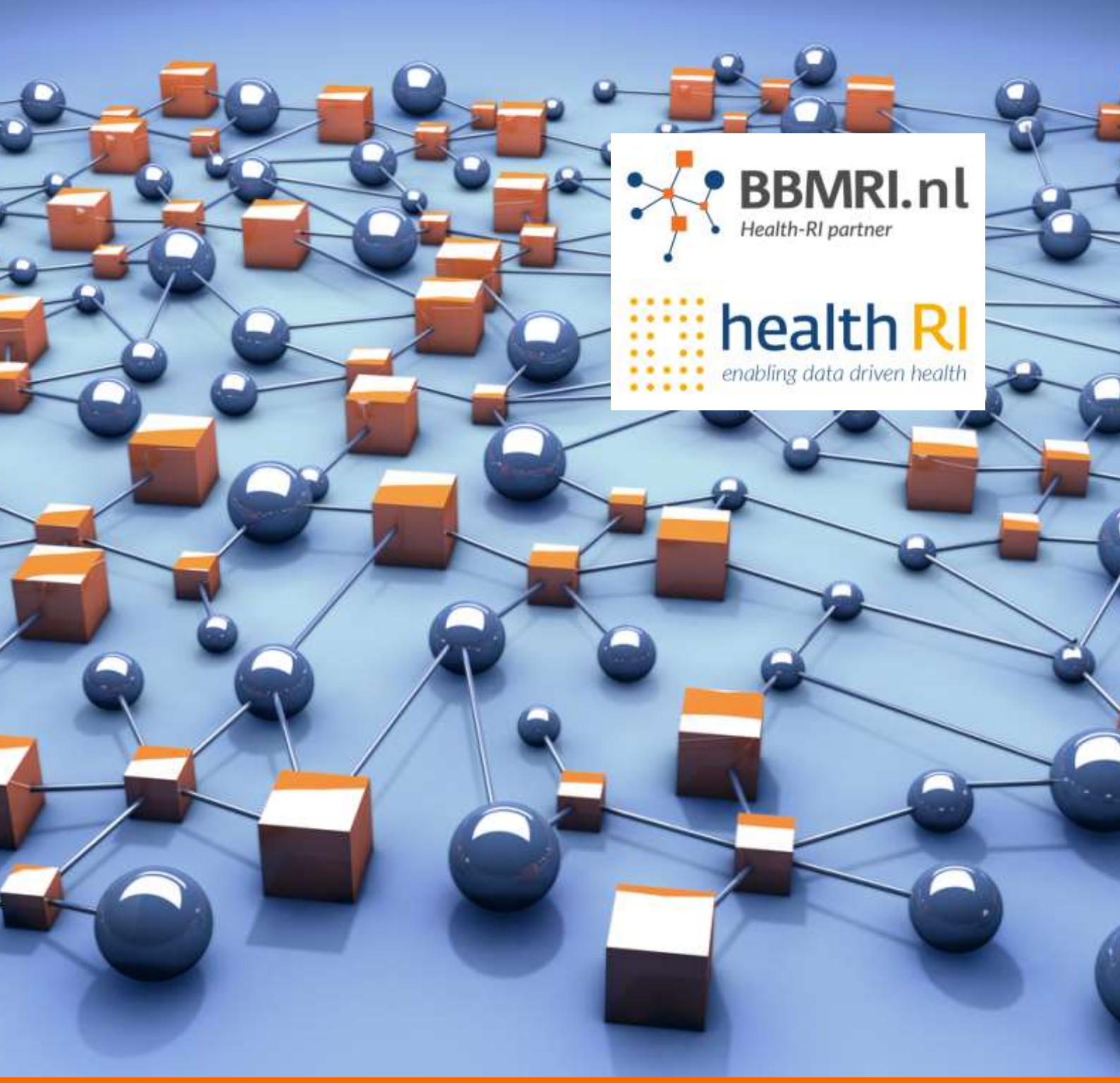

Good Practices in Sustainable Biobanking

A Case Study Analysis

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Table of Content

1. Background

1.1. Project context

Good Practices in Sustainable Biobanking: A Case Study Analysis is a product of Biobanking and BioMolecular resources Research Infrastructure The Netherlands (BBMRI.nl) work package 6: Sustainable and Interactive Biobanking. BBMRI.nl is an initiative of the eight Dutch university medical centres, other Dutch research centres and organisations, as well as the Parelsnoer Institute. In addition, it serves as the Dutch node of the European network of biobanks, united under BBMRI-ERIC.

It is BBMRI.nl's mission to maximize the use of biobanks for health research on the prevention, diagnosis, and treatment of diseases. To achieve its mission, BBMRI.nl provides access to samples, images, and data; tools for capturing, integrating, and analysing data; and support on ethical, legal and societal implications. BBMRI.nl is part of Health-RI, the overarching Dutch research infrastructure on personalized medicine and health.

