

The Harvard of the Web

His name may be familiar, but it's his problem solving nature that's behind Al O. Pacino II's efforts to streamline the research process. As an employee of a CRO in the late 1980s and early 1990s, Pacino—president of Austin, TX-based trainingcampus.com—became aware of a phenomenon taking place in clinical research. “I knew there was a drift in knowledge base, and that's one of the main reasons why things start failing,” he told *Applied Clinical Trials*.

Pacino later coined the phrase “trial drift” to describe the experience, identifying the minutia in research and the ease with which one gets lost in it as the culprit. What happens is, as weeks turn to months, the trial's duration and day-to-day demands begin to take a toll on study personnel. The result is an exponential decrease in knowledge and interest on their part, which according to Pacino translates into lost dollars. His solution: Streamline training and communication processes in research and health care with the help of technology to minimize trial drift.

In 1999, the biologist by trade along with colleagues launched trainingcampus.com, a global, Web-based platform that allows sponsors to build virtual “campuses” where trial



Al O. Pacino II, a cancer survivor, first got involved in research as a trial volunteer.

personnel can “go” to train in real time, 24/7, and at their own convenience. The idea is to counter trial drift by making it easy for investigators, staff, CRAs, etc., to maintain their knowledge base and thereby their interest in the study—while they do their job. It's an approach Pacino calls “Clinical Blended Learning” (a take on the phrase blended learning: i.e., the combination of face-to-face and online activities), which stresses evidence-based education—and proof of competence. Thus, tracking, collecting, and documenting training activities is made simple for sponsors.

In addition to offering different types of training software (e.g., eLearning management) and an interactive virtual

meeting center, the centralized 21 CFR-11 compliant infrastructure lets users build and share clinical education materials, including diagnostic tools and copyrighted information. But don't confuse this platform with a single Web portal. “That's old technology,” Pacino said. “Companies like to have their own Web sites, and each Web site could actually be specific to a project or clinical trial”—and up and running in as little as 30 minutes, branding optional.

In order to use trainingcampus.com, however, you must be a member of the International Electronic Education Network (IEEN), which is what makes the business model unique. Instead of charging users for services or software, the company charges an annual IEEN membership fee that starts at \$490 and goes up depending on what members choose to do with the platform.

Today, there are about 120,000 members, with the majority based in the United States and Canada. They include pharma, biotech, and medical device companies; CROs; SMOs; IRBs; hospitals; authors; and health care providers, and according to Pacino are the driving force behind the platform's success: “That's what's giving it the power: the growth effect,” he said, “[but] it didn't come overnight.”—*Kerri Nelen*

Paradigm Spine Backs Data Integration with PharmaPros

Paradigm Spine, headquartered in New York with operating facilities in Germany, provides indication specific posterior non-fusion solutions for orthopedic spine surgeons and neurosurgeons focused on treating spinal conditions and diseases. Paradigm Spine wanted to

keep its concentration on building a multiproduct non-fusion portfolio, with emphasis on its signature product, *coflex™*, a functionally dynamic interspinous implant for the treatment of patients suffering from lumbar spinal stenosis. Its development of an U.S.-based multicenter IDE clinical trial of

the *coflex* implant started in May 2006.

Moving forward, Paradigm Spine wanted to deploy the right mix of technology, experience, and talent. But it was challenged with data integration issues typical to many companies: a proliferation of clinical data resulting in electronic data capture and other In-Stream data acquisition tools being stored not only in multiple and disparate data repositories, but often managed by multiple vendors.

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