

# From GMP to GBP\*

## Fostering Good Bioethics Practices Among the European Biotechnology Industry

### Biobanks

#### Project Summary

The project: "From GMP to GBP – From Good Manufacturing Practices To Good Bioethical Practices" is a Specific Targeted Research Project funded by the European Commission, Sixth Framework Programme.

The project aims at integrating bioethical practices as an intrinsic part of industrial standards, just as Good Clinical Practices (GCP) or Good Manufacturing Practices (GMP) are. These standards of Good Bioethical Practices (GBP) would allow the industry to define its own issues and recommendations inform to European Union legislators and relevant authorities. The project also aims to improve understanding of bioethical issues, based on the current practices of biotech companies, as well as to elaborate clear and independent positions on bioethics, based on regularly updated scientific and technological data. The final step will involve disseminating this information to the industry and to society.

The project is piloted by the French biotechnology association, France Biotech, in partnership with a consortium comprising the European biotechnology association, EuropaBio, and national biotechnology associations from Estonia (the Estonian Biotechnology Association), France (France Biotech), Hungary (the Hungarian Biotechnology Association), Sweden (SwedenBio) and Spain (ASEBIO), as well as the French Institute for Health and Medical Research (INSERM U558).

#### Issues

The definition of a biobank varies between European countries. In some countries, the term does not exist in any legislation. Two trends however are evident with respect to the way countries view biological samples and data:

- The first makes a distinction between the physical biological samples themselves, which together constitute a sample collection, and the database made up of the information derived from these samples and their donors.
- The second trend, which currently predominates in the world of genomics, uses the term "database" to denote the physical samples as well as the information derived from them.

The issues most commonly mentioned by stakeholders in the European biotech industry regarding biobanks are:

#### **The definition of biobanks**

*The absence of a common definition is a source of problems and difficulties in an international context where exchange plays an important role, as well as the harmonisation of regulatory modalities, organisations and operations.*

#### **The lack of international regulation**

Currently there is no international, legally binding, instrument that applies to biobanks. Instead, biobanks are nationally regulated, through a combination of general and specific laws and oversight bodies, all of which differ greatly from one another. There is a need for a clearer framework and for tools to facilitate the exchange of relevant information.

From GMP to GBP is funded by



Project partners



Institut national de la santé et de la recherche médicale



# From GMP to GBP: Biobanking

## Informed consent of donors

As described in the [Nuremberg Code](#) and the [Declaration of Helsinki](#), the principle of informed consent has largely been recognised and is considered a pillar in the practice of bioethics. Although it does not in itself protect a person, informed consent allows individuals to exercise their fundamental right to decide whether, and how, their body, body parts and associated data can be used in research. The principle of informed consent is applicable for any research on human beings or on human material.

However, how is consent to be given? In general, blanket terms? Or are there some operations (transfer to another country, new kinds of experiments, another domain of application, etc.) where consent should be repeated? For what length of time is consent valid? It is also important to point out that whilst one might assume that most donors are anxious that their samples not be used broadly without their consent, others are anxious about the opposite: that their sample be used as much as possible to help.

## The property rights of an individual

Two issues must be addressed regarding property. The first is the individuals' right concerning their own biological material. The legal approaches to property rights cannot apply and should be adapted for biobank activities. In general there are no property rights on biological samples, as they are body parts that should not be placed in the commercial circuit, but individuals retain a right of control over the use of their body parts.

The second is collaboration between academic researchers and private companies in the development of biobank research. Here, the question of ownership of the collections and intellectual property rights needs to be addressed.

## Confidentiality

Addressing the confidentiality issue is central to current legislation on biobanks. From the storage of human biological material to its exchange among researchers, confidentiality must be protected.

## Access to data

To encourage the production of useful data for research, the number of people available and therefore the number of related samples is increasing. However, the policy by which access is determined needs to be inclusive and systematically defined for each biobank and communicated to the participants at the time of consent, or as early as possible.

## Recommendations

Biobanks make substantial contributions to research both by validating the biological importance of previous findings, identifying unknown causes of disease and testing new drugs. To ensure future advances in understanding diseases and their cause, there is a real need to establish a common ground on biobank research.

## Definition

Finding a definition of the term "biobank" that all Member States could accept is the most pressing issue. Without this, it will be difficult to agree on a common framework and consequently on regulations.

**1 ► The consortium recommends that the EU Commission establishes at EU level an agreed definition of biobanks used in research. This could be done as part of an infrastructure programme (ERI: European Research Infrastructures<sup>1</sup>), biobanks and biomolecular resources programme (BBMRI: sBiological and BioMolecular Resources Infrastructure), or as a recommendation by the EU Parliament, or as part of the Framework Programme. In addition, the EU should foster the use of a unified vocabulary regarding anonymisation and degree of identification, and more specifically that agreed by the ICH and the EMEA.**

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<sup>1</sup> ERI : ECRIN European Clinical Research Infrastructure Network [www.ecrin.org](http://www.ecrin.org), BBMRI Biological and BioMolecular Resources Infrastructure [www.bbmri.eu](http://www.bbmri.eu), EATRIS European Advanced Translational Research InfraStructure in Medicine [www.eatris.eu](http://www.eatris.eu)

## Legal Frameworks

Biotech companies expressed the wish to operate in a stable legal framework with clear rules on how to operate. They agreed that researchers and companies active within biobanking need a clarified legal framework with regard to privacy issues, quality of results, how to collect, store and use samples, and how to share cross-border samples.

A number of projects funded by the EU Commission have examined various aspects of ethical and legal frameworks for biobanking. However, the results are not easily available in a practical form which can be used by the biotech industry.

### **2 ► The consortium recommends that:**

**1) The EU Commission organises coordination of results on ethical/legal aspects of biobank projects and promotes the implementation of a common format and of a central database, or document deposit, that would make them usable in practice.**

**2) The EU Commission promotes an EU policy with regard to sharing bioresources and corresponding data that guarantees both protection of individual rights and optimal use of resources, and lays down adherence to this policy as a rule for receiving funds from the EU.**

### **3 ► The consortium recommends that the EU Commission creates a unified framework for biological samples and associated data used in research.**

The lack of uniform application forms sent to the Ethics Committees and their subsequent evaluation also needs to be addressed. Discussion with the European Network of Research Ethics Committees ([EUREC](#)) would help to reach consensus among different Member States. Harmonization through the action of the Research Ethics Committees is important to accommodate the different legal frameworks existing in Europe with regard to biobanks.

### **4 ► The consortium recommends that the EU Commission intensifies efforts to coordinate Research Ethical Committees for biobanks and aspects of clinical research across Member States; this could be done in conjunction with the relevant ERI (European Research Infrastructures).**

## Informed Consent of Donors

Consent for samples and data given to biobanks should be codified at the European level in order to facilitate studies. Participants should have the right to decide whether their data or samples can be distributed to other institutions or other countries. They should be asked either, and ideally, at the moment of the donation, or afterwards. If participants cannot be contacted (anonymous donation, deceased, no known address, etc.) an Ethics Committee should rule. This should also apply if the samples or data are used for other purposes not foreseen at the moment of donation, and so not covered by the original consent process.

### **5 ► The consortium recommends that all projects at EU level address the issue of long-term and further use for collections of samples and data as a condition to obtaining EU funds (for setting up collections, or using them), or for being part of any ERI; specific provisions should be clearly stated and mentioned in the information and consent forms.**