

Biobankonomics: Developing a Sustainable Business Model Approach for the Formation of a Human Tissue Biobank

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The preservation of high-quality biospecimens and associated data for research purposes is being performed in variety of academic, government, and industrial settings. Often these are multimillion dollar operations, yet despite these sizable investments, the economics of biobanking initiatives is not well understood. Fundamental business principles must be applied to the development and operation of such resources to ensure their long-term sustainability and maximize their impact. The true costs of developing and maintaining operations, which may have a variety of funding sources, must be better understood. Among the issues that must be considered when building a biobank economic model are: understanding the market need for the particular type of biobank under consideration and understanding and efficiently managing the biobank's "value chain," which includes costs for case collection, tissue processing, storage management, sample distribution, and infrastructure and administration. By using these value chain factors, a Total Life Cycle Cost of Ownership (TLCO) model may be developed to estimate all costs arising from owning, operating, and maintaining a large centralized biobank. The TLCO approach allows for a better delineation of a biobank's variable and fixed costs, data that will be needed to implement any cost recovery program. This article represents an overview of the efforts made recently by the National Cancer Institute's Office of Biorepositories and Biospecimen Research as part of its effort to develop an appropriate cost model and cost recovery program for the cancer HUMAN Biobank (caHUB) initiative. All of these economic factors are discussed in terms of maximizing caHUB's potential for long-term sustainability but have broad applicability to the wide range of biobanking initiatives that currently exist.

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The pace of cancer research in the United States and other countries is hampered, to a large extent, by limitations to the availability of high-quality human biospecimens linked to highly annotated epidemiological, clinical, biological, and molecular information collected from large numbers of patients and made available by biobanks. Biobanks collect a variety of biological samples that are critical for biomedical research, including DNA, RNA, tumor/non tumor tissues, cells, blood, plasma, and other body fluids (1). Certain biobanks specialize in hard-to-obtain tissues such as eyes or bones; others focus on moving various tissues from primary sources to researchers, whereas still others concentrate their efforts on identifying and isolating specific cells from donated tissues (2). Today, such biospecimens play a prominent role in research efforts aimed at identifying the key genes, proteins, and signaling networks involved in cancer and at using this information to detect cancer at its earliest stages and to develop personalized therapeutic regimens for treatment (3). Pharmaceutical companies, for example, employ molecular analysis, tissue microarrays, and immunohistochemical techniques in efforts to reveal mechanisms or "biomarkers" linked to specific types of diseases and cancers (4).

Insecurity of Funding

A second major bottleneck to accelerating advancements in cancer research is the lack of long-term secure funding for developing and sustaining biobanks and biobanking research. The start-up

infrastructure investment and operating cost requirements for even a modest biobank represent a significant commitment (5). Although biobanks have tested an assortment of funding models—from private venture capital, to government-funded, charitable not-for-profit, and government-commercial collaborations—all must equally consider fundamental business principles to achieve economies of scale and understand the costs of doing business, as well as establish a compelling value proposition. A value proposition is the offer of quantifiable benefits that an organization makes to its stakeholders (6,7). The lack of data on costs and outcomes in biobanking makes quantifying value in this sector extremely difficult, yet is critical to demonstrating the biobank's role in facilitating translational research and in providing a calculable return on public and private investments.

To be sure, not all biobanking initiatives succeed. History can point to a number of programs that had difficulties in either creating sustainable value propositions or viable funding models. Some failed and disappeared altogether, whereas others restructured through bankruptcy or were acquired by other entities (eg, deCODE Genetics, Genomics Collaborative, Inc, Ardais, Lost Mountain, IMPATH, SeraCare, Swedish UmanGenomics, Bibliobank Quebec, and onCore UK). In addition, since early 2008, the economic downturn has taken its toll on large pharmaceutical companies, leading them to severely reduce research and development budgets, close laboratories and research facilities, lay off scores of workers, or merge to survive (8–10). Private foundations,

universities, and nonprofit organizations in the biomedical research arena have all experienced a similar downturn. Taken together, these factors have created severe funding constraints for biobanks in the private sector. However, the current economic climate also presents a significant public policy opportunity for the government to serve as a steward of research and development, and invest in the formation of a national biobanking resource to facilitate scientific discovery, advance cancer research, and ensure that the needs of the broader biomedical research community are met.

