Terry Louison

Straight talk with…**Ken Getz**

How should clinical trials be improved? Ken Getz, a senior fellow at the Tufts Center for the Study of Drug Development, has been thinking up answers to this question for two decades. In 2003, Getz took on a new challenge when he launched the Center for Information & Study on Clinical Research, a nonprofit focused on providing education and outreach on clinical research to the public. **Cassandra Willyard** asked Getz for his thoughts on trial recruitment, financial conflicts of interest and keeping trial participants safe.

Why did you decide to start the Center for Information and Study on Clinical Research Participation (CISCRIP)?

I had just been through a journey where I was providing education information and analytical information for managers and research professionals, and I realized during part of that journey that there was a whole segment of our community that was not receiving even basic educational information—that was the public and patient communities. There was really a public need. There's often been the assumption that health care providers would essentially be the conduit to educate the public. And yet they're about as disengaged as the public.

Do you see a role for social media in recruiting trial participants?

There have been a number of startup companies as well as even some established companies really trying to leverage Facebook and Twitter and other forms of social media. At CISCRIP, we view them as important channels for communication, but until the overall level of what we call 'clinical research literacy' is improved, they will only have a marginal impact. You can bombard the public and patient communities with promotional messages through a variety of media including Twitter and social networking and regular advertising, but until [they] understand why clinical research is important personally to them, they'll only receive that information with a passing curiosity.

Have the Health Insurance Portability and Accountability Act [HIPAA] privacy rules had any adverse impact on clinical research?

There was a lot of concern pre-HIPPA launch. [But] once HIPPA came out, I think the response was rapid. In general, the sense was that it was not nearly as disruptive as expected, and it had not had a negative impact.

Most late-stage clinical trials now take place abroad. Are there cases in which it is unethical for researchers to conduct clinical trials in developing countries?

The issue that we see that is the most concerning is the lack of [clinical research oversight and logistics] infrastructure in a number of developing countries today. There's major interest on the part of research sponsors to conduct trials in developing countries, but recently we've seen even some withdrawal because the regulatory agencies themselves, or the ethical review committees, or the drug supply—some of these operating and regulatory areas—lack the necessary infrastructure to ensure that proper oversight and support will be required.

What impact has the Food and Drug Administration's (FDA's) rejection of the Declaration of Helsinki had on clinical research?

The impact has been to stimulate more discussion and more focus on trial design, but it has not altered practices at this time.

Has the FDA's decision put trial participants at greater risk?

No, it hasn't. I think the FDA's response has been that the greater benefit to patients and to the community is to do scientifically robust and credible research.

Financial conflict of interest continues to be a big issue. Should investigators with financial ties to a drug-maker be barred from participating in clinical trials to test that company's products?

I absolutely think that, in those cases where egregious conflicts of interest exist, that these parties should not be allowed to continue their involvement. But there are some conflicts of interest that can be mitigated. Sweeping conflict of interest reform sometimes really ignores some of the natural relationships [between industry and academia] that benefit the research enterprise. We really need to look at what should be deemed an egregious conflict of interest.

What would you consider egregious?

We look at a researcher who's been receiving exorbitant consulting fees, or a researcher who has equity stake in a therapy under investigation and one in which he's an actual PI [principle investigator] on the project—those are the places that I'm really describing as egregious.

There have been several incidents in recent years in which subjects became very ill or died while participating in clinical trials, most notably the six British men who had to be hospitalized after receiving the anti-inflammatory drug TGN1412. What trends have you observed in the wake of these incidents?

I've been actually seeing a variety of reforms that have been put in place over the last five or six years, many of them tied to the TeGenero case that you're describing and some even tied to earlier tragic events that occurred like Jesse Gelsinger's death [in a gene therapy trial] and Ellen Roche's death [in an asthma study]. We've seen new guidelines around conflict of interest disclosure. We've seen the FDA requiring much more safety data in early-stage clinical trials like the TeGenero case. [And] we've seen increases in training and accreditation and certification of research professionals—coordinators, study monitors and physician investigators.