commercial team in the entire process of selecting the biobank, however the **chief decision makers are Head of Procurement and Head of Clinical Research**
- **Conferences are the most prominent places for the CSOs to seek information about the vendors**. Closing a deal with the partner is challenging due to lack of sufficient resources for a streamlined project management

FinnGen

Population cohorts

Broad Consent

- CSOs consider **large population base with high quality samples a key factor for future collaboration with the Finnish Biobanks**. Such samples are utilized in genome sequencing projects and in oncology

Source: Frost and Sullivan Analysis

…demand in sample and services requirements. Revenue sharing model for CSOs is tied the outcomes or milestones achieved by the CSO for Pharma company

CSO

Key Research Areas

- Immunotherapy studies
- Translational research
- Biomarker Studies
- Preclinical/Early Phase
- Late Phase/RWE studies
- Genome sequencing studies
- Cell Line development

Research driven data

- OMICS Data
- Clinical Data

Targeted Therapies development | **Genomic Applications** | **Biomarkers** | **DNA/RNA applications**

Sample demand

Virtual Access to Portal

Biofluids | **Tissue** | **DNA/ RNA extracts** | **Stem Cell**

CSO preference for Online Portal is LOW

Information on Biobanks

CSO Engagement

Shortlisting and Selection

Scientific record | **Accreditation** | **Regulatory Compliance** | **Therapeutic Expertise**

Biobank

Head of Clinical Research
Head of Procurement

Conferences and symposiums

Terms of Engagement

Strategic Engagement | **Fee for service** | **Service Provider** | **Revenue sharing**

Source: Frost and Sullivan Analysis

End User Assessment Framework

Service Alignment

- This section covers the end users requirement of services from the biobanks
- Service alignment of the end-users with the biobanks in terms of sample and services utilization, application areas, data utilization, is discussed

Selection Criteria

- This section covers the assessment of the biobanks by the end-users
- Capability assessment specifies the key selection criteria of the end-users to assess the biobanks for a potential partnership

Partnership Fit

- This section covers various factors that contribute to partnership between the end-users and the biobanks.
- Assessment fit is analyzed based on business and pricing model fit as well as key stakeholder involvement

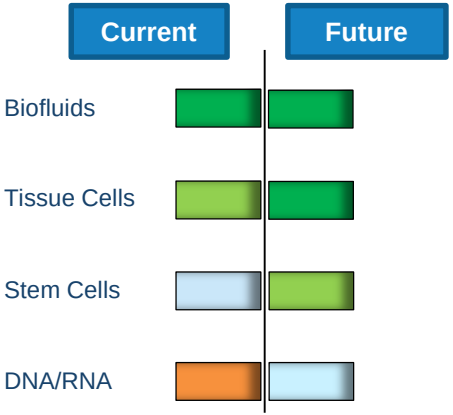
Source: Frost and Sullivan Analysis, AMR Market Study

End User Assessment-Pharma

FROST & SULLIVAN

Genomic Applications and Biomarker studies are the key areas of collaboration with Pharma

Sample Utilization



Service Utilization

Type of Services	Description	Number of Projects (Past 1 year)
Targeted Therapies Development	Utilization of tissue samples especially in research in novel treatment therapies	~8
Biomarker Profiling	Utilization of tissue samples and DNA/RNA extracts	>15
Genomic Applications	Biofluids such as blood, serum, plasma were used as well as tissue samples	>10
DNA/RNA applications	DNA/RNA extracts were used mainly for biomarker profiling	~6
Diagnostic Studies	Tissue samples and DNA/RNA extracts were used	~6

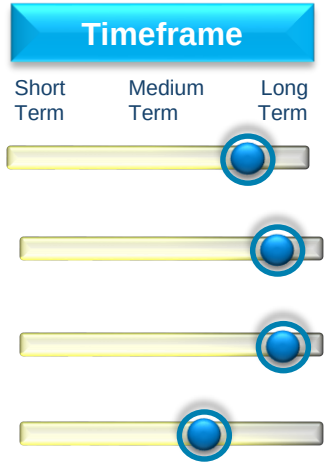
Insights

- *Biofluids such as blood, plasma, serum, etc. and tissue samples are the most commonly utilized samples mainly due to high utility across all types of applications and simplified access*
- *Biomarker studies are expected to remain the focus of the Pharma due to increasing number of diagnostic applications, and prevalence of cancer. Other areas where the Pharma can collaborate include personalized medicine applications, genomic applications involving gene mapping and chromosomal studies*

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

High Quality samples and robust genomic data are the key requirement for the Pharma

End-User Application Area Alignment			
Application Area	**Unique Proposition offered by Biobanks**	**Biospecimen Utilized**	**Key Therapy Areas**
Companion Diagnostic	High quality of tissue and biofluid samples	Biofluids and tissue samples	Neurovascular, Oncology, infectious diseases, allergic diseases, cardiovascular
Genomic Sequence	High quality samples, extensive genomic data	Biofluids, Tissue samples, sequenced genome, protein samples, exome sequence	Neurology, Oncology
Oncology Clinical Development	High quality samples	Biofluids, Tissue samples, cell lines	Oncology
Real World Evidence	Individual level data and patient health record data	Patient health record data	Neurology



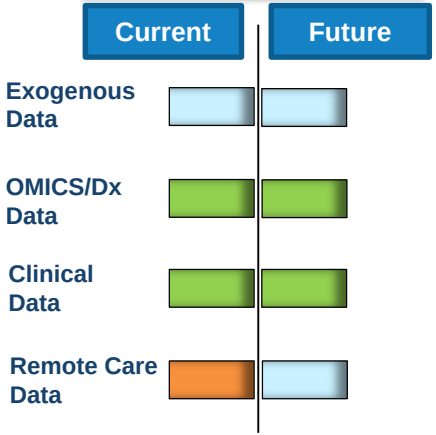
Insights

- *Oncology remains the most common therapy area across all key applications for the Pharma due its high disease burden. The number of new cancer cases are expected to rise to 23.6 million by 2030 and it remains the leading cause of mortality worldwide*
- *Pharma view Oncology Clinical Development and Genomic sequence as the application areas where they are likely to engage with the biobanks in the longer term as the novel therapies are mostly associated with the oncology therapy area. As per market studies the major therapies include adaptive C-cell therapies, checkpoint inhibitors, TNF-receptors, vaccines, etc.*

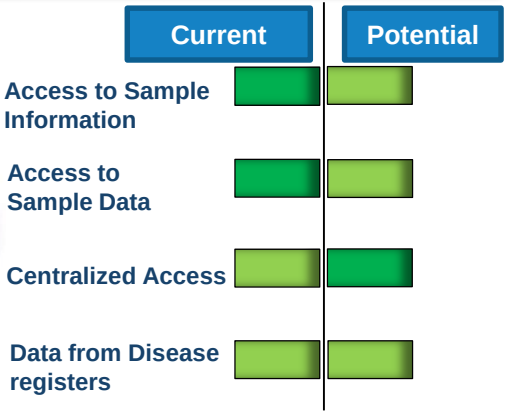
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Pharma clients mostly prefer OMICS and clinical data. Ease of access and enhanced data security are most desirable attributes for one stop access

Type of Data Used



One Stop Access



Engagement Type

Type of Engagement (for data services)	Preference of End Users
Data Owner model	Medium
Research Provider model	High
Service Provider model	Low-Medium

Insights

- *As there is a greater demand for novel therapeutic applications and research studies, the Pharma companies consider the clinical and the OMICS/Diagnostics data is of paramount interest. One Stop Access is considered efficient, informative and useful means of sharing data*
- *If the Pharma engages in data based partnership with the Biobank, a Research provider model is preferred. Such engagements facilitate more collaboration between the Pharma and the biobank which are critical in projects such as in genomics, etc. where a greater clarity on the data type and modalities are key to effective outcomes*

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Sample quality, scientific publications, large population base, etc. are key criteria for the Pharma

Decreasing Order of Importance

Services

- Scientific record
- Population Base
- Expertise

Operational

- Sample quality
- Accreditation
- Years of experience
- International Partnerships

Performance

- Regulatory Compliance
- Data privacy
- Project Management

Insights

- *Pharma considers large population base and expertise along with the good record of publications as key to understanding the biobank's service alignment and capabilities in order to match their project specific requirements.*
- *Accreditation and partnerships are the key factors that are considered by the Pharma as a measure of reliability and authenticity for the Biobank.*
- *Quality of samples remains a non-negotiable factor for the Pharma as it is a key to their R&D processes and outcomes*

Yes, a high degree of scientific track record reaffirms our belief on that biobank being the best possible option to get those specimens from. If we talk about UK Biobank, it has a terrific track record of scientific collaborations, so that was one of the reasons of choosing it.- Head of R&D, Large Pharma

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Strategic engagement is a highly preferred engagement model for the Pharma clients

Decreasing Order of Preference

	Number of projects (past 1 year)	Type of projects	Implementation challenges
Strategic Engagement	~10	Drug development projects across therapies, Genomic studies, targeted therapy	Sample availability, communication gaps, project delays
Research provider model	~6	Targeted therapy	Data ownership
Data Rent Model	<5	Real World evidence studies, OMICS studies	Data gaps

Insights

- *Strategic engagement is a highly preferred model as there is a greater collaboration between Pharma and the Biobanks and is generally for longer duration projects. The model is structured on complementary strengths where the Pharma and the Biobank do an assessment of the areas where each one complements other capabilities in terms of services, therapeutic experience, research capabilities, etc.*

- *Pharma also engages in data rent model to gain data access for a temporary period based on project requirements. If the company wants to co-engage with the vendor for specific research, it prefers the research provider model*

The strategic engagement model involves contracts of long duration which collaborates the R&D of our company with the biobank. I have used these engagements in genome sequencing applications, neurology studies, oncology, etc.
Head of Clinical Operations, Large Pharma

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Availability of High quality samples and data is the key to enter into value based pricing with the Pharmaceutical clients

Value based pricing

Value determinants are timely availability and high quality samples and accuracy of data

Easily available samples are priced less while rare/severe diseases sample prices are high

Sample and data may be priced differently

Fee for service

Biobanks are paid for all the services utilized

Sample, data and even consulting/advisory services can also be a part of the agreement

Milestone based payment

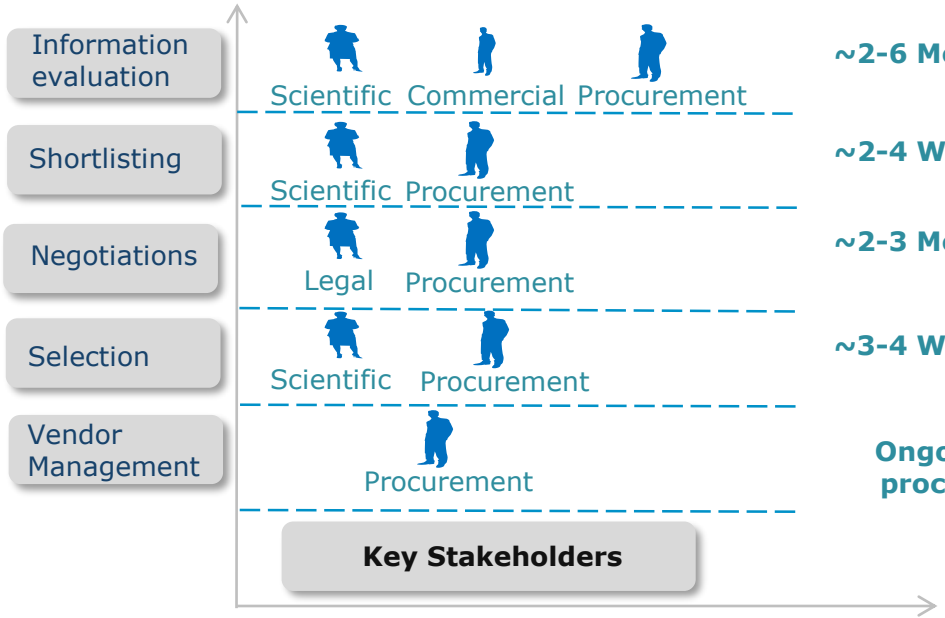
Pricing method is adopted when there are clear objectives to be met in strict timelines

Both sample and data form the part of the total payment

Value-based pricing model is considered as in this case, the prices of the samples and the data is decided as per the value so that top-notch quality is ensured and we actually pay the right amount for the samples and the data.
Medical Director, Large Pharma

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Medical Directors are actively engaged in the biobank selection process and are the key decision makers



Influencer

Head of Administration, Head of Clinical Operations, Medical Director, Head of R&D
Head of Procurement, Head of Marketing

Decision Maker

Head of R&D
Head of Procurement

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Print media such as brochures and flyers are the most preferred information sources for the Pharma

Preferred Media Outreach

Low 1 2 3 4 5 High

Deal Negotiation Difficulty

Low 1 2 3 4 5 High

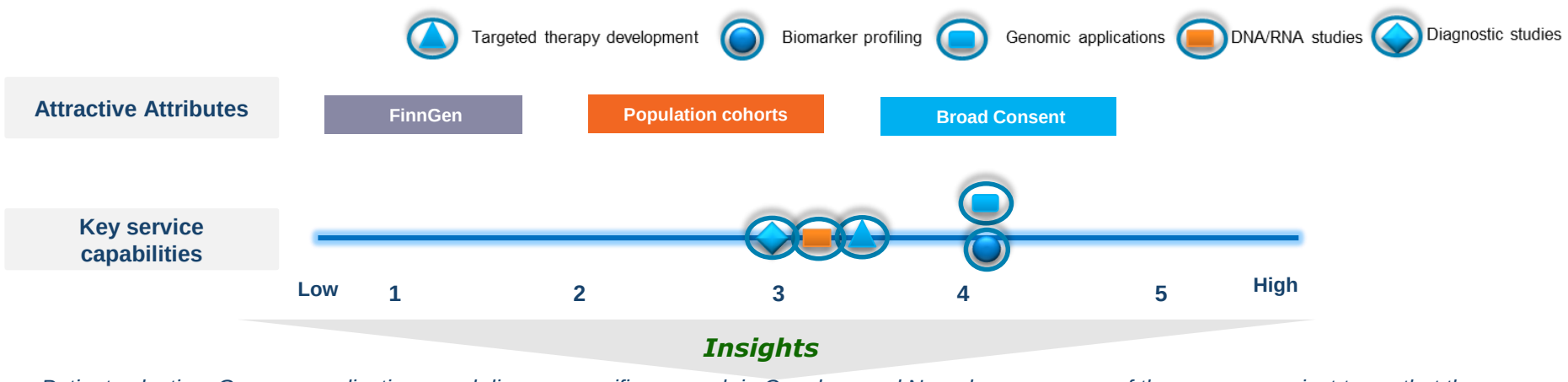
Insights

- *Pharma considers the media outreach of the biobanks as a significant step to know about their activities, samples and services and overall resources*
- *However deal negotiation with the biobanks is lengthy and complex. Security concerns of the vendors, multiple approvals, legal procedures are the major challenges that the Pharma face while working with the vendors*