In Search of a Biobank Economic Model

Published material and available documentation on constructing cost and business models for biobanks are scarce. Perhaps one explanation for this is the fact most biobanks have been guided predominantly by “quest for research” directives rather than by conventional supply-and-demand mechanics and a careful study of the business principles required to ensure that such an enterprise is viable. A thorough understanding of the economic and financial issues associated with building and sustaining such an entity, however, is critical to successfully leverage both public and private support. Within these limitations, this report presents a synopsis of a study, conducted by the National Institutes of Health, Office of Biorepositories and Biospecimen Research (OBBR), for a proposed national biobanking initiative, caHUB (cancer HUMAN Biobank). Specifically, the study examined 1) factors affecting the biospecimen market; 2) development of a biobanking cost model; and 3) considerations for viable funding mechanisms (eg, cost recovery models) to ensure the biobank’s long-term sustainability (11).

Understanding the Market Need

Building any economic model begins with the development of a strong list of data sources to inform the model, including experts who can shed light on the cost structure of the business, key challenges, and lessons learned in the industry, as well as critical business practices and market forces that deserve close attention if one is to succeed. In addition, evidence must be collected to clearly demonstrate a market need. The market for biobanking services is primarily driven by biomedical research funded by agencies of the federal government and demand from the pharmaceutical industry, academic research, and other life sciences institutions, as these stakeholders increasingly make use of human tissue research in their preclinical drug development and discovery research groups (12). Consequently, a biobank’s financial viability depends, to a large degree, on its ability to successfully meet the various needs and market demands of customers across this broad research spectrum. Industry reports from investment firms that follow the pharmaceutical sector, and biobanking firms, in particular, are important sources of information for understanding the market. Research published by such firms indicates global demand for human tissue, and associated human tissue research services in 2009 was estimated to be approximately \$700 million, with the biobanking marketplace growing between 20% and 30% annually (Figure 1). In addition, the biobanking industry is a highly competitive and fragmented market. Although there are approximately 180 commercial biobanks in the United States with accruals of nearly 400,000 donors

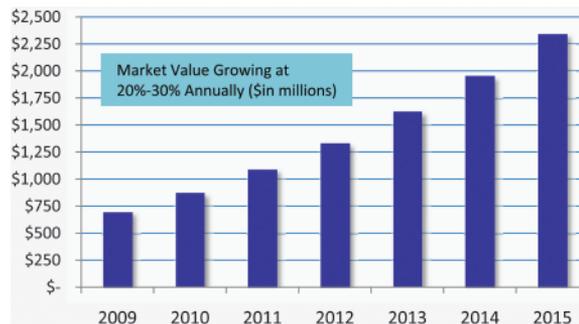


Figure 1. Global market value of the demand for human biospecimens and related services.

(13), no single company holds more than a 3% share of the global biobanking market. In 2000, the Rand Corporation estimated that more than 300 million human biospecimens (eg, formalin-fixed paraffin-embedded tissues, frozen tissue and fluids) had been stored across the United States, with this volume growing at a rate of about 7%, or approximately 20 million specimens, annually (14). This market growth data suggest an industry producing nearly 600 million biospecimens today. To date, this fragmented industry’s absence of generally accepted best practices and standard operating procedures for biospecimen management has led to issues with specimen preservation and quality, as well as data integrity. Consequently, the current biobanking landscape may present a significant opportunity for a national institution providing biospecimens of the highest quality to a diverse set of researchers.

