

Presidenza del Consiglio dei Ministri



Pharmacological trials in developing countries

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Abstract

As part of the growing process of globalization, there are frequent international multicenter clinical trials which involve the relationship between developed and developing countries. What has emerged with ever increasing frequency is the concern that the "relocation" or "outsourcing" of the experimentation is activated to reduce costs and simplify paperwork, in order to facilitate the rapidity and finding of "bodies" to be used to penetrate new markets. This leads to the fear that commercial interests could hide behind scientific interests and may take precedence over respect for fundamental human rights, resulting in forms of bioethical 'colonialism' and 'imperialism', unfair exploitation and manipulation due to the differences in scientific-technological knowledge and socio-economic and cultural inequalities.

The NBC document, starting with an analysis of documents and international guidelines, highlights various elements of ethical importance, with particular reference to the clinical justification for the research in the country in which experimentation is conducted, community consultation, informed consent, confidentiality, the protection of the safety and health of participants, the testing of non-communicable and communicable diseases, the use of placebo, the duty of solidarity during and after the trials, 'social ecology', and the role of ethics committees.

The NBC recommends that research should be oriented according to the common ethical criteria considered essential to avoid any form of discrimination in order to ensure health and global justice, and reduce inequality. It stresses, in addition, how international experimentation should constitute a specific sphere within the context of a broader promotion of the defense of fundamental human rights as a whole, with particular attention to the specific needs of populations in particularly vulnerable conditions.

The Committee believes that research should avoid hidden forms of involvement that take 'advantage' of a lack of awareness or state of need and should take into account the health requirements of the population, with solidarity, ensuring to the research participants and, hopefully, to the population as a whole, appropriate assistance even after the experimentation.