I would say that initiating the discussion with any personnel of a biobank is a comparatively tough task. Also, you cannot contact them directly. Whenever we order a sample of tissues then, we first send them an email regarding all our concerns which is then forwarded to their advisory committee. Now, after checking and ensuring all the data points, this committee gives its approval. So, this overall process is quite lengthy and it is quite difficult to initiate.
Medical Director, Large Pharma

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

FinnGen study remains a major interest area for the Pharma clients to collaborate with Finnish biobanks



Insights

- *Patient selection, Genome applications, and disease specific research in Oncology and Neurology are some of the common project types that the Pharma considers to be the key areas of collaboration with the Finnish Biobanks. Furthermore, Isolated population cohorts, and large scale genomic data are some of the major attributes of attraction. FinnGen study is a key enabler for the Pharma to explore working with the Finnish Biobanks*
- *Pharma Companies opine that better communication, adherence to promised timelines, increasing number of scientific staff are improvement areas for the Finnish Biobanks*

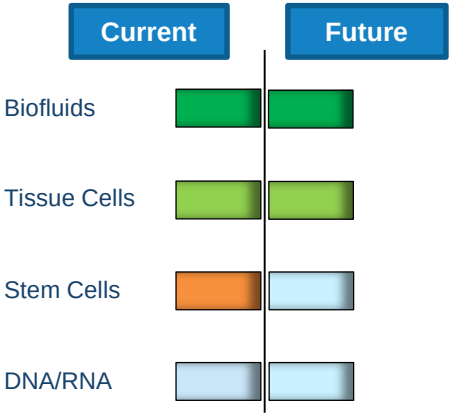
We have collaborated with FinnGen based biobanks mainly for projects in which research is focused on target-based therapies for chronic inflammatory diseases and neurocognitive disorders.
Head of R&D, Large Pharma

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

End User Assessment- Biotech

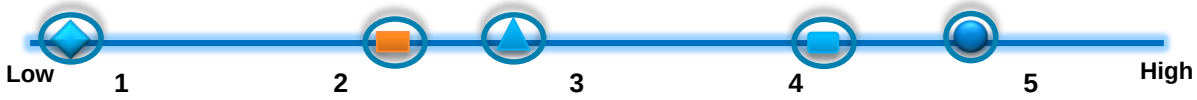
Genome sequencing projects and biomarker profiling are key areas for the biotech companies

Sample Utilization



Service Utilization

Type of Services	Description	Number of Projects (Past 1 year)
Targeted Therapies Development	Specialized therapy development projects	~4
Biomarker Profiling	Biomarker profiling is based on the disease area	~7
Genomic Applications	Genome sequencing projects, genotyping	~9
DNA/RNA applications	Gene expression profiling	~3
Diagnostic Studies	-	-



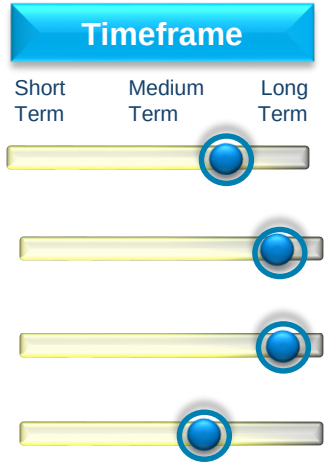
Insights

- *Biotech companies utilize the samples and services based on their therapeutic focus.*
- *For instance, if the company is into development of oncology therapies, then tissue samples/blood can be utilized for HER2 or EGFR development. For the genomic applications, the biotech would utilize stem cells, DNA/RNA extracts and tissue related samples*

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Oncology remains a key therapeutic area for the biotech companies across different application areas

End-User Application Area Alignment			
Application Area	**Unique Proposition offered by Biobanks**	**Biospecimen Utilized**	**Key Therapy Areas**
Companion Diagnostic	High quality of tissue and biofluid samples	Biofluids such as blood, plasma and tissue samples	Oncology
Genomic Sequence	High quality samples, extensive genomic data	Biofluids such as blood and urine, tissue samples (liver, brain, etc.), DNA/RNA extracts,	Oncology, GI, Neurology
Oncology Clinical Development	High quality samples	Blood, Urine, plasma, stem cells, tissue samples from different sources	Oncology
Real World Evidence	-	-	-



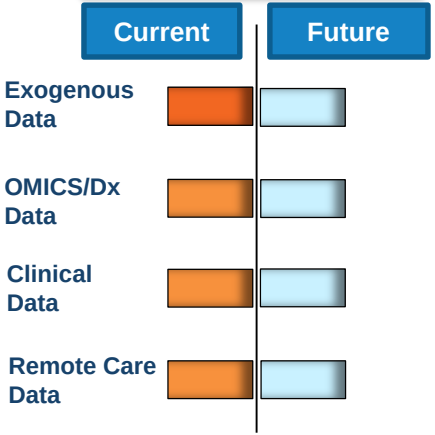
Insights

- *With a high disease burden and increase in novel targeted therapies in oncology development , it remains a key focus area for the biotech companies. Some of the key targeted therapies include hormone therapies, signal transduction inhibitors, gene expression modulators, immunotherapies, and cancer vaccines*
- *In line with expected increase in gene therapy applications globally, the biotech companies consider genomic sequences as a long term opportunity to collaborate with the biobanks. Research around cell and gene therapies has seen increase lately especially with recent launches such as* **Novartis' Kymriah** and **Gilead's Yescarta** which are expected to be the growth drivers in the segment

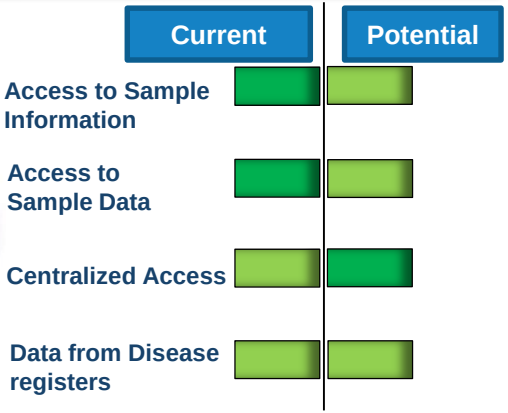
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Biotech utilization of data services from the biobanks is relatively low as compared to their Pharma counterparts

Type of Data Used



One Stop Access



Engagement Type

Type of Engagement (for data services)	Preference of End Users
Data Owner model	Medium
Research Provider model	High
Service Provider model	Medium

Insights

- *Sample based partnerships are more prevalent for Biotech companies as the prime requirement of the end-user is to procure highly specific samples for disease areas in order to meet research demand for that specialty*
- *If a biotech company engages for data related services then research provider model is preferred as data accuracy, timely availability, consent norms and desired data format are major requirements for the end-user*
- *Compliance to EU-GDPR regulations and protection of patient information is a top priority for biotech to prevent any misuse of data in research studies*

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

High quality samples, good scientific record and accreditation from recognized organization are key selection criteria for biotech

Decreasing Order of Importance

Services

- Scientific record
- Expertise
- Population Base
- Coordination

Operational

- Sample quality
- Accreditation
- Regulatory Support

Performance

- Compliance
- Data privacy/ integration
- Communication

Insights

- *Samples with high purity and optimum storage conditions play a key role in analysis and results for genomic/disease based studies which are the key focus areas for the biotech*
- *In order to prevent the violation of local regulations, biotech consider regulatory support from the biobanks as essential services. Biotech consider good scientific record as a credible measure of their ability to engage in complex disease based projects*

Well, the topmost requirement from a biobank would be to procure quality sample so that the outcomes of our study are accurate.
- Medical Director, Mid-size Biotech

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Strategic engagement encourages active collaboration between the end-users and the Biobanks to achieve outcomes

Decreasing Order of Preference

	Number of projects (past 1 year)	Type of projects	Implementation challenges
Strategic Engagement	~10	Genome based projects of long duration	Patient consent issues
Service based	~6	Projects in oncology, neurology, hematology therapies	Delivery timelines

Insights

- *Service based engagement is preferred based on clear requirements with defined timelines. Here the requirement criteria such as for samples is pre-decided based on set conditions by the end-user and provided by the biobank*
- *Strategic engagement by the Biotech is more for long term projects which are beneficial for both parties. This type of engagement encourages higher collaboration and flexibility between the end-users and biobanks and as per the requirements, both parties work together to achieve results i*

We are involved in the strategic partnership with the biobanks so that this collaboration can help both the parties equally. Here, we are working together and are definitely benefitting together.
- Head of R&D, Small-size Biotech

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Value based pricing determinants include market demand, availability, competitor prices and sample characteristics

Value based pricing

Perceived value of the sample in terms of its characteristics, availability of the samples, prices of competitive samples and demand of the sample is considered by the Biotech to arrive at a price

Dynamic Pricing

Dynamic pricing makes use of the market demand for the samples and flexibility in the prices based on the demand

Fee for service

For the fee for service model the pricing is done based on level of sample and data services provided to the end-user

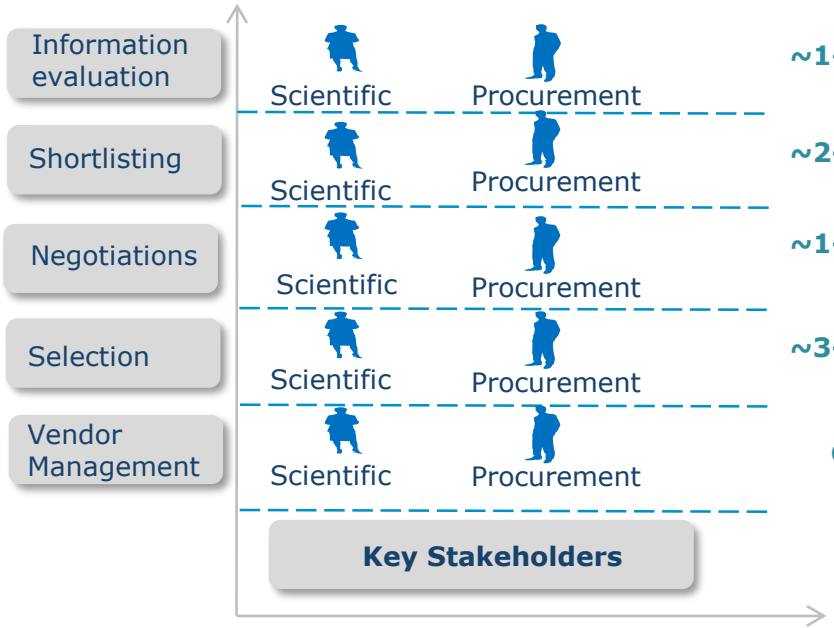
Milestone based payment

Milestone based model is generally applied when progress of a project is determined by outcome of pre-agreed milestones between the end-user and the Biobank

I have only used value based pricing model. It is the preferred model type. It works all around. It is a competitive model and we were happy to pay what was negotiated and agreed upon for the services we avail.
- Head of Regulatory, Mid-Size Biotech

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

R&D head is actively involved in biobank selection process along with the procurement division for the Biotech



Influencer

Head of R&D, Head of Procurement, Head of Regulatory, Medical Director

Decision Maker

Head of R&D
Head of Procurement

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Conferences and exhibitor presentation are the key places where the Biotech find prospective partners

Preferred Media Outreach

Low 1 2 3 4 5 High

Deal Negotiation Difficulty

Low 1 2 3 4 5 High

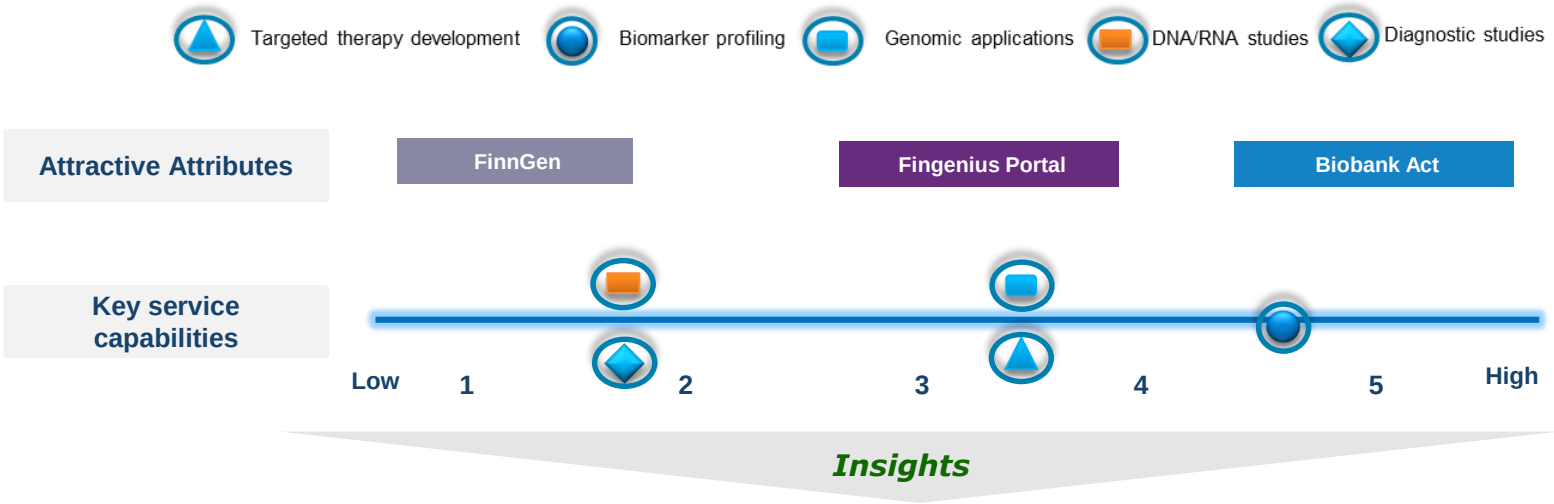
Insights

- *Biotech companies find it difficult to look for prospective partners as they consider the visibility of the biobanks to be low*
- *Once the partner is deemed for collaboration, Biotech consider it relatively easier to negotiate if the partner has streamlined guidelines and procedures for client management, short turnaround time for query handling, and access to right contracts for ongoing client management*