1.2. A BBMRI.nl series on sustainable biobanking

Good Practices in Sustainable Biobanking: A Case Study Analysis is part of a BBMRI.nl series on Sustainable Biobanking. In this series we provide recommendations, good practices, business tools, and background information, all to help individual biobanks improve their sustainability. The series consists of:

1. Recommendations for Sustainability Biobanking
2. Sustainable Biobanking: The Financial Dimension
3. Good Practices in Sustainable Biobanking: A Case Study Analysis
4. Business Tools for Biobanks

1.3. Definitions

This report adheres to the BBMRI-ERIC definition of **biobanks**: *Biobanks are collections, repositories and distribution centres of all types of human biological samples, such as blood, tissues, cells or DNA and/or related data such as associated clinical and research data, as well as biomolecular resources, including model- and microorganisms that might contribute to the understanding of the physiology and diseases of humans* (European Commission 2016).

In addition, this report follows the Organisation for Economic Co-operation and Development definition of research infrastructure **sustainability**: *Sustainability is the capacity of a research infrastructure to remain operative, effective, and competitive over its expected lifetime* (OECD Global Science Forum 2017).

There is no generally accepted definition of **good practices**. It is closely related to best practices, which are methods, techniques, or approaches that have been generally accepted as superior to any alternatives. Due to the varied and contextual field of biobanking it is difficult to find and proof best practices for the financial dimension. Therefore in this report we speak of good practices: methods, techniques, or approaches that have shown, based on experience, to improve sustainability for one or more biobanks.

1.4. Focus on the financial dimension

Sustainable biobanking consists of an interplay between financial, social, and operational dimensions (Watson, Nussbeck et al. 2014). In this report we focus on the financial dimension, from a business perspective, as it is considered the most challenging and is currently insufficiently addressed within

the Dutch biobanking community. In addition, there have been several recent publications by BBMRI.nl and other organisations addressing topics and best practices within the social (Boeckhout, Reuzel et al. 2014, Eijdems, Boeckhout et al. 2018) and operational dimensions (NCI 2016, ISBER 2018). The BBMRI.nl report *Sustainable Biobanking: The Financial Dimension* provides further background information on the financial dimension.

2. Introduction

Biobanks are considered a critical resource for translational biomedical research and better preventive and personalised health care. However, their sustainability is a major challenge. This is of growing concern for organisations, policymakers, and funders, as they invest millions of euro's each year into the biobanking field.

Being sustainable involves balancing a biobank's financial, social, and operational dimensions, with the overarching aim to create value (Watson et al. 2014). Finding the right balance is difficult as biobanks operate in a complex environment, acting at the interplay of ethical, scientific, and commercial values; and balancing both societal and research expectations. In this environment, a biobank's sustainability is constantly challenged by technical, logistical, legal and privacy-related issues, and a growing demand for quality, FAIRness[1], transparency, and accountability (Stephens, Dimond 2015, Timmons, Vezyridis 2017, Watson et al. 2014, Wilkinson et al. 2016). Furthermore, the fact that most biobanks operate on a timescale of 10 to 30 years and need to acquire stakeholder commitment and funding over such a long time period does not make sustainability any easier.

The increased interest in sustainable biobanking has not yet led to shared solutions. And as biobanks exist in many forms –in terms of organisational setup, scale, and focus–, it is unlikely that one-size-fits-all solutions exist. Still, the scientific literature contains numerous case studies of how biobanks tackled or tried to tackle their own sustainability challenges. By analysing 22 of these case studies we aim to extract methods, tools, and strategies that have shown to improve biobank sustainability. Hereby we hope to provide biobanks, biobanking professionals, and researchers with insights into good practices that they can use in their own search for sustainability.

3. Approach

3.1. An analysis of 22 biobank case studies

We analysed 22 case studies published between 2014 and 2018 in scientific journals or presented at international conferences. The group contains seven case studies from Europe, seven from the United States, and eight from other parts of the world. In addition, the group contains two commercial biobanks, both from the United States. The other twenty biobanks are affiliated to research institutes or hospitals, either as a separate entity or integrated within the hosting institute. The case studies do not include any population biobanks, but consist solely of clinical biobanks that occasionally function as centralised infrastructure to the hosting institute. We analysed each case study on the basis of five topics (see 3.2.), extracting methods, approaches, strategies and lessons. After the analysis, we determined if certain practices or strategies were used by multiple biobanks or had a clear benefit for the individual biobank. Both could be indicative of a potential good practice.

[1] FAIR stands for Findable, Accessible, Interoperable, and Reusable. For more information see: https://www.dtls.nl/fair-data/fair-principles-explained/ (Wilkinson, Dumontier et al. 2016).

There are several limitations to our case study analysis: First, as the case studies contain a lot of information it is likely that potentially valuable information was missed during our analysis. Second, the case studies also discussed operational and social topics that may be relevant for biobanks in their struggle for sustainability. However, we only included those topics in our analysis when they were closely related to the financial dimension. Third, the pool of case studies lacks population biobanks, so good practices that might be particularly relevant for these type of biobanks could not be determined. However, many identified practices will, to a certain extent, be transferable between biobanks. Fourth, we often had to deduce the adopted business models from the text as most case studies did not specify the models used. Therefore, it is likely that this topic contains errors or is incomplete.

