A Patient's Story

For Coard, One Trial Wasn't Enough

"When the train stops and there is nowhere else to go, you're at Hopkins."

That's how Coard Simpler describes the Baltimore subway. But he might just as well be describing his experience with the clinical trial process.

In 2000 Coard was diagnosed with chronic myeloid leukemia (CML). After undergoing more than six months of chemotherapy, which left him thin and exhausted, the 55-year-old retired banker agreed with his doctor: it was time to try something new.

On December 22, 2000 Coard went to Johns Hopkins to join a Phase 3 Novartis trial for STI571, also known as Gleevec. The protocol was simple: two pills twice a day with water. Coard was to record any side effects in a journal, visit the clinic twice a week and have periodic bone marrow scans.

"I still remember the nurse walking down the hall with the bag of pills," he says. "I remember looking at that bag and thinking, 'She's holding life in that bag.'"

The trial wasn't easy. The Gleevec "beat up my red cell count," says Coard, who had to undergo a platelet infusion and take medications to boost his red cell production. What's more, the protocol called for frequent bone marrow tests which left Coard feeling stiff and sore.

Despite the side effects and the painful tests, Coard says the researchers were attentive and caring. "They treated me like I was a special person."

Thirteen months after he joined the trial, Coard was in remission. Encouraged by his positive experience, Coard agreed to participate in two additional Hopkins trials: a vaccine trial for CML patients who still had measurable cancer cells despite taking Gleevec for at least a year and a subsequent booster trial. Toward the end of the booster trial, however, Coard began to develop a resistance to Gleevec: the cancer cells were growing again.

Coard sought help from Dr. Carole Miller at St. Agnes Hospital in Baltimore who was running a trial on a new Novartis drug called Tasigna aimed at helping patients who had become resistant to or could not tolerate Gleevec. Just weeks after Coard joined the trial in fall 2007, Tasigna received FDA approval and Coard was back in remission.

Today, Coard's leukemia remains in remission. He still takes Tasigna, but at a lower dose. The reduced dosage has helped alleviate the rash and dry skin he was experiencing as side effects of the medicine.

"My story is a message of hope and gratitude," says Coard, who still cherishes the brown paper bag that contained his first dose of Gleevec. "My clinical trial experience showed me that there are people who paid attention in science class who are looking in test tubes and microscopes every day and we all need to be grateful for that."

What are the different types of clinical trials?

A clinical trial is a research study involving human volunteers. Trials are conducted to find and test ways to improve our health. Trials can be conducted in a variety of different settings, including hospitals, universities, community clinics and doctors' offices, and fall into a number of different categories:

- **Treatment** trials test new or modified treatments, new combinations of drugs or new approaches to surgery or other procedures.
- **Prevention** trials look for better ways to prevent a disease from occuring or returning with medicines, vaccines, vitamins or behaviors.
- **Diagnostic** trials are conducted to find better tests or procedures for diagnosing a particular disease or condition.
- **Genetic** trials look for links between human DNA and health conditions.
- **Epidemiological** trials study patterns of disease in different populations.
- **Quality of Life** (or Supportive Care) trials explore ways to improve comfort for people with chronic illnesses.

To safeguard volunteers, trials are conducted in step-by-step phases. Before conducting research with human volunteers, researchers conduct pre-clinical trials to study the treatment in a lab or on animals. If the preclinical research is promising, researchers move forward with human testing.

Phase I trials are used to establish the effects of a new treatment on humans. Phase I trials are usually conducted on a small group of healthy people to evaluate a medication's safety, determine a safe dosage range and identify any side effects.

Phase II trials are conducted after a successful Phase I trial to evaluate the effectiveness and safety of the treatment in a slightly larger group of volunteers who suffer from the disease or condition the drug is designed to treat.

Phase III trials involve thousands of volunteers and are used to confirm a drug's effectiveness, monitor side effects, compare it to other treatments and collect information that will allow it to be used safely.

Phase IV trials are conducted after a treatment has received government approval. They are sometimes used to compare a drug to a competing treatment or evaluate its use in a new patient population.

Regardless of the category or phase of a trial or the setting in which the research is being conducted, every trial must follow a protocol or study plan. The protocol is designed to safeguard the health of the participants, describe how the trial will be conducted, and ensure accurate, consistent data.

No matter what type of research is being conducted or what phase the research is in, a clinical trial volunteer is always free to leave a study. Participation is always voluntary.