Well, not regularly. We do hear about them through conferences and brochures, but it does not happen that frequently.
- Head of R&D, Mid-Size Biotech

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

FinnGen study, Fingenius portal and the Biobank Act are most attractive attributes for the Biotech to partner with Finnish biobanks



Insights

- *Biotech consider the FinnGen study and Fingenius portal as key attractive attributes as it has the potential to make the sample and data access easily available to them for research*
- *Furthermore, the digital capabilities in the Finnish ecosystem is also rated highly by the biotech companies*

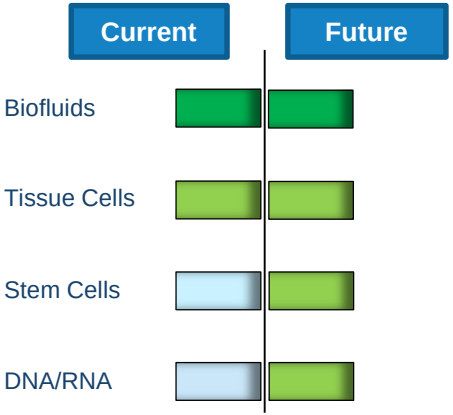
I am aware that Finland has a great reputation in digital health. Nearly 98% of the patient information of the country is present in the digital format. The major attraction is the Finnish Biobank Act
.- Head of Regulatory, Mid-Size Biotech

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

End User Assessment- Health tech

Genomic applications and biomarker profiling are key service areas for healthtech

Sample Utilization



Service Utilization

Type of Services	Description	Number of Projects (Past 1 year)n=7
Targeted Therapies Development	Biofluids such as Blood, feces and tissue samples are used. Focus areas include cancer diagnostics, human microbiome studies, chronic disease studies	~10
Biomarker Profiling	Blood and tissue samples, DNA/RNA extracts. Focus areas include Cancer diagnostics	~15
Genomic Applications	Cancer diagnostics, genome sequencing projects, meta-genome analysis	~20
DNA/RNA applications	DNA/RNA sequencing for tumor biology. Blood samples, tissue samples and stem cells are also utilized	~12
Diagnostic Studies	Biopsy, companion diagnostic studies	~14

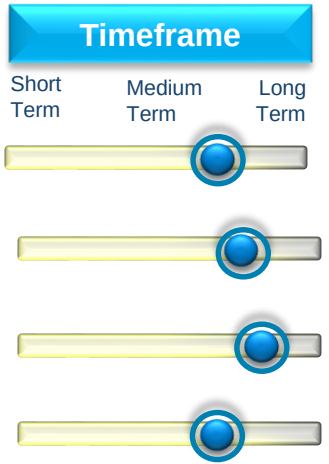
Insights

- *Cancer diagnostics is a key utilization area for the healthcare tech companies in all types of services largely due to increasing prevalence of oncology, constant technology interventions in diagnostics , and increasing demand for effective screening tests for cancer*

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Oncology is likely to remain a major demand driver for the healthtech across application areas

End-User Application Area Alignment			
Application Area	**Unique Proposition offered by Biobanks**	**Biospecimen Utilized**	**Key Therapy Areas**
Companion Diagnostic	High quality of samples and biomarkers for tests	Biofluids such as blood, FFPE samples, tonsil, plasma, feces, stem cells,	Oncology, neurology, cardiovascular
Genomic Sequence	High quality samples, extensive genomic data	Biofluids such as blood, feces, tissue samples, DNA/RNA extract, genomic data	Oncology, Neurology
Oncology Clinical Development	High quality specific samples, cell lines for diagnostics	Specific tissue samples (lung, renal, breast cancer, etc.) blood, tissue	Oncology
Real World Evidence	Lifestyle data and other clinical data	Exogenous data	Oncology



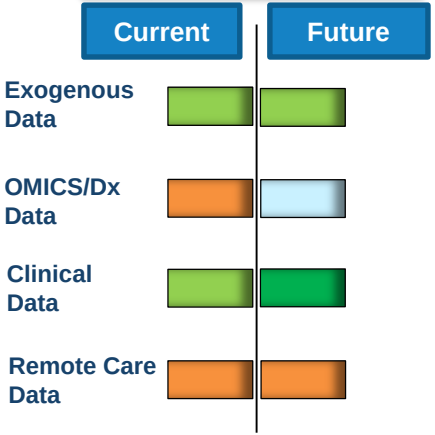
Insights

- *Oncology applications in genome sequencing, companion diagnostics, etc. are likely to be the key drivers of demand for the healthtech companies*
- *The trend is attributed to increasing projects in next generation sequencing (NGS), gene expression profiling, and different cancer types being the prime focus areas for research.*
- *Early detection of the disease and cost-effective treatment of cancer are the key criteria for the companies to advance research in the oncology segment*

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Healthtech sees great potential in data services and one stop access services from the biobanks

Type of Data Used



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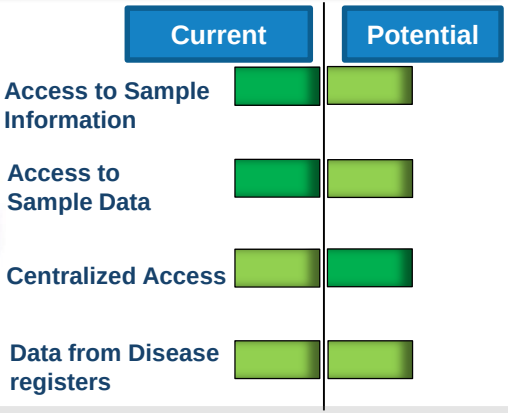


Engagement Type

Type of Engagement (for data services)	Preference of End Users
Data Owner model	Medium
Research Provider model	Medium-High
Service Provider model	Medium-High

Insights

- *Healthtech companies increasingly utilize data based services from biobanks largely due to the use of advanced technologies in their solution offerings. Such companies are pioneers in the use of AI/ML in drug discovery, RWE applications and other R&D offerings. They consider the sample and data services from the biobanks to be of high value*
- *Easy access to data and its interpretation, unimpeded communication, and regulatory compliance are key factors that the healthtech consider valuable for any engagement type with the bionbank*
- *Healthtech also considers the privacy norms, data protection of utmost importance as the projects involve large scale data especially in genomic applications projects such as in precision oncology, gene sequencing, etc.*

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Sample quality and variety, good scientific record and accreditation are key selection criteria for healthtech

Decreasing Order of Importance

Services

- Population Base
- Biospecimen variety
- Scientific record
- Coordination

Operational

- Sample quality
- Accreditation
- Reputation

Performance

- Regulatory Compliance
- Data privacy/ integration
- Communication

Insights

- *As data is a key enabler for their engagements, data privacy measures, efficient sharing of data, easier integration, and better communication are major factors that the healthtech look for in a partner*
- *As the healthtech engage in multiple project types such as omics, real world studies, microbiome studies, etc. the sample variety is a strong selection factor for the healthtech*

If a larger type of biospecimen is available then, we will be collect more precise data from a larger population. It will even ensure the authenticity of results.
.- Medical Director, A precision medicine firm

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Strategic engagement is preferred by the healthtech to enter into long term partnership with the biobanks

Decreasing Order of Preference

	Number of projects (past 1 year)	Type of projects	Implementation challenges
Strategic Engagement	~26	Genome based projects of long duration, Oncology	Delivery timelines
Data Rent	~6	Genome based projects, Microbiome studies, OMICS,	

Insights

- *Strategic engagement by the healthtech is more for long term projects which are beneficial for both parties. This type of engagement is for complex projects such as in genome sequencing , or therapy specific projects in oncology, neurology.*
- *The strategic partnership with the biobanks can also include other industry partners for a pooled approach in a project where the scientific outcomes for a commercial product is involved such as for clinical trials.*
- *Data rent model is preferred by the healthtech mostly for shorter engagements where timelines are not critical. Here the detailing of the data provided is an important criteria for the healthtech. Some of the key engagements include diagnostic applications, RWE studies, omics studies, etc.*

Strategic engagement involves strong associations between the biobank and the company for research purpose that usually happen for projects with long time frame. The arrangements involve streamlined process and less costs.
.- Medical Director, Top Diagnostic Firm

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Value based pricing determinants include sample availability and number of research studies where sample is utilized

Value based pricing

Samples are priced based on their value. Key value determinants are availability of the samples, and number of research studies where sample is utilized. Price is subsequently negotiated between the partners

Bundled payment

Healthtech consider bundled payment approach when the partner offers a large number of services as a package and a uniform price is charged

Fee for service

Fee for service pricing is done based on level and the type of sample and services provided to the end-user

Revenue Sharing model

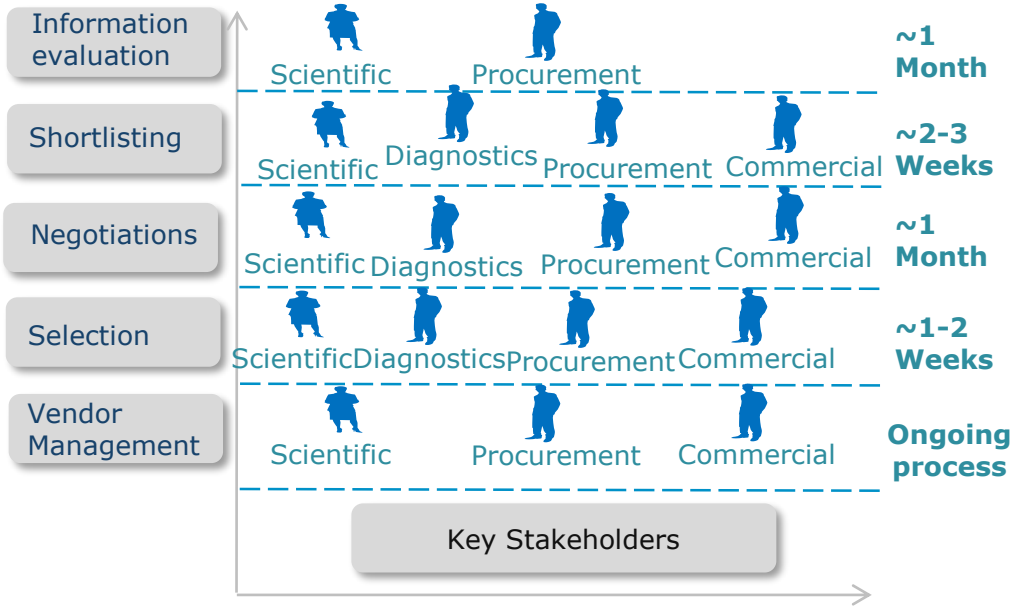
Companies also engage in revenue sharing model where the prices of services and samples are determined as per the outcomes of the engagement and a % share based distribution of the sales between stakeholders and partners

We have been associated with the biobanks from last few years and as far as partnership with the biobanks is concerned then, we mostly opt for value-based pricing model. The main reason behind the adoption of this model is that it gives it us the best price of the sample based on the value of the samples that we are asking for.

- Medical Director, Drug discovery technology firm

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Diagnostics department also plays a key role in selection process for the healthtech companies



Influencer

Chief Scientific Officer, Head of Procurement, Head of Marketing, Head of Diagnostics, Medical Director, Head of R&D, Head of Clinical Ops

Key Decision Makers

Head of R&D
Head of Procurement
Head of Diagnostics

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Conferences and journals are the key places for the healthtech to find partners; Negotiation of deal is difficult, though

Insights

- *Healthtech companies consider the visibility of the biobanks to be average and the conference presentations, journals are the key sources where they get to know more about the prospective partners*
- *They do face challenges in negotiation of deals with the partners mainly due to stringent procedures and guidelines in which the partners function, difficulty in initiating the discussion, more involvement of owner institutions which fund the biobanks, and lesser flexibility around pricing of samples and services by the partners*

This is because, there is a lack of segmentation of different departments within the biobanks and if we want to approach a biobank then, we have to contact their directors. Honestly, it is quite difficult for us to get a prompt response from them due to their busy schedule.
.- Medical Director, Precision Medicine firm

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

FinnGen study, regulatory structure, and large population base are most attractive attributes for the healthtech to partner with Finnish biobanks

Targeted therapy development | Biomarker profiling | Genomic applications | DNA/RNA studies | Diagnostic studies

Attractive Attributes

FinnGen | Large Population base | Broad Consent

Key service capabilities

Low 1 2 3 4 5 High

Insights

- *Healthtech companies consider sample and data capabilities to be paramount in order to work with the Finnish biobanks . Such companies mainly work the highly sophisticated diagnostic tests in novel therapeutic applications in oncology, rare disease, cardiovascular, neurology, etc. where sample specificity and quality impacts the outcomes*
- *Healthtech consider genomic studies and diagnostics as key areas where the Finnish capabilities can be utilized*

Our main agenda is to procure samples from these Finnish biobanks so that we can perform highly advanced diagnostic tests and can study the anatomy o a particular disease followed by the diseased pattern so that a proper solution can be developed for the treatment.
.- Medical Director, Top Diagnostics firm