3.2. Five analysis topics

Each case study was analysed on the basis of five topics: business models, stakeholders, funding, costs, and business tools. Any noteworthy practices that did not fit these topics were noted as "additional comments". Below we provide a short description of each topic. The topics are addressed in more detail in the BBMRI.nl reports *Sustainable Biobanking: The Financial Dimension* and *Business Tools for Biobanks*.

Business models

A business model describes how an organisation creates, captures, and delivers value for its customers (Osterwalder, Pigneur 2010). More practical, a business model describes the processes required to run a successful organisation, including the value proposition, the sources of revenue, the intended customer base, the organisation's products and services, and the details of financing (Oxford Dictionaries , Magretta 2002). Choosing a feasible business model and organising your biobank, its personnel, and its activities accordingly will help plan for sustained success. At the moment, biobanks often use a mix of several business models. In our analysis, based on the information available in the case, study we name the business models used by each biobank. For background information on each specific biobank business model we refer to the BBMRI.nl report *Sustainable Biobanking: The Financial Dimension*.

Stakeholders

Stakeholders are individuals, groups, or organisations that are affected by or can affect a particular action undertaken by others (Bjugn, Casati 2012). Biobanks exist in an extensive ecosystem of different stakeholders. Ultimately, the key to success for any commercial or non-profit organisation is the satisfaction of its key stakeholders (Bourne 2009, Bryson 2011, Bjugn, Casati 2012). This is no different for biobanks. In our analysis we describe the approaches and strategies employed by biobanks, as related to their stakeholders and the financial dimension.

Funding

A biobank needs to collect sufficient resources to cover both its start-up and its operational costs. Funding sufficient funding is considered a major concern (Cadigan, Lassiter et al. 2013, van der Stijl, Scheerder et al. 2018, Rao, Vaught et al. 2019). Particularly the unpredictable and often short-term nature of the available funding makes long-term planning and sustainable exploitation difficult (Gee, Oliver et al. 2015). In practice most biobanks rely heavily on research grants and the hosting institute's budget. Ideally, biobanks would have multiple sources of funding and revenue, some of which scale with increased use and costs. In our analysis we describe the strategies and funding streams used by the different biobank cases.

Costs

Each individual biobanks' cost build-up is complex and depends on the biobanks' setup, size, services, and adopted workflow. The scarcity of available resources makes cost information essential to plan

for the future and take informed decisions towards sustainability (Ecological Society of America 2010, Gonzalez-Sanchez, Lopez-Valeiras et al. 2014). In our analysis we list the cost strategies or cost-effectiveness decisions taken by biobanks.

Business tools
Multiple business and management tools exist. Such tools enable organisations to capture their complex environment in an understandable format. The resulting insights help organisations to make choices, set priorities, and align strategies. In our analysis we name the business tools used by biobanks in their search for sustainability. The BBMRI.nl report *Business Tools for Biobanks* provides additional background information and business tool templates.

4. Case study analysis

Table 1 contains the case study analysis per biobank, ordered per topic. Seven case studies are earmarked as recommended reading. In chapter 5 we discuss the results and identify good practices.

Table 1. Analysis of 22 case studies on good practices in financial sustainability	
BIOBANK GRAZ (Sargsyan, Macheiner et al. 2015, Macheiner, Huppertz et al. 2017) **(recommended reading)**	
Business model	Cost recovery, core facility model, project-based model
Stakeholders	Broad informed consent for prospective studies to ensure future use
Funding	Periodic screening of national and international funding opportunities
Costs	Find synergies with other institutes and/or departments for sharing (e.g. storage, equipment, procedures, employees) to lower costs
Business tools	Business plan (updated annually), cost calculation model, Boston Consulting Group analysis, SWOT analysis.
Additional comments	Optimal utilization of a biobank begins with the idea of sharing resources, infrastructure, and investments
THE DUKE KATHLEEN PRICE BRYAN BRAIN BANK AND BIOREPOSITORY (Uzarski, Burke et al. 2015) **(recommended reading)**	
Business model	Cost recovery, contract research model, service-based model, project-based model
Stakeholders	• Secure institutional buy-in as early as possible • Inform researchers and industry collaborators on sample and data availability • Contact with a biomarker research broker has resulted in several inquiries for research collaborations
Funding	A market-focused approach facilitating external collaborations and cost recovery
Costs	Leverage institutional resources, such as faculty, finance and business strategy staff and students, to lower costs
Business tools	Business plan, market research (to understand customer needs)
Additional comments	A business strategy, vetted by key stakeholders, is the cornerstone of the biobank's sustainability effort. The strategy was created by asking hard