Getting the Viewpoints of Those in the Business

Another primary source of market intelligence in the OBBR study was a survey tool (additional to the surveys conducted by National Cancer Institute and described in other articles in this monograph) used in conjunction with interviews conducted with a number of representatives from commercial biobanks, university biorepositories, and large pharmaceutical companies. These discussions served two main purposes. The first was to obtain data on market conditions for various biospecimens, as well as other information directly from biospecimen providers (eg, market supply) on how they viewed their particular strengths and weaknesses in the marketplace. The second was to obtain the perspectives of the large drug companies—that drive much of the market demand—on the value proposition that would need to be presented by a government formed entity. Those interviewed included personnel from biospecimen providers, such as Asterand, Indivumed, SeraCare, BioServe, and ILS Bio, as well as from the pharmaceutical companies Amgen, Eli Lilly, Johnson & Johnson, and Merck. Last, at the academic level, interviews included representatives from biomedical research facilities at Harvard University Medical School, Louisiana Cancer Research Center, University of Pennsylvania, and the University of Alabama at Birmingham.

The Biobanking Value Chain Framework

In the financial industry, banks collect deposits through various mechanisms, manage, leverage, and even invest these deposits, and

then make loans available to commercial and/or consumer clients. The success of the institution in generating adequate returns and remaining solvent depends largely on its ability to efficiently manage its value chain and a number of critical corresponding business processes: penetrate the market with competitively priced products; manage marketing and acquisition costs; ensure customer systems, data, and account management processes are streamlined and efficient; and maintain a high-quality portfolio at acceptable levels of loan losses. In a similar sense, a biobank's viability rests with its ability to successfully meet customer demands while effectively managing a value chain that, although characteristically different, parallels many of the conventional business processes resident to the banking industry. Functions, such as individual donor case acquisition, quality assurance and control, clinical and histological data annotation, pathology review, informed consent management, biospecimen-inventory and -storage management, biospecimen distribution, customer relations, administration and facilities, are all critical elements that must be considered when constructing a business model approach to support the development of a biobanking initiative (15). There has been a heightened interest in documenting and improving the quality of biospecimens before their use in downstream research, as variations in the conditions under which samples are collected, processed, and stored may affect specimen quality (16). A framework structured around five key biobanking value chain pillars was used to develop a comprehensive cost model for National Institutes of Health's caHUB initiative (Figure 2).

Case Collection

Case collection typically composes the highest percentage of overall costs for a biobank's activities and includes the costs for tissue acquisition, pathology/histology review, informed consent documentation, case data collection, Health Insurance Portability and Accountability Act adherence, preparation of collection kits (eg, sample collection tubes, slides, cassettes, etc.), and the shipping of those kits back to the biobank. The cost of various shipping containers configured to accommodate ambient, cold pack, or liquid nitrogen shipping methods, and courier costs for batched shipments are highly variable depending on the number of tissue collection sites and the frequency of shipments. In addition, unique barcoding is used to link the participants to their tissue, blood, serum, urine, and other biospecimens in a secure and anonymous way that mitigates the risk of data entry errors and also prevents biorepository personnel from incorrectly processing samples since automation is programmed to identify specific barcodes for specific protocols (17).

Tissue Processing

Processing costs account for another major component of a biobank's total costs. Comprehensive well-documented processing and

extensive annotation are essential to the research value of biospecimens (18). Included here are the costs associated with additional data annotation, confirmation of diagnosis, detailed pathology work-up, including digital imaging and image analysis, molecular analysis and genetic marker tests, establishment of a comprehensive case profile, and any bioinformatics system data entry that is necessary. Stringent quality reviews are performed to verify the integrity of collected biospecimens and to properly ensure matching of the tissue received to the pathology reports. Additional barcode tracking is performed as tissue blocks are fragmented, and biospecimens are moved from, for example, the repository to a laboratory area, and an audit trail is established.

Specimen Storage Management

The main "vault" for a biobank is its storage area, and this holds the inventory of physical biospecimens. Storage costs will vary depending on the types of biospecimens stored (eg, blood, tissue, DNA/RNA, etc.), the number of aliquots, and the volume of each item. Storage infrastructure costs include liquid nitrogen freezers, -80°C mechanical freezers, and room temperature cabinet and rack systems (5). Freezer storage areas are constantly monitored by video and alarm systems, requiring either dedicated staff or use of a contracted service firm. Other costs include freezer maintenance and periodic recalibration as well as backup power systems. Last, storage management will also entail the labor costs associated with following standard protocols, such as periodic auditing, inventory control and reconciliation, and certification of biospecimen identity to ensure the accuracy of data maintained in the biobank's biomedical informatics, laboratory information management, or other enterprise resource planning systems.