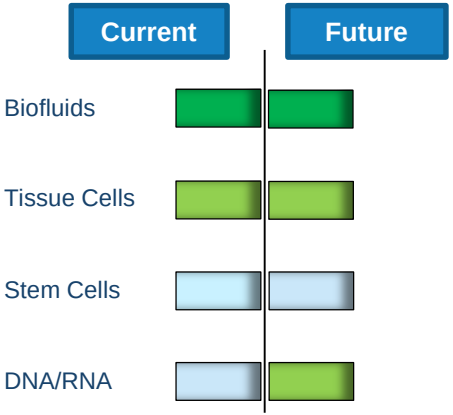
Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

End User Assessment-Contract Services Organizations

FROST & SULLIVAN

DNA/RNA applications are major focus areas for the contract services organizations; diagnostics is not the area of interest

Sample Utilization

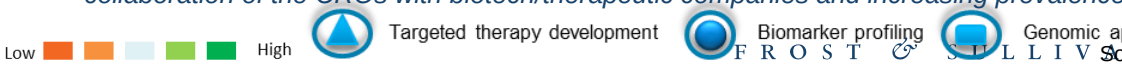


Service Utilization

Type of Services	Description	Number of Projects (Past 1 year)n=3
Targeted Therapies Development	Cell line development, oncology specific studies involving malignant cells, FFPE tissue samples,	~5
Biomarker Profiling	Biomarker discovery and analysis. Samples utilized include blood, plasma, tissue, urine,	~5
Genomic Applications	Genome sequencing projects for proteomics, and biomarker based research. utilization of tissue samples, DNA/RNA extracts	~4
DNA/RNA applications	Oncology specific research applications, epigenetics and genome analysis and utilization of DNA/RNA extracts	~12
Diagnostic Studies	-	-

Insights

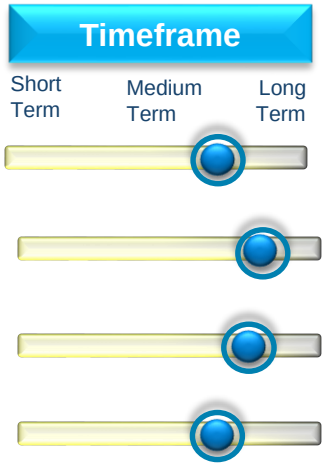
- *DNA/RNA based applications are the focus for the contract research organizations due to increasing research activity in areas such as oncology, neurology, etc. and utilization of DNA/RNA extracts in epigenetic studies, and genome studies*
- *Epigenetic studies are key application area for the contract research organizations and it is likely to grow in the wake of decreasing sequencing costs, collaboration of the CROs with biotech/therapeutic companies and increasing prevalence of oncology*



Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Novel therapeutic applications in Oncology are the key areas where the CSO are expected to see continued demand for samples and data

End-User Application Area Alignment			
Application Area	**Unique Proposition offered by Biobanks**	**Biospecimen Utilized**	**Key Therapy Areas**
Companion Diagnostic	High quality samples	Blood, serum, FFPE tissue samples	Oncology (Lung, colorectal, bladder), Infectious disease, Cardiovascular, Neurology,
Genomic Sequence	High quality samples and genome data	DNA/RNA extracts, blood, protein sequences	Oncology and Neurology
Oncology Clinical Development	High quality samples for specific types and patient recall	Mammalian cells, tissue samples, blood sample	Immune therapies
Real World Evidence	Patient data	Health record data, tissue, blood samples, DNA/RNA	Oncology and neurology



Insights

- *Contract service organizations are likely to see more number of oncology specific projects largely due to increasing novel therapeutic applications globally.*
- *For example the immuno-oncology therapies are key application area in the oncology therapeutic category. The overall market for such therapies is expected to reach a revenue of $3.9 billion in 2022.*

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

CSOs utilization of data services from the Biobanks is relatively lower compared to other end-users

Type of Data Used

	Current	Future
Exogenous Data		
OMICS/Dx Data		
Clinical Data		
Remote Care Data		

One Stop Access

	Current	Potential
Access to Sample Information		
Access to Sample Data		
Centralized Access		
Data from Disease registers		

Engagement Type

Type of Engagement (for data services)	Preference of End Users
Data Owner model	High
Research Provider model	Low
Service Provider model	Low

Insights

- *CSOs prefer to carry out research and data analysis on the samples in-house for the clients they work and thus the focus is mainly to procure high quality biospecimens from the biobanks. If the CSO partners for data related services, it is mainly project specific and on need basis.*
- *If the CSOs partner with the biobanks for data related services, they prefer to enter in a data owner model as the ownership rights are clearly defined*

Low High

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Sample quality, good scientific record, accreditation and regulatory support are key selection criteria for CSOs

Decreasing Order of Importance

Services

- Population Base
- Expertise
- Scientific record
- Coordination

Operational

- Sample quality
- Accreditation
- Regulatory support
- Reputation

Performance

- Regulatory Compliance
- Data privacy/ integration
- Project Management

Insights

- *For the CSOs the focus is on the clinical research outcomes on the projects that they work on for the pharma, hence a biobank with good scientific record, regulatory compliance to guidelines and expertise in therapy assists in the CSOs end objectives*
- *As the CSOs engage in multi-center studies globally, regulatory support by the biobanks in the country of presence is an additional benefit to the CSOs as a part of their engagement*

Regulatory support is an absolutely important criteria, when it comes to biobanks because if they have expertise in regulatory approvals, maybe they can help us in gaining the approvals where we get struck, helping in the partnership.
.- Head of Regulatory, CDMO

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

CSOs engage in multiple engagement type though strategic engagement is a preferred model

Decreasing Order of Preference

	Number of projects (past 1 year)	Type of projects	Implementation challenges
Strategic Engagement	~15	RWE studies, disease specific projects on drug development in Oncology and Neurology	
Service based	~5	RWE studies, and drug development projects based on cell culture	

Insights

- *Strategic partnership by the CSOs is preferred especially when the project duration is long and there is greater flexibility in terms and conditions. Here the CSO is aware of the capabilities and service offerings of the partner and depending upon the length of the project and the services utilized the CSO and the partner could implement modifications in the procedures*
- *CSOs also engage in service based models, data rent model however such engagement is more based on the need of the project and on ad-hoc requirement of samples and data services*

We prefer strategic engagement for almost all of our collaborations with the biobank. The process is like, we select a specific biobank by analyzing their capabilities, services and then set a proposal for collaboration, such that we can utilize their bio samples as per our requirement. It is usually a long-term partnership.

- Head of Operations, Top CRO

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Fee for service model is most utilized by the CSOs as it is most flexible and simple to execute

Milestone based model

Milestone based model is adopted by the companies generally when the CSOs themselves achieve milestones for the Pharma clients they work. Same milestones are used while negotiating with the biobanks

Fee for service

Fee for service pricing is done based on level and the type of sample and services provided to the end-user. It is considered to be more flexible

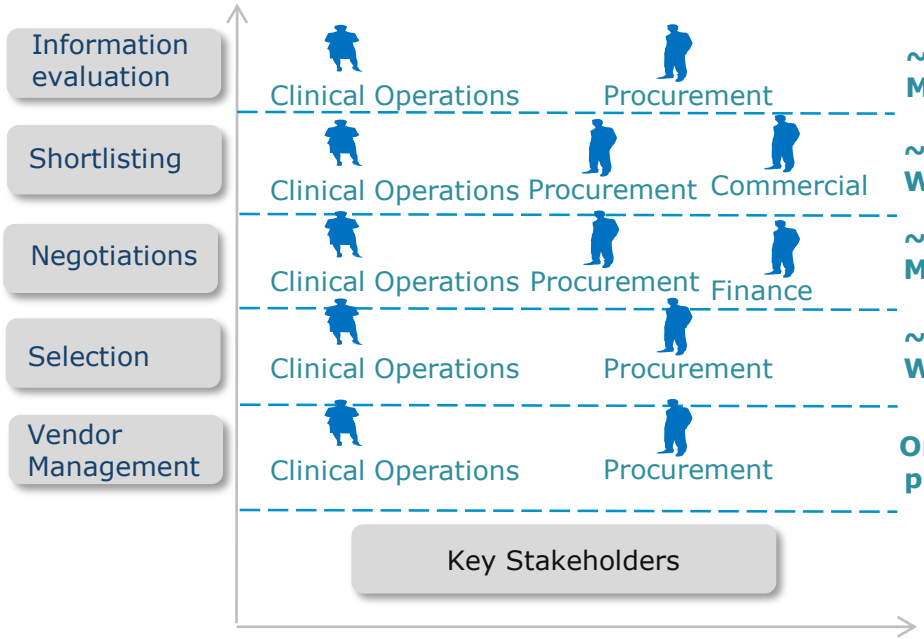
Revenue Sharing model

Companies also engage in revenue sharing model a portion of the revenues is shared with the partner based on the pre-agreed terms and services utilized

For the revenue sharing model, we share some portion of our revenues with the partner biobanks. We do not pay per sample, but rather in the bulk.
.- Director, Top CRO

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Clinical Operations and Procurement play major role in selection process for contract services organizations



Influencer

Clinical Operations, Procurement, Commercial team, Finance

Key Decision Makers

Head of Clinical Research, Procurement

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Conferences are the key places for the CSO to find prospective partners

Preferred Media Outreach

Low 1 2 3 4 5 High

Deal Negotiation Difficulty

Low 1 2 3 4 5 High

Insights

- *CSOs consider the visibility of the biobanks to be good and the conference presentations are the key sources where they get to know more about the prospective partners*
- *They sometimes face challenges in initiating a discussion as its not easy to connect to the appropriate person in the bioabank which is also subject to delays. Negotiation of deals with the biobanks is not easy mainly due to lack of resources to ensure smooth project management*

Sometimes the information of the biobanks are not available publicly and contacting the vendors is not easy.- Director, Top CRO

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

FinnGen study, large population base and regulatory structure are most attractive attributes for the CSOs to partner with Finnish biobanks

Targeted therapy development | Biomarker profiling | Genomic applications | DNA/RNA studies | Diagnostic studies

Attractive Attributes

FinnGen | Large Population base | Regulatory Structure

Key service capabilities

Low 1 2 3 4 5 High

Insights

- *CSOs consider population base, and the Biobank Act to be the key attributes for partnership with the Finnish Biobanks especially the availability of specific samples for disease based studies in oncology, genomic sequencing, etc.*
- *A better project management and operating model are the areas where the Finnish Biobanks have a scope of improvement as per the CSOs. Business model alignment with the end-users is significant to enter into any prospective partnership with the Finnish biobanks*

We look for an efficient operating model which is able to fit right into our business practices.
.- Director, Top CRO

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Drug Development Value Chain- End-User mapping

Pharma utilizes the services mainly for the early clinical stages; others are more broad and based on need basis

Drug Development Value Chain

Type of End-user	Majority of Active engagements	Type of projects
Pharma	Lead Optimization, Preclinical, RWE	Biomarker profiling, clinical trials for oncology, neurology, etc. individual level data for RWE studies
Biotech	Lead Optimization, Preclinical, Phase I,II,III	Sample repository, Pharmacokinetics, Pharmacogenomic samples, targeted analysis, preclinical evidences, preclinical testing, efficacy studies
Healthtech	Preclinical, Phase I, II, III	Samples, genomic data for diagnostics studies, biomarker studies, preclinical validation studies
Contract Services Organizations	Lead Optimization, Preclinical, Phase I,II,III, IV	Samples are mainly used depending upon the stage of clinical research projects where CSO are engaged

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Finnish Competencies Analysis

FROST & SULLIVAN

Trend Comparison

Trends- Global vs. Finland

Increase in Genome based research	A large number of projects in the world are focusing on collection of bio-samples of different individuals for research purpose. • For instance, the UK biobank has registered 500,000 participants from 2006 to 2010 that have donated the samples for monitoring their health data. • "All of Us" project in the U.S. launched by NIH is targeting 1 million participants, the Danish National Biobank initiative currently has more than 10 million bio samples from 5.7 million participants.	Finland has also embarked upon a genomic study, FinnGen with an aim of collecting 500,000 Finnish samples. • It is a public-private partnership between Finnish Universities, biobanks hospital districts and pharmaceutical companies.
Shift towards centralization of data and samples for the purpose of research.	• There is a shift towards centralization of data and samples for the purpose of research. The agency then further distributes it to industrial and academic research partners. • For example Biobank Graz in Austria is a centralized facility for collecting samples from clinical sites and further distributing it to industrial and academic research partners.	• Finland Biobanks are gradually evolving towards sample and data centralization. Currently biobanks- population and disease have separate focus areas and difference in the type of services offered. • However initiatives such as Fin Biobank (FINBB) aim to have a centralized window for Finnish Biobanks both for academic researchers and industry.

Finnish Biobanks share a similar trend with the global biobanks on focusing on genomic based research; data centralization efforts however need to be improved

Source: Frost and Sullivan Analysis, genomeweb.com

Trend Comparison

Trends- Global vs. Finland

	Global	Finland
Patient consent remains a major aspect	• The term "**broad consent**" has been in use in the UK Biobank, CARTa-GENE (Montreal), and the Norwegian HUNT study. • This type of consent includes the possibility of using the bio specimen from donor for multiple research purposes without placing restrictions rather than for individual study. • The other model is called **dynamic consent** . It is also utilized by some of the biobanks where they inform and obtain consent from the individual for every research project.	• As per the existing Biobank Act in Finland, **broad consent** is utilized by the biobanks. • The new proposed Biobank Act might well suggest the use of the **presumed consent**- where patient would have the right to refuse their samples and data being used for biobanking activities. However, without a separate refusal bio specimens would be automatically used for research.
Use of Advanced technology/AI in Biobanks is evolving	• While there are development of AI in personalized and precision medicines, use in the biobanking applications is likely to evolve further. • AI could be useful in patient consent and can develop standard operating procedures (SOPs) for acquisition of samples. • It could also define and measure quality of biosamples. For example systems could assess DNA integrity with AI based imaging. • A Sweden based biobank entered into partnership with ContextVision, for AI based decision support tools for cancer diagnosis. Biobank provided access to a large amount of data, images, etc. in cancer diagnostics.	• Finland Biobanks are evolving when it comes to AI applications in Biobanking services. • Leading biobanks such as Auria, Helsinki have either custom based solutions or partnership with AI based firms. • Commercial biobank such as Terveystalo partnered with Medsapiens for bioinformatics solution. • Text mining, image analysis solutions, are some of the areas in AI for Finnish biobanks.