	questions, basing decisions on financial and research impact, using the institution's network, involving industry, and using research broker matchmaking services. The plan was used to garner institutional support
BC CHILDREN'S HOSPITAL BIOBANK (Tarling, Lasser et al. 2017, Brown, Kelly et al. 2017) **(recommended reading)**	
Business model	Core facility model, service-based model, cost recovery
Stakeholders	• A strong, transparent, and inclusive governance involving many key stakeholders has led to advocates that exponentially promote the biobank • Great customer satisfaction because of good services by passionate and diligent biobank team
Funding	Principal investigator-driven biobanking services are a significant source of income
Costs	Educating users on the actual costs results in a better understanding of the cost-effectiveness of biobanking
Business tools	Business plan (made with consultant before implementation and approved by key stakeholders)
Additional comments	• Operational performance is assessed yearly via key performance indicators • Our experiences suggest that creating a business plan before embarking on implementing a large biobank is worthwhile and is beneficial for monitoring the sustainability, bearing in mind that adjustments and deviations may occur.
AUSTRALIAN BREAST CANCER TISSUE BANK (Carpenter, Clarke 2014)	
Business model	Project-based model, cost recovery
Stakeholders	Obtain in-kind support from local health care facilities (e.g. nurses administering consent).
Funding	• The biobank consists of a central hub and regional collection sites. Individual collection sites were encouraged to gather their own local funding and support. • For future revenue the biobank aims to engage clinical trial groups, offer profit-based analytical services, and link with electronic medical records.
Costs	Use technological solutions whenever possible to enable cost savings in personnel time
WALES CANCER BANK (Parry-Jones 2014, Campos, Schreeder et al. 2015)	
Business model	Project-based model, service-based model, cost recovery
Stakeholders	• A marketing strategy was made based on two surveys: 1) biobank users and 2) prospective users • Users receive a user survey after three months to establish constant feedback and improve the biobank's strategy and processes
Costs	The use of a cost-benefit analysis to evaluate the potential impact of efficiency measures and cost reductions on biobank sustainability.
Business tools	Business plan (valuable exercise, the marketing plan is the key section), cost-benefit analysis
Additional comments	Regular audits of processes and policies to ensure they remain fit-for-purpose, cost effective, and scientifically relevant.

NOTTINGHAM HEALTH SCIENCE BIOBANK (Matharoo-Ball, Thomson 2014) **(recommended reading)**	
Business model	Service-based model, contract research model, cost recovery, strategic partnership model
Stakeholders	• The capacity to make a rapid request decisions is essential for commercial partnerships • Develop a cost-effective and user friendly consenting process • Clear 'unique selling points' help to secure your competitive position in a rapidly changing market
Funding	We used a variety of methods (e.g. scanning published information, telephone interviews with commercial companies, dialogue with potential customers) to establish the market value of samples and linked clinical data.
Costs	• Ensure cost-efficient processes, careful staff utilization, and maximization of sample turnover • Prior to any sample collection we made a detailed financial report on the real costs related to samples. Calculations were primarily based on the time per activity. Result was an itemized costing structure for all types of samples, derivatives, and clinical annotation. • By incorporating sample related processes into routine clinical care for small incremental charges we significantly saved on infrastructure costs.
Business tools	Business plan (made with key stakeholders and external consultants before starting operations)
Additional comments	Business model developed with external consultants and founded on 1) key therapeutic areas fitting the biobanks strengths, 2) systematic identification of relevant companies, 3) engagement with non-commercial stakeholders to agree on strategic sample collection, 4) consistent high quality samples, 5) rapid response time, and 6) cost effective processes.
UNIVERSITY OF PITTSBURGH HEALTH SCIENCES TISSUE BANK (Kelly, Wiehagen et al. 2017)	
Business model	Cost recovery, collection on demand model, service-based model, core facility model
Stakeholders	• Annual user survey for continuous improvement. Results are compiled and shared with respondents. • Extensive internal marketing of available samples and services (incl. presentations to research groups and marketing posters) • Maximize value to researchers by minimising their efforts in accessing and acquiring materials via user-friendly online tools for project requests and inventory searches. • To achieve sustainability, fully engaging the researcher as our customer is a must.
Costs	• Transparent cost model • Leverage economies of scale by serving as central repository for own and other samples
Additional comments	Stopped collecting excess material that is not utilized, only gather researcher-driven specimens.
BEAUMONT HEALTH SYSTEM BIOBANK (Wilson, D'Angelo et al. 2014)	
Business model	Core facility model, service-based model, contract research model, cost recovery