Specimen Distribution

The retrieval and distribution of biospecimens to customers in the research community comprise the next important component in the biobanking value chain. Once researchers have placed an order for a specific set of samples, the samples are retrieved from inventory either manually or through the use of robotic systems. This includes the labor associated with order entry management activities, and the back-end packaging and shipment of biospecimens, and barcode tracking of biospecimens removed from storage to ensure accurate inventory reconciliation. Other costs entail verification of order receipts and validation that samples received met quality and fit-for-use standards. System integration costs must be considered as well to ensure that order entry systems are integrated with the biobank's financial accounting system to record transactions, affix the appropriate pricing, and generate customer invoices.

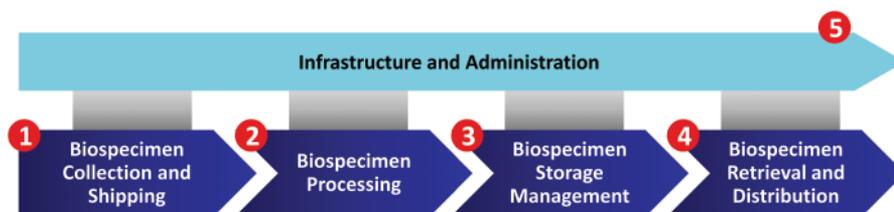


Figure 2. Biobanking value chain framework.

Infrastructure and Administration

The fifth and last major area of biobanking value chain costs is Infrastructure and Administration. This is typically one of the highest cost categories and comprises many costs that are fixed in nature. These fixed costs include all of the administrative personnel required to carry out enterprise operations (eg, executive management, human resources, ethical and legal policy, regulatory compliance, accounting and finance, customer relations, quality assurance, facilities management, etc.). Major capital investments are required to purchase or build out the site; design and outfit laboratory facilities; install fire prevention, building access, security and surveillance systems; furnish offices; and to install backup power generator systems to maintain freezer storage stability and ensure business continuity. Designing the facilities to meet or comply with specific design, energy, or disaster standards can also add significant costs. In addition, comprehensive biomedical informatics systems are necessary, as they are critical to optimizing the value of biospecimen collections (19). Other information technology costs that must be considered are the data center, storage, cybersecurity, local and wide area networks, as well as any web-based portals and applications that are necessary for customers to access the biobank for research or business purposes.

Building a Biobanking Total Cost of Ownership Model

A Total Life Cycle Cost of Ownership (TLCO) analysis is an economic method of evaluation in which all costs arising from owning, operating, maintaining, and disposing of a program or project are included in the study and measurement (20). In developing a TLCO model for a biobanking project, it is important to capture all investment and operating cost requirements from initial startup, through the business ramp-up phase, and into a sufficient steady-state period (Figure 3). Up-front capital investments (eg, lab facilities, freezer equipment, and information technology) should be delineated from annual operations and maintenance costs, and estimated over a period of at least 10 years. However, building a model to accommodate a 15- to 20-year life cycle period is generally considered a cost-estimating best practice for projects of \$50 million or more.

Economies of scale improve over time as infrastructure is optimized, the core biorepository is in place with only modest periodic

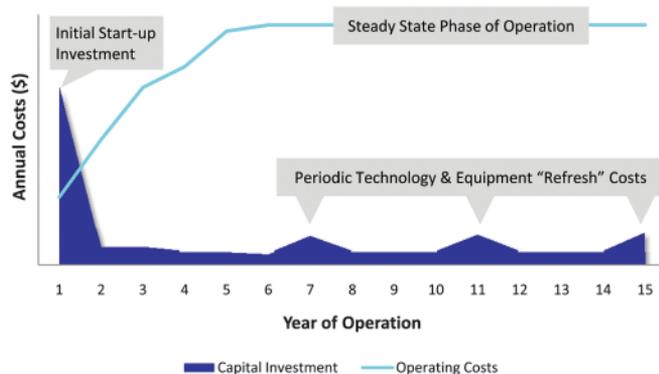


Figure 3. Biobank total life cycle cost of ownership.