In line with the global biobanks using AI based applications in biobanking services, Finnish counterparts have made strides in this area; patient consent guidelines in Finland might change with the introduction of the new Biobank Act

Source: Frost and Sullivan Analysis, terveystalo.com

Trend Comparison

Trends- Global vs. Finland

	Global	Finland
Efforts towards data Harmonization across systems and samples are ongoing	• Efficient use of hospital data in research is a major challenge in biobanking. • Some of the factors include challenges in integrating data from multiple sources, data integration with the hospital EHR systems, and lack of standardization of protocols. • Privacy issues, heterogeneous information systems, lack of agreed vocabulary, etc. are some of the reasons that impede successful data harmonization. • Globally, biobanks have attempted to address these challenges. For example in UK Biobank study, participants allowed UK Biobank to integrate information from their electronic health records.	• Finland has the unique advantage as the EHR is linked to a unique personal identification number. • Biobanks have made progress towards linking EMR/EHR data to biobank specimen, which is required for optimal biobank performance. • From a legislative perspective, passing of the law of secondary use of health data, and infrastructure perspective, coordinated efforts towards increasing data harmonization would act as an enabler for biobanking growth in Finland.
Compliance to Legal and Ethical Considerations around prevailing biobanking laws remain paramount	• Legal and ethical considerations are paramount in the global biobanking market trends. • Countries have taken several measures to address the ethical, legal and social implications (ELSI). • For example in the US, the National Cancer Institute (NCI) and Biorepositories and Bioresearch branch (BBRB) have worked together with international partners to harmonize ideas around biospecimen governance.	• Finland is committed to comply with all legal and ethical considerations for data safety and access control. • Other challenges include bureaucracy due to multiple ethical reviews. • Patient recall process not optimal. • Ambiguity around interpretation of laws.

Data harmonization efforts are likely to continue in Finland and across the global biobanks as a part of streamlining biobanking service offerings

Source: Frost and Sullivan Analysis, biospecimen.cancer.gov

Trend Comparison

Trends- Global vs. Finland

Improving the financial sustainability of biobanks is a high priority activity for the biobanks

- Financial sustainability for biobanks is a common challenge globally.
- Operational costs that includes maintenance, and storage of samples is high not sustained by grant based funding.
- Biobanks have utilized several ways such as engaging more with commercial organizations, keeping lower inventories, having a business plan.
- For example in the US, Conversant Bio disowned the Field of Dreams Model- “if you build it, they will come”. Instead the biobank switched to just-in-time collections repository to prevent hoarding and mitigate costs.
- A greater engagement with the commercial organizations is likely to increase, however, legal guidelines around using samples for profit pose challenges.
- Business models with the academia are also likely to focus on federated centralized models with consolidated and centralized access to sample data, online repository management systems to reduce inventories, cost recovery and sustainability built in the overall project and incentives to investigators.

- Finnish Biobanks are no different in terms of dealing with financial sustainability challenges.
- The focus of the FinnGen study, in particular was also to enhance the levels of collaboration with the industry rather than depending upon the academia for research.
- In general, majority of the total engagements of the Finnish biobanks is with academic partners and efforts are ongoing to engage more with the prospective commercial partners including pharmaceuticals, diagnostic firms, CROs, etc.
- Opportunities exist for the Finnish biobanks in terms of modifying their pricing models such as focusing more on value based payments rather than fixed fee.

Finland is gradually catching up with the global biobanks on engaging with the partners to improve long term financial sustainability

Source: Frost and Sullivan Analysis, aacc.org

Overview

Finland Competencies Overview

- Finland is considered to be a hub of **innovation**
- It is the **3rd most advanced digital** economy in the EU and the Startup Ecosystem in Finland is globally recognized
- The 2018 **Global Startup Ecosystem** Report classified **Greater Helsinki** to be among the global leaders
- An **evolving ecosystem of research institutes, universities, innovative companies**, etc. can act as a complementary system to enable high end innovative research in healthcare applications

- The **ICT infrastructure** in Finland is highly **developed**
- **Data collection** in the form of **registries** has been **available over decades**
- Healthcare system **linked with social security numbers** giving access to the longitudinal data for individuals
- More than **98%** of the patient records are available in the **electronic format**
- Large amount of annotated data presents enormous opportunities to attract customers for high end research in novel therapeutic applications

- Finnish Laws and regulations are aimed to **foster the highly innovative research ecosystem** in Finland
- **Biobank Act** is considered to be one of the most progressive set of laws
- **National Health sector growth strategy**, establishment of **National Genome Center**, and the development of **National Drug Development**, etc. are some of the **forward looking initiatives** of the Finnish Government
- **Close cooperation** between the **public and private** organizations and enterprises is also a key enabling factor for facilitating health research in Finland

Source: Frost and Sullivan Analysis, finland.fi, export.gov

Top 5 Growth Opportunities

Strategic collaboration with the end-users in key growth opportunities such as, Companion diagnostics (Biomarker studies), Large Scale Genome Sequencing projects, Oncology Clinical Development…

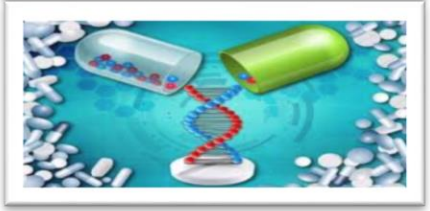
Companion Diagnostics Co-Development

- By 2025, targeted therapeutics focus shift beyond oncology toward infectious, CNS, and cardiovascular diseases.
- Predictive biomarkers for various diseases will be a sensational area for future investment and growth.

Large-Scale Genome Sequencing Projects

- NGS-as-a-service a dominant business model to make genomic data actionable in precision medicine practice.
- Emerging liquid biopsy and point-of-care testing technologies will start to compete against established NGS space for precision diagnostics.

Oncology Clinical Development



- Immuno-oncology therapies are key application area in the oncology therapeutic category.
- DNA barcoding, molecular/integrative nomenclature in genome sequencing projects, testing on multitude of species, adding new barcoding markers are utilized by Cancer Biobanks.

Top 5 Growth Opportunities

… Digital Pathology, and RWE studies is driving future growth for the Biobanks

Digital Pathology and Imaging Services

- Biobank network or hub based models providing online access to high-quality samples and images globally with advanced data management and informatics solutions will be the key differentiator for the future success of both commercial and public biobanks.

Real World Evidence Studies

- Clinical patient data that is generated in health care outside clinical trials.
- Real world data is increasingly utilized in influencing healthcare decision making, regulatory assessment, clinical practice and policy.
- Population sample data plays a major role in RWE studies for cost-effectiveness, disease burden, diagnostics, etc.

Market Overview

SWOT analysis of the Finnish Biobanks - I

Strength

Policy and Vision

- Country aims to position itself at the forefront of pharmaceutical research and health care provision and prides in a highly efficient healthcare system

Regulatory Structure

- Active Government support by establishing laws/regulations conducive to biobanking activities
- Biobank Act has a unique feature of “broad consent”. Upcoming laws on Secondary Data use; the Biobank Law amendments are aimed to streamline activities

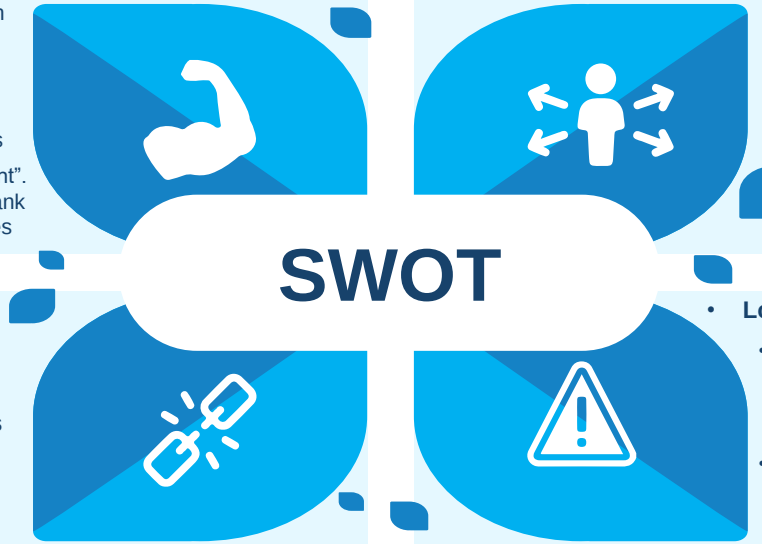
Opportunity

Evolving Biobank Ecosystem

- Presence of an active innovative ecosystem of data science companies, universities, hospitals, etc.
- Evolving customer segments such as biotech/life-science research companies, diagnostics, CRO/CDMOs, EHR, besides pharmaceutical firms

Central Coordinating Agency

- Establishment of a cooperative organization, FINBB for facilitating biobanking activities



Weakness

Long Term Funding Structure

- Biobanks currently depend on short term funding and independent grants

Current Dependency on Academic Activities

- Biobanks are largely driven by research oriented academic based studies and the contribution of commercial engagements is relatively less

Threat

- **Long Term Financial Model**
  - Financial sustainability of the biobanks is under threat due to mounting operational costs and lack of long term financial models to generate revenues
  - Though Biobanks possess enormous data with huge utilization potential, there is a lack of know-how in data monetization through services or data based selling approach

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Market Overview

SWOT analysis of the Finnish Biobanks - II

Strength

Biobank Service Infrastructure

- Active coverage of service applications across the drug discovery and development value chain
- Service capabilities of the biobanks are further strengthened as the biobanks are associated with the hospitals, or universities that offer support in research activities

Opportunity

Data Infrastructure

- Presence of data lakes in hospitals and availability of large amounts of genomic data
- Availability of large amount of data provides ample opportunities for data utilization opportunities through advance analytics (AI/ML) with both academic and commercial vendors

One-Stop Access

- One Stop Shop access to customers for biobanking services would improve strategic focus of engagements. The Finngenious platform is a forward looking step

SWOT

Weakness

Lack of Commercial Model

- There is no clarity on engagement and pricing models while working with academic or industry partners.
- Majority of the pricing models are based on simple calculation of utilization of hours rather than strategic value drivers of the biobanking activities
- Biobanks largely have experts with a background of research experience rather than the commercial side. This further contributes to lack of commercialization potential

Threat

Data Security and Privacy

- Finnish biobanks are wary of any data leaks of the highly sensitive patient information.
- This could lead to negative publicity and can also discourage donor willingness for sample donation

Unequal Competency Among Biobanks

- More experienced biobanks can move ahead with faster execution of activities as compared to newly established biobanks

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Market Overview

SWOT analysis of the Finnish Biobanks - III

Strength

Registry Data

- Availability of health registry data in the electronic format which is also linked to personal identification number

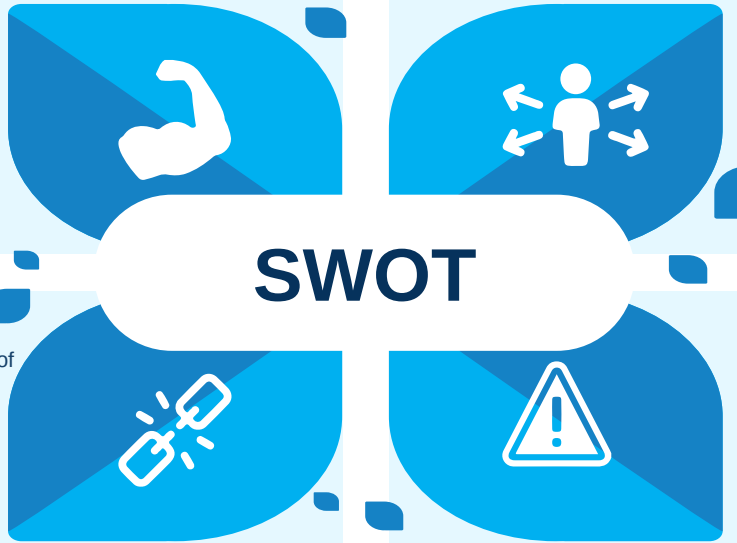
Population Base and Sample Size

- Access to one of the largest isolated population cohorts in Europe
- Access to large number samples accumulated over the years

Opportunity

Research Activities

- Ongoing research activities in precision medicine, OMICS studies, etc.
- Large studies such as Finngen offer additional scope for smaller, spin-off research studies with pharmaceutical firms
- With the implementation of the national genome strategy in 2020, there exists a number of opportunities to exploit the commercial and research potential of the genome data



Weakness

Marketing and Business Development Plans

- Finnish Biobanks lack in promotional efforts in terms of a robust marketing plan, promotional activities, sales force support, etc. to reach out to potential clientele.

