



Bioethics Position Statement: Multinational Clinical Studies

Eli Lilly and Company is a global biopharmaceutical company serving the medical needs of a global population. Multinational clinical studies (studies conducted in more than one country) are necessary for understanding how best to address global medical needs and for understanding how genetic and environmental diversity may impact the safety and effectiveness of investigational medicines. Multinational clinical studies also provide a means to satisfy global regulatory requirements because many countries require local clinical studies before a medicine can be approved for local use.

Regardless of where clinical studies are conducted, Lilly places paramount importance on the safety and well-being of individual clinical study participants. Lilly uses a single global ethical standard that applies to the conduct of clinical studies to ensure that clinical study participants are protected and that there is fair distribution of the benefit and burden of research across various geographies. This global standard incorporates basic ethical principles and essential elements of ethical research, and is consistent with: i) ethical principles derived from international ethics guidelines; ii) scholarly literature in the field; and iii) applicable laws and regulations of the country or countries where studies are conducted. The global ethical standard is integrated into global quality standards, thereby ensuring studies are conducted in a manner that will protect clinical study participants' rights and well-being and yield scientifically reliable and socially valuable data.

In choosing locations to conduct clinical studies, Lilly considers i) the local prevalence of the disease under study, ii) the relevance of the research to local or community health needs, iii) the potential for the research to yield important scientific advances, and iv) the risks and benefits for research participants and the host country or community. Lilly only conducts clinical studies in countries or communities in which the benefits of research can be made reasonably available for research participants and the host country or community.

The primary benefits of pharmaceutical research are the knowledge generated and the medicines developed. Lilly commits for all its clinical trials i) to disclose the research results in a public forum (e.g., clinical trial registry and/or medical journal) that is accessible to local professionals; and ii) to proceed with a clinical trial only when it has a good-faith intention to make the product developed commercially available to the population of the host country or community in which the research is conducted. Making the benefits of research available is necessary to be responsive to the health needs of the host country or community.