capital refreshment required for some freezers, laboratory equipment, and information technology, and annual case collection and processing activities level off. These assets are typically depreciated over life cycle “refresh” periods ranging from 3 to 7 years for equipment, and over 30 years for buildings, with the US Tax Code and Generally Accepted Accounting Principles serving as best guidance for the appropriate treatment of each asset’s useful life and the allowable methods for their depreciation. Case collections take time to accumulate and to fill the biorepository with biospecimens that prove to have the highest value to the research community. Establishing a comprehensive cost element structure to parallel each of the five biobanking value chain components is highly recommended. Building the model this way serves several purposes. First, it provides a better understanding of the variable or fixed nature of specific costs (eg, barcode labeling materials, tissue collection and laboratory/pathology processing equipment, freezer equipment, shipping materials, facilities, and labor functions) for each value chain area as the business model is scaled over time. A detailed cost element structure also helps alleviate the risk of missing costs or of double counting. Finally, it also helps to identify capital costs that must be amortized over the life cycle, as well as the specific operating costs associated with acquiring, processing, storing, and managing tissue collections—both of which are needed to inform cost recovery pricing as biospecimens are made available to customers in the research community.

Using Appropriate Data Sources and Cost-Estimating Methods

Although published information does exist on investments that have been made in specific biobanks, actual case studies complete with detailed business model, and cost information are rare. Consequently, building a biobanking cost model from the bottom-up requires use of a wide variety of data sources and cost-estimating approaches. Some of the key data sources used in the OBBR study were:

1. Equipment pricing information obtained through vendor sales representatives.
2. Internet catalogs.
3. General Services Administration advantage-pricing schedules.
4. Benchmarks obtained from industry-related articles and publications.
5. Historical contract price quotes obtained for similar equipment and supplies.
6. Parametric cost estimates using cost database reference information.
7. Information collected from biobanking industry subject matter experts through the use of interviews and survey tools.

Where possible, cost estimation information should be obtained from project personnel, researchers, contractors, and stakeholders who are familiar with previous biobank initiatives, and who can offer valuable historical perspectives on lessons learned, key successes, as well as failures. In addition, it is important to establish a basis of estimates dictionary to document the logic and methods used to derive the specific cost estimates. Because annual cost estimates will be in Constant Year figures, these dollar amounts must be inflated accordingly using the appropriate inflationary rates

depending on the type of cost. For instance, annual inflation rates for salaries and labor, maintenance, technology, and other equipment will vary. Inflated, or Then Year, figures reflect the “budget perspective” financials and are intended to capture and depict the annual funding requirements associated with a long-term project.

Adjusting for Risk

Consistent with cost-estimating best practices and policy guidance and due to a significant number of uncertainties with the operating assumptions of any biobanking business plan, the TLCO estimates should be risk-adjusted (21). Varying a number of key business assumptions across each of the biobanking value chain components allows the final cost estimate to be presented as a “range” rather than “point” estimate, facilitates more prudent budget planning, and helps focus attention on the role that key business drivers play on determining overall costs. A sampling of five biobanking business drivers that were adjusted in the OBBR biobank study to demonstrate their impact to the overall TLCO estimate included the following: 1) the details of the case accrual plan, 2) tumor module segmentation, 3) case collection labor productivity, 4) information technology and bioinformatics architecture, and 5) the sample inventory turnover rate. Each of these business drivers were modeled in a high, low, and most-likely scenario to determine variances to their individual cost estimates and then aggregated to illustrate their cumulative impact on the projected budget estimate.

Implications for Long-Term Sustainability

Financing and Cost Recovery

In the current economic climate, both government and private sector budgets face a difficult battle for finite resources. This trend has sparked the sharing of program resources to improve economies of scale—and to maximize the return on investment—for infrastructure supporting cancer research end user communities. Most people would agree with the principle that public taxpayers should not bear all of the costs of a government program where private industry and other not-for-profit entities derive a benefit from the use of that service or its output. To be fair, others argue that all government generated data and information is “civic capital” and should be available at no cost. However, charging entities or end-users that consume resources, use services, or leverage infrastructure in the public domain to advance their own interests promotes an equitable approach for the financing of public programs. The US National Weather Service offers an example as the largest US Government agency on the Internet in terms of data flow, specifically for real-time weather information that is provided to the public for free, and to industry and commercial businesses on a cost recovery basis.

