

Addressing the Challenge of Financial Sustainability in Biobanking

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BIOSPECIMENS AND DATA are increasingly needed to support biomedical research and clinical care. Biobanks are created to support the ready access to fit-for-purpose biospecimens and data for drug target identification, drug discovery and development, and are vital in efforts focused on precision medicine. To support the increasing need for quality biospecimens and data, the infrastructure of biobanking must be strong and sustainable. Each biobank should be supported with a business model that is deliberately and methodically planned in advance of the collection, processing, storage and usage of the biospecimens and data. The business plan should address ways to achieve sustainability in operations, social acceptance, as well as financial support over the intended duration of the repository. Financial sustainability may be achieved through various means including institutional support, short- and long-term grants, cost recovery, and sales of services. Biopreservation and Biobanking asked several biobanking professionals their views on financial sustainability and the means to achieve it as addressed in their business plan.

The A C Camargo Biobank, São Paulo, Brazil

THE A C CAMARGO BIOBANK is a poly-user, cancer-oriented biobank created at the A C Camargo Cancer Center, São Paulo, Brazil. It is comprised of two sub-units, a tumor tissue bank (established in 1997 to collect tissues and blood) and a bank of macromolecules (established in 2004 to centralize the extraction, quantification, quality analysis, and distribution of DNA and RNA to research projects). The biobank is used primarily by researchers and students from CIPE (International Center for Research, also connected to the A C Camargo Cancer Center), and external researchers through collaboration agreements.

Based on your biobank model, what is your definition of financial sustainability and how to measure that?

Our definition of financial sustainability is largely dictated by Brazil's regulatory landmark for biobanks related to

health research.^{1,2} This means that we can only deliver fit-for-purpose samples and services to the research community without generating profit. Since academic researchers are charged a fee that covers only consumables used by the biobank, an important part of our funding must be provided by grants and direct investments from our institution. Therefore, many diverse metrics are needed for valuing sustainability.

Currently, the most important metrics are: 1) the number of research projects that request and receive samples from the biobank; 2) the value of research grants obtained by such projects, compared to our operating budget; 3) the number of publications that acknowledge the biobank; and 4) proportions of specimens used in a research project. Although other metrics are also important, these four are critical to our goal of showing the biobank's usability and justify the need for continued investment by funding agencies and our own institution.

Is there a need for the biobanking community to reconcile the different definitions of financial sustainability?

There is definitely a need to reconcile different definitions of financial sustainability, since the very definition of "biobank" differs among the biobanking community. It is not possible to apply appropriate metrics for a poly-user biobank on a project-specific collection. The differing national laws and regulations on biobanking further complicate this. If profit is not permitted for biobanks in some countries, there must be room for different definitions of financial sustainability.

In managing your biobank, when did you start thinking about sustainability: Was it designed in from the beginning or did you incorporate a sustainability plan later on? What do you believe to be the important factors?

Our history mirrors that of many international biobanks. The A C Camargo Biobank was created with research funding for five years and subsequently renewed for two

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additional periods of three years. We started thinking about sustainability when it became apparent that this source of funding would not go on forever. We not only saw that we could not depend on a single source of funding, but also began to outline a cost-recovery model. Briefly, a partial cost recovery model (which includes only consumables used by the biobank) is applied to internal or external academic researchers and/or projects that are strategic to our Institution, while a full cost recovery model is applied to projects related exclusively to the private good (e.g. pharma sponsored projects).

We also started thinking of the necessary metrics to show our institution the strategic value in maintaining what was the first tumor bank to be established in Brazil, which is a critical component of the tripod of activity of the institution—as a center for treatment, teaching and research in cancer.

Based on your experience, how has your business plan helped your biobank achieve sustainability?

The main benefit has been the increasing institutional awareness of the strategic value of the biobank in the long-term planning of the institution to which we are bound. Recognition of this value is critical because Brazil, unlike some other countries, has no perennial mechanisms of funding to stimulate the creation and maintenance of biobanks. Currently, available funding models are short-term (maximum time of 3 to 5 years), and only one of them is intended directly to the creation of tumor banks (not to other types of research biobanks) through a mechanism of tax relief for private companies that wish to invest in this sort of initiative. In this scenario, it is essential to have financial support from our institution.

What are the key areas covered by your business plan?