Stakeholders	• The reputation of the biobank, hosting hospital, and our accreditation were key factors in facilitating contact with companies • It was illuminating to learn what samples and types of processing were requested by industry. Surprisingly, formalin fixed paraffin-embedded samples were most requested. • Philantropic endeavors are supported by providing donor tours, documents, community-based presentations and outreach activities
Funding	In our case, philanthropy and commercialisation, in contrast to grants, represent the best options to sustain operations in the face of stalling internal support
Costs	A matrix including all costs for each type of donor and sample formed the basis of our pricing structure
Business tools	Kaizen assessment (process improvement)
Additional comments	Combining high-quality biobanking with additional research facilities attracted commercial interest. Companies commented that dealing with a single entity that provides both samples and, for example, pathology-based genomic or proteomic analyses increases the value of the samples.
SYDNEY BRENNER INSTITUTE FOR MOLECULAR BIOSCIENCE (Soo, Mukomana et al. 2017)	
Business model	Cost recovery, service-based model
Stakeholders	Ensure that you have the necessary support from your institution
Funding	Researchers pay for what they use, including costs for consumables, personnel time, and storage
Business tools	Cost-benefit analysis
THE INSTITUTE OF HUMAN VIROLOGY-NIGERIA H3AFRICA BIOREPOSITORY (*Global Biobank Week Posters Abstracts Book 2017.*)	
Business model	Project-based model, service-based model, donation-based model
Stakeholders	Advocate to universities, researchers, governmental and non-governmental agencies to establish partnerships. Partnerships facilitate diversity in clients, contracts, resources, and samples.
Costs	Leverage institutional resources, including facilities and expertise, to lower biobank spending
Additional comments	Biobank sustainability in resource-challenged environments depends upon service quality, affordability, sound planning, advocacy, and partnerships
NETHERLANDS BRAIN BANK (Rademaker, Huitinga 2018) **(recommended reading)**	
Business model	Cost recovery model, donation-based model, project-based model
Stakeholders	• Marketing to prospective donors of tissue and funds (e.g. partner websites). • Hiring account and marketing managers
Funding	Implement tiered cost-recovery scheme (subsidise cost price of academic users) to off-set irregular grant funding, subsidies, and (private) donations

Business tools	Business plan that identifies the interests of all stakeholders, insures funding streams through these stakeholders, and aims for cost efficiency. Annual reports (e.g. output)
Additional comments	Value proposition: availability and accessibility of human brain samples and data; neuropathologic reports and clinical summaries; diversity in anatomic region and diagnosis; tissue enrichment; product and service customisation
LUNG CANCER HOSPITAL-INTEGRATED BIOBANK (Washetine, Heeke et al. 2018)	
Business model	Cost recovery model, strategic partnership model, service-based model
Stakeholders	• Certification (ISO 15189 and NFS 96-900) important factor for collaborating with academic and industrial partners • Biobank visibility increased by collaborating with lung cancer research groups on publications. Obligatory citation of biobank as co-author, in M&M, or acknowledgements with specific identifier
Business tools	SWOT (to better orientate short- and long-term strategies)
Additional comments	• Duplication of collections of strong interest to ensure their safety (DNA duplicates of frozen tissues) • The increase in projects and MTA-sample release have allowed sustainability • Sample pricing, contract formulation, and MTA together with research and innovation department • It is essential to maintain a dynamic strategy and thinking process concerning the approaches of choice by involving all biobank members
Trustbank (Timmons, Vezyridis 2017)	
Business model	Cost recovery model, core facility model
Stakeholders	TrustBank was seen as being for the 'local' hospital, which instills trust in participants
Costs	• Use of lay volunteers for participant recruitment (intermediaries between patients, hospital and biobank, ease administrative burden of recruitment) • Use of existing facilities (e.g. incorporate consenting and recruiting into clinical procedures)
ASTERAND BIOSCIENCE (Brown et al. 2017)	
Business model	Contract research model, collection on demand model
Stakeholders	• Samples sourced from a worldwide network of 100+ strategic partners • Marketing team to create awareness (e.g. advertisements, conferences) and perform market research
Business tools	Financial planning (12-24 months ahead), market research
Additional comments	• Monthly stock and issuance evaluation • Business development teams • ISO and CAP accreditation ensure high quality samples, resulting in trust and continued demand
THE OREGON HEALTH & SCIENCE UNIVERSITY KNIGHT BIOLIBRARY (Brown et al. 2017)	
Business model	Core facility model
Stakeholders	When developing a marketing plan decide on your core business services and target the most appropriate customer base. Adopted marketing channels: web presence and networking opportunities at conferences
Business tools	Business plan, SWOT (at regular times to keep focus), marketing plan

