

Can I Stay on a Study Drug?

In some special cases, you or your child may be able to stay on an investigational treatment once the trial is over.

If you or your child are participating in an early phase of a clinical trial, you probably will not be allowed to continue the treatment being tested. Researchers will need to analyse the study results to ensure that the treatment is safe, effective, and better than current treatments. It would not make sense to continue the potential treatment until this process can be completed.

Open-label Use

Some clinical trials have what is called an open-label extension study, which means the doctors and participants know what treatment is being provided. This study typically occurs after a Phase 3 clinical trial, usually the last clinical trial before a drug is approved. This trial is intended to gather more information about the general risk-benefit of the drug and how to administer it so that additional safety information can be gathered about long-term use as part of scrutinising the treatment for approval.

Expanded Access

The study sponsor can provide expanded access (sometimes called compassionate use) to a new treatment to patients with serious or life-threatening conditions who do not meet the enrolment criteria for the clinical trial. Government regulations allow manufacturers to provide the drug as long as it does not pose unreasonable risks to the patients and the patients do not have any other options.

Approved Drug Being Tested for CF

Some CF clinical trials test drugs already approved for another use. If the government regulatory authorities have already approved the drug your CF doctor can prescribe it to you after your participation in the trial has ended.

How the Pipeline Fits In

CFA maintains a robust pipeline of therapies that target CF from every angle. The progress of these therapies can be tracked by using its interactive Drug Development Pipeline tool. The pipeline shows each major category of therapies and although the pipeline is not comprehensive it provides a valuable and broad snapshot of drugs under development.

At a glance, the colourful bar chart shows how far a drug has advanced through the phases of clinical research. Here is how you can use it:

- Click on the name of each drug category to see a definition of the category.
- Click on the name of the drug to get a quick overview of what the drug does, the current phase and recent changes.
- Click on the Clinical Trials tab, and you can find information on whether trials are recruiting, in progress or completed.