The key areas of the biobank's business plan are: Description of the biobank; historical aspects; description of the current regulatory landmark in Brazil; description of the biobank's mission and vision; description of the biobank's current structure, main interactions within the Institution, and staff; description of the biobank's products and services; operational aspects; SWOT (strengths, weaknesses, opportunities, and threats) analysis; financial indicators; and long-term plan.

How often do you revisit your business plan? How, and with what metrics, do you evaluate when something is not working and when to change course? How agile is your organization when you need to make changes?

The first version of the business plan was revisited one time in 2013, in order to apply for external funding from private companies (using the tax relief mechanism previously mentioned). The next major revision is scheduled for 2016–2017. On the other hand, yearly reports are prepared, in which we use many metrics in order to provide a clear picture of the biobank's current state and to identify and correct problems. Some of the metrics include the ability of the biobank (and the institution) to engage participants (overall and department-specific rates of informed consent responses). Some metrics refer to the evolution of the biobank in terms of accrued participants and samples, which we

use to project the future needs in terms of infrastructure. Some refer to the biobank's "usability" (number of projects that accessed samples, number of delivered samples, representativeness of the samples and quality of derived macromolecules). Finally, one important metric—value of research grants obtained by investigators compared to the operating budget—is also used to justify ongoing support from the institution and funding agencies to the biobank (since these projects could only be carried out because they had access to samples and annotated data retrospectively, collected by the biobank). As expected, problems uncovered by metrics that refer to internal processes of the biobank are the easiest to correct, while those linked to the biobank's interaction with other departments and the institution itself demand more time to be addressed.

Tell us what your biobank's biggest sustainability challenge is and how you are addressing it.

Since the creation of the biobank, roughly 24% of the tissues collected were delivered to research. On the other hand, only 5% of blood derived products were requested by investigators. Therefore, the greatest challenge is to increase the proportion of samples delivered to research. This is necessary to reduce the increase in infrastructure needs, limiting the spending in this area with equipment and processes updates. The pursuit of this goal is also necessary to increase the proportion of our cost coverage fees in the financial structure of the biobank. For this, it is necessary to review the policy for samples and data access by external researchers, and by the pharmaceutical industry. Furthermore, it is necessary to stimulate opening of the biobank for use by foreign researchers. This is especially important in a scenario of limitation of access to research funds in our country. For this, a review of the current regulatory framework in the country is required, reducing access restrictions and accelerating the time to review and approval of international collaborative projects. If none of these actions is effective, we will have to think about limiting the collection of samples to those with a higher likelihood of future use, or start a collection only when there is a request submitted by an investigator.

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Conversant Bio, Huntsville, Alabama

CONVERSANT BIO was founded in 2006 because the founders knew that the drug discovery research model was broken. It simply takes too long for drugs to get to patients, there are too many drugs and diagnostic tests that fail late in clinical development, and the entire process costs too much. The lack of well-characterized, appropriately consented human biospecimens continues to hamper the development of new treatments and diagnostics. Conversant Bio exists to meet this need through its biospecimen network and operations as well as its consulting services aimed at helping existing biobank networks.

Based on your biobank model, what is your definition of financial sustainability and how do you measure that?

Conversant Bio is a commercial biobank so our definition of financial sustainability is pretty straightforward: our revenue must be greater than our expenses. Put another way, we must take in more money than we spend each year. Expenses include: (i) those associated with generating revenue directly, (ii) indirect costs such as overhead, and (iii) investments in equipment, innovation, and new product growth. We believe that we must focus on sustainability in the present business while also investing for growth so that we maintain financial sustainability in the future.

Is there a need for the biobanking community to reconcile the different definitions of financial sustainability?

Are there really different definitions of financial sustainability or are there just different ways that biobanks can reach financial sustainability? There is not a one-size-fits-all model to becoming financially sustainable because each biobank serves a different purpose and mission. Financial sustainability is about having sufficient funding today and in the foreseeable future to support the organization's mission-focused goals. This funding may come from grants, institutional support, and/or external researchers (who also have different sources of funding). Ultimately, a biobank—and any organization for that matter—must continually reassess its goals and funding sources if it hopes to remain viable.

In managing your biobank, when did you start thinking about sustainability: Was it designed in from the beginning or did you incorporate a sustainability plan later on? What do you believe to be the important factors?

