



# GLOBAL FORUM

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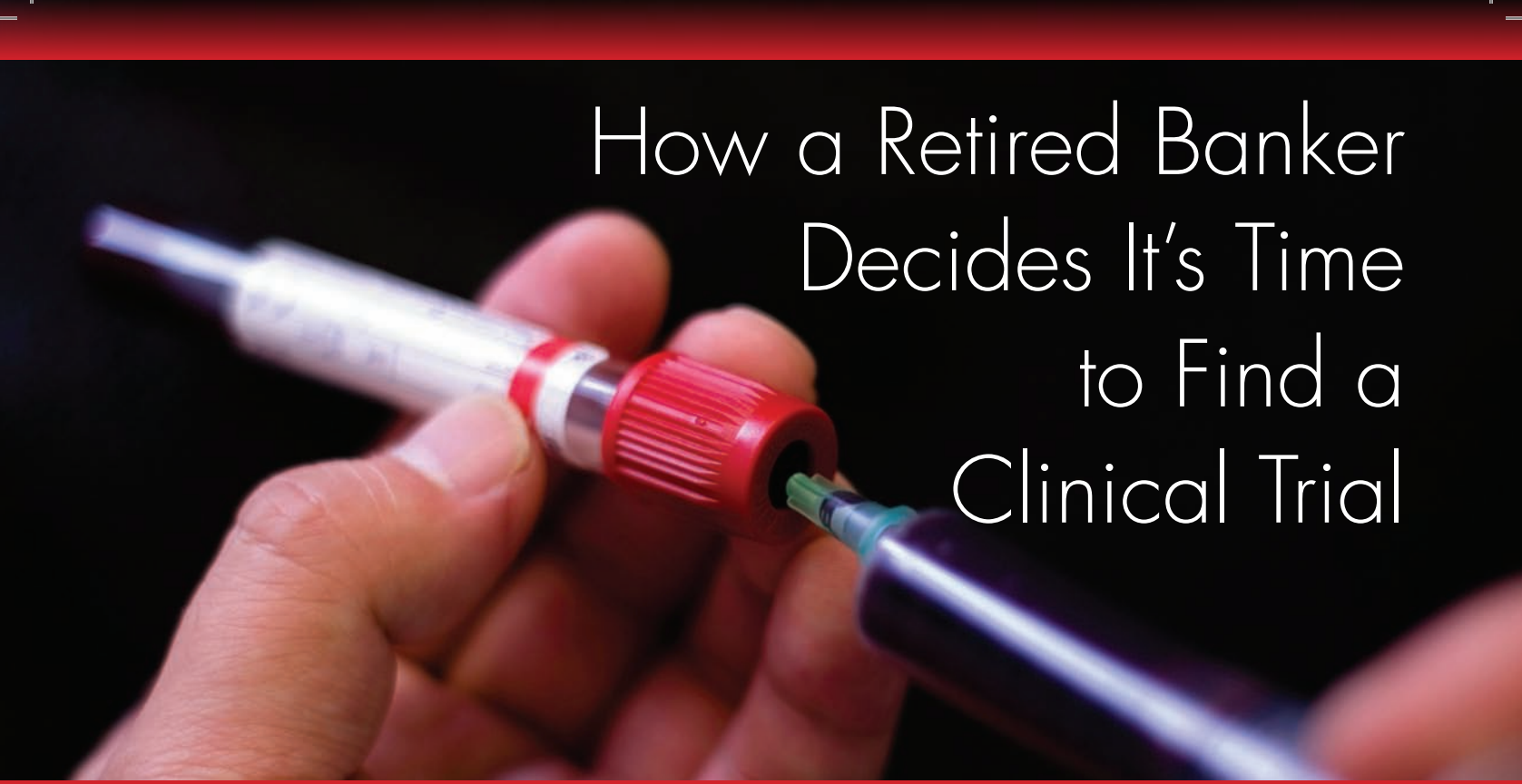
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# How a Retired Banker Decides It's Time to Find a Clinical Trial

*“When the train stops and there is no where else to go, you’re at Hopkins.”*

**T**hat’s how Coard Simpler describes the Baltimore subway. But he might just as well be describing his experience with the clinical trial process.

Coard’s journey began in the summer of 2000 with a routine physical. At the time Coard, a Baltimore resident and retired banker, was 55. He’d been seeing his primary care physician for decades and they knew each other well. So when Dr. Hunter Wilson asked him to come back to the office to talk about his blood work, Coard knew something was very wrong.

