Ensuring Sustainability of a Biorepository Through Strategic Planning: Our Experience at the McCain GU BioBank

Ana Bolanos, Miran Kenk, Sangita Paul, Alisha Bhimani, Susan Nguyen, Karen Hersey, Neil Fleshner, Heidi Wagner

McCain GU BioBank (MGB)/Princess Margaret Cancer Centre; Toronto, Ontario

INTRODUCTION & BACKGROUND

Biobanks support clinical trials and epidemiological research programs, providing a vital resource for precision medicine and playing a key role in accelerating research. The demand for high quality bio-specimens increased considerably in the last decade and will continue to expand in the future**. With significant and growing demand, why are many biobanks not sustainable?**

Millions of human biospecimens are stored yearly, however, "only between 10% and 50% of biospecimens stored in tumor tissue biobanks will ever be used."(1) According to the National Cancer Institute Study, "Key stakeholders don't have a thorough understanding of the true costs, and challenges associated with initiating, running and maintaining a biobank."(2)

Developing a detailed business plan with market analysis, clear usage targets, financial planning, marketing strategies and a clear organizational structure provides the key for a biobank to endure today's changing market.

Understanding the current market needs/trends is essential to better match bio-specimen supply and demand. A business plan allows us to strategically plan to accommodate these needs.

Figure 1- Stages of biorepository development.

OBJECTIVES

The business plan was developed and implemented to:

1. Clearly express the overarching goals of MGB (vision/mission)
2. Provide a structured analysis of the biobank, including an overview of the market in which it operates
3. Develop a strategic short and long term growth plan
4. Formalize the leadership structure of the McCain GU BioBank
5. Evaluate the risks and challenges faced by the McCain GU BioBank

METHODS

In order to utilize bio-specimens efficiently and guarantee the capacity to endure as a biorepository, a business plan was developed in collaboration with an external consultant.

1. Staff, management, and clients were consulted on current characteristics of the biobank, focusing on unique properties.
2. The following analyses were performed on the biorepository:
   - SWOT
   - Risk assessment
3. In order to evaluate future steps, we performed the following:
   - Revised sample collection protocols
   - Market analysis
4. The business plan integrated the following future directions:
   - Marketing plan with milestones
   - Detailed financial plan
   - Organizational chart
   - Risk analysis and mitigation
5. Plan was presented to stakeholders. Feedback was incorporated.

CURRENT CHARACTERISTICS OF THE GU BIOBANK

Figure 2 – McCain GU BioBank's Strengths and Unique Properties as a Biorepository: Established in 2008 with the aim of facilitating the discovery of new diagnostic and prognostic biomarkers to achieve the ultimate goal of personalized medicine and improved outcomes for GU oncology patients.

Since its inception, over 16,000 participants have been consented to the program. MGB collects samples from active clinics, as well as from investigator and industry sponsored clinical trials. Retrospective collaborations have utilized approximately 25,000 samples to date. Our prospective biospecimens are from over 30 study-directed banking protocols.

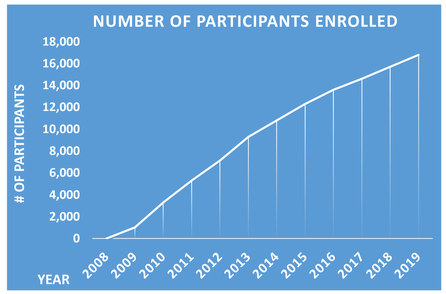
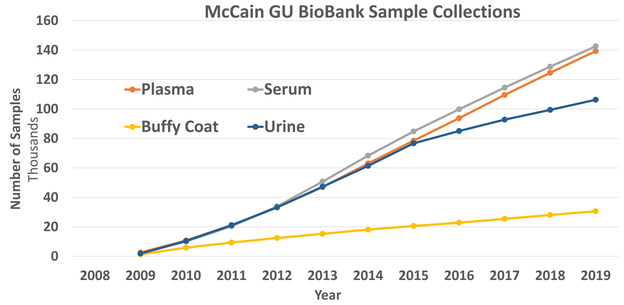


Figure 3 - Patient enrollment: Since its inception, over 600,000 biospecimens have been collected over the years from patients with genito-urinary cancers. The associated clinical follow up data of up to 12 years is available for bio-specimens collected from more than 350,000 participants. Consent rate is ~93%.

Figure 4 - GU BioBank sample collection: Nature and quantity are adjusted In response to the changing market and the demand for specific biospecimens, to ensure the biobank is fit for purpose.