Evaluating the notion of a national biobank for OBBR required the use of conventional methods to determine the long-term financial viability of the proposed business model, and a study of potential funding mechanisms that could be used, such as a public-private partnership (22). The proposed caHUB initiative may necessitate the application of cost recovery mechanisms to ensure that end-users bear a fair share of the costs for developing, maintaining, and sustaining the enterprise.

For many biobanks, the challenge of long-term sustainability has stemmed from the cyclical nature of project-specific financing that has long been the tradition in the biomedical research and development sector (23). Funding has typically been dependent on localized research strengths and capabilities aimed at serving a specific research need, often to a limited number of end users. As new research questions emerge and a new demand for biospecimens arises, subsequent funding sources are made available, either through grants, nonprofit foundations, or in some instances, private sector venture capital. However, this “start and stop” style of incrementally funding biobank projects in short durations is inconsistent with the need to annotate biospecimens with longitudinal data over an extended period of time (24). Biobanks require dedicated personnel as well as well-maintained infrastructure to adequately preserve specimen collections ensure quality and standardization and to thrive over many years during which clinical and research questions evolve and inform the use of samples for subsequent studies.

First year start-up costs for even a small biorepository storing 50 000 biospecimens can easily range from \$3 million to \$5 million, not including additional costs for information systems, while operating costs over a 10-year period of twice this figure are not uncommon (25). In addition, because of the high investment costs required to install infrastructure (eg, laboratory facilities, liquid nitrogen as well as mechanical freezers, and bioinformatics systems), sufficient scale must be obtained for a biobank to efficiently leverage such infrastructure over time and optimize “cost per sample” throughput. For an institution planning to store and manage biospecimens numbering into the millions, substantial upfront capital, as well as ongoing funding for operations, is a bare necessity. Business models focused on the development of cost reimbursement strategies for the provisioning of biospecimens should be given serious consideration if a biobank is to reduce its dependence on public funding. Cost recovery models, therefore, must be able to capture the costs associated with biospecimen collection, processing, data annotation, storage, and retrieval for a business model to truly be self-sustainable (26). If public financing is sought, requests for government support should be bolstered by sound cost-effectiveness and cost-benefit analyses that more clearly demonstrate the benefits derived by patient populations from the biobanking component of clinical research endeavors. Now more than ever, biobanks must also measure the degree to which they effectively leverage other public investments in science and biomedical research and development while establishing clear links between investments made and progress realized.

Building a Cost Recovery Model—Some Key Considerations

Cost recovery models have taken many shapes and forms, vary by industry, and depend on the resource or service for which costs are recovered. Several important factors should be considered when developing a cost recovery model for a biobank:

Building Scale. Building scale for a biobank is critical and requires the ability to collect and store a significant volume of biospecimens to effectively maximize the return on investment in the infrastructure and human capital required to support and

perform a wide variety of functions for the organization. In addition, its ability to acquire biospecimens that are in high demand by the research community to ensure that sample distribution (eg, turnover) targets are achieved, and in general building a good reputation, will also contribute to leverage. Without leverage in the business, the biobank will not be able to license biospecimens at an acceptable cost reimbursement fee that will be competitive in the marketplace and generate sufficient revenue to successfully attain cost recovery goals. Discussions with industry experts, as well as published documentation, suggest that a steady-state operation should be achieved within a period of approximately 5 to 7 years.

Case Mix Desirability. Successfully building capacity also means accruing the right mix of tissues that are of the highest quality and which demonstrate strong demand by pharmaceutical companies, universities, life science firms, and others in the research community. This requires in-depth knowledge of the landscape and the varying needs of each of these customer groups so that tissue acquisitions can be designed accordingly.