We started Conversant Bio because we wanted to impact research “because patients are waiting.™” This is our vision statement and we know that we cannot advance healthcare if we are not financially viable. Therefore, we have been thinking about sustainability from day one. In the early days, we had minimal funding, so every decision was assessed through the lens of generating profit that then could be reinvested back into the business. This bootstrap mentality coupled with a sense of urgency regarding our company's purpose meant that we had to focus our energy and dollars on things that moved the business forward. We had to make tough decisions like minimum inventory levels,

limited staffing, and homegrown systems, but these were necessary in order to be financially sustainable.

Also, the concern about financial sustainability is not just something of our past. We are always evaluating what is and isn't working in our business and making decisions that we believe put Conversant Bio in a better position to remain sustainable in the future.

Based on your experience, how has your business plan helped your biobank achieve sustainability?

Our business plan is our roadmap and it includes specific financial and non-financial goals. We believe that each goal is critical to advancing the company and putting us in a more sustainable position. Many times, we miss our targets, but we learn from these misses and improve each and every year. This planning and review effort allows us to think about strategic opportunities and challenges so that we remain a financially sustainable entity.

What are the key areas covered by your business plan?

Conversant Bio's business plan includes both 1-year and 5-year goals for quality, customer service, product growth, site partnerships, financial metrics, and our company's culture. Each of these areas has specific strategies that help guide daily and long-term activities for the business.

How often do you intend to revisit your business plan? How and with what metrics will you evaluate when something is not working and when to change course? How agile is your organization if you were to need to make changes?

Our business plan is a strategic document that outlines high-level goals and strategies. As such, we typically revisit our plan at least twice a year. During this review, we discuss progress on strategic activities, identify new initiatives and goals, and modify the key success factors and metrics that we believe are needed to successfully meet these targets. This effort allows us to have a rolling 12-month business plan that stays up to date.

On a monthly basis, we review financial, operational, and business development metrics and we discuss key opportunities and risks that each manager sees in our business or in the industry in general. We are a very metric-driven organization and look at our data from a number of different perspectives such as by disease, by sample type, by research use, and by territory. Many of these metrics are compared to the same data from the previous year as well as our current-year budget. This allows us to benchmark progress, identify problems and opportunities, and make changes as needed on a month-by-month basis.

Tell us what your biobank's biggest sustainability challenge is and how you intend to address it.

Our biggest challenge is change in our industry. Science and healthcare are always changing and there continue to be

new and emerging areas of research. We have to stay focused on executing our business while listening to the market and discerning new opportunities and threats. This challenge is also why we remain so excited and engaged in our business. We must always focus on how to move Conversant Bio forward through innovation and continuous improvement in everything we do. Thankfully, the industry changes are also helping bring better diagnostics and novel therapies closer to the patients that need them.

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The Wales Cancer Bank, Wales, U.K.

THE WALES CANCER BANK was established in 2004 to collect tissue and blood samples from patients in Wales, U.K. to store for future cancer related research. The biobank was designed to collect from the cancer-affected population in Wales to supply well-annotated, fit-for-purpose samples to researchers to further the knowledge of cancer, its progression and treatment. The collection was not specifically to support local researchers, but to support the best research. It was an academic venture in collaboration with the National Health Service (NHS) in Wales, with the aim to improve the health and wealth of the people of Wales through coordinated research resulting in the identification of more targeted, effective treatments. The biobank was set up as a prospective collection, consenting patients with any cancer diagnosis to donate samples that are surplus to diagnostic requirement. Researchers from around the world, working in any sector, can apply to access samples, and they are charged a cost recovery fee on supply of samples. Research nurses and laboratory staff are employed in each NHS collection center, with administrative and IT staff based in two universities (Cardiff and Swansea). The project is grant funded by the Welsh Government and cancer charities and offers services to the research community to supplement income. WCB has ethics approval from a U.K. ethics committee as a research tissue bank to collect, store, and issue samples for research and is licensed by the Human Tissue Authority under the U.K. Human Tissue Act (2004) to store human tissue for research.

Based on your biobank model, what is your definition of financial sustainability and how do measure that?

A biobank's sustainability is assessed by: examining its value to the research community, the patients, and the healthcare system, as well as its continued funding. Financial sustainability is the ability to operate successfully within the income streams available. This is clearly highly dependent upon the available income and may include grant income, which is increasingly unreliable. To be self-sustaining means, to me, that the biobank is financially

sustainable without grant or charitable income, *i.e.* all the income is generated by the biobank and this is sufficient for sustained operation.