Cohort Expansion: The McCain GU BioBank has expanded in the last few years to include additional oncology sites into their protocol, such as Gynecology – Oncology and Thoracic Oncology, which was included in early 2020. In response to demand from other institutions and clinical groups, MGB is continuing to expand to additional disease sites and sample types.

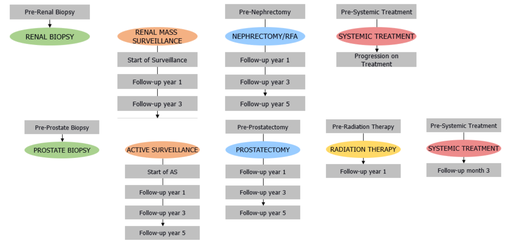
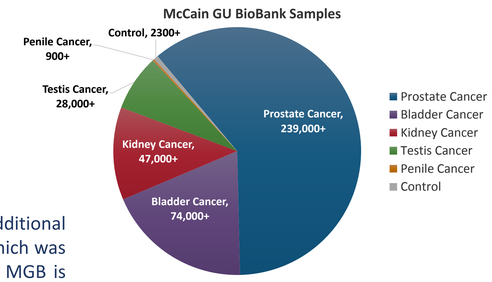


Figure 5 - Serial sample collections: Patients are followed throughout their treatment, achieving serial unbiased sample collections, updated based on current standard of care.

Figure 6 - Collected samples by type. While prostate cancer makes up the majority of the biorepository's samples (reflecting the research interests of the initiating researchers), renal, bladder, penile and testicular cancers are represented. Control samples from healthy volunteers are also available.



FUTURE DIRECTIONS

Financial analysis: A thorough financial analysis determined the costs and revenues available in the Mc Cain GU BioBank in its operational activities. The yearly financial needs were calculated from the sum of the total costs of each subcategory and a strategic cost-recovery system.

Risk Analysis: Risk management and risk mitigation are essential to allow future planning. Possible internal and external threats were assessed and stratified based on severity and likelihood of occurrence. The assessment included risks such as: economic, environmental, legal and social. Institutional policies, management strategies and key personnel were also evaluated. Contingency planning and succession plans were put in place to minimize the most threatening possible risks. Quality control procedures through an independent third party have been implemented to ensure high-grade biospecimens fit for the clientele.

Marketing plan: Marketing and communication strategies were developed with a defined budget, set milestones and a timescale to:

- Increase sample collection sites.
- Develop new collaborations with academic/commercial entities within Ontario, Canada, and globally.
- Increase sample utilization and growth within a changing market.

Marketing strategies include: upgrading the website and online presence, launching social media campaigns, effectively tracking publications and research acknowledgments, increasing utilization of biospecimen brokers and platforms (e.g., Trans-Hit Bio, CTRNet, ISBER).

The plan also includes enhanced communication with stakeholders (participants, patient advocacy groups, philanthropic supporters).

Figure 7 – Global Collaborations: A marketing strategy was developed to expand the current network of collaborators and clients.

Organizational Chart: A combination of a functional and divisional structure was used to develop a governance model that ensures efficiency in the processes and services provided as well as strong inter-relationships between the different activities performed within the McCain GU BioBank.

Figure 8 – Examples of cost recovery strategies: With the implementation of a cost recovery process, the biobank is pursuing consistent sources of stable income.

Additional Services Provided		
Specimen collection and storage	Participant recruitment	Grant writing support
Protocol specific banking	Blood, urine and tissue procurement	Staff training/Continuing education
DNA/RNA extraction	Sample Processing	Consulting on biobank procedures, budget /SOP development, QA, etc.
Sample transport	Adverse event monitoring	Data collection and management

Philanthropic Support: In addition to cost recovery strategies, MGB obtains philanthropic support for its operational activities.

Certifications: The MGB is fully accredited by the Canadian Tissue Repository Network (CTRNet). It is currently in pursuance of other national/international certifications.

CONCLUSIONS

- Biobank sustainability is critical for biorepositories globally.
- There is not a "one size fits all" model of sustainability. A biobank should build on current strengths and unique properties of a biorepository to achieve sustainability by using a responsive business plan to adapt to changing market conditions.
- By utilizing its strengths efficiently, ensuring adaptability to economic and social changes, and replacing declining funding sources, the McCain GU BioBank is on its way to be self-sustainable.
- A persistent challenge to an established biobank is keeping up with the demands of the changing market, responding to driving forces within research and medicine, and remaining fit for purpose.

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CONTACT INFORMATION

Ana Bolanos – ana.bolanos@uhn.ca
Miran Kenk - miran.kenk@uhn.ca
Heidi Wagner – Heidi.wagner@uhn.ca
www.gubiobank.com