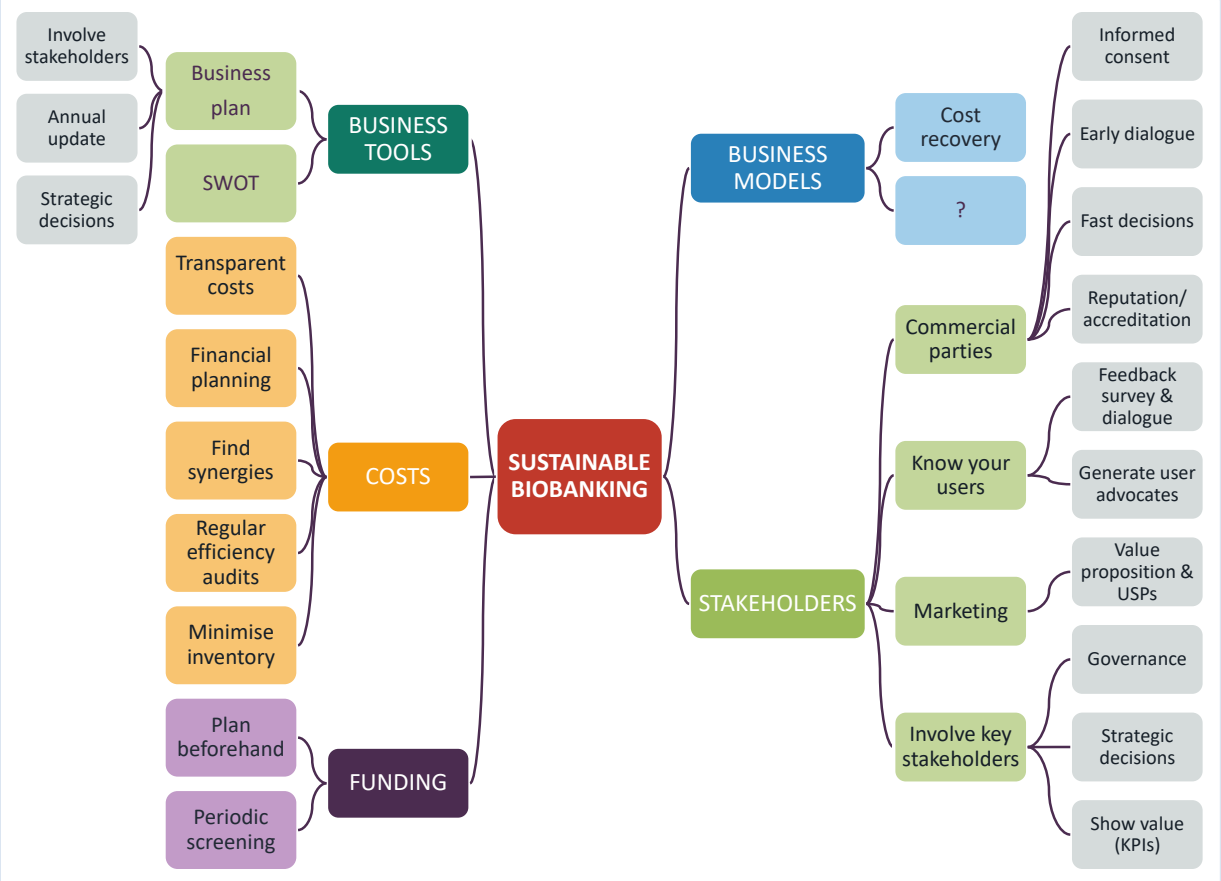
Additional comments	• Also measure utilization via nr. of support letters and grant applications intending to use the biobank • Business planning guided by considering the intersection between: (1) the demographics of our patient population, (2) the needs of our researcher community (research foci and required samples), and (3) our financial constraints
AURIA BIOBANK (Lehtimaki, Helen et al. 2017) **(recommended reading)**	
Business model	Strategic partnership model, service-based model
Stakeholders	A biobank becomes attractive if it has something 'unique' to offer to a partner
Funding	Auria needs to adopt an organisation form compatible with business collaboration
Additional comments	The biobank considers its data, data management expertise, and potential for clinical trial related phenotipic patient stratification as its main assets in global biobank business
BIOBANK CORE FACILITY ST. JOSEPH'S HOSPITAL AND BARROW NEUROLOGICAL INSTITUTE (Seiler, Eschbacher et al. 2015)	
Business model	Core facility model, cost recovery model, project-based model
Costs	Calculate the true cost of samples and services to feed into a tiered cost recovery model
Business tools	Business plan, SWOT
Additional comments	• Planning for the sustainability of your biobank is a must • Our approach to sustainability is to ensure that value is added for each key stakeholder, enable research, and have the broadest impact on scientific discovery • When aiming for sustainability, consider the entire ecosystem. A biobank makes the hosting institute's researchers more competitive in obtaining grants. The subsequent increase in grant funding may offset losses made by the biobank.
A C CAMARGO BIOBANK (Campos et al. 2015)	
Business model	Cost-recovery model, project-based model
Stakeholders	Determine the necessary metrics to showcase our strategic value to our institution. Recognition of value is critical to have financial support from our institution
Business tools	Business plan, SWOT
CONVERSANT BIO (now called Discovery Life Sciences) (Campos et al. 2015)	
Business model	Collection on demand model, service-based model, contract-research model
Costs	In the beginning minimum inventory levels, limited staffing, and home-grown systems allowed for financial sustainability
Business tools	Business plan (review efforts allows us to think about strategic opportunities and challenges)
Additional comments	• A biobank must continually reassess its goals and funding sources if it hopes to remain viable