Local Client Base

- Finnish subsidiaries of the large pharmaceutical firms do not possess sufficient budgets to support the biobanking activities

Threat

Human Resource Base

- Lack of sufficient human resources in highly skilled intensive biobanking services

International Biobanks

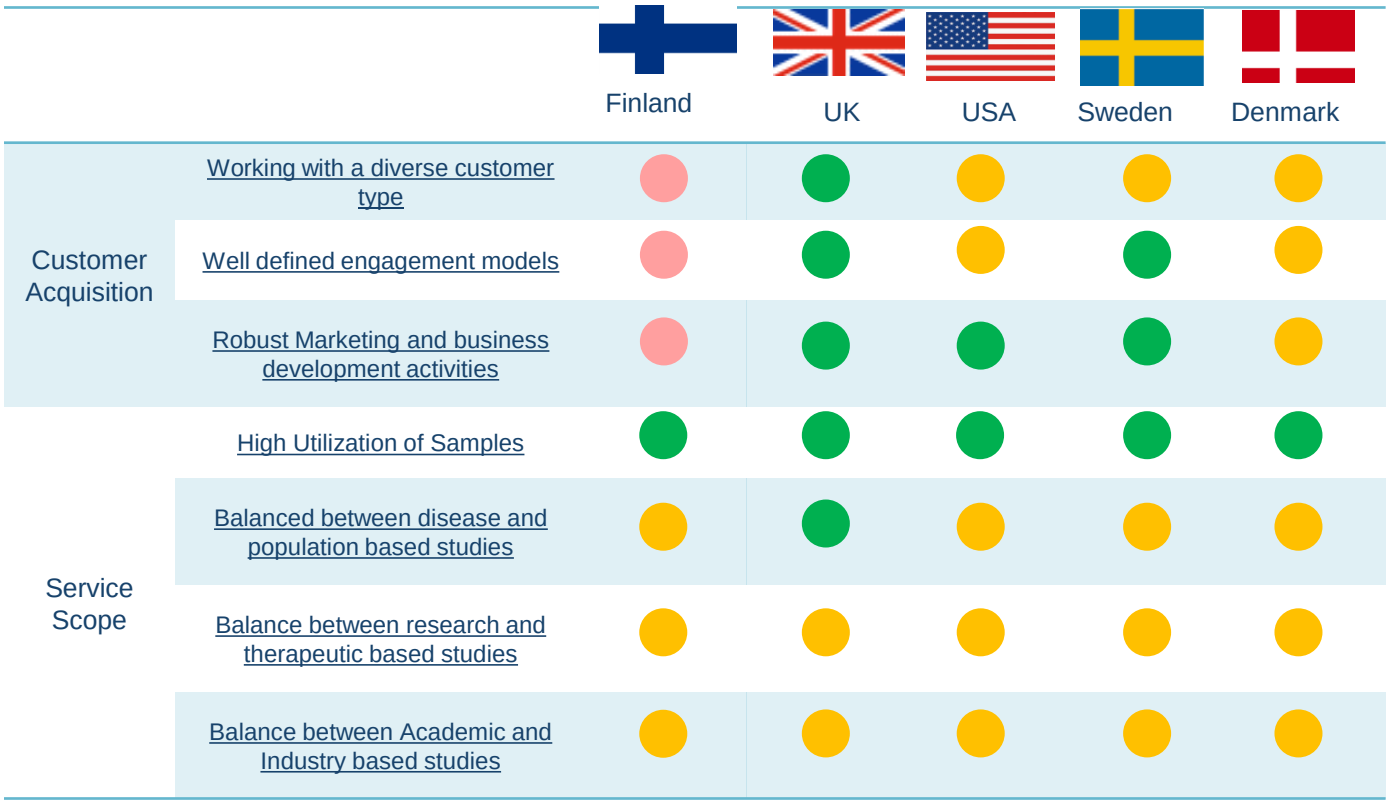
- At a country level the Finnish Biobanks operate on a more tactical approach of doing as it comes, rather than being future ready as compared to their international counterparts

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Gap Analysis

Gap Analysis- Executive Summary

While the sample utilization of the Finnish Biobanks is at par with global standards, much needs to be done to improve the customer acquisition strategies…



Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Oncology Clinical Development and Genome Sequencing can be the immediate growth levers for the Biobanks while strengthening the capabilities in digital pathology, companion diagnostics and RWE studies

		Finland	UK	USA	Sweden	Denmark
Service Scope	Companion Diagnostics	Moderate	Strong	Moderate	Moderate	Moderate
	Oncology Clinical Development	Strong	Strong	Strong	Strong	Strong
	Genome Sequencing	Strong	Strong	Strong	Strong	Moderate
	RWE Studies	Moderate	Weak	Moderate	Moderate	Moderate
	Digital Pathology	Moderate	Moderate	Moderate	Moderate	Moderate

Best practices

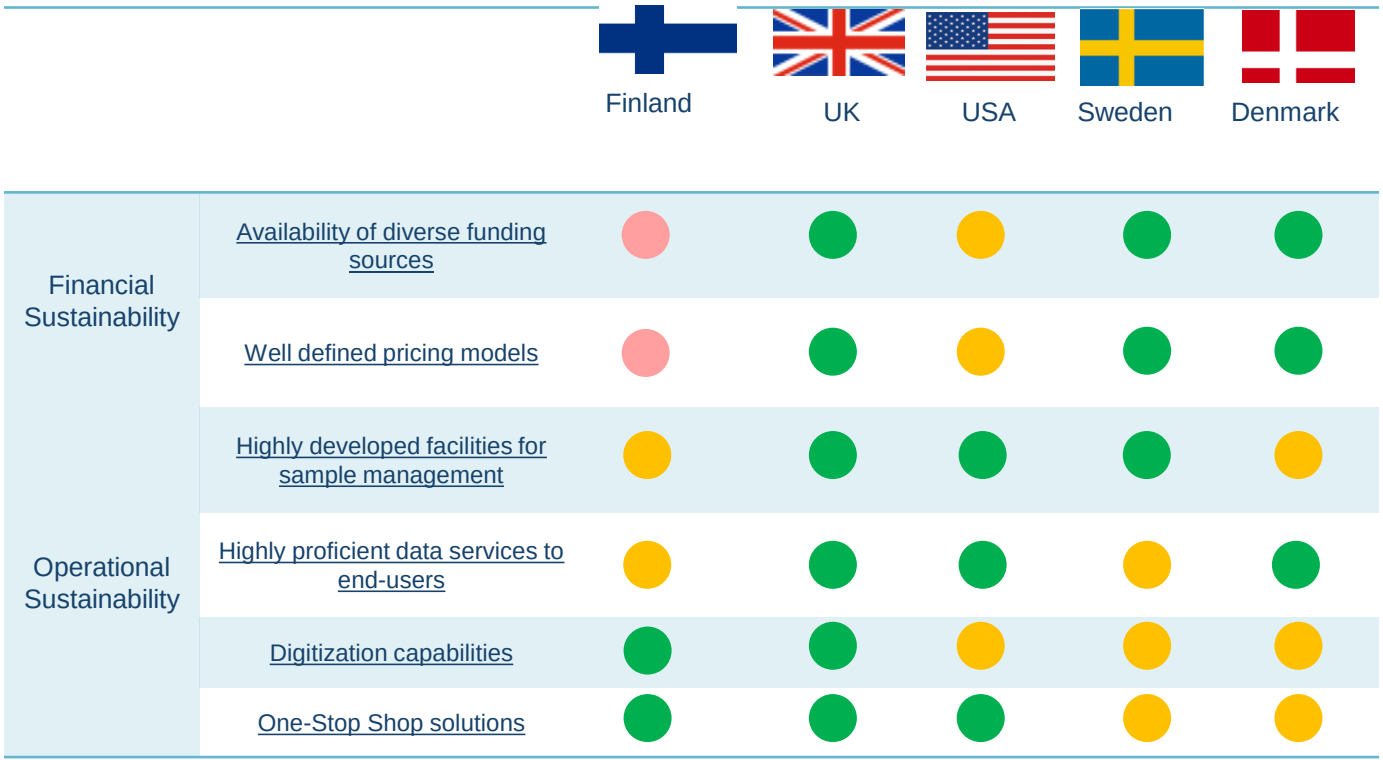
Strong

Moderate

Weak

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Finnish Biobanks have less diverse funding sources and there is a need to work with the end-users with well defined pricing models



Best practices Strong Moderate Weak

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

A greater participation in regional and international networks will enable to increase the competitive standing of the Finnish Biobanks

		Finland	UK	USA	Sweden	Denmark
Social Sustainability	Regulatory Scenario	🟢	🟡	🟡	🟢	🟢
	Favorable Government Policies	🟢	🟡	🟡	🟢	🟢
	Participation in regional and international networks	🟡	🟢	🟢	🟢	🔴

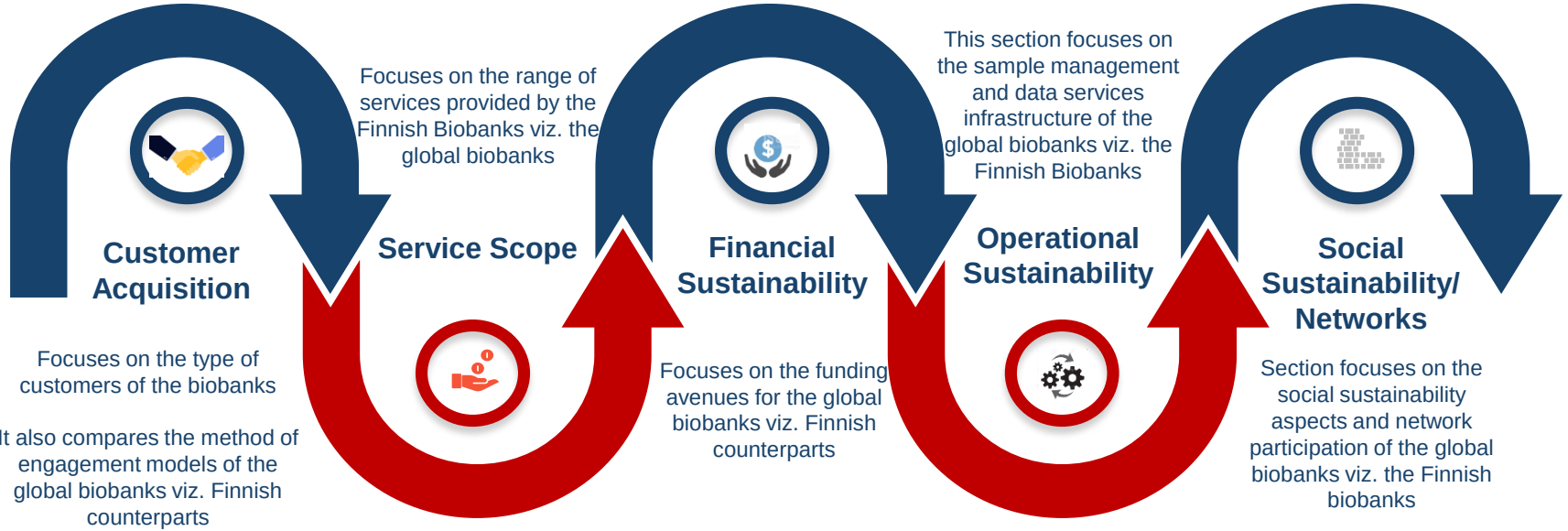
Best practices 🟢 Strong 🟡 Moderate 🔴 Weak

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Gap Analysis Framework

Gap Analysis Framework

- Gap Analysis framework provides a broad comparison between the practices of the global biobanks and their Finnish counterparts on a set of five parameters viz. customers acquisition, service capabilities, sustainability (operational, financial and social) and participation in networks/collaborations



Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Gap Analysis- Finnish vs Global Biobanks

Customer Acquisition

Customer Type

Academic institutes are the major customers followed by Pharma

- **Only a few Biobanks have a greater share of commercial partners than the academic. Decode Genetics, UK Biobank, and Biobank Vast** have a share of 90%, 60% and 50% share of commercial customers respectively

Finnish biobanks have **limited variety of customers and academic** institutions form the majority of the customers for the Finnish Biobanks

- Auria biobank, Helsinki Biobank and THL Biobank have experience of working with commercial customers

Customer Acquisition

Engagement Models

Strategic engagement is the preferred engagement model type for most of the Biobanks, followed by service based, research provider and data owner model

- Long term association, greater flexibility on terms and conditions, sharing of scientific expertise and resources, are key benefits

Largely utilize fixed price or hourly based models for academia and industry alike

- Some of the biobanks have price list for the samples and services. For example THL Biobank has a price catalog based on sample type, process, etc.

Marketing and Business Development Activities

Active presence in **exhibitor conferences, symposiums, followed by brochures and research articles in magazines are key sources for customer outreach**. Majority of the Biobanks have a dedicated marketing team and many of them have a dedicated budget.

- **Annual budget for Marketing activities is 1% for Uppsala Biobank and 2-3% for Kaiser Permanente Biobank**. Biome Biobank spends 10-15,000 USD annually for Marketing activities

- Marketing outreach for the Finnish biobanks has been sub-optimal
- Lack of commercial teams, dedicated budgets, and business development activities in the biobanks, contribute to lesser outreach to potential clientele

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Gap Analysis- Finnish vs Global Biobanks

Service Scope (1/2)

Sample Utilization

Biofluids such as blood samples, serum, urine, etc. are the most commonly used.

- Application in gene therapies, and oncology have driven the demand for tissue samples globally.
- Stem Cell applications are likely to grow in areas such as rare diseases, regenerative medicines, targeted therapies, etc. which are the focus of both commercial and academic research

- Biofluids are most commonly utilized followed by Human Tissue/Tumor Cells which are used in cancer research.
- Fresh frozen tissue samples, and liquid biospies are highly utilized in areas such as cellular level genomics, biomarker studies for diagnosis, imaging and bioinformatics, metabolism and novel administration and modeling of cancer drugs. This trend is likely to contribute to the growth of the segment in Finland

Service Capabilities

Segment Type

More than **60% of the projects carried out by the Biobanks are disease based studies** compared to the population based studies

- Both Academics and commercial partners have been a part of the **disease based studies**
- **The CIGMR Biobank has collaborated** with different academic research institutes like **The University of Manchester, Salford Royal NHS Foundation Trust, University Hospital of South Manchester and The Christie Hospital NHS Foundation Trust and AstraZeneca**

Proportion of disease based studies is higher for the Finnish Biobanks compared to the population based studies.

