

Financial sustainability of BRCs and networks of BRCs in both developed and developing nations

Executive Summary

The OECD model of a BRC includes considerable diversity of funding mechanisms for individual centres. However, it is to be expected that most BRCs, whether single large national centres or smaller distributed or specialized centres, will require some degree of commitment to core funding by their respective national governments or host institutions. Other kinds of funding sources include support from industry, grants from agencies that support research, cost-recovery through fees-for-service, development of databases and other tools that compliment the core role of BRCs, and even funding from charitable sources, especially those associated with public health or sustainable development.

The needs and capacities of individual countries vary, and the needs of developing countries must be understood and accommodated. National governments should identify collections and centres already capable of being designated as BRCs or forming a network, and build upon and improve these rather than starting up new BRCs, especially in developing countries where resources are limited. Similarly, partnerships must be developed among BRCs and appropriate existing agencies, identifying their capacities and interests in terms of support for BRCs.

The diversification of activities in moving from the 'Culture Collection' model to a BRC holds out the expectation of additional sources of revenue, both from existing activities and projects related to new technology based partnerships. A workshop organised by the OECD Biological Resource Centres Task Force in Genoa recognized two types of income streams. "Existing" income streams are those that support existing models of culture collections. "Anticipated" income streams represent activities in which BRCs will or may participate and that may generate recoverable income from stakeholders.

Existing Income Streams Anticipated for BRCs

- Government support
- Private industrial support for participation in the functioning of BRCs
- Private industrial support for internal restricted BRC activities
- Public and private foundation support
- Public fundraising
- Sale of biological resources and technical materials
- Provision of specialist services and technical consulting expertise
- Research income (grants and contracts)
- Fees for repository service (safe deposits and patent strain maintenance)
- Provision of technical courses
- Exploitation of and adding value to genetic resources

Potential Income Streams Anticipated for BRCs

- cDNA libraries, genomic libraries, filter sets, clones, plates, PCR products
- Microarrays and reagents

- RNAi resources
- Accreditation/standardization-added value products and services
- Data storage and retrieval
- Software development/collaborations - data mining tools
- Technology development/collaborations - LIMS/robotics
- Sequence database annotation/phenotypic analysis
- Linking genomics databases to proteomics
- MLST (multilocus sequence typing) - population studies

There must be a balance between governmental support, commercial and other income lines to provide support for collections. There are several collections that are supported by governments but rarely are they fully supported. The government supports 167 of the 468 culture collections registered with the World Data Centre for Microorganisms, a further 33 are semi-governmental, 141 are supported by university, 7 are supported by industry and 20 are private (WDCM Statistics - <http://www.wfcc.info/>). It can be argued that governmental funding is essential and appropriate the long-term stability of such funds is allows under threat. Culture collections perform many functions for governments not least helping them meet their obligations to the Convention on Biological Diversity and making available biological resources to underpin science, education and the economy. Such Government funding is usually balanced against the income received for the various services and products offered by the collection. This leaves very little for investment and to enable the collections to improve their coverage and incorporate new and advancing technologies. Collections need sound and innovative business plans to allow them to keep pace with the ever increasing demands of their users.

Developing income lines

Commercial

Development and ownership of spin-of biotechnology companies

Sale of products and services

Consultancy

Research Programme funding

A series of projects to meet donor requirements

Engage Research Programme Funders to protect their investments by paying for deposits in collections

Government department support

Provision of services to Government's to help them achieve their conservation and utilisation of biodiversity commitments, their environmental policies and their commitment to poverty alleviation.

Sponsorship

Attracting donations to cover costs of biological resource provision

Seek a consortium of research programme funders and sponsors to fund CABI's

There is not one financial model that can be applied to all culture collections or BRC. A combination of governmental, commercial lines and project portfolia offers the best chance for long-term sustainability.

Introduction

The experience of existing culture collections provides working models of BRCs. Culture collections may be described as either specialist or generalist collections, with differing financial models supporting each. In contrast, BRCs include a variety of activities directly related to quality control, collection development and operation that may include opportunities for some additional cost recovery activities. Among several potential new sources of revenue is the generation of genomics and proteomics data that complement and add value to biological materials themselves. The degree to which such activities may actually provide support sufficient to ensure financial sustainability of a BRC is unproven.

