

From GMP to GBP*

Fostering Good Bioethics Practices Among the European Biotechnology Industry

Genetic Testing

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 Association of Bioindustries, 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

Genetic testing is one biotech application that has attracted the most attention as regards ethical aspects and the corresponding framework. The indications concerning best practices for research in genetics and for pharmacogenetics are less clear than for clinical diagnostic genetics. The present challenges are anchored in new developments. They include:

- high throughput techniques generating large amounts of data,
- uncertainty on the clinical significance of much preliminary genetic data,
- limits of patentability,
- assessment of clinical utility and return of results to research participants.

In addition, during the period of the present project, the considerable development of direct-to-consumer genetic tests has generated a need to consider regulation in this domain.

At present, there is no universal standard definition of genetic testing. A broad definition was used by the projects' EU expert group for genetic testing, "*any test that yields genetic data*". Genetic data or information relates to inherited or acquired properties that are transmitted during cell division and that affect subsequent generations of offspring, or cells and tissues. This definition needs to be specified.

As no general ethical and regulatory frameworks exist, considerable divergences remain as to ways of taking into account the development of genetic testing. In general, this activity is not yet regulated within the EU Member States. Nor are there any specific rules or framework for validation of genetic tests, including pharmacogenetic tests at EU level.

*GMP to GBP - Good Management Practices to Good Bioethical Practices

From GMP to GBP is
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From GMP to GBP: Genetic testings

There should also be measures taken to prevent undesirable consequences in society as a result of genetic testing, including:

- greater public information and education,
- an assessment of validity (in particular of the clinical utility of tests)
- ensuring there is information on existing validated tests,
- genetic counselling on clinical utility and
- conditions of access.

Confidentiality, privacy and autonomy need to be considered. Protection from discrimination, irrespective of confidentiality issues, applies to genetic data as it does to other data. Personal medical data including genetic data must not be used to discriminate against individuals, including with regard to ethnicity.

Recommendations

This section presents recommendations arising from the *From GMP to GBP* project regarding genetic testing.

1► The consortium recommends the use of the definitions for genetic testing given by the Council of Europe additional protocol to the 'Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes' (2008) and the ICH definitions of pharmacogenetics and pharmacogenomics that was adopted by the EMEA and the FDA

2► The consortium recommends that clinical utility must be assessed as a paramount element for introducing new genetic tests into health systems. For this purpose, an independent EU authority in charge of quality control and validation of said tests will be needed.

3► The consortium recommends that a curriculum for genetic counselling should be agreed upon at EU level, and that conditions in which the results of genetic testing are delivered be properly defined.

4► The consortium recommends that an approval for DNA/genomic data storage used for testing be created in order to ensure professional control and greater confidentiality.

5► The consortium recommends that:

- 1) The EMEA continues to establish guidelines for pharmacogenomic tests and their validation;
- 2) The EU Commission establishes a policy for using and sharing data from genetic research projects (EU funded; but this policy would be a reference in Europe)

6► The consortium recommends that there is broad communication with patients and the public so that they understand the difference between personalized medicine and discrimination.

7► In order to develop a European position, the consortium recommends that:

- 1) The EU Commission should establish specific projects to debate ethical and societal issues surrounding direct-to-consumer genetic testing, involving a variety of stakeholders including the industry;
- 2) The question of direct-to-consumer genetic testing should be introduced in Eurobarometer surveys, and the European Parliament should act regarding direct-to-consumer genetic tests.



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