Inventory Turnover. It can be argued that the real measure of success for a biobank is not the volume of samples in inventory, but the number of outgoing samples and research projects supported. Spending significant costs to collect and inventory biospecimens for which there is little demand will quickly lead to high storage management costs and an unnecessary labor and equipment cost burden on the collection and processing value streams. Consequently, samples must have all of the desired attributes of being “fit for purpose” (eg, quality, processing standards and protocols, appropriate consent, sufficient data annotation). Annual turnover rates for case collections vary widely and depend on several factors: the type and quality of samples distributed by the biobank (eg, frozen tissue, blood, DNA/RNA extraction, etc.), the customer mix (eg, private industry, government agencies, or research institutions), and the established reputation of the biospecimen collection. Inventory turnover rates for biorepositories vary greatly and can range from less than 5% to more than 50% (27,28).

Market Price Parity. In the commercial biobanking arena, biospecimens for which collection and distribution costs are recovered must effectively compete with prices that customers are willing to pay for other samples of comparable type, availability, and quality in the marketplace. Many biobanks tailor pricing to specific customer segments (eg, academic institutions vs commercial entities) and base their fees on a number of variables: patient and specimen type, degree of difficulty in preparing the specimen, specimen size requirements (eg, larger blood specimens may require special consent which impacts cost), special clinical parameters (eg, clinical outcome data), pathology parameters (eg, tumor subtypes, positive tissue markers, etc.), and the fulfillment of customized processing requests. In addition, market demand also plays a significant role in determining price as the needs and priorities of research evolve. Because customers may request an array of configurations of biospecimens and/or associated processing, the use of effective cost accounting and allocation methods becomes critical to capture the “full” costs for provisioning samples. Biobanks that are unable to

operate with an efficient cost structure (eg, collections and processing costs) and scale their collections adequately to leverage capital investments and drive unit costs down will ultimately have a difficult time competing on price.

What Costs to Recover. Establishing cost recovery targets for a biobank depends on how the biobank is funded, the maturity of the organization, and the timeline set for self-sustainability. For large biobanks that invest in the construction of standalone facilities costing tens of millions of dollars, it is unreasonable to expect the recovery of these up-front costs in the short term. Instead, the cost of these investments should be spread out over a longer time horizon, with a capitalized portion included in the recovery of other annual operating costs (eg, depreciation). Given an organization that is funded partially by the government and partially by a consortium of organizations in a public-private partnership structure, it may be acceptable to subsidize the operation in the short term and target cost recovery to the level of partnership contributions or to also include recovery of a percentage of public funding. A model such as this—commonly referred to as a “stepped” or “graduated” cost recovery model—can be modified over time as the business model is scaled and the institution is able to generate sufficient revenues to cover a significant portion of its operating costs and overall funding requirement. Consequently, the cost recovery ratio of total costs is gradually increased as the operation matures.

Don't Overlook Other Potential Revenue Sources

In addition to commodities-based revenue from the licensing of biospecimens, a number of other potential service-oriented sources of revenue have been identified that could be used to augment cost recovery objectives. These opportunities include customized datasets, offering molecular and proteomic analysis, performing custodial collection services, providing pathology validation services, and offering training and education on biospecimen/biorepository management best practices (Figure 4). In many industries, for instance, “data” by itself have value and are sold in the marketplace for various prices depending on the maturity and historical nature of the information—consumer credit bureau report data, Dun and Bradstreet business credit ratings, and even Internet “cookie” data associated with an online user's behavior—are a few common examples (29). Similarly, market research conducted with drug development, biomarker research, and other medical research institutions has shown that comprehensive biospecimen datasets are in high demand for use in clinical studies. The real value addition occurs when biospecimens are linked with the clinical, pathological, histopathology, treatment response, and disease outcome data (30). Biospecimens that are accompanied by extensive datasets of this nature typically command twice the licensing fee of a sample that is not as highly annotated, and this price differential may be driven even higher in the case of rare biospecimens for which longitudinal datasets are not easily available.

