

FINANCING A NATIONAL BIOBANKING RESEARCH INFRASTRUCTURE

1. BIOBANKING: ENABLING DISCOVERY, INNOVATION AND GROWTH

The term 'biobank' commonly refers to a collection of human biological samples (tissues, blood, body fluids and their derivatives) and associated data provided for research and development.

The provision of human biological samples (HBS) with associated data is a critical resource for experimental biomedical research, most notably to discover biomarkers and to implement stratified medicine. It is also a critical resource for the development and validation of new diagnostics and treatments. As a consequence, biobanking has been identified as an activity of national strategic importance by, for example, the Department for Business, Innovation & Skills, the Economic and Social Research Council, Research Councils UK and the Stratified Medicines Innovation Platform.

"A recent CBI study found that the quality of our scientific research base is one of the most significant factors encouraging international companies to bring high-value investment here."

Rt Hon George Osborne MP (2012)

Sufficient provision of HBS offers benefits to key actors in the UK economy:

Pharmaceutical companies	<ul style="list-style-type: none">• To increase the probability of success in the development of new medicines• To reduce the times and costs for development of new medicines• To tailor treatment and segment markets• To increase cooperation across and along the value chain
Biotechnology and diagnostic companies	<ul style="list-style-type: none">• To develop diagnostics• To develop new treatments• To catalyse emerging innovation opportunities
Public science base	<ul style="list-style-type: none">• To support knowledge creation and scientific discovery across a wide variety of disciplines• To promote international collaboration• To attract external funding• To enhance the international profile
Wider society	<ul style="list-style-type: none">• Toward earlier intervention in disease• To improve quality of life• Toward more cost-effective and personalised treatments• To reduce the societal health care burden• To increase economic welfare

2. CURRENT SITUATION: MARKET & SYSTEM FAILURE

There are insufficient accessible numbers of HBS of adequate quality and with associated detailed clinical data to enable efficient biomedical research across the R&D value chain in the UK.

- The UK's biobanks are diverse, highly fragmented and un-coordinated
- Many existing samples are largely invisible to prospective users, creating high 'search costs'
- Poor coordination has resulted in low levels of standardisation and consistency
- A lack of coordination means that consistency between biobanks may not be readily demonstrated or assured
- Resources are poorly deployed: little synergy has been exploited when funding sample accrual, processing and storage

→ Under-exploited opportunities

→ Disease & tissue specific networks demonstrate the potential for a national solution

3. NATIONAL BIOBANKING RESEARCH INFRASTRUCTURE

A biobanking research infrastructure (RI) refers to a national network of biobanks, including disease or tissue-specific networks.

The creation of a biobanking RI will mitigate or eliminate many of the failings identified in the previous section. There are several examples of good practice and of coordinated efforts promoted by funders and others that are not representative of the system as a whole but serve as important building blocks. A nationally coordinated (yet distributed) RI will increase the visibility and accessibility of HBS, as well as increasing the productivity and quality of publicly funded research by raising standards and by reducing unintended duplication and the under-utilisation of equipment. It will enable firms, including SMEs, to build business models through secondary access. Ultimately, there will be improved access to large cohorts of samples across individual biobanks, with reassurance regarding consistency and quality.

INITIAL COMPONENTS:

- A form of coordinating body that promotes and assists the implementation of agreed policies, standards and practices, manages membership, manages the catalogue and grows the RI.
- A searchable catalogue that describes human biological samples (HBS) and facilitates access.

KEY PRINCIPLES:

- 'Controlled access' with open access features supports the 'best possible use' of samples. Access should be controlled via peer review of new proposals. This supports knowledge-sharing while conserving a finite resource. Open-access (with the usual anonymity practices) to associated data has the most beneficial impact on knowledge creation and innovation.
- Biobanking RI should operate as a dynamic and sustainable resource (such that the value will increase over time). Samples should be continually enriched with high-quality new annotations (both clinical and experimental) by users.

4. FINANCING A SUSTAINABLE RESEARCH INFRASTRUCTURE

Private companies benefit from biobanking but are normally unable to capture enough of those benefits directly to justify covering the investment needed to establish and operate the infrastructure. In addition, even though their products and services form an essential part of patient care, private companies are typically detached from patients without direct involvement in the collection or storage of HBS. When private benefits are added to the wider social benefits arising out of better R&D there is a compelling case for investment. In these circumstances there is a strong rationale for centralised public funding at a level to make the investment worthwhile. Most biobanks receive public funding from multiple sources, including internal financing. They often exist only to underpin discrete research projects and so while this has the benefit of ensuring samples are of high research value, it rarely supports the coordination needed for speedy accrual of large numbers or for making samples more widely available. Research undertaken by The University of Manchester for STRATUM finds that a new financial approach is required.

A national biobanking RI cannot be financially self-sufficient where there is market failure. Core public funding is required to meet the costs of coordination across existing and emerging biobanks to create a distributed RI. In designing a financial model, it is important not to dis-incentivise researchers, and other users, from participation. It is also important not to consume extensive resources in administering large numbers of small transactions as would be the case in a full market model designed to cover costs at the point of use.

Any new core financing arrangements should be supplemented by coordinated funding for individual biobanks. General recommendations include:

- **Co-ordination** across the UK's diverse population of biobanks requires dedicated resources. A coordination centre may be required and this should be financed centrally by public funds, possibly supplemented by industrial funding.
- Distributed biobank **facilities** (physical space, storage, core staff etc.) should be supported directly by their host public sector institution using central public funds to overcome discontinuity of funding problems and enable investment in best practice..
- Sample **acquisition** should continue to be costed into projects and project proposals to ensure biobanking is driven by research needs.
- **Access** costs (the marginal cost of providing samples on request) should be paid directly by (secondary) users through a tiered access fee.
- The **sharing** of samples via the RI should be promoted, e.g. by funders of research.
- Data **enrichment** should be promoted.

The timely provision of large numbers of quality human biological samples with associated data will strengthen biomedical R&D in the UK. Coordinated investment in a sustainable national biobanking infrastructure will support the development of new pharmaceutical business models and the growth of a strong diagnostic and biotechnology sector. Biobanking RI will help the UK's position as a global leader in science and innovation, attracting investment, promoting research and supporting commercialisation.

→ **Opportunity costs of *not* investing are high**

→ **A biobanking RI: creating opportunities for UK business and research**

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