



# What Happened with my Clinical Trial?



When a clinical trial ends, most volunteers are curious to know what came of their efforts. After spending time participating in a trial—and perhaps hoping for a new treatment—it's natural to want to hear about the results.

The Food and Drug Administration (FDA) recognizes that participants and the public have a right to know about clinical trial outcomes. As a result of the FDA Amendments Act (FDAAA) passed in 2007, companies that conduct trials have to do a better job of making results available and understandable to the public.

Starting March 2010, trials sponsors will be required to post expanded study results that include a lay summary—written for people who aren't scientists. These results will describe the data from the trial, the protocol (study design) and the quality control procedures used throughout the study.

Some steps have already been taken as a result of the FDAAA. Currently, the results of many completed trials are available to the public through sites such as [www.clinicaltrials.gov](http://www.clinicaltrials.gov), [www.searchclinicaltrials.org](http://www.searchclinicaltrials.org), and others. Those results include demographic and health-related characteristics of the patients who participated in the trial, including the number who dropped out and the number who were excluded from the analysis, if any, as well as the outcomes.



But starting next March, the studies published will be much more user-friendly.

There is still time before clinical trials in lay language are routine. Meanwhile, CISCRP will help by presenting another in a series of clinical trial results for people who want to know more about trials outcomes.

## Gleevec Clinical trials update

More than 10,000 patients participated in over 200 trials of Gleevec, made by Novartis Pharmaceuticals. The majority of patients had Philadelphia chromosome-positive chronic myeloid leukemia (CML). Many of these patients also had gastrointestinal stromal tumors (GIST), a very rare form of cancer that Gleevec targeted. Expected survival for most patients was about 5 years.

Gleevec clinical trials made important, life-enhancing improvements to cancer treatments. Volunteers who participated played a key role in developing a very effective treatment for leukemia and other cancers, which is now available to patients in over 90 countries.

“The vast majority of patients entered not to help register the drug, but under an expanded access program,” says Laurie A. Letvak, MD, of Novartis Oncology, East Hanover, NJ. “It had such fantastic efficacy that we had to make it available to patients before it became commercially available.”

## Key findings

- Gleevec was originally approved in May 2001 for treating advanced stage CML.
- In February 2002, Gleevec was approved for the treatment of GIST, and was shown to be very helpful in extending the lives of patients with advanced GIST. According to Letvak, “With GIST, we literally had people in hospice who responded and were still doing well about 5 years later.”
- Most patients in the early trials that tested Gleevec for safety showed some improvement at low doses of the drug. The first improvement seen was a reduction in white blood cell count, which showed that there was less disease present for the body's immune system to fight. Also, at a dose of 300 mg. to 400 mg., abnormal chromosomes associated with the disease began to disappear. This made it less likely that new disease cells would be produced.
- Later Gleevec trials showed that the drug was effective for Ph+ acute lymphocytic leukemia (ALL). At the end of 2005 Novartis filed for approval in the US and Europe for use of Gleevec in treatment of ALL.
- Because Gleevec showed potential in other subsets of patients, approval is being sought to use Gleevec in several other cancers, some rare.
- Thanks to the Gleevec trials, more cases of GIST are being diagnosed, which means that patients are getting treatment sooner.
- Gleevec trials prompted researchers to start examining genetic mutations that happen in the advanced stages of CML. Looking at these mutations helped them learn more about what happens as cancer progresses.
- Gleevec has enabled major long-term improvements in many patients' lifestyle. Patients report that they can travel, work, and lift weights with few or mild physical complaints.