Is there a need for the biobanking community to reconcile the different definitions of financial sustainability?

Yes, otherwise we are potentially comparing apples with pears. Firstly, recognition that there are different definitions and also different methods of calculation within a single definition is important. Comparisons between biobanks and their reported sustainability (or unsustainability) are inevitable and for those to be meaningful the denominator has to be known, especially if it is not common. It would be helpful if defined definitions could be agreed upon and used in the literature. In my view, financial sustainability is not the same as self-sustainability, although the two are used interchangeably and we need to be clear exactly what people mean when they talk about being financially sustainable.

In managing your biobank, when did you start thinking about sustainability: Was it designed in from the beginning or did you incorporate a sustainability plan later on? What do you believe to be the important factors?

Financial sustainability was not high on the original agenda. The concept of the biobank was purely based around supporting research to increase knowledge and accelerate access to better, more effective treatments. It was seen as a long-term venture that would have health and wealth benefits in the future and so academic value was placed above business modeling. There was a perception, based on the reported lack of good quality, well-annotated human biosamples that researchers would flock to the biobank once the inventory started to mature. This has not been the case.

Three years after starting to issue samples, it was recognized that self-sustainability would be impossible to achieve within the operating model and that biobank-generated income would not entirely replace grant income. In fact, only 5% of total income over 10 years has been self-generated. It was only when reviewing the first 10 years of operation, with a threat of reduced funding, that sustainability became a more important factor.

Biobanks broadly need to achieve two things: i) be able to supply samples and data to satisfy the needs of researchers now and, ii) be able to future proof a collection to be useful when larger sample numbers are collected and the data has matured. Number one fits more easily into a financial sustainability plan. Number two takes greater investment with longer-term (if at all) returns. If biobanks are forced to focus on the first activity in order to survive, the larger, potentially more informative studies of the future may be compromised.

Based on your experience, how has your business plan helped your biobank achieve sustainability?

The business plan has helped to focus attention and think about short-term goals as well as the longer term, less-tangible goals. Having a plan will not achieve sustainability

per se, but it is a highly valuable tool and the process of developing a plan, and the policies and systems that feed into it, is hugely informative. Closely examining the costs incurred and breaking down those costs by collection site, person employed and samples banked versus issued, showed which areas were financially unviable and these have subsequently been closed down or reduced.

Changing the mindset away from the biobank as an academic endeavor and moving towards a more business-like approach has been challenging. Reliable, well-sized commercial contracts need to be sought and won to move towards sustainability. Understanding that cost recovery alone, especially if the majority of projects receive a discounted price, will never give financial sustainability has made us look at providing additional services to generate further income.

What are the key areas covered by your business plan?

The marketing plan is the key section. In order to move towards self-sustainability, the biobank has to attract greater use. The marketing plan is designed to set out how that will be realized and quantify how it will be measured. Measurable, challenging, but achievable goals, such as: increase applications from local researchers by x% or reduce time to supply by x number of days are detailed with deadlines and review dates. Strategies are described that will facilitate these goals, such as how to promote the bank to make it more visible, ensuring sample collection strategy fits with requirements, and pitching pricing points at realistic and market bearing levels.

The other important section is the risk and sensitivity analysis section, which looks at the “what if?” questions: What if there are further reductions in funding? What if we lose public/patient support? A robust quality management system with a well-considered crisis management plan feeds into this part of the business plan and gives more in-depth detail of the policies and approaches that will be taken.

How often do you revisit your business plan? How, and with what metrics, do you evaluate when something is not working and when to change course? How agile is your organization when you need to make changes?

Although the biobank had a vision and an operational plan from inception, it would be generous to call it a business plan. It was not based on financial sustainability and the first major review was undertaken after 10 years of operation and only then because of the danger of decreased core grant funding. This is not to be recommended! The resulting business plan with an updated operating model will be reviewed initially at the 12-month post implementation stage, and then every two years after that.

Operational sustainability will involve reviewing sample requirements against sample collection, the cost per consent and per sample collected and whether processes are fit-for-purpose. Adopting “lean” management approaches is useful to analyze each process, the amount of “non-value added” time in each process and adapt the process to minimize error and increase customer satisfaction.

