



Bioethics Position Statement: Continued Access to an Investigational Medicine

Commercial access to an investigational medicine is achieved once it is proven safe and effective and is approved by regulatory authorities. Sometimes an investigational medicine is not locally commercially available at the conclusion of a clinical study and as a result, clinical study patients who are benefiting from an investigational medicine are not able to access the treatment. Therefore, under certain conditions (listed below), Eli Lilly and Company may offer continued access to an investigational medicine after a patient's participation in a clinical study has ended.

Because investigational medicines are unproven treatments with unknown long-term risks and benefit, and because individual benefit during a clinical study does not guarantee continued benefit, it is not appropriate to provide continued access for every patient who participates in a clinical study. Lilly may offer continued access to an investigational medicine when all of the following conditions are satisfied:

1. The disease or condition being studied is serious or life threatening.
2. The patient is benefiting (with no undue risks), and discontinuation of treatment might adversely affect the patient's health or well-being.
3. There are no other suitable treatment options for the patient.
4. Sufficient efficacy and safety data exist in order for Lilly to make a reasonable assessment of a favorable benefit-risk balance.

An offer of continued access to an investigational medicine will be made in the context of a clinical study setting in accordance with local regulations. This context provides for proper safety monitoring and evaluation of continued benefit for the individual. Expected duration of continued access should be specified and communicated to clinical study participants prior to their enrollment in a study.
