
Bioethics Position Statement: Choice of Control in Clinical Trials II: Use of Active Control

Part of ensuring the scientific validity of research is designing trials that have sound methodology. Therefore studies that measure differences among active treatments should be designed to make fair comparisons.

An active control is an agent used as a comparator in a clinical trial that is presumed to have beneficial effects related to the disease being studied. Use of an active control is often considered scientifically necessary to obtain valid comparisons between two or more treatments. However, Lilly wants to ensure that trial outcomes from an active control trial are not biased by selection of an ineffective or inappropriate active control (i.e. control group).

To protect against biased comparisons, Lilly follows these rules:

- The active comparator generally should be an established effective treatment (considering type of comparator, dosage, dosage regimen, and formulation).
- The patient population studied should not be known to be significantly less responsive to or treatment resistant to the active comparator.
- Trial objectives should not be selected as to give an advantage to the investigational treatment.

Lilly makes the decision to use an active control after giving careful consideration to several factors, including the severity of the illness, the adverse event profile of the investigational treatment (i.e. potential for harm), and the scientific and regulatory objectives of the trial.