- Academics are the major partners and focus areas include hematological disorders, metabolic, muskoskeletal, chronic diseases and Oncology
- Population based studies have been conducted by THL Biobank, Helsinki Biobank, Biobank Borealis, Central Finland Biobank and FCBT

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Gap Analysis- Finnish vs Global Biobanks

Service Scope (2/2)

Project Categories

- **Research based projects form ~70% of the total projects**. Key areas include identification of biomarkers, transplantation research, and investigating the underlying genetic mechanisms common diseases
- **Therapeutic Applications** for Biobanks focus on **Biomarkers, Oncology, Chronic Therapies and Pharma, Diagnostic and Biotech are key end-users**
- For instance **UK Biobank has worked with University of Bristol, King's College London for research based projects. GSK and Regeneron for therapeutic based projects**

- Finnish Biobanks have an almost equitable share between the Research and Therapeutic based project types, with research slightly higher
- **Precision Medicine Research, OMICS studies, oncology, hematology,** are the key areas where the biobanks are actively involved in **research projects**.
- Partnerships with pharmaceutical companies are likely to drive the growth of the therapeutic segment in biobanking services in drug discovery and development and RWE studies

Service Capabilities

Type of Research

- **More than 70% of the studies are initiated with the help of academic institutes** and rest with either local or international based studies
- **NCI Biobank (USA**) for instance worked with **Children National Hospital for academic research studies** while it partnered with the **local affiliates of AstraZeneca and Amgen** for industry studies. For international studies, the NCI Biobank mostly focused in Europe with **University of Zurich as its partner**

- **Out of 195 studies (2017) initiated, 61% were carried out with the help of academic institutes** and rest of them with the local or international industry driven
- For industry driven studies, **Bayer followed by Novartis were the key partners for disease based studies with the Finnish Biobanks**
- **Auria Biobank was the major player** with maximum number of industry driven studies

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Gap Analysis- Finnish vs Global Biobanks

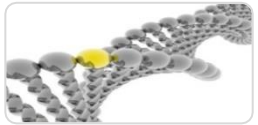
Service Scope- Application Areas

Genome Sequence

- More than 15 of the 17 biobanks interviewed had a focus on the genome sequencing projects for the end-users
- High quality samples, purity tests especially on DNA extracts, exclusively sequenced genetic maps, high genome assays and advanced technologies are major differentiating factors
- **All of US research program aims to collect 1 million** samples to create a database for research especially in **precision medicine applications**. It has almost **20,000 genome assays per year providing a better quality of genotyping and genome sequencing data** helping in advancement in the technologies used for genome analysis.

- **Access to genomic data is a strength** of the Finnish biobanks largely due to availability of isolated population cohorts. Helsinki Biobank, FCBT Tampere, THL Biobank especially have experience in genetic studies
- However **commercial potential for genomic studies for the Finnish Biobank is slowly improving** especially with the launch of the FinnGen study. **Finnish Biobanks aim to pitch for more genome related projects with the launch of the FinnGen study**

Application Areas



Companion Diagnostic

- Companion Diagnostics (biomarker**) is a key application area for a large number of biobanks globally**
- High quality samples, modern sample storage systems, large variety of biospecimensand advanced technology platforms for quicker analysis of the data are key differentiating factors
- **Biobank Graz has a large variety of samples (10-12 types)** and has **utilized its collaboration in Codex4SME project to enhance its biomarker capabilities**

- Biomarker studies are carried out by some of the biobanks such as Auria Biobank, FCBT Tampere, etc.
- In-house capabilities for better analysis of the biomarkers for drug development is less as compared to the global Biobanks
- **THL Biobank partnered with Nightingale health** to analyze close to 40,000 samples with **Nightingale's biomarker testing technology**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Gap Analysis- Finnish vs Global Biobanks

Service Scope- Application Areas

Oncology Clinical Development

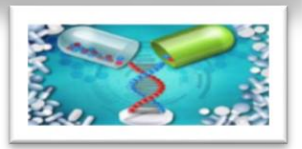
Oncology is the area **with maximum utilization for the global biobanks in its applications**

- **Highly specific samples** types for cancers such as lung, breast, skin, etc., **utilization of genome sequences in cancer** studies, collaboration with **multiple partners for sample collection**, **digitization and advanced data analysis competencies, access to oncology registers**, are key factors

Oncology is a key focus for most of the Biobanks in Finland

- Large number of projects carried out by Auria Biobank, Helsinki Biobank are in Oncology. **80% of the samples in Auria Biobank are cancer samples**
- **Comprehensive Cancer Center Finland (FICAN) is established to improve cancer treatment and research.** This is further likely to increase collaboration between hospitals, Biobanks for sample and research sharing, thus increasing sample utilization

Application Areas



Real World Evidence

Large population sample base and exogenous data are highly utilized for RWE studies.

- **Not many of the global Biobanks have focused on RWE studies**. Biobanks that have RWE capabilities have utilized mainly epidemiological, exogenous and even clinical data for such projects
- **IARC Biobank has experience of RWE solutions for oncology studies**. Sample procurement is a major challenge as per the Biobank for such studies

Finland has a great potential and capabilities to conduct RWE studies especially due to **genetically isolated population, data lakes, national registries, government support and comprehensive healthcare system**.

- A study by MedENGINE in 2018 revealed that in the next two years the **number of RWE projects in Finland will either increase significantly (43%) or modestly (33%) after the introduction of act on secondary use of health and social data**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Gap Analysis- Finnish vs Global Biobanks

Service Scope- Application Areas

Digital Pathology

Biobanks globally consider the digital pathology applications as the new frontier due to **increase in demand for highly specific diagnostic tests, analysis of large volumes of data for diseases**. **Although not yet a mature category for the Biobanks globally**, it is expected to grow in the coming years

- Large quantity of samples, digitization, data integration with systems, AI based computing platforms, are key areas
- **Danish National Biobank uses LIMS to integrate the data types for digital pathology solution offering**

- Finnish Biobanks are **growing in the digital pathology segment with biobanks offering TMA blocs, whole slide imaging data for such studies**
- Auria Biobank, Helsinki Biobank, Biobank Borealis, have capabilities in the segment

Application Areas

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Gap Analysis- Finnish vs Global Biobanks

Financial Sustainability

Funding Sources

Funding sources for Biobanks are diverse and Government/ Non-Profit grants are the biggest funding sources for large number of Biobanks globally. **On an average it contributes to more than 60% of the total funds received by the Biobanks**

- Other key sources of funding include **internal funds, private grants, commercial partnerships and fee recovery from operations**
- Of all the funds received by **KI Biobank 30% is from non-profit grants and 70% is recovered from its operations**

Financial Sustainability is a major challenge for the Finnish Biobanks and **funding sources are limited**

- As the Finnish Biobanks are mainly non-profit and owned by universities or hospitals, **cost recovery of the Biobanking operations is difficult to achieve**. **Less commercial partnerships further reduces the scope for getting additional funds**
- Most of the biobanking operations are sustained by **research grants, independent funding or simple cost plus fee** type of pricing model.

Financial Sustainability

Pricing Models

- **Cost recovery pricing model and fee for service is the preferred** pricing model type for the Biobanks
- As the academics still form the major portion of the customers, the **Biobanks subsidize the prices for them while charging higher for the commercial clients**.
- IARC Biobank adopts differentiated pricing for all its customers. For commercial customers **dynamic pricing where it increases the sample prices based on availability, and market demand.**

Pricing models for the Finnish biobanks is **not clearly defined** and most of them are in the process of **exploring the right pricing strategies for different engagements** viz. **commercial and academic.**

- Some biobanks have price list for the samples and services. For example **THL Biobank has a price catalog based on sample type, process, etc**.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Gap Analysis- Finnish vs Global Biobanks

Operational Sustainability (1/2)

Sample management

Most of the global Biobanks **have state of the art facilities for sample management services in regards to sample collection, storage and processing, sample retrieval and QC procedures**

- **Biobank Vast has large freezers with a range of -80 to -150 degree** for storage. **IARC Biobank has remote monitoring and access to all samples** to be aware of its storage conditions**. Decode genetics uses cryopreservation and cryovials to maintain the purity** of the samples for genetic studies

- While Finnish Biobanks have strengthened sample collection, there are **differences in operational maturity between the biobanks in term of sample storage and handing facilities**, and sample management services
- **Auria biobank**, for instance utilizes automated sample processing technology, and various tube sealing methods. It is the only biobank that uses capping method to seal tubes. Biobanks also use spectrophotometric methods, freezer rooms for storage, etc.

Operational Sustainability

Data services

- Most of the Biobanks do provide data based services to the end-users **either by developing in-house capabilities or outsourcing data collection, processing and analytics to third party vendors**
- **Clinical Data is most utilized by the biobanks followed by OMICS/Dx data**

Finnish Biobanks have **robust capabilities in handling multiple data types such as genomic data, exogenous data, disease data, population cohorts, data lakes**, etc. There exists good scope to provide data based services to the end-users

- Initiatives such as **National Genome Strategy is expected to make genomic datasets richer**. Law on **secondary use of data will improve access to data for research**

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Gap Analysis- Finnish vs Global Biobanks

Operational Sustainability (2/2)

Digitization

Biobanks are revving up the digitization capabilities largely due to **efficiency in data sharing and analysis in complex disease areas**

- Biobanks consider **access to sample data and information to be main objectives for their digitization efforts**. Another feature is the centralized access, which can act as a single point for feasibility and access requests by the end-user

- **Digitization of data is gradually evolving** with a major step being launch of Finngenious portal
- In order to harness the increasing potential of **digital pathology, imaging studies, and providing one access to services, biobanks are expected to improve upon digital capabilities**
- A combination of genetic information, health data and digitization would be key to fully utilize the potential of the Biobanks

Data Access

One Stop Access

- **One stop access to samples and data is a recent trend** in global biobanking
- Biobanks consider such solution advantageous due to **quick access to samples** and information, **reduced turnaround time** for sample delivery, **regular update about end-user preferences**, **one point contact for ongoing partnership**.
- **UK Biobank, CIGMR Biobank, NCI Biobank, Biome Biobank and Decode Genetics** have capabilities in providing virtual access through portals

- Only recently Finnish biobanks have established a **digital portal, Finngenious portal to serve academic and industry researchers globally**. It acts as a gateway to provide access to samples, genotype and longitudinal health records with sample donor recall opportunities. It is positioned to act as a one stop access to connect to all Finnish public biobanks
- The portal is in its formative stage as compared to other established biobank portals such as UKCRC directory which is a benchmark for providing access to biobank samples information through digital portals.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

Gap Analysis- Finnish vs Global Biobanks

Social Sustainability and Collaborations

Social Sustainability

- There are differences between the laws and regulations that govern Biobanking activities across the countries
- Some of the countries **such as in USA, France, UK, there are fragmented laws** that govern the Biobank activities. It poses **challenge for patient consent and sample collection from the donors as well as data sharing policies**
- Countries like Sweden and Denmark consider the laws to be satisfactory and progressive

As compared to global biobanks, **Finland has a robust regulatory infrastructure and well designed laws to ensure ethical, legal and social practices in biobanking**

- The Finnish Biobank Act is unique in terms of its dedicated supervision of the biobanking activities. Broad consent is another unique feature that simplifies the use of patient data for additional research purpose
- Laws such as Secondary Use of Data are pivotal to ensure highly improved access and use of health data for research purposes in Finland

Social Sustainability and Collaborations

Network Participation

Participation in regional and international network is a key priority for majority of the global biobanks

- Such participation helps to **increase the credibility** of the biobanks in front of the end-users, helps to **stay updated on the latest trends in research**, become **aware of the best practices of the other biobanks**, **enable the sharing of data and information on research studies**, among others
- Major networks include **EuroBioBank**, Organization of European Cancer Institutes- TuBaFrost, Canadian Tumor Repository Network **(CTRNet)**, Cooperative Human Tissue Network **(CHTN)** etc.

BBMRI and Elixir Nodes are the two networks where the Finnish Biobanks are a part of.

- Finnish **Biobanks need to increase the participation in network and consortium based collaboration** that can improve outreach of the biobanks, access to larger sample pool, information sharing and best practices in focused areas, greater visibility of the biobanks and opportunity to work on international projects be it commercial or academic.

Source: Frost and Sullivan Analysis, Primary Interviews, Company websites

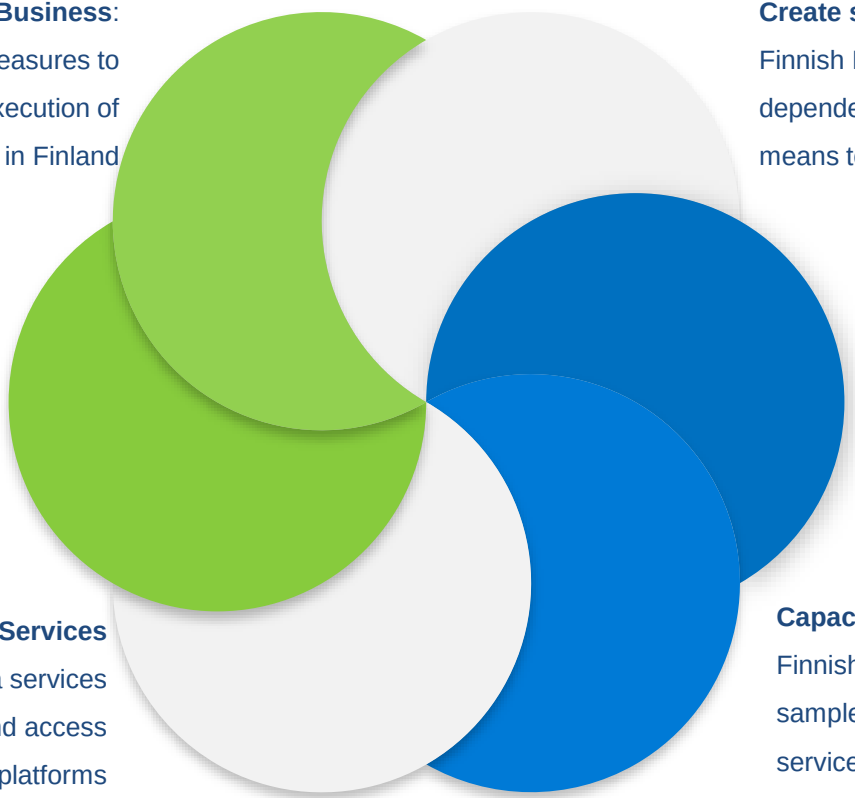
Recommendations

Finnish Biobanks can focus on six key recommendations as a part of the transformation process

Ease of doing Business: Regulatory and Policy measures to improve the initiation and execution of biobanking collaborations in Finland

Developing Brand Finland: Leverage the core competencies of the Finnish Healthcare landscape to distinctively communicate the brand Finland for Biobanking activities

Enabling Digitization and Data Services Strengthen the capabilities in data services offerings to the end-users and access through digital platforms



Create sustainable revenue streams: Finnish Biobanks must look for opportunities to reduce dependence on short term funding models and seek means to have continuous funding structures

Increase linkages between biobanks and industry Finnish Biobanks must look out for opportunities and increase visibility to engage more with the commercial partners and stand out ahead of the competition

Capacity Expansion Finnish Biobanks can focus on expanding sample variety, sample management services and

Source: Frost and Sullivan Analysis

Targeting the right stakeholders within the organizations and increasing visibility on communication channels can act as force multipliers to successfully engage with the commercial partners.

