

Biobank Sustainability Recommendations

Guidance Document

Prepared by: Biorepository Task Force
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EXECUTIVE SUMMARY

A goal of the Biorepository Task Force is to provide recommendations and strategies for PCORnet biobank sustainability. CDRN Milestone 7.4 and PPRN Milestone 6.5 state that “Approaches to sustaining this network/PPRN without future PCORI funding are developed and implemented”. The practical solutions, tools and strategies provided in this document will assist CDRNs and PPRNs comprising PCORnet to achieve these milestones as they relate to biorepository activities.

BACKGROUND & SIGNIFICANCE

The existence of biorepositories within Clinical Data Research Networks (CDRNs) and Patient-Powered Research Networks (PPRNs) that are regulatory-compliant, comprehensive, and sustainable is essential to the future success of PCORnet’s research endeavors. The unique advantage and challenge presented to PCORnet relates to building and maintaining biobanks and the linkage of biospecimens to clinical data from health systems and patient networks. This presents technical, regulatory and ethical issues.

Human biospecimens provide a critical resource that underpins research directed towards better health outcomes (Watson et al., 2014). Biorepositories provide tremendous scientific value, and have become a key resource in recent years within many academic, commercial, governmental, and pharmaceutical institutions (McDonald et al., 2012). However, as valuable as biorepositories are to research endeavors, they face many challenges with regard to their ability to be self-sustaining.

Sustainability is defined as the “capacity to endure [...] and remain diverse and productive over time” and as a property relating to three pillars of economy, environment, and society (Wikipedia Free Encycl., 2013). In a recent manuscript published in *Biopreservation & Biobanking*, Peter Watson et al. (2014) proposed that although the term is often used to mean fiscally self-sustaining, biobank sustainability should be considered within a framework of three dimensions – financial, operational and social. The Sustainability work stream of the Biorepository Task Force embraces this framework in its recommendations to PCORnet members.

Developing an awareness of each of these dimensions is critical for successful biobanking. This document addresses both financial and social considerations and recommendations for PCORnet CDRNs and PPRNs; those building an in-house biobank, considering sharing a biobank or contracting with a commercial vendor, and currently managing a biobank. Although not addressed in this document, operational sustainability recommendations may be provided by Biorepository Task Force members upon request.

DESCRIPTION OF EXISTING RESEARCH

It has been an underlying belief within the industry that after initial start-up and infrastructure funding, biobanks should be “self-sustaining”. However, for most types of existing biobanks, this has not proved possible, and the challenges of initiating and then sustaining biobanks over time has only increased in the face of the ongoing worldwide financial depression since 2008. (Vaught, 2011).

The body of industry evidence supports that biobanks, regardless of funding models and organizational structures, would benefit from the application of standard business principles to address the challenge of shrinking public and private grant funding (Vaught, 2011). There is a growing need to shift to a market-focused approach, enabling a biobank to establish internal and external collaborations, and thrive financially. Given the challenge of limited resources, non-commercial private and academic biobanks could improve their ability to become “nearly” sustainable by leveraging resources available within their organization to the greatest extent possible. It is suggested that biobanks 1) understand biobanking customer needs through market research, 2) develop a compelling value proposition, 3) achieve economies of scale and understand the true costs of doing business, 4) adopt a well-defined cost recovery program that may include a fee-for-service model to cover operations costs, 5) implement industry best practices to reduce regulatory and legal risk, and 6) develop communication strategies to inform researchers and industry collaborators of biospecimens available for future research.

Although evidence supports the need for developing a cost recovery system as a business model for biobanks, publications evaluating the effectiveness of cost recovery models and their relationship to long-term viability of biobanks are limited.

A. KEY FACTORS FOR CONSIDERATION

Organizations should direct attention to several areas of focus when seeking to ensure biobank sustainability.

Table 1 details these specific areas of focus, and provides useful questions for consideration.

AREAS OF FOCUS	QUESTIONS TO ASSESS LEVEL OF BIOBANKING READINESS
Mission, vision & strategic objective (Collis & Rukstad, 2008)	Mission -What is the underlying motivation for biobanking? Vision -What does the biobank strive to be in the future? Strategic Objective – Has a single goal for biobanking been developed that is measurable and time bound?
Availability of resources	What current resources exist and what resources are needed to plan and manage a successful biobank? What unique scientific expertise is available? Is a biospecimen science resource accessible? Is business expertise available to develop a viable business plan? What economies of scale are present to provide value? Are research subjects and biospecimens readily available? Is there a community of researchers to use collected biospecimens? What technologies are needed and available for successful biobanking?
Organizational/stakeholder requirements & structure	Will biobank collection(s) support a single user, several research studies within one institution, or multiple users from multiple organizations? Does the infrastructure exist within the organization to support biobanking? What are stakeholder goals and motivations? What business model is most appropriate given this information? (centralized vs. decentralized; in-house vs. external vendor, or using an existing biobank) If in-house, who will manage and operate the biobank?

