Publisher’s Letter

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When I first started HIV drugs, back in December 1994, I enrolled in a clinical trial at Beth Israel Medical Center in New York City. I’d tested positive nine months earlier but put off treatment, in part because the meds then available hadn’t done much to save my friends’ lives. But promising new drugs -- the protease inhibitors and NNRTIs -- were just being developed, and I could get early access to them by participating in a study.

The four-arm trial I enrolled in was randomized, placebo-controlled and double-blinded -- a complicated way of saying that I had absolutely no idea what pills I was actually taking and neither did the researchers. I had a 75 percent chance of ending up on an arm with the new drug -- the NNRTI delavirdine (Rescriptor) -- in combination with one or two others; if I was really lucky, I’d be on the arm that got a three-drug regimen that included delavirdine. (I never found out what I was on during those 48 weeks, though my side effects offered a clue: A temporary rash -- red bumps from head to toe -- is common with delavirdine.) At the outset, I understood very little about HIV treatment. But the clinical trial required frequent visits, thorough blood work and physical exams, all free. I formed good habits. My adherence was scrutinized and supported, my side effects closely monitored and discussed. For me, it was a much-needed treatment boot camp.

In addition to these tangible benefits, I felt that I was making a contribution to the AIDS research effort. My medical care was no longer just part of my lonely personal struggle with HIV, but something bigger than myself, something that might help others, something noble even.

Call me naïve, but attitudes about clinical trials were different then. As a community, we were deeply invested in them because they represented hope and progress. Today, there’s a more cynical view: Clinical trials are part of a commercial drug-development process that is more profit-driven than patient-minded. Studies are designed less to answer critical treatment questions than to showcase a product’s best attributes. The “ideal patient” for such trials is not only relatively healthy with a high CD4 count and low viral load but also treatment-naïve -- someone who doesn’t have difficult-to-treat, drug-resistant virus. Given that there are already 16 HIV drugs on the market, it’s no wonder that recruitment for clinical trials has become a serious challenge. If, in the bad old days, the No. 1 incentive to participate was sheer desperation -- *drugs into bodies!* -- what will motivate us now?

Industry and the research establishment should do their part by designing and fielding studies that are real-world relevant and offer a clear benefit to clinicians and the patients they care for. Advocates can influence these efforts, but advocacy is most effective when it’s supported by

people like you and me: ready, willing and able to enroll in a clinical trial. Each of us with HIV should ask, “Am I willing to participate in a clinical trial? If so, under what circumstances? What trials are enrolling in my city right now?” You can start out by visiting the AIDS Clinical Trials Information Service website at www.actis.org.

Today, I’m once again a patient in search of a trial. I browse the ACTIS website frequently and read through the entry criteria for interesting studies. Inevitably, I don’t match -- and the ones I do match, I’m not interested in. (Funny, it’s a lot like the personals.) I’ve come to realize that while eligibility requirements are fixed, my treatment status and lab values are moving targets. If I want to enter that trial where you must have 300 to 500 CD4 cells and been on a current HAART regimen for less than six months, I’d better act now, because that window is closing. Finding the right trial takes not just research but careful planning and close monitoring to increase your chances of meeting strict enrollment criteria.

HIVers beginning HAART today have more choices and the benefit of more research and clinical experience than ever before. That’s worth acknowledging and even celebrating, but there is more to be done. Given the growing rates of drug resistance and treatment failure, we all need safer, more effective meds and more hard data on how best to use the drugs we already do have. If access to experimental therapies no longer provides enough of an incentive to propel AIDS research forward, then maybe we can again tap a community spirit of altruism -- that sense of connection to the fate of others. Within each of us there exists the will to create change. Sometimes all it takes is getting in touch with your inner guinea pig.