“Coard,” Wilson said, “I’ve been your doctor since you were a teenager and these results are just not right for you.” While Coard sat on the other side of his desk, Wilson called the lab that had done the blood work. He verified with the technician that he had the right patient and the right blood draw. That they’d run the right tests.

Everything squared. The results were accurate. “Coard,” he said. “You need to see a hematological oncologist.”

Coard spent the evening searching the Internet, trying to interpret his test results. Everything he read pointed in one direction: leukemia.

The next day, Coard Simpler’s worst nightmare played out. He was diagnosed with chronic myeloid leukemia (CML). He immediately began chemotherapy. His hair fell out. He lost 35 pounds. He was utterly exhausted. At times it seemed the regime was helping, but the disease persisted. Coard’s hematological oncologist, Dr. John Nesbitt, began researching clinical trials that might help him. Johns Hopkins was running a phase 3 trial for a new leukemia drug, he said, but participants had to undergo – and fail to respond to – six months of chemo first.

“My attitude was ‘if there is a clinical trial that can help, sign me up,’” says Coard, “but as I got to the end of my six months of chemo it seemed like it was almost working. I told my doctor I wanted to stay on the chemo for a while longer. He was worried about that. He didn’t want me to lose any more time. We decided we’d give the chemo two more weeks and if it didn’t work, I’d join the trial.”

The chemo failed.

On December 22, 2000, Coard went to Hopkins to join a Novartis trial for STI571, also known as Gleevec. The protocol was simple: two pills twice a day with water. He 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 got life in that bag. She’s holding life.’”

The Gleevec “beat up my red cell count and I felt myself tiring easily,” Coard recalls. For several months he took another drug, first Amgen’s Procrit and later Aranesp, to boost his red cell count. He also had to have a platelet infusion. He underwent frequent bone marrow tests to see how his body was responding to the therapy. Although the tests were performed under local anesthesia, they left Coard feeling stiff and sore.

Despite the painful tests, Coard says his overall experience was extremely positive. “They treated me like I



was a special person. They'd come and greet me. I had everyone's cell number. All of the people were just really caring, interested people."

Six months after Coard joined the trial, Gleevec received FDA approval. Seven months after that, Coard was in remission.

Coard's experience was so positive, he was more than happy to participate when the Hopkins research team approached him a couple years later about participating in a vaccine trial. The trial involved 19 CML patients who had measurable cancer cells, despite taking Gleevec for at least one year. A series of 10 skin injections were given every three weeks for a total of four times. The Hopkins team later asked Coard to participate in a second trial testing a booster of the same vaccine. Toward the end of the second vaccine trial, however, Coard began to develop a resistance to Gleevec: the cancer cells were growing again.

To Coard, that meant one thing: it was time to find another trial. Coard sought help from Dr. Carole Miller. Miller, who had worked as the principal investigator on the Gleevec trial at Hopkins, now practiced at St. Agnes Hospital in Baltimore. She 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. Miller was able to squeeze Coard into the trial on an expanded access basis.

To qualify for the study, which involved taking two pills twice daily, Coard had to have multiple EKGs and another bone marrow test. 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 his doctor reduced the dosage last fall. That has helped alleviate the rash and dry skin he was experiencing as side effects of the medicine.

Looking back on his experience, Coard says he's learned a lot about CML and clinical trials. He's learned that, despite anesthesia, bone marrow exams are painful and that walking after a test helps alleviate the soreness. He's learned that dealing with insurance companies can be challenging and it's good to have an advocate: just before he was to join the first vaccine trial his insurer balked about covering the costs. Coard said he was grateful that the team at Hopkins included insurance experts who were able to resubmit his paperwork and resolve the problem.

But mostly, Coard says, the experience has taught him about people and how supportive they can be.

There were the friends and neighbors who would leave cookies and cards

at his door. There was the roofer acquaintance who stopped to give him a lift to the clinic, claiming he was heading in that direction anyway. There was the nurse who took him out for coffee and promised to do everything she could to help, and his support network at the Leukemia & Lymphoma Society who were always there to listen and offer advice. Each and every one of them played a crucial role in his battle with leukemia, Coard says.

"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. "I'm grateful to everyone who made a difference: to the lab technicians who did the blood draws and the doctors and nurses and the people who signed me up at the registration desk."

"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." ■

*This story is from a series of articles created by CISCRP as part of their educational awareness campaign to increase public understanding that those who volunteer to participate in clinical trials are genuine "Medical Heroes."*