AREAS OF FOCUS	QUESTIONS TO ASSESS LEVEL OF BIOBANKING READINESS
	Who will develop and maintain resources (e.g. clinical databases, LIMS, etc.)? What teams will be involved (e.g. informatics, programming, faculty, PM, etc.)? What biospecimens need to be collected? (Type of specimen, and disease focus) What value does the biobank have to the institution? What funding sources have been identified, and does the organization/stakeholders expect to contribute financially to the biobank? Is a fee-for-service model appropriate to fund biobank operations? Is there an expectation that the biobank will be financially self-sustaining?
Value proposition	Are identified value metrics relevant to stakeholders and users? What is the societal value of the biobank? What scientific/research value may be derived from the biobank?
Efficiencies (Internal & external)	What are the existing efficiencies that may be practically operationalized? Is it reasonable that costs for providing services be recouped if needed? What annotation of biospecimens is necessary, and can this data be efficiently obtained? Can users access the biobank and receive samples/data in a reasonable time?
Acceptability	Who are the biobank's stakeholders? Do public or private stakeholders trust in biobanks? Who will provide oversight (e.g. advisory board, community, ethics, legal)? Is the governance policy fair, allowing for transparent distribution of biospecimens? Is the biobanking of specimens viewed as acceptable by potential sample donors? Has the organization established communication about biobanking and received public input and representation? Do sample-sharing models meet NIH GDS policy, and organizational values?
Standards	Is the biobank committed to sound and responsible best practices and standards? Have stakeholders demonstrated commitment to accepted standards of practice and quality approaches? If so, was this commitment communicated to user and donor groups?

Note: The Areas of Focus column has been adapted from Table 1 in Watson et al. ((2014)

RECOMMENDED STRATEGIES

Although operating with a variety of organizational models, successful biobanking programs develop a comprehensive business model; one that integrates all aspects of operations, biospecimen resource management, and evaluation. The model provides justification for financial and institutional commitment, and quantifies start-up and sustainability costs (Vaught, 2011). The following business strategies are consistently used throughout the industry, according to the most recently available publications. All strategies listed below are applicable for both start-up and existing biobanks:

1. Develop a Strategic Business Plan - A solid and comprehensive plan should be written and revised annually, and may include these components:
 - a. Vision, Mission, and Goals – Include societal value
 - b. Opportunity – including stakeholder needs
 - c. Value Proposition (and value-added service offerings)
 - d. Definition of Services – Define service offerings
 - e. Competitive Analysis

- f. Business Development Strategy (Marketing Plan)
 - g. Communication (Outreach) Plan
 - h. Organizational Structure
 - i. Management Team & Resource Identification
 - j. Quality Assurance Procedures
 - k. Capital and Resource Requirements (Operations Budget)
 - l. Revenue Projections – May include grant, donor & service revenue if applicable
 - m. Biospecimen Collection Targets
 - n. Formal Continuity Plan – addressing possible operational disruptions
 - o. Quality Assurance Procedures
 - p. Performance Metrics – Desired measures of success - including societal value and research impact
2. Develop an Implementation Plan including timeline, milestones, contingencies, and path to secure short-term funding. The identification of additional resources including teams and key players involved in day to day operations is required.
 3. Develop a Cost Recovery Model; a crucial means to maintain economic viability, and ensure both short and long-term financial support. Financial support is typically derived from a variety of methods, including public and private funding, grants, philanthropic donations, and contracts. In increasing numbers, biobanks are developing fee-for-service models, recouping operating costs by charging fees to researchers and industry a fee to access and utilize a biobank's biospecimens. Biobanks may also recoup costs by providing researchers with biobanking services for their collected biospecimens. The following information is typically utilized to develop a biospecimen fee schedule:
 - a. Revenue projections - Accurate revenue estimates from all anticipated revenue sources
 - b. Cost analysis – Total infrastructure and biobanking operations expenses (including collection costs) identified during each stage of biospecimen management. Specific costs should be identified for each biospecimen type and volume (if applicable).
 - c. Projected or historical biospecimen service data (i.e. the number of samples allocated per year)
 - d. Market data to determine typical industry charges for comparable biospecimens (if applicable)

RESOURCES

The following resource materials have been made available by Biorepository Task Force members and industry partners for your use. They are provided in the Biorepository Task Force folder on the PCORnet shared desktop. For additional assistance, you may contact the individual listed below.