The OECD model of a BRC includes considerable diversity of funding mechanisms for individual centres. However, it is to be expected that most BRCs, whether single large national centres or smaller distributed or specialized centres, will require some degree of commitment to core funding by their respective national governments. Other kinds of funding sources include support from industry, grants from agencies that support research, cost-recovery through fees-for-service, development of databases and other tools that compliment the core role of BRCs, and even funding from charitable sources, especially those associated with public health or sustainable development.

The needs and capacities of individual countries vary, and the needs of developing countries must be understood and accommodated. National governments should identify collections and centres already capable of being designated as BRCs or forming a network, and build upon and improve these rather than starting up new BRCs, especially in developing countries where resources are limited. Similarly, partnerships must be developed among BRCs and appropriate existing agencies, identifying their capacities and interests in terms of support for BRCs.

Overview of Financial Aspects

The financial challenge of developing Biological Resource Centres was recognized in OECD's report on BRCs report in 2001. This report concluded:

- BRCs should be encouraged to co-ordinate their activities so as to best serve their essential functions in response to the needs of sectors that depend on their biological resources.
- Governments must be encouraged to provide a baseline of long-term core funding to centres that qualify as BRCs. This is necessary to encourage high standards of quality and to promote research, development, new technology and commercial exploitation.
- Various foundations and philanthropic or charitable organizations should be asked to extend the level of support given to BRCs.

- Marketable products and services may be developed within BRCs, including those aimed at meeting regulatory demands and for sale to specialized customers, as long as they do not divert capacity from the core activities of BRCs.
- Industry should be persuaded to take a long-term view of its interests and to offer core support for BRCs, either through funding or through direct participation in the functioning of BRCs, provided the latter maintain their independence.
- Efforts should be made to harmonize fee structures in situations where fees are usually charged and to see that charges are affordable for users.

The financial models provided by existing “Culture Collections” of various types are well recognized and include:

- The “General Collection” - often a national/regional facility
 - “Popular” items for distribution can guarantee income.
 - Archive function requires subsidy.
- The “Specialist Collection” – usually more localized
 - The “Institutional Collection” - can provide internal institutional service or wider external community/network service.
 - The “Research Collection” - provides a service relevant to one or more research interest.

These models vary considerably in the proportion of income derived from the various sources defined below. It must be emphasized, however, that the larger the archiving function carried out for strategic reasons rather than supply, the greater is the need for public and private subsidy.

Financial Models for Biological Resource Centres

The diversification of activities in moving from the 'Culture Collection' model to a BRC holds out the expectation of additional sources of revenue, both from existing activities and projects related to new technology based partnerships. A workshop organised by the OECD Biological Resource Centres Task Force in Genoa earlier this year recognized two types of income streams. “Existing” income streams are those that support existing models of culture collections. “Anticipated” income streams represent activities in which BRCs will or may participate and that may generate recoverable income from stakeholders.

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Culture collection funding

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Commercialisation

There is a requirement for adequate funding to support culture collections not only their continued maintenance but also their future development (OECD, 2001). There is no single

model that can be applied to the financing of a collection. However, a formula for sustainability must include Government support for services provided by collections to them in conservation, underpinning life sciences and meeting biodiversity obligations. The traditional products must be extended by the provision of new products to meet the needs of today's users for example, DNA, enzymes, metabolites and other derivatives from authenticated strains. Collections can move beyond this by developing commercial products through the provision of biotechnological solutions, active compounds and funding it through public/private investment and establishing spin off companies. CABI Bioscience has been moving in this direction since the 1990's when direct UK Government funding ceased in 1989.

CABI identified the need for a rapid test kit to detect fungal contamination in kerosene as the detection methods of the time took 3-10 days. The company Conidia Bioscience (<http://www.conidia.com>) was established to develop the FUELSTAT™ resiniae detection kit that currently is attracting a lot of interest from air craft fuel providers and airlines. The use of the kit is recommended in the Boeing Aircraft Maintenance Manual. It is not beyond culture collection staff to come up with solutions to current microbial problems and establish similar companies whose profits can be partly used to support biosystematics, biological collections and fundamental research. There will be a need to develop new products and Conidia Bioscience plans to develop further kits, for bacteria and yeast in fuel and for storage complexes, marine vessels and land fleets. CABI Bioscience has also been involved in developing biocontrol agents and one particular success has been *Green Muscle* a product used for control of African Locust (Dent, & Lomer, 2001). The profits from the sale of this product go into a fund to support biodiversity initiatives in Africa.