Social sustainability is also important, but is harder to quantify. Questionnaires asking for feedback from re-

searchers accessing samples will be analyzed and will be used to investigate further improvements.

Both operational and social sustainability are an integral part of financial sustainability. The speed and ability to implement change depends on the level and impact of change needed. At the biobank level there is greater flexibility to implement change and improvements can be introduced via the executive group. If larger organizations, such as the university or hospitals, are involved the process, it will inevitably be slower and more bureaucratic.

Tell us what your biobank’s biggest sustainability challenge is and how you are addressing it.

The biobank’s biggest challenge is how to address underutilization while balancing the increased workload that greater usage would entail. The process of centralizing, processing, checking and issuing samples is very labor intensive and increasing the size and scope of this process would require additional input. Increasing the customer base and sample requirements while maintaining a rapid turnaround to retain customer satisfaction is the ultimate balancing act.

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The Egyptian National Cancer Institute (ENCI) Biobank

THE EGYPTIAN NATIONAL CANCER INSTITUTE (ENCI) biobank received the award of Centers of Excellence Grant, funded from the Egyptian Science and Technology Development Fund (STDF) of the Ministry of State for Scientific Research. ENCI biobank is affiliated with the National Cancer Institute, Cairo University, which is the biggest foundation dealing with cancer in Egypt. In the first stage, ENCI biobank is going to collect samples from newly diagnosed breast cancer patients including tissue as well as blood/plasma/serum samples. Later on, ENCI biobank will collect samples from other cancer groups as well. The biobank will start as a medium-sized biobank but will grow into a large one within the next five years.

Based on your biobank model, what is your definition of financial sustainability and how do measure that?

The ENCI biobank is a nonprofit organization. Financial sustainability of nonprofits does not mean achieving profit or distributing dividends. However, nonprofit does not mean “for loss.” Sustainability means that the biobank is able to

get revenue to continue performing its functions of providing samples and data for researchers for the intended period of time. In order to ensure sustainability, cost recovery mechanisms should be implemented to get revenue, which can cover costs. To carry out this goal, business planning is important to perform necessary steps towards achieving this mission.

Is there a need for the biobanking community to reconcile the different definitions of financial sustainability?

In the initial phase of work, the ENCI biobank will aim at cost coverage and survival. Later on, the goal should be modified. Survival is one step in the journey towards sustainability. The definition of financial sustainability should be upgraded to involve achieving surplus available for use by the biobank. To be able to achieve this goal, biobanks should aim at having consistent and secure sources of revenue enough to create independence.

In managing your biobank, when did you start thinking about sustainability: Was it designed in from the beginning or did you incorporate a sustainability plan later on? What do you believe to be the important factors?

Funding for establishment of the ENCI biobank comes from the STDF grant that will support work of the biobank for three years. Later on, the expenses are expected to be covered at least partially by the National Cancer Institute. However, to avoid interruption of work, financial sustainability should be addressed while still in the establishment phase. Since ENCI is supposed to grow in size and persist for a long period of time to serve the research community in Egypt, thinking of sustainability should be early and other sources of funding should be looked for to ensure maintenance and stability.

What are the key areas covered by your business plan?

Although a detailed business plan has not been created yet for the ENCI biobank, some items of the business plan are available including mission, vision, structure, and governance. A detailed marketing plan is also available which will be used for communication with stakeholders, to attract potential customers and to recruit other grants and sources of funding. The marketing plan focuses on the advantages of the ENCI biobank and that its products, human biospecimens, are a limited valuable source that has an increased value over time. Pricing of the products and services provided by the biobank has not been implemented yet since the biobank is still in the development phase. The ENCI biobank is going to depend on a user fee calculator developed by the Canadian Tumour Repository Network for pricing and calculating user fees.

However, a financial plan is still missing in the process of development of the ENCI biobank. This plan is necessary to set specific figures or income goals to cover costs. Dependence on grants only as a source of income is not enough for most biobanks. That is why ENCI biobank will implement user fees in the early stages of work. Later on, the knowl-

edge and experience developed in the areas of sample collection, storage and preservation as a center of excellence can be transferred through training or consultancy services providing another source of revenue.

How often do you revisit your business plan? How, and with what metrics, do you evaluate when something is not working and when to change course? How agile is your organization when you need to make changes?