Increase linkages between biobanks and industry

1 Reaching out to the stakeholders

Target the right stakeholders

- Commercial organizations have different levels of decision makers and influencers that guide the biobank selection process
  - **Pharma**- Head of R&D and Head of Procurement are key decision makers. Influencers include Head of Clinical Ops, Medical Directors, Head of Marketing
  - **Biotech**- Head of R&D and Head of Procurement are key decision makers. Influencers include Head of Regulatory, Medical Directors
  - **Healthtech**- Head of R&D, Head of Procurement and Head of Diagnostics are key decision makers. Influencers include Chief Scientific Officer, Medical Director, Head of Clinical Ops
  - **Contract Research/Development Organizations**- Head of Clinical Research and Procurement are key decision makers. Influencers include Commercial and Financial stakeholders

Increase visibility on communication channels

- Finnish Biobanks must increase their visibility on the preferred communication channels to reach out to the stakeholders
- Participation **in major exhibitor conferences where commercial stakeholders participation is high. For example Biobanking and Regenerative Medicine Congress, ISBER Annual meetings, etc.**
- Besides, **Finnish Biobanks can also leverage the print media such as brochures, flyers, newsletters to be speaking about the capabilities of the biobanks, past research experience and key strengths**.

Expected Timelines

0-6 months

Responsible Stakeholders

- Biobanks

Source: Frost and Sullivan Analysis

Participation in networks and engaging with well defined models is a critical need for the Biobanks to grow. ISBER, EuroBioBank, BCNet, p3g are some of the well known global consortiums that can be considered

Increase linkages between biobanks and industry

2 Engagement model with end-users

Lay out the terms of engagement

- Define the engagement models for all the projects with commercial or academic partners. **Models can be based on the length of partnership, service requirements (sample and data), and internal resources of biobanks utilized**. For example strategic partnership for long term whereas research/service based model for short term engagements
- Biobanks can also **collaborate with the CRO/CDMO as strategic alliance partners** where they can engage with them as a part of larger collaboration with the Pharma

Expected Timelines

0-6 months

Responsible Stakeholders

- Biobanks

3 International and regional networks

Increase Participation in regional and international networks

- Finnish Biobanks should increase their participation in regional and international networks in order to have advantages of **networking with global biobanks, opportunity to share learning and best practices in focused areas, sample and data sharing, reach out to stakeholders, and market the capabilities of the biobanks**
- Finnish Biobanks can prioritize participation in such networks based on the complimentary fit of their capabilities with the objectives of the network. For example **ISBER is one of the largest global biobanking organization** , **EuroBioBank** is a partnership **of more than 25 Biobanks globally in the area of rare diseases**, **BCNet is primarily into cohort building and network**, **p3g is a non profit consortium dedicated to research in the area of human population genomics**.

Expected Timelines

6-12 months

Responsible Stakeholders

- FINBB

Source: Frost and Sullivan Analysis

Biobanks should focus on developing a brand for their services by leveraging the core competencies of the Finnish Health ecosystem. Investment into marketing activities, having an annual publication of

Developing Brand Finland

1 Health Innovation Playbook for Finland

Highlight the key strengths of Finnish Health landscape through an innovation playbook

- Develop **an innovation playbook for Finland** that highlights **key competencies in the area of digital health, data assets, population cohorts, scientific resources, country vision and policies, research infrastructure, key contacts in health industry and so on**.
- The playbook can also feature interviews, anecdotes, case examples that demonstrate the proficiency of the Finland in healthcare innovation
- The **playbook can be updated annually with the key insights and research in healthcare activities** in Finland that leverage the Finnish competencies and provide an overview of the latest activities in healthcare research
- This playbook **should be showcased and distributed through conferences, electronic media such as mails, and snippets can be communicated through online platforms such as Twitter, LinkedIn** to generate interest about the content in the audience.

Expected Timelines

6-12 months

Responsible Stakeholders

- Business Finland, FINBB

Source: Frost and Sullivan Analysis

Health innovation playbook and developing key performance metrics are initial steps. International Biobanks regularly spend ~1% of the total budget on marketing and promotion

Developing Brand Finland

2 Marketing and Business Development activities

Invest in Marketing activities

- Have a dedicated marketing personnel for sales promotion and a dedicated budget for marketing activities. Best practice of the **biobanks include having approximately 0.5-2% of the total budget dedicated to marketing activities**
- Finnish Biobanks can utilize this budget for identification of the customers and reaching out to them based on their preferred **communication media such as conference participation, print media such as brochures, newsletters, social media, etc.**
- The **marketing pitch can highlight the key strengths for the Finnish Biobank ecosystem, biobank infrastructure and case examples of past experience of working with the end-users** that can be leveraged in the marketing materials

Develop key performance metrics

- **Develop metrics to track trends** such as the tracking of sample usage, solicit feedback from customers, community engagement, shipping trends, distribution trends, social media engagement, sentiment analysis, and so on

Improve Web presence

- Biobanks must improve the web presence in order to create interest and showcase their offerings. Features can include list of projects handled, details of service offerings, sample information, infrastructure details, number of visitors to sites, key contacts, etc.

Expected Timelines

6-12 months

Responsible Stakeholders

- Business Finland, FINBB, Biobanks

Source: Frost and Sullivan Analysis

In order to expand data subtypes, variety of sources to collection sample data can be used. Patient questionnaire, data from imaging studies, health outcome studies, are few examples

Enabling Digitization and Data Services

1 Expand the data services

Increase the data variety

- Finnish Biobanks can expand the data collection from the donors and increase the variety of data types viz. Exogenous data, Clinical/Dx data, OMICS data and remote care data. **Data collection can be done from a variety of sources such as patient questionnaire, physical activity monitoring, environmental measures, health outcomes studies, imaging data, genotyping data and so on.**
- **Utilization of data services is high for the Pharma and the Healthtech segment** and data based partnerships can be explored with **data rent model under which the Biobank can grant temporary access to data to the end-users while keeping the ownership of the data with themselves**

Expected Timelines

6-12 months

Responsible Stakeholders

- Biobanks

2 Enhance the digitization capabilities

Strengthen the One-Stop services through Fingenius portal

- Fingenius portal for the Finnish Biobanks as a one stop shop access to sample information and access is a step forward in enhancing digitization capabilities.
- **FINBB can focus to enhance the features of the portal such as easy login details, lesser complexity in access of sample information and data, less complicated navigation for additional features, contact details of the Biobank personnel, frequent updates of the Finnish Biobank activities and so on.**

Expected Timelines

0-6 months

Responsible Stakeholders

- FINBB, Biobanks

Source: Frost and Sullivan Analysis

A major way of mitigating financial risks is to diversify the sources of funding by having a broad customer mix and well defined pricing models.

Create Sustainable Revenue Streams

1 Multiple Funding Sources

Diversify the sources of funding

- Finnish Biobanks need to adopt to the global best practices such as UK Biobank to have a large number of funding sources and not dependent on short term academic funding or sole commercial partners
- Biobanks need to **approach different set of end-users based on their requirements and seek large scale or small scale projects.** Finnish Biobanks can make the use of the **large scale Finngen study to gauge the requirements in terms of sample and data and generate separate projects with partners such as in biomarker studies, patient recall studies, targeted therapies, among others** (as an addendum to the national initiative)
- Finnish Biobanks can **target a wide variety of customer types** including but not limited to large and mid size Pharma and Biotech, Healthtech companies specializing in drug discovery, diagnostics, precision medicine, RWE companies, data analytics

Expected Timelines

6-12 months

Responsible Stakeholders

- Biobanks

2 Pricing Models with the end-users

Have well defined pricing models

- Finnish Biobanks **need to move beyond arbitrary pricing of samples and data and need to have well defined pricing for its ongoing engagements**
- Biobanks can **allocate prices of samples based on the market demand for the samples, rarity of the samples, severity of the disease and timely availability to end-users and other such parameters . Additional services such as consulting, regulatory support, etc. can also be priced as a part of the whole offering**

Expected Timelines

0-6 months

Responsible Stakeholders

- Biobanks

Source: Frost and Sullivan Analysis

Finnish Biobanks should sharpen the focus on networking and niche research areas within Oncology and Genomics. MIABIS, CEN norms are utilized by leading Biobanks in Oncology whereas EMBL-EBI is

Capacity Expansion

1 Focus on the identifying the growth levers in growth opportunities

Identify key growth levers in the different segments

- **Oncology Clinical Development**: Focus on precision oncology areas such as **molecular signature, mutation pattern analysis, immunotherapy, etc.** Furthermore the Biobanks can also look for expanding areas in Oncology such as **molecular and genetic epidemiology (cancer causation), molecular pathology, and pharmacogenomics/pharmacoproteomics**. Biobanks can also leverage their expertise in Oncology by incorporating tools for effective networking and resource sharing between biobanks. Examples include **Minimum Information about Biobank Data Sharing Model (MIABIS 1.0/2.0), European Committee for Standardization (CEN) norms and Sample PREanalytical Code (SPREC)**

- **Genomics**: **Next generation sequencing (NGS)** will remain a key focus area however Biobanks should leverage participation in networks such as European Bioinformatics Institute (EMBL-EBI). Other potential research areas for Biobanks to explore include but not limited to **single cell transcriptome analysis , tumor neoantigens from NGS data, among others.**

- Utilization of AI based technologies is a key to seize growth opportunity within the **Digital pathology segment**. The use of whole slide imaging technology has further increased the use of AI and ML tools in digital pathology. **Google developed an AI based algorithm Lymph Node Assistant (LYNA) in the area of digital pathology. Company reported that it can successfully detect metastatic breast cancer on the slides 99% of the time.**

Expected Timelines

6-12 months

Responsible Stakeholders

- Biobanks

Source: Frost and Sullivan Analysis

…a leader in large scale genomic data sharing. AI and big data analytics suites is a key to seize the growth in digital pathology. Google's AI based algorithm LYNA is a case in point

Capacity Expansion

1 Focus on the identifying the growth levers in growth opportunities

Identify key growth levers in the different segments

- RWE is a potential opportunity for the Finnish Biobanks however the utilization of biosamples and biodata for such studies is currently low and likely to grow further. **Finnish Biobanks can position themselves as leaders in the category due to existing robust data infrastructure such as registries, population cohorts, patient records, and digitization of data.**
- Biomarkers are immediate growth opportunities as the applications are across therapy areas and scope of work with both commercial and academic clients is large

Expected Timelines

6-12 months

Responsible Stakeholders

- Biobanks

2 Sample types and variety

Invest in strengthening sample management infrastructure

- **Finnish Biobanks need to invest on infrastructure for sample storage and management** with the aim to increase biospecimen variety in the Biobanks and maintain the quality of the samples for utilization. Focus on **research repositories hosting biomedical and clinical data** and consider performance attributes for track the utilization and effectiveness.
- **There are unequal competencies among biobanks even with respect to sample management infrastructure** where some biobanks such as Auria, Helsinki, etc. having state of the art equipment whereas others do not.
- **Automated sample handling, tube-scanning, cryopreservation units, LIMS data management systems, temperature controlled freezers, liquid nitrogen storage systems, track and trace technologies, remote monitoring of samples, DNA/RNA aliquoting are adopted as best practices by the major biobanks globally**

Expected Timelines

6-12 months

Responsible Stakeholders

- Biobanks

Source: Frost and Sullivan Analysis

Finnish Biobanks need to expand the human capital to adequately mange the operations in the Biobank. Having a team of scientific advisors or a board of members can further increase the credibility as a partner

Capacity Expansion

3 Increasing human capital

Invest in building human capital in Biobanks

- Shortage of human resources is a challenge faced by the Biobanks. Since biobanking value chain involves scientific expertise，lack of sufficiently trained staff can adversely impact the operations
- Biobanks need to invest in hiring and retaining talent for managing activities in operations and for marketing and promotion. Biobanks have also included a board of management with highly skilled and scientific resources as members or advisors who act subject matter experts

Expected Timelines

6-12 months

Responsible Stakeholders

Biobanks

Source: Frost and Sullivan Analysis

Ease of interpretations of laws such as Act of Secondary use and Biobank Act and use of SOPs, WBS in project management will enhance business effectiveness of the Finnish Biobanks

Ease of doing Business

1 Regulations and Policies

Simplification and ease of interpretation of laws

- There should be more clarity for the partners and the biobanks themselves around the usage of data and samples for the studies
- Although the current Biobank Act is unique to Finland to provide a set of guidelines to govern the Biobanking activities, there is a need for better dissemination of laws in the area of broad consent, sample procurement and data sharing by the Biobanks
- The introduction of Act of Secondary use of Data and laws related to national genome strategy, will enable researchers and service providers to collect, process data from different Finnish registries for broader use in Health such as personalized medicine, public health programs, etc.
- **In order to ease the interpretation of these laws , the Biobanks and FINBB can focus on ways to reach out to the research partners with knowledge modules, courses, hold seminars or webinars with FAQs on data access and application in research in context of the laws applicable**

Expected Timelines

6-12 months

Responsible Stakeholders

- FINBB, Biobanks

2 Project Management

Have a robust project management plan

- Develop a **robust project management plan and standard operating procedures (SOPs) with details of activities, stakeholder responsibility for the activities, delivery timelines, current status, work breakdown structure (WBS)**.
- Having established Ongoing communication with the end-users and updates about the project status are of importance to the end-users.

Expected Timelines

0-6 months

Responsible Stakeholders

- Biobanks

Source: Frost and Sullivan Analysis