Guido Rasi, Executive Director, AIFA

In welcoming all the participants to the Round Table today, I would like to underline the reasons that induced the Italian Medicines Agency to support this initiative and the general framework in which it falls.

The Italian Medicines Agency is a regulatory institution, and as such, among its main duties, it authorizes the marketing of drugs, on the basis of the results of clinical trials that show their efficacy and safety.

The recent and progressive increase in the number of clinical trials conducted in developing countries is determining an increase in the request for authorization of marketing for drugs the efficacy data of which are based on clinical trials conducted in developing countries.

The acceptability and reliability of those data depends, as envisaged by the national law and in line with the European Directive, on two factors:

1. That the clinical trials are conducted according to the ethical principles of the Good Clinical Practices
2. That the clinical trials are conducted according to the scientific and procedural principles of the GCP.

As the experts know, GCP is "an international ethical and scientific quality standard for designing, conducting, recording and reporting trials. Compliance with the standard provides public assurance that the rights, safety and well-being of trials subjects are protected,

consistent with the principles that have origin in the Declaration of Helsinki and that the clinical trials data are credible".

Among the ethical principles of the GCP to which the clinical trials have to conform in any country in which they are conducted, two have a fundamental relevance:

1) a trial should be initiated ad continued only if the anticipated benefits justify the risk;

2. the rights, safety and well-being of the trial subjects are the most important consideration and should prevail over interests of science and society.

Also the scientific and procedural principles of the GCP contain ethical considerations:

They state in fact the necessity that

1. the clinical trials be scientifically sound and described in clear, detailed protocols;
2. the protocols have received prior independent ethics committees approval
3. the trials be conducted in line with an approved protocol.

It is evident that the lack of these elements that ensure the scientific and methodological appropriateness of the trial represent a risk for the safety of the trials subjects and translates into a lack of protection of their fundamental rights.

What I said applies to any country, irrespective of whether it is developed or under developed and its compliance will be the more higher, the more the following instruments are in place:

1. Laws that permit the marketing of drugs only if duly authorized and that sanction any violations;

2. Laws that permit trials of drugs only if previously authorized and that sanction any violations;
3. The actual existence of Research Ethics Committees, that can be truly independent and professionally sound;
4. Systems of control of clinical trials while they are being conducted, through the use of GCP Inspectorates.
5. Laws that envisage the possibility of refusal by the Regulatory Agencies to authorize marketing of drugs for which safety and efficacy has been shown through trials which are not conducted according to the GCP principles.

Numerous initiatives by International, regional and national organizations have been launched to collaborate with the developing countries in order to implement the points above mentioned.

These initiatives, that obviously only partially can be illustrated and discussed in this Round Table, in many instances are implemented without having a clear picture of what has been already done, what are the results and what is being done in the same geographical area, in the same field of study etc. As a consequence, there could be little knowledge of neglected areas of intervention or of the necessity for complementary interventions that can be more effective.

The Italian Medicines Agency, in collaboration with UNICRI, have considered the necessity to start a process, with this Round Table as a first step, to bring:

1. a reciprocal knowledge of what is being done in this field;
2. an evaluation on what has been done to date;
3. a continuous update on what is going to be done.

In other words, the Italian Medicines Agency, in collaboration with UNICRI and the other international organizations, the developing countries, the European Union and non European Union countries as well as the NGOs, aims to create a Clearinghouse Service that can provide a continuing assistance to professionals working in this field or who are directly or indirectly involved in the field of clinical trials conducted in developing countries.

This service will provide assistance for example to the different developing countries, beginning from those countries in Africa on which AIFA and UNICRI have carried out a research study that will be presented later in this meeting, the following information:

1) The laws and regulations governing this field for each country;

2) The existence of Research Ethics Committees and GCP Inspectorates

3) The existence of centres or research groups with experience on conducting trials according to ethical principles of GCP, as shown by favourable reports from GCP Inspectorates

4) The existence of investigators that have followed training in GCP and in bioethics

5) Other elements that will emerge in the implementation process.

In this way, this service will allow the professionals to be up to date on the latest developments in the field as occurring in developing countries and will be useful in these circumstances:

1. An international, regional or national organization or a NGO wants to support a country through training programmes for investigators or for members of ethical committees or GCP inspectors.
2. A regulatory agency needs to verify the compliance to the principles of GCP for a certain clinical trial;
3. A scientific institution or a pharmaceutical company wants to conduct a clinical trial
4. A qualified institution wants to provide a consultancy for the issuance of regulation in the field and so on.

The implementation, the development and the immediate update of a map is also necessary that visualizes this type of interventions already adopted and/or planned in this field; a description of the normative situation and the organization of the clinical trials, a report of data on

the real efficacy of such interventions and of the obstacles encountered, as the round table will partially illustrate.

It is hoped that this will provide a useful support for implementing interventions that can be more targeted to the real needs, more selective, and complementary and avoid duplication. The interventions should be in fact defined on the basis of the results of the experiences already carried out with success, to contribute to the process of obtaining a research on drugs that respects the ethical and human rights principles.