In order to assess success of the different components of the plan, various indicators can be used by staff of the ENCI biobank. These indicators include revenue assessment and detection if there is a full cost recovery. Other indicators include the ability to pay debts and replace depreciated equipment or add new assets. The indicators and other actions in the plan should be assessed and revised at least once a year. However, since the internal and external environments are dynamic, more frequent changes might be needed. For example, when the ENCI biobank introduces training or consultancy services in the business model or with introduction of a new national legislation affecting work within the biobank.

Tell us what your biobank's biggest sustainability challenge is and how you are addressing it.

Even with these activities, the journey towards financial sustainability will not be easy. The ENCI biobank will take several years to build an inventory of samples and data of a single cancer type. Research performed on those samples also takes some time to be translated into publications then into valuable results for patients. During this period, quality control and validation measures may represent a persisting cost before building a sustainable model.

Another challenge is limitation of funding from governmental and nongovernmental organizations to support different research organizations. Although there has been an increase in funding resources over the past years, competition has also increased causing a problem in the distribution of these resources. Lack of funding is associated with growing operating costs with reagents, equipment, ongoing maintenance, and salaries showing progressive increase. Underutilization of samples in some cancers also represents a risk which cannot be assessed at the current stage of the biobank's development.

Another challenge is related to social sustainability and cultural issues. The concept of biobanks is new and the value of biobanks is not clear for many organizations and researchers in Egypt. The attitude of some participants and researchers towards research and transfer of samples across borders as well as the legal framework in Egypt controlling these issues might also control and limit collaboration with external partners. Building mutual trust with these organizations and researchers may take some time. ENCI biobank members will try to do proper environmental analysis, be flexible and communicate with local scientists and decision makers in order to decrease the risks and deal with the challenges they face. Collaboration with Egyptian partners and being a part of international networks such as Biobank and Cohort Building Network (BCNet) for Low and Middle-

Income Countries can also provide means for exchange of experience and solutions for similar problems in different countries.

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Beaumont Hospital BioBank, Royal Oak, Michigan

THE BEAUMONT HEALTH SYSTEM BioBank was established in 2008, not only to leverage the potential to collect biospecimens for translational research, but to undertake such research in a seamless facility that combined high quality biobanking with state-of-the-art laboratory platforms geared towards biospecimen-based research. The biobank is a Beaumont Health research center that is focused on developing innovative methods of early detection of disease and personalized treatment plans through leading edge analysis, techniques and state-of-the-art technologies. We conclude that grants are not a feasible avenue, in our case, to support a biobank and that philanthropy and commercialization represent the best options for external funding to support stalling internal support, in order to sustain the operations of the biobank.

Based on your biobank model, what is your definition of financial sustainability and how do measure that?

Financial sustainability for our biobank translates to the ability to maintain and support our internal projects. It became clear to us that growth could no longer be sustained by institutional support alone and alternative sources of funding had to be found. The biobank also must enhance the academic mission of the Beaumont Health system through high-quality biospecimen-based research.

Is there a need for the biobanking community to reconcile the different definitions of financial sustainability?

Yes, and it depends on the QMP (Quality Management Plan) of each institution, which outlines the goals of the biobank whether it be hospital-based, institutional, or a commercial bank.

In managing your biobank, when did you start thinking about sustainability: Was it designed in from the beginning or did you incorporate a sustainability plan later on? What do you believe to be the important factors?

It became clear that growth could no longer be sustained by institutional support alone and that the current climate of grant funding coupled with the academic status of many Beaumont clinicians made it difficult to bring significant money into the health system. When the budget was ad-

justed by hospital administration requiring us to become self-sufficient, we developed a new strategy to attract revenue while still fulfilling our primary goal, which is to enhance the academic mission of Beaumont Health through high-quality biospecimen-based research. Patient care and specimen quality were contributing factors.

Based on your experience, how has your business plan helped your biobank achieve sustainability?

Our goal is to achieve complete autonomy from institutional support and maintain our projected growth through collaborative relationships, contracts and fee-for-service, with commercial entities and laboratory services with continued grant applications and contributions from philanthropic organizations. In addition, we plan to increase productivity in terms of specimens collected and used, as well as amount of material collected for commercial purposes, which was the driving force behind implementing the Kaizen philosophy; Kaizen refers to a philosophy and practices that focus upon continuous improvement of processes in manufacturing, engineering, business management, or any system including healthcare.

What are the key areas covered by your business plan?