	• Each month we review financial, operational, and business development metrics and discuss key opportunities and risks in our biobank and in the field • We compare our metrics to the previous year as well as our current year budget, allowing us to benchmark progress, identify problems and opportunities, and make changes as needed
THE EGYPTIAN NATIONAL CANCER INSTITUTE BIOBANK (Campos et al. 2015)	
Business model	Cost recovery, project-based model, service-based model
Stakeholders	Collaborate with national and international networks
Funding	Financial sustainability and sources of funding should be addressed in the establishment phase
Costs	Calculate user fees using the fee calculator developed by the Canadian Tumour Repository Network
Business tools	Marketing plan, user fee calculator
RESEARCH INSTITUTE OF THE MCGILL UNIVERSITY HEALTH CENTRE LIVER DISEASE BIOBANK (Campos et al. 2015) **(recommended reading)**	
Business model	Cost recovery, project-based model, service-based model, contract research model, donation-based model
Stakeholders	At start we partnered with the research ethics board to correctly include working with private parties into our patient consent process
Funding	• 4-tier cost recovery mechanism • Researchers applying for grants included in their budgets the costs related to sample acquisition
Costs	To reduce continuous operating costs we consented patients, but only collected when the samples were needed, established priorities in sample collections and reduced material waste
Business tools	Business plan (gave us a good overview of requirements and costs)
Additional comments	• Well-designed business strategy is important at a biobank start-up phase • Because requests and projects evolve and we need to adjust quickly we revisit our business plan every 4–6 months • Developing partnerships with private parties is well aligned to our mission and expected by our patients • Industry quality requirements are very stringent, therefore we focus a lot on quality to ensure utilization from industry is continuous
BIOBANK/CLINICAL RESEARCH CLINICAL TRIALS LABORATORY (McQueen, Keys et al. 2014)	
Business model	Core facility model, project-based model, contract research model, strategic partnership model
Additional comments	Collaboration, collegiality, consistency, creativity, and clinical collaborators, are the keys to progress, but there must first be a vision, one that can expand to embrace new opportunities

5. Good practices for sustainable biobanking

Here we discuss the results of our analysis and any good practices we were able to identify (see figure 1 for an overview). Because biobanks vary considerably in context and setup, each biobank has to decide which good practices would be beneficial considering their own individual circumstances.

Figure 1. An overview of good practices for sustainable biobanking



Based on an analysis of 22 case studies we identified multiple good practices for sustainable biobanking within the topics business models, stakeholders, funding, costs, and business tools. USP, unique selling point; KPI, key performance indicator.

5.1. Business models[2]

The case study biobanks used the cost recovery, core facility, project-based, service-based, donation-based, contract research, strategic partnership, and/or collection-on-demand model. And always in a mix of several models adjusted to the individual situation. Cost recovery was the most prevalent (16 out of 22 case studies), followed by the service-based (13/22) and project-based models (11/22). However, none of the case studies indicated how successful their cost recovery was, either in absolute numbers or percentages. In addition, it is unclear how their user community responded to the requested price for samples and data.

[2] For background information on each specific biobank business model we refer to the BBMRI.nl report *Sustainable Biobanking: The Financial Dimension*.

The donation-based, collection-on-demand, and strategic partnership models were used by, respectively, three, three, and four biobanks. Both commercial biobanks used the collection-on-demand model, complemented with the service-based model. This suggests that the collection-on-demand model, which collects samples from consented participants only after a specific issuance request has been made by a researcher, can be economically viable. However, this model is not feasible for all types of biobanks. For example, population biobanks for longitudinal and observational research will have to collect samples and data beforehand.

5.2. Stakeholders

Within the topic of stakeholders several good practices can be identified. Foremost, biobanks need to develop a clear understanding as to the identity and needs of their users, be they academic researchers or private parties. Knowing your users and their requirements for downstream research ensures that the samples and data are collected and processed in a manner fitting with future research efforts (ISBER 2018). Through direct dialogue with and surveys of past and future users, biobanks can gather feedback on needs and user satisfaction. Satisfied users will provide advocates that promote the biobank's products and services within their own networks.

Multiple case studies stressed the importance of marketing. This includes a marketing strategy based on solid market research, emphasising the biobanks unique selling points[3] and value proposition[4] towards all key stakeholders. Some biobanks even stated the use of account or marketing managers and the involvement of third-party biomarker or tissue brokers as part of their marketing strategy.

Show value to your key stakeholders

It is considered a good practice to directly involve key stakeholders, for example in the biobank's governance or in approving the chosen business strategy. A key stakeholder is often the hosting institute, and ensuring their buy-in can be vital for sufficient financial support. Showing the value of your biobank, for example through performance metrics, can help to acquire institutional buy-in. The same, or additional, metrics can also be used to track performance of the biobank for internal optimisation purposes. Biobanks should not forget to leverage the indirect value they bring, as indicated by one biobank's remark that "[the biobank's] availability in the institution and in the community may enable researchers to be more competitive at obtaining grant support for their research because of ready access to specimens. The increased grant funding for the institution may offset some of the losses sustained by the facilities' operations" (Seiler et al. 2015).