RESOURCE	CONTACT	DESCRIPTION
The Cost of Building a Biobank	John.mize@biostorage.com	Highlights various cost inputs required to build and maintain a biorepository.
Biobank Operations Budget – biobanking in-house	Diane.uzarski@duke.edu	Sample operations budgets for <i>in-house</i> biobanking
Biobank costs – line items for internal biobanking	JOYCE.JEFFREY@mcrf.mfldclin.edu	Estimated costs for an internal biobank shared by the Marshfield Clinic Research Foundation.
Biobanking Service Offerings – LabCorp®	maynorh@labcorp.com	Description of external biobanking services offered, including accessioning, storage, biospecimen removal, and biobanking related services with LabCorp®
Biobanking Service Offerings – BioStorage Technologies®	John.mize@biostorage.com	Description of external biobanking services offered, including accessioning, storage, biospecimen removal, and biobanking related services with BioStorage Technologies®.
Biobank Project Overview	Diane.uzarski@duke.edu	Outline for white paper aimed to get initial buy-in for biobank development or existing biobank sustainability project.
Fiscal & Operational Sustainability/Business Plan	Diane.uzarski@duke.edu	Template for a comprehensive business plan that delivers a detailed business strategy for a new or existing biobank.

CONSULTATION

Although it is not feasible for task force members to provide extensive consultation to PCORnet CDRNs and PPRNs, members of the Biorepository Task Force are available to assist CDRNs and PPRNs to answer questions and to make effective use of the tools and strategies outlined in this document.

REFERENCES

1. Watson, P., Nussbeck, S., Carter, C., et.al. (2014) A Framework for Biobank Sustainability, Biopreservation and Biobanking, Vol 12, No 1.
2. McDonald, S., Sommerkamp, K., Egan-Palmer, M., Kharasch, K., Holtschlag, V. (2012), Fee-For-Service as a Business Model of Growing Importance: The Academic Biobank Experience. Biopreservation and Biobanking, 10(5), 421-424.
3. Sustainability. Wikipedia Free Encyc.2013. Available from: <http://en.wikipedia.org/w/index.php?title=Sustainability&oldid=562266292>. Last accessed 2014 Aug 25.
4. Vaught, J. (2011) Biobank Business Planning and Economic Impact, Office of Biorepositories and Biospecimen Research, U.S. National Cancer Institute
5. Vaught, J., Rogers, J., Compton, C. (2011), Biobankonomics: Developing a Sustainable Business Model Approach for the Formation of a Human Tissue Biobank, Journal of the National Cancer Institute Monographs, No 42.
6. Vaught, J., Lockhart N. (2012) The Evolution of Biobanking Best Practices, Office of Biospecimen and Biobanking Research (OBBR), Clinica Chimica Acta. Retrieved from: www.elsevier.com/locate/clinchim
7. Hewitt, R., Hainaut, P. (2011) Biobanking in a Fast Moving World: An International Perspective, Journal of National Cancer Institute Monographs, No. 42. Oxford University Press.
8. Porter, M. (1996), What is Strategy? Harvard Business Review, Reprint Number 96608.
9. Collins, M. (2012), Is Your Biobank Ready for the Challenge of Biomarker-Based Research? BioFortis White Paper, October 2012
10. Rogers, J., Carolin, T., Vaught, J., Compton, C. (2011), Biobankonomics: A Taxonomy for Evaluating the Economic Benefits of Standardized Centralized Human Biobanking for Translational Research, Journal of the National Cancer Institute Monographs, No. 42.
11. Yamada, K., Patel, A., Ewald, G. (2012) How to Build an Integrated Biobank: The Washington University Translational Cardiovascular Biobank & Repository Experience, Clinical & Translational Science, Volume 6, Issue 3.
12. Polinske, N. (2014), Hot Topic: Establishing a Specimen Fee Structure, ISBER News. Retrieved from <http://www.isber.org/?page=Newsletters>
13. Odeh, H., Rao, A., McLean, J., (2014) Developing a Cost-Recovery Modeling Tool for Long-Term Sustainability of Biobanks, National Cancer Institute
14. Collis, D., Rukstad, M. (2008), Can You Say What Your Strategy Is? Harvard Business Review