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The market for microbial genetic resources

Biotechnology has harnessed living organisms in bioremediation or detoxification of polluted sites, biodegradation of waste, biocontrol, production of useful chemicals, such as enzymes, biocides, drugs and dyes and in processes such as biotransformations and as food. Micro-organisms will provide even more solutions to our problems in the environment, health,

agriculture and the economy. At a time when natural resources are being depleted and alternative sources of energy and food are being sought, microorganisms will provide answers. Action must be rapid because we are also in a period of exploration of microbial potential against a background of rapid species depletion.

The economic value of biodiversity

Data from ten Kate & Laird (1999) demonstrates the value of the commercial use of biological diversity. Pharmaceuticals: more than half of all prescriptions filled in the USA in 1993 contained at least one major active compound now or once derived or patterned after compounds derived from biological diversity. 42% of sales of the 25 top-selling drugs worldwide are either biologicals, natural products or entities derived from natural products. The annual global sales of medical drugs are currently £200 billion a year. However, of every 5000 – 10000 products screened only one becomes an approved drug. Biotechnology may speed bioassays and the production of new drugs, explain more accurately how drugs act in the human system and may reduce the vast costs of pharmaceutical research and development. The annual market for industrial detergent enzymes is £0.5 billion. Bioremediation of soil in the EC in 2000 was considered to be worth £40 billion. There are huge revenues from fungal derived drugs e.g. cyclosporin, £0.8 billion: clarithromycin, £0.9 billion and amoxicillin £1 billion. As it is not uncommon to find that 15-30% of fungi found in the tropics or in unexplored environments are unknown to science the potential is enormous.

The Eighth Annual European Life Sciences Report 2001 produced by Ernst & Young demonstrates the importance of the biotechnology industry in economic growth and human welfare. The report covers only the entrepreneurial life science companies that use modern biological techniques to develop products or services to serve the needs of human healthcare or animal health, agricultural productivity, food processing, renewable resources or environmental affairs. Medical device and large pharmaceutical companies are excluded from the figures. In Europe 105 new companies were established in 2000 and a total income of 8.68 billion Euro (US\$ 7.64 billion) realised with a growth rate over the year of 38%. Figures for the USA saw 300 new companies established with a growth rate of 10% and a total revenue (again without the large Pharmaceutical companies) of US\$18.9 billion. Biotechnology is providing solutions in many fields most particularly in health care.

Not only do collections need to find novel ways of funding but also need to keep abreast and harness new technologies to produce information on the strains, adding value with the aim to provide today's users with the information they need. It is not always possible to establish these technologies in house but it is possible to establish partnerships with manufacturers, other collections or institutions with the expertise and facilities. Bioinformatics is of increasing importance to the operation of collections and new ways of collecting, storing, analysing, presenting and interrogating information are required to make best use of biodiversity information. Molecular techniques are increasing in use to differentiate between strains and in identification. However, recent work at CABI have shown through PCR fingerprinting with Mr Primer of replicates of an isolate of *Metarhizium anisopliae* after non-optimised preservation techniques that polymorphisms were introduced (Ryan *et al.* 2002).

Therefore at the very least collections should be adopting such techniques to determine if they are preserving strains without change.

Perspective of Developing Countries joining the OECD BRC Network

- National governments should identify collections and centres already capable of forming a network, and build upon and improve these rather than starting up BRCs “de novo”.
- Partnerships must be developed among BRCs and appropriate agencies, identifying their needs in terms of BRC support (e.g. WHO and the Pan American Health Organization, TB Research Programme, and the FAO and IPGR for food crop resources).
- Regional and international activities must be initiated with a long-term perspective (10 years or more) for such developments.
- Income streams from particular activities that are in demand locally (e.g. specialist service to industry and technical courses) need to be defined and developed.
- Even though it may be possible to involve BRCs in further exploitation of genetic resources, it is important to avoid conflicts of interest with other core BRC roles (e.g. IDA status for patent deposits).

Financial Aspects of Operating a BRC Network

The Issues

While a uniform structure of funding is not necessarily critical, many BRCs will require a significant component of government funding. Some guarantee of on-going funding is necessary to ensure that their essential functions remain reliable for R&D and support of biotechnology.

Collections will be put at risk if a BRC network eliminates duplication in holdings and then one or more of the individual BRCs fails for lack of support. All rationalization of collections must be planned to allow for necessary back-ups of all materials.

The following points were derived from the SWOT analysis of financial models of BRCs and a proposed model for BRC development.

Strategic implications

- A prerequisite for any network is that it is built upon standards and accreditation. This defines the network. This may require further investment.