Furthermore, offering customized collection and/or processing services in the areas of DNA/RNA expression profiling, derivative molecular analysis, genotyping, sequencing, and microarrays would be extremely useful for pharmaceutical and bioscience companies

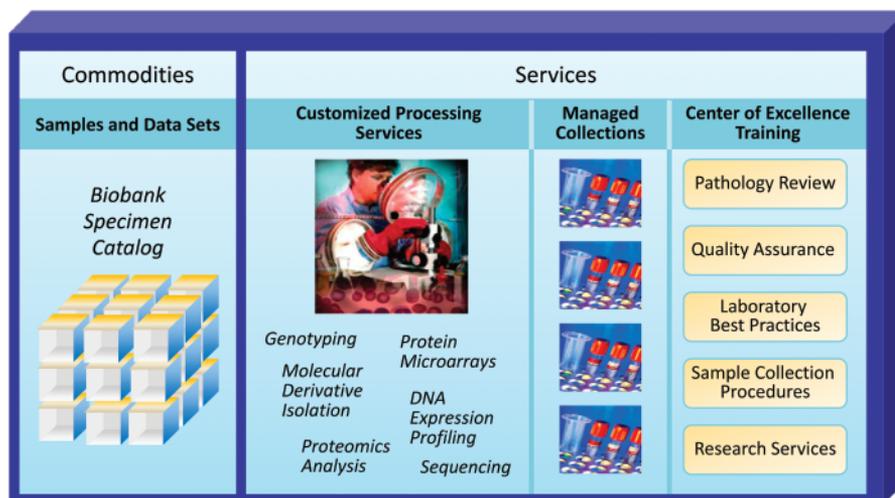


Figure 4. Biobanking commodities and service-based cost recovery model.

that are heavy investors in drug development and biomarker research. To assist smaller organizations that may not be able to fund their own infrastructure, another possible source of revenue would be to effectively reserve freezer space, for a fee, or to perform specific tissue acquisitions for contracted “custodial collections.” Confirming pathology diagnoses at various fees depending on difficulty of analysis and tumor type examined would be another possible source of revenue. Finally, because caHUB will serve as a center of excellence for best practices and the highest standards for quality assurance and quality control around tissue processing, specialized training certification and classes could be offered to the research community on either a per class or bundled curriculum basis. Biobanking system tools could also be offered.

Conclusions

The primary purpose of this article has been to offer perspectives on using a TLCO approach for a biobank that is effectively aligned with a value chain-oriented business model. Detailed cost analysis based on benchmarked industry standards for operating and capital costs show that even small biobanks represent a significant investment. The TLCO approach also shows how consolidation of efforts and operational efficiencies could very easily significantly affect the bottom line of any biobank. Establishing reliable costing for any biobank, developing a greater understanding of the direct and indirect costs associated with collection, processing, storage, and distribution of human biological material for research, will lead to a more sustainable and widely accessible supply of these critical materials. Understanding biobanking costs is also critical to establishing the cost-effectiveness and cost-benefit evidence base to justify continued taxpayer investment in this enterprise. This discussion also emphasized the value of achieving sustainability through the use of cost recovery practices prudently aimed at addressing resource utilization issues for a publicly funded national biobank. Serving as a key enabler of cancer research and catalyst for innovation in translational medicine, a national biospecimen resource would contribute financial benefits that, while as yet unsubstantiated by published research, are supported by OBBR’s

market research and by expert opinion. Examples of these benefits include the following:

1. Improvements in data-modeling efficiencies and research experiment time frames.
2. A potential reduction in the duration and cost of clinical trials and subsequent time to market for cancer-fighting drugs.
3. More accurate patient diagnosis and the associated impact on better treatment and lower health-care costs for payors, providers, individuals, and the nation.
4. Improved quality of life from reduced cancer treatment durations and lost work time.
5. Convergence to an industry “standard” for biospecimen quality.
6. Optimization of information technology, data, and capital infrastructure.
7. The adoption of best practices spilling over to influence an increase in workforce demand and trends toward professional recognition and accreditation within the industry.

The value creation that a national biobanking resource would bring to the research community would, arguably, exceed the costs for developing and sustaining such an institution. Considerations for the investment in the formation of a national biobank, however, require more than a comprehensive understanding of the drivers behind the science of this industry. A deep economic analysis of the market and pricing dynamics, business requirements, and funding models is essential to ensure not only the establishment, but sustainability, of this vital national resource. The OBBR will continue to investigate these issues through follow on research and pilot studies.

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