The components driving sustainability in the Beaumont BioBank are: fulfilling primary goal-research; grants; philanthropy; CAP accreditation; Kaizen-process improvement; and commercialization of specimens and laboratory services.

The plan focuses on the ability of the biobank to provide a diverse, accessible infrastructure of state-of-the-art technology and specimen collection. Equally important is the ability of the biobank to bring current Beaumont Health clinicians into the research arena generating an academic environment.

How often do you intend to revisit your business plan? How and with what metrics will you evaluate when something is not working and when to change course? How agile is your organization if change is needed?

Annually, as this is required with our CAP accreditation. We utilize monthly metrics, such as percent of samples utilized, Kaizen metrics, and quality metrics. Upon review of incoming feasibility and lab services requested, our biobank has a mechanism in place to review policies and make changes to adapt to the dynamic incoming requests.

Tell us what your biobank's biggest sustainability challenge is and how you intend to address it.

The biobank is a research facility and not a CTO (Clinical Trials Operation). The Beaumont Administration has categorized us into a Clinical Trials Operation with a structure that is clumsy, unnecessarily complicated, financially sub-optimal, and is not conducive to biobank operations. Our goal is to propose a new structure that takes the biobank out

of the CTO equation. This organizational structure will provide a seamless and transparent framework that permits the most efficient workflow for both the research and commercial ventures of the biobank.

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Research Institute of the McGill University Health Centre Liver Disease Biobank

OUR RESEARCH INSTITUTE of the McGill University Health Centre (RI-MUHC) Liver Disease Biobank (RI-MUHC-LDB), a hospital-based disease-specific biorepository, is based on an oligo-user model where biospecimens are shared within an institution, but also made available to different collaborators such as industry to allow another source for financial sustainability. Our biobank maintains an infrastructure based on the collection of biospecimens towards known projects and also for future use of these biospecimens. This is embedded in our ethics protocol and consent.

We are focused on the collection of liver tissue with blood specimens that are accessible to numerous projects, based on companion protocols, providing freedom of usage. It's an open-resource for the research community and it's prospectively designed to be a durable resource for current and future research needs.

Based on your biobank model, what is your definition of financial sustainability and how do you measure that?

Our RI-MUHC Liver Disease Biobank (RI-MUHC-LDB), a hospital-based disease specific biorepository, is based on an oligo-user model where biospecimens can be shared within and across institutions but also made available to different collaborators such as industry. This allows for a proactive method of cost recovery. In support of our model, our biobank maintains an infrastructure based on the collection of biospecimens towards known projects and also for future use of these biospecimens. This is embedded in our ethics protocol and consent. We are focused on the collection of liver tissue with blood specimens that are accessible to numerous projects, based on companion protocols, providing freedom of usage. It's an open-resource for the research community and it's prospectively designed to be a durable resource for current and future research needs.

Financial sustainability is embedded in our strategic plan and becomes one of our measures of success. It requires us to develop and maintain strong stakeholder relationships, increasing visibility and exposure, ensure continuous output of publications through the availability of high quality biospecimens, all focused on a 4-tier cost recovery

mechanism. We have implemented unique fees for internal usage, local universities, external academic and industry costing.

Financial sustainability, however, does not ensure overall sustainability of the biobank. Although this question focuses on financial sustainability, there are three forms of sustainability that we think requires balance to fully have a sustainable biobank. Our model of sustainability revolves around three intertwined facets: financial, "smart" usage of biospecimens, and publications.

Is there a need for the biobanking community to reconcile the different definitions of financial sustainability?

Sustainability is a concept with multiple facets and financial sustainability is one of these facets. Having one definition of sustainability for the biobanking community is difficult because sustainability assessment will differ among different organizations' missions and strategic initiatives. However, all biobanks must have a plan of sustainability, whether financial or other needs to be defined. It is not clear that there is an agreed definition of financial sustainability in biobanking and this is where there is a need to reconcile the different definitions.

In planning/implementing your biobank, when did you start thinking about sustainability and what do you believe to be the important factors?

