

CULTURAL UNDERSTANDING IN THE CLINICAL TRIAL SPACE

Dr Narges Mahaluxmivala

President, Clinical Development Services
Quintiles India

It is anticipated that major pharmaceutical companies will outsource a large proportion of their clinical trials to non-traditional research geographies and there is every likelihood that a substantial number of clinical trials will be directed India-wards. Though a developing country, India has a rapidly growing healthcare infrastructure and a technologically advanced and already globally competitive pharmaceutical industry. With 16% of the world's population, a booming economy, high medical expertise, varied disease patterns and socio economic changes in urban areas associated with increasing education, it should not be surprising that India will see accelerated growth in the number and complexity of clinical trials that enter India. Having said this, it is only the naïve who will be complacent in regard to India's degree of preparedness to deal with increasing activity in the clinical trial space and it is realized that capacity building is to be considered on an urgent basis. It is encouraging that this is being acted upon through both government and industry initiatives.

An aspect which has not received adequate consideration is that of cultural diversity in the world and its impact upon globalization of clinical trials. When the sponsor of the clinical trial programme is in one geography and the sites are in different geographies with different disease burdens or differently perceived disease burdens, a number of questions surface – and a large number of them will be ethical in nature. Not only do the questions refer to the suitability of the study population for the clinical study, but often extend, among other aspects, to actual or perceived differentials in standards of care, real or perceived differentials in attitudes of the stakeholders to risks and benefits, provision or not of therapy in the post trial period and approaches to the informed consent process.

In the contemporary globalizing world when multicountry clinical trials will be increasingly considered, host country and sponsor country approaches to a given clinical trial call for acceptance of the cultural diversity that exists in different geographies. Cross country and cross cultural sensitivity will result in mutual benefit.

Culture is probably the most basic distinguishing factor between people of different geographies and also of societal groups within a geography. This paper briefly discusses the impact of culture on a multicountry clinical trial.

As always, a good starting point is a clear definition of the word. In the case of culture, this is not easy, probably because culture has an emotional dimension which is all-pervading. It should therefore be easily believed that a large number of descriptions of culture exist. There are commonalities of course and these are given below

- Specific Beliefs to which are attached Specific Values
- Specific Patterns of Behaviour
- Transmission of these Beliefs and Behaviour Patterns from the older members of the group to the younger over generations
- Occurrence of emotional reactions when expected roles and behaviours are not observed.

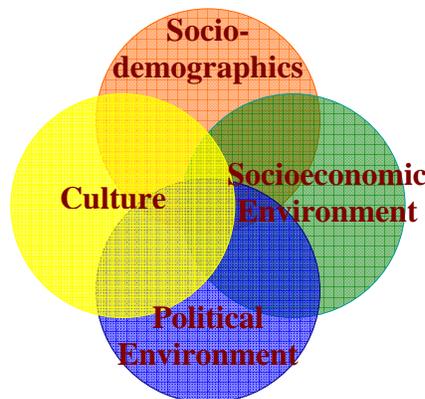
Included in the above are specific perceptions of gender roles and prescribed attitudes to seniority, to distribution of power, to uncertainty/ambiguity/risk-taking and to individualism and collectivism.

Culture is accepted to be an important determinant of ethical and social values that are held by a group of people in a geographical region. Global businesses already recognize that ethical and social values influence decision-making in a given situation and are putting in place training programmes to appropriately sensitise employees from different geographies to these aspects. In a clinical trial, which takes place in a healthcare setting which already is more emotion-laden than a business setting, it is realistic to accept that the culture or cultures of a geography would play an even greater role. For comprehensive cross cultural and cross country understanding and in order to arrive at informed decisions on clinical trial-related issues, it is important for both the sponsor country and the site countries to understand the social/cultural contexts within both geographical regions.

Culture causes people to instinctively think and respond in a particular manner which will be acceptable to most within the social and societal group they belong to, due to a mindset established over generations. At the same time, it cannot be forgotten that culture is influenced by and interacts with other people-related aspects. Therefore when societal factors undergo change, usually through political and economic influences, culture gets modified. Education, socioeconomic advances and increasing exposure to other cultures, become major enablers of cultural change, especially in rapidly developing countries like India. In contemporary India, the influencing factors operate to a greater extent in urban India compared with rural India and may be a contributory reason to the urban/rural differences often observed.

**Culture –
Influencers**

Interactions &



In the clinical trial setting, the informed consent procedure is an example to illustrate a cultural difference, though there are other aspects that could also be considered.

India is not an individualistic society – there is collective autonomy of a particular group, - family, village, region, community but individual autonomy may not be given the same relevance in society as in developed countries today. Roles for men and women in society may be culturally prescribed. India's geographical size and differentials in education and in exposure to other countries and culture cause these to be practiced differentially in different parts of the country.

In the clinical trial context, a decision to participate or not in the study will be considered important enough for a collective decision to be taken (if the potential subject is a woman, there may be a request to consult with her husband or an older male member of her societal group). Such requests are not unusual. It is important that the investigator realizes this and allows time and opportunity for the prospective subject to have such discussions. Though it is rare that the family will coerce a proposed subject to enter the study against her wishes, the investigator will do well to ascertain through questioning whether the decision is also agreed to by the participant.

A clinical trial endeavours to minimize variables – therefore a multicountry study, especially in the contemporary global environment which seeks increasing collaboration between sponsor and host countries, should ideally not encounter differences of any kind between participating geographies. Cultural distinctions between geographies, though changing in degree and relevance because of economic development, education and reasoning, may not permit them to disappear.

To put the differences into perspective and decide on degree of significance, the Ethics Review Board plays a role of paramount importance.

It is imperative that the Ethics Review Boards of contemporary clinical trials accept the responsibility to bridge and balance the cultural differences if they are present. It is the Ethics Review Boards which should decide on the differences and the degree which would be permitted in a given case and the Boards need to develop capabilities to do so. The Boards require members who take broad perspectives against a background of global GCP understanding and practice. Justice M. N. Venkatachalliah's view points in the foreword to the Ethical Guidelines for Biomedical Research on Human Subjects issued by Indian Council of Medical Research, New Delhi in 2000 are of the utmost importance. A few lines are excerpted below.

“Biomedical Research raises delicate and difficult issues of ethics which need to be dealt with sensitivity to human values and great circumspection.”

“Biomedical Research is perched on the threshold of a bold and brave new world. Crucial to its management is the ability of scientists and society to handle these forces of change.”

In conclusion it is emphasized that inter-country differences in attitudes, understanding and interpretation in specific, people-related aspects of a clinical study may have a cultural basis and are the natural consequences of a cultural mindset established over generations. Such cultural mindsets change with economic development and exposure to other cultures, but the process cannot be expected to be dramatic. A greater emphasis on cross country and cross cultural sensitivity will reveal that certain differences between geographies exist because of a cultural basis and do not reflect lower ethical standards.

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