

How Accurate are the FDA Investigator Databases?

By Norman M. Goldfarb

Dr. L has been conducting clinical research studies since 1985 in the area of gastroenterology. Because his site is often a high-enroller, the FDA has inspected his site four times, generating one NAI (no action indicated) letter and three VAI (voluntary action indicated) letters.

Ms. M, his long-time study coordinator participated in the inspections and post-inspection meetings with the FDA investigators. When she recently heard about First Clinical Research's online database of government actions, she decided to see what it would say about Dr. L. Says Ms. M, "I was keenly aware of the findings of each audit, so I knew what I would find in the postings, or I thought I knew."

As it turns out, Ms. M found two entries for the audit in 1993. One of them is the NAI – 00 (No problems found) listing that she expected, but the other includes the code VAI2C – Consent problems found. "Surprise! In all our communications with the FDA no one said anything about that! The audit follow-up letter from the FDA says, 'there were no significant departures from FDA regulations or commonly accepted drug investigational practices.'"

The listing is 13 years old, so it probably has not affected Dr. L's clinical research business or selection for the subsequent three inspections. Nevertheless, Ms. M has contacted the FDA to correct the error.

It is unknown how many errors exist for the other 44,000 people in the 11 government databases that First Clinical Research has indexed at <http://www.firstclinical.com/actions>. It is also unknown how many study sponsors have missed problems with potential investigators because they did not hunt through the 11 databases.

Author

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