In planning/implementing our biobank, we were more focused on objectives and outcomes, getting papers in peer-reviewed journals to facilitate our application to major grants. As most disease-focused biobanks, we started with a front-end financial sum at start-up phase to cover costs such as storage, processing, salaries, and space requirements. Then, a considerable amount of time was put into the operational aspect of the biobank and the framework. Once the biobank was operational, we included a 4-tier cost recovery process for all requests. Researchers applying for grants included in their budgets the costs related to sample acquisition. These cost-recovery amounts were part of our sustaining costs for the biobank. An important factor we included in our financial sustainability model was the corporate partnerships with pharmaceutical and biotechnology companies. When putting our RI-MUHC-LDB framework together, we partnered with the research ethics board to make sure we correctly included this aspect into our patient consent process.

In our case, developing this partnership was well aligned to our mission and expected by our patients. The quality requirements by industry is very stringent, therefore we focused a lot on quality to make sure utilization from industry is continuous. This is a measure of success for our biobank and can become a significant contributor to our biobank's long-term financial sustainability.

Based on your experience, how will your business plan help gear your biobank towards sustainability?

A well-designed business strategy is important at the start-up phase of a biorepository. In terms of sustainability,

the Centre of Applied Ethics at the MUHC, where all protocols must be submitted, reviewed and approved for all biobanks, requests that all protocols submitted must include a business strategy indicating where funding will come from for the set up and short term management of the bank.

Our strategy was to include the purpose and goals of the biobank in addition to operational and financial requirements. By putting in place a basic business plan, it gave us a good overview of the requirements and costs. Knowing the plan and associated costs helps foreshadow the payables and receivables in addition to all costs and implications related to salaries, maintenance, material/equipment, etc.

What are the key areas covered by your business plan?

Business models in biobanking are not very well defined. The vision of the RI-MUHC-LDB is to be a world-class leader and nexus in collaborative research that translates scientific discoveries into new treatments in patient-oriented medicine. Based on the vision of our biobank, we were able to use some strategic tools such as enhancing availability, quality through standardization and improvement of biobanking processes and frameworks to build our business plan.

We based our business plan on three business models, mentioned by Warth et al.¹ The first part of our business model includes an institute or project-based component. We included a start-up amount that we received based on a funded project, NAFLD (Non-Alcoholic-Fatty Liver Disease), to start our biorepository. In our startup cost, we secured continuing operating cost (salaries, supplies, and maintenance) over a three-year period. In addition to fixed costs, we included strategies to reduce continuous operating costs such as consenting patients, but only collect when the samples are needed, establish priorities in sample collections and reduce material waste.

Since our start-up cost was a multi-year grant, we developed additional revenue streams and financial projections to include in our business plan. Such revenues included a 4-tier cost-recovery procedure and a service fee to other users of the biobank facility as well as services rendered such as consultations, protocol reviews, etc. This represents the second part of our business model, a price-based model. Collaborations with various local, national and international groups have brought in short-term contracts that provide continuous support to our fixed costs. Since our vision was to become a world-class leader, we ensure we provide the highest quality samples because high-quality samples provide visibility to our biobank. With visibility and with acknowledgement in peer-reviewed journals, it has helped researchers and collaborators to apply to major grant agencies.

The last section of our business plan includes the donation-based model. A lot of focus and projections were

put in this section of the business plan. We included major fundraiser events towards the continuous support of our biorepository. Our vision is to provide new treatments in patient-oriented research. We included our patients in the discovery process. With one of our collaborators, a genetic counselor facilitated this exchange of information with our patients raising awareness of the value that biorepositories bring in research. Such forecasting in a business plan is important towards the biobank's financial sustainability.

How often do you intend to revisit your business plan? How, and with what metrics, will you evaluate when something is not working and when to change course? How agile is your organization if you were to need to make changes?

We try to revisit our business plan every 4–6 months because requests and projects evolve, and, as a team, we need to adjust very quickly.

Tell us what your biobank's biggest sustainability challenge is and how you intend to address it.

Our biobank's biggest sustainability challenge is covering salaries on a long-term basis. These costs are operational costs and they are needed to ensure the success of our biorepository. We have a full-time manager and a full-time technician as well as a full-time clinical research associate. Even if cost-recovery is included in our business plan, it is not enough to cover salaries. Different collaborators have used the biorepository and through these collaborations and funding agencies, we have used it as additional source to cover the expenses. Again, we focus a lot on visibility and quality. In addition, we unify support in biobanking across the institute and, therefore, receive support from that end.

Reference

1. Warth R, Perren A. Construction of a business model to assure financial sustainability of biobanks. *Biopreserv Biobank* 2014;12:389–394.

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