- A national strategy that provides core financial support for a national BRC (or BRCs) should be viewed as a pre-requisite for participation in the international BRC network, to ensure that the network is sustainable.
- The international BRC network will be built upon national initiatives that in turn will evolve from existing activities (including culture collections). These activities are already based upon a range of income streams with varying levels of government support.
- Governments will be fundamental partners in the creation of national BRCs contributing to the international network, regardless of the level of financial support.
- Many existing culture collections will not wish to participate in the BRC network if this is inappropriate to their aims or goals, or if this is not justifiable given the level of investment required to raise/alter standards. Links to enable BRCs to draw resources from such centres will need to be created.
- Governments need to recognize that BRCs will take a regulated role in the supply and maintenance of dangerous/pathogenic organisms. This important core aspect of BRCs provides a controlled framework for the availability of these sensitive resources. In turn, fulfilling this role requires a level of financial commitment.
- BRCs must use the opportunity of establishing an international network to seek sponsorship from a variety of new sources of support (national, international, public, private and industry).

Operational Implications

- BRCs have to take a prominent role in capacity building and ensure a link between research-based collections and the BRC and the ultimate user.
- BRCs need to function as a strategic, national repository for key academic and industrial research resources, which will in turn provide an income stream. This is unlikely to operate on the basis of full cost recovery from sales income.
- Governments and their funding agencies must ensure that products derived from publicly funded research programmes are deposited in BRCs as part of the conditions attached to any award. (This could result in a small element of the grant allocated to this task as appropriate - see below)
- BRCs need to provide greater support to research based collections in terms of training and advice on standards, quality control and integrate more with the national activities in key related priority research areas (e.g. model organism research consortia).
- Governments must ensure that infrastructure aspects of the support for research are funded through relevant research programmes.

- BRCs must create partnerships with centres of excellence working with and developing new technologies and also databases to ensure that linkage is possible between these leading edge aspects of research and the physical resources held in BRCs.

It is anticipated that all of these strategic and operational changes relevant to the national role of BRCs will enhance their position in providing services of benefit to the scientific community and thus in turn benefit them by maximizing the potential for financial support.

A key element for discussion, however, remains the degree to which BRCs may benefit from the direct commercial exploitation of the resources that they hold. 'Ownership' as a concept has, to a large degree, been avoided in the past with the BRC acting as a 'Custodian' of the resource. Widespread introduction of Material Transfer Agreements and implications that IPR and reach-through are requirements for access to resources would fundamentally alter the relationship between Depositor, User and the BRC.

A proposed Collaborative Framework for BRCs and Long-term Financial Support

The Proposed Mechanisms

- It is recommended that a Management Board be created for the international BRC network, with representation from all countries contributing to the network. The Management Board should work under defined and agreed Terms of Reference.
- A series of technical sub-groups or sub-committees should be created by the Management Board to represent each area of technical expertise relevant to the operation of the BRC network. The sub-committees would have roles in the standards, operation, quality control and data aspects of the network. These could include:
 - Monitoring accreditation
 - Advising organizations on standards
 - Reviewing and recommending software packages for particular applications
 - Providing a user interface with the BRC network
 - Providing a link to GBIF, the Global Biodiversity Information Facility

Network Organization and Funding

It is recommended that any organization created to facilitate the international BRC network should work in cooperation with GBIF, and perhaps eventually function under GBIF. At present it would seem inappropriate to hand the task of creating the network to GBIF, as the establishment phase is a critical part of the proposed development of the BRC concept and best handled by BRCs themselves. In order to be sustainable, BRCs need to create a robust management system. It is essential to do this at minimal cost and to avoid the unnecessary expense of establishing a large stand-alone secretariat.

Once established it may be possible to have a more 'virtual' relationship and integrate the future needs of the BRC network with the future needs of GBIF. It may be possible to seek funds from GBIF to establish aspects of the network relevant to the requirements of GBIF.

The BRC Task Force needs to make a firm recommendation to Ministers to establish funding for the international BRC network on a short-term basis (3-5 years) at marginal cost. An estimate is required of the investment necessary to establish the network, based on identification of appropriate work packages.

An Interim Advisory Group may have to be set up prior to the nomination of the BRC Management Board to facilitate the identification of participating organizations and call on expertise for this task drawn from a range of appropriate disciplines. This group would only exist for the period leading up to the launch of the project and have a defined remit, Terms of Reference and life span.

Conclusion

There is not one financial model that can be applied to all culture collections or BRC. A combination of governmental, commercial lines and project portfolia offers the best chance for long-term sustainability.