

From GMP to GBP*

Fostering Good Bioethics Practices Among the European Biotechnology Industry

Clinical Trials

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

Medicinal products need to be tested scientifically before widespread use. The clinical trials required for this purpose should be carried out under conditions affording the best possible protection for the subjects who are included.

Clinical studies are necessary research experiments on human beings. A strict methodology is applied in order to ensure that the design of the trial 1) has the highest chance of leading to a relevant conclusion, while at the same time 2) provides adequate protection of the rights of the individuals being included. Ethical aspects are fully embedded in the methodology of clinical trials. Without such ethical trials there would be neither new medicines nor new or improved treatments for patients. Participation in such research must be voluntary and based on fully informed and free consent. Protection of participants takes priority over the interests of researchers and society. In the carrying out of clinical trials there are also several key issues that need to be resolved.

There is an urgent need to develop a coordinated, synchronised approach to innovative therapy in Europe since the early initiatives to harmonize the clinical trial regulatory framework, the EU Clinical Trials Directive 2001/20, are at present inconsistent. This inconsistent implementation of Directive 2001/20 in EU Member States results in unnecessary complexity of multinational clinical trials. The diversity of Member State implementation of the Directive has resulted in particular difficulties for organizations facing different obstacles in different Member States. This has made Europe less attractive and as a result early clinical trials, in particular, are being done outside Europe.

Another issue is the fact that patient information to obtain informed consent has led to extremely complicated documents, looking almost like contracts. These documents are too long, too detailed, too scientific and too difficult for the average person to understand.

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From GMP to GBP: Clinical Trials

In trials for advanced therapies and surgery there are some difficulties in controlling the quality of the steps for manufacturing / preparation, in particular for biological products. There are very few formal clinical guidelines for surgery. This is an issue when efficacy of treatment is highly dependent on a surgical act. The absence of correct quality control of the administered investigational product / surgery represents a potentially lethal risk for patients.

Recommendations

1► The relevant EU institutions consider the need for legislative change of Directive 2001/20 in order to bring about better harmonization, transparency and consistency in the approval and undertaking of clinical trials across the EU; this might require a specific instrument such as a Regulation for clinical trials.

It is important to note that it is not more rules that are requested, but rather harmonization of those already existing.

2► As an approach that could reduce the approval period, the content of the Clinical Trial Authorisation (CTA) dossier should be made identical in all EU member states.

3► The EU Commission takes the initiative of a survey across Members States in order to explore practical possibilities for simplification of the Ethics Committees approval procedure for multinational studies within EU. It should be possible to make one common application to several Ethics Committees, to send a common application form and to get a common result of the evaluation in several EU countries.

4► The EU sets up a taskforce to produce harmonized guidelines on content and structure of consent, taking into account, in particular, the UNESCO International bioethics committee on consent (2008). The overall goal being to simplify the presentation of informed consent.

5► The interaction between Competent Authorities and Ethics Committees is not well established and varies from country to country. Harmonization between Member States is requested rather than a centralized EU Ethics Committee.

1) Ethics Committees need a system of accreditation or certification by a suitable EU structure.

2) For the purposes of implementation of clinical trials, Member States should take the measures necessary for the establishment, accreditation and operation of Ethics Committees.

6► All personnel involved in clinical trials including Competent Authorities, Research Ethics Committees, sponsors and investigators should be EU qualified by means of education and training.

7► In the case of clinical trials that cannot be designed double-blinded, protocols must respect a strict and explicit methodology such as evaluator-blinded.

