Clinical research in developing countries should follow international recommendations aiming to the protection of participants.

A.L. Knellwolf (1), S Bauzon (2), S Vella (1)
(1) National Institute of Health, Rome. Italy (2) University of Tor Vergata, Rome. Italy
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Introduction

Methodology
Review of the international legislation/guidelines. Barriers and opportunities arising from the implementation of these international recommendations.

Results
Ethical principles for biomedical research expressed in the Declaration of Helsinki, the Universal Declaration on Bioethics and Human Rights, the Convention on Human Rights & Biomedicine, the European Charter of fundamental rights are fully applicable to clinical trials performed in developing countries. These principles are enforced by law in all EU countries. A specific guidance on Ethical aspects of clinical research in developing countries states that: …the scientific and ethical evaluation of the research protocol should be carried out by ethical committees from all countries involved. Host countries need to have a legal and ethical framework.The relevance of the research should comply with health priorities of the host country; the risk/benefit ratio at the individual and the community level; the impact of the project after its completion…
In case of non respect of this ethics principles, international scientific journals will not published clinical research. The marketing authorization delivered by the European Commission can also be refused .

Limits that deserve specific efforts:
French ethics committees (ECs) are by law, so far, not allowed to evaluate studies conducted in emerging countries. In Europe, ECs requirements are not harmonized for multi-national trials. Most developing countries have to face: research ECs accreditation procedure implementation; limited inspection & regulatory capacity; lack of support for local infrastructures; insufficient resources for education and training. No regular monitoring and examination of the balance of risk and benefit. Complexity of the informed consent process because of cultural environment and educational standards.
Insurance coverage for clinical trials is a matter of concern for the sponsor and physicians in charge of patients enrolment.

Conclusion: Implementation of biomedical research in developing countries respecting all the ethical rules remains therefore very challenging. Sharing the best practices among stakeholders with a multidisciplinary approach, trust confidence and self respect may be an opportunity for all actors.