Commercial collaboration

Commercial parties can be an important biobank stakeholder, by acting as user and partner, and by providing revenues. It all comes down to building an organisation that is compatible with industry collaboration. An important good practice is to organise an informed consent that ensures the future use of samples and data in new research projects and allows for collaboration with industry under specific conditions. Furthermore, when collaborating with commercial parties, biobanks need to be organised in such a way that they are able to make rapid sample and data request decisions, both positive and negative. A fast turnaround time is essential for industry. Two additional factors that commercial parties consider are the biobank's reputation and accreditation. The right qualifications help to build trust in the biobank's ability to deliver high quality samples and data. To get market approval for a new drug industry eventually has to comply with the requirements set by regulators. As a result, industry also sets strict and specific quality requirements for biobank samples and data.

[3] A unique selling point (USP) refers to any unique feature exhibited by a company, service, product, or brand that enables it to stand out from competitors and provide benefits to the client. Communicating USPs is a key marketing element.

[4] For background information on the value proposition we refer to the BBMRI.nl report *Sustainable Biobanking: The Financial Dimension*.

Talking with potential industrial partners at an early phase, before implementation, is strongly recommended to avoid making wrong choices at the start that could prevent collaboration in the future. Such early discussions help to understand, for example, what samples, data, and services are requested by industry, what form of pre-analytical processing and documentation is required, and what the market value of your products and services is. Academic biobanks should seek the support of their universities' technology transfer office to help them manage such industrial contacts.

5.3. Funding

Within the topic of funding there was little overlap between the case studies. Still we were able to identify some good practices. Foremost, biobanks need to plan beforehand and already address financial sustainability and the intended sources of funding during the biobank's establishment phase. This should be combined with realistic financial forecasts.

Furthermore, what multiple case studies agreed on is the need to implement a cost recovery system. Such a system often has a tiered setup with different levels of cost recovery per user group (e.g. internal academic users, commercial users). To determine the prices for cost recovery biobanks need to know their own cost structure. Subsequently, prospective academic users will need to put the costs for the use of samples, data, and biobank services into their own research grant application. This will enable a cash flow from researchers to biobanks.

The case studies showed that many biobanks are forced to move away from pure project-based funding, due to the irregularity, unreliability, and competitiveness of project grants. Still temporary grants can be relevant and should not be discarded entirely. Periodic screening for new local, national, and international funding opportunities was recommended. Commercialisation was often named as an alternative source of funding, provided it is done within the right preconditions. One case study also indicated that their biobank-related services provided a major source of income.

5.4. Costs

Good practices on costs relate to cost efficiency measures and financial planning. As a starting point it is necessary to determine the biobank's real costs, resulting in itemised and transparent cost structures per product and service. An added benefit of the resulting cost transparency is that it allows biobanks to educate their users, and other stakeholders, on the real costs of biobanking. Financial plans should be drafted on an annual and long-term basis, based on real costs.

To lower costs, several case studies emphasised the need to find synergies. For example by embedding biobank processes into the regular health care system or by leveraging economies of scale by joining efforts with other groups at a local, national, or international level. Minimisation of sample inventory levels is another cost saver. This can be accomplished by, for example, consenting participants beforehand, but only collecting samples and data after an issuance request has been approved. Next to saving on inventory levels, this strategy also prevents any unnecessary up-front expenditures. Regular internal audits of biobank processes and policies can help identify additional cost-efficiency measures.

5.5. Business tools[5]

The studied biobanks employed multiple business tools to support and guide their strategy towards sustainability. Half of the case studies made a business plan, marking this activity as a clear good practice. This figure corresponds with a recent survey on business planning amongst 276 biobanks that showed 28% of respondents had a business plan and 27% was working on one (Henderson,

[5] See the BBMRI.nl report *Business Tools for Biobanks* for additional background information on business tools and business tool templates.

Goldring et al. 2019). Making a business plan was considered a valuable exercise; providing new insights and a necessary overview. The business plan was used to articulate a future vision, determine corresponding strategies, and overcome challenges. The case studies emphasised the importance of drafting a business plan before the actual start of operations, and the importance of involving key stakeholders and external consultants in doing so. Most business plans are updated annually to account for changing conditions and to remain flexible. In some extreme cases business plans were even updated every two to six months.

Using a SWOT analysis – or Strengths, Weaknesses, Opportunities, and Threats analysis – is another good practice, used by five of the case studies. A SWOT is an accessible tool that does not require specialised knowledge or a large time investment, but can provide good insights and clarity. The results can be used for strategy development and forward planning. Some biobanks state performing a SWOT analysis on a regular basis to maintain focus.

Other, less frequently reported, business tools used by biobanks were a marketing plan, often developed as part of a business plan exercise; market research; cost-benefit analysis; Boston Consulting Group analysis; and the Kaizen assessment, a method for the continuous improvement of processes.

The identified good practices were combined with the results from the BBMRI.nl reports *Sustainable Biobanking: The Financial Dimension* and *Business Tools for Biobanks* to draft a set of *Recommendations for Sustainable Biobanking*.

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