

Meet the EAB

Getting to know *ACT*'s Editorial Advisory Board

Gail Elber

Sabritt recalls the challenge of building a data management organization from the ground up while striving to retain the pioneering spirit, flexibility, and rapid decision-making capabilities of a startup culture.

David Sabritt, director of strategic technologies for clinical research and development at Immunex, is a relative newcomer to *ACT*'s editorial advisory board, having joined in 2000. But his contributions to the rest of the pharmaceutical industry have been considerable. Not only has he helped bring Immunex from a startup to a successful biopharmaceutical company, but he has contributed considerable time to the Drug Information Association (DIA), the Society for Clinical Data Management (SCDM), and the Pharmaceutical Research and Manufacturing Association (PhRMA). Managers pondering whether to support their employees' involvement in professional societies can look at David Sabritt to see what the benefits can be.

A roundabout route

In the early part of Sabritt's career, the closest he got to pharmaceuticals was a three-year stint setting up an education program for recovering drug addicts in New York City. His undergraduate studies were in sociology and anthropology, with an excursion into French literature, in which he has a graduate degree. Not long after getting that degree, he entered graduate school in sociology, with special interests in quantitative methods and research management. That led him to positions in program

monitoring and evaluation in government and academia. In 1988, interested in pharmaceutical research and also needing to care for ailing parents on the East Coast, he accepted a position at what was then ICI Pharmaceuticals (now part of AstraZeneca) in Wilmington, Delaware.

For Sabritt, the organization of a large pharmaceutical company represented a big change from academia. "I liked the work and the science, and learned a lot from some very bright people. When I came to Immunex two years later, in 1990, I saw the move as an opportunity to join a younger, emerging company where I could make more of a difference. I was especially impressed, and still am, by the company's intellectual climate and its fast-paced entrepreneurial culture."

When Sabritt arrived, Immunex was nine years old and had about 450 employees, but it still had the classic startup atmosphere, especially within his own discipline. "Immunex was just beginning to conduct its own clinical trials, and the biometrics function consisted of me, a SAS programmer, and the statistician who had just hired both of us. I came in as the head (where $n=1$) for clinical data systems, but

there were not yet any clinical data systems in place. Literally, there wasn't a computer plugged into the wall for clinical data management or biostatistics. My job was to build it from scratch. It was an exciting challenge, but also scary in a way to wear all the hats at once. My hope was that the company would continue to succeed and grow, and that by helping the company I'd be able to grow with it."

Indeed, Immunex did succeed and grow into a fully-integrated biopharmaceutical company with about 1500 employees, an enviable pipeline and portfolio of marketed products, and a state-of-the-industry corporate research and technology center under construction in Seattle. Immunex's data systems and data management operations eventually became a team of over forty. Recently, Sabritt has somewhat refocused his own energies at Immunex. Stepping away from



Photo by Joye Emmans and Helene Sherlock

directing data management operations, Sabritt has assumed the newly-created position of Director of Strategic Technologies. In this capacity, he intends to keep Immunex an industry leader in the effective use of emerging technologies for clinical research.

Reflecting on the experience of building a data systems and data management organization from the ground up, Sabritt recalls the challenge of developing more formal, specialized, and finely tuned processes while striving to retain the pioneering spirit, flexibility, and rapid decision-making capabilities of a startup culture.

No CRF bonfires scheduled

That flexibility will come in handy as Sabritt ushers Immunex into today's emerging era of Web-enabled clinical trials. Right now, like many other clinical data technology strategists, Sabritt sees the need for a heterogeneous environment where electronic data capture coexists with other solutions, including traditional paper CRFs.

"Our approach," he explains, "is to move ahead into the world of electronic data capture, especially using the Internet, without expecting these tools to completely replace traditional methods immediately. Over time," he adds, "the baseline will surely change. New tools will emerge as the 'leading edge,' and some of today's new technologies will become routine.

"A challenge for us, and for other companies, will be to harness multiple tools to collect and manage information from many sources in as seamless a way as possible," he says. "Electronic data capture holds enormous promise, but no one technology is the ultimate quick fix. If paper is going to be around for a while, we shouldn't neglect improving our processes for dealing with it."

Sabritt points to Immunex's success over the last several years with a CRF imaging and workflow automation solution, which has streamlined some internal processes and facilitated the preparation of several electronic regulatory submissions. "Our success doesn't depend on holding a bonfire for paper casebooks," he says.

It's critical, Sabritt notes, to understand your company's culture and manage technological change in a manner that fits. "You need to operate with a sense of what kinds of risks are acceptable, when, and where," he says. "If you're leading people anywhere near the 'bleeding

SCDM's Board of Trustees, and serves as the Board's liaison to the organization's Committee for Effective Use of Technology. In DIA, he's a member of the organization's Steering Committee for the Americas. Besides chairing numerous sessions and speaking at DIA meetings for ten years, Sabritt initiated and co-chairs DIA's annual West Coast Clinical Data Management and Biostatistics meeting. In 1999, the organization honored him with its Outstanding Service Award. He is nearing the completion of a three-year elected term on PhRMA's Biostatistics and Data Management Steering Committee. In that role, he serves as

larger professional and scientific context."

Sabritt sees his participation with PhRMA as a way of helping Immunex bring its voice to industry initiatives involving clinical data management and its related technologies. "It's obvious," he says, "that a company's success depends on an ability to anticipate and critically evaluate industry trends. It's in our interest, as a company and as a part of our industry, to understand these initiatives while they're still at formative stages, and—when it's useful and possible—to join in helping to shape them."

A musical "second job"

Outside of work, classical music plays a large part in Sabritt's life. His wife, Mina Miller, is a concert pianist and the founder of Music of Remembrance (www.musicofremembrance.org), a nonprofit organization devoted to preserving, understanding, and performing music by musicians who suffered or perished in the Holocaust. Sabritt is active in the organization. "It's kind of a second job for me," he says.

Bringing the societies together

Just as a project like Music of Remembrance brings people together in understanding, Sabritt's involvement in multiple professional societies can help those groups work together. Says Douglas Schantz of Pfizer, president of SCDM, "David has the opportunity to be instrumental in forming a collaborative relationship between SCDM and DIA." With Sabritt showing no signs of slackening his efforts on behalf of the clinical data management profession, we can look forward to a future of fertile collaborations.

Gail Elber is a writer based in Eugene, OR, a former member of ACT's editorial staff, and an occasional contributor to the magazine.

David Sabritt

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edge,' you need to know how to make sure it's the little finger and not the jugular that risks getting cut."

Part of the job involves being prepared for the unexpected. "As much as you anticipate the changes on a broad scale, and plan for every detail that can be imagined, you're always going to need the ability to deal on the fly with details that catch you by surprise."

Professional leadership and the big picture

One thing that has helped Sabritt bring Immunex a vision of emerging trends has been his industry leadership through DIA (Drug Information Association), SCDM (Society for Clinical Data Management), and PhRMA (Pharmaceutical Research and Manufacturers of America).

Sabritt recently was elected to

liaison to PhRMA's Electronic Regulatory Submissions Working Group.

"A wonderful part of working in clinical data technologies is that people's jobs can involve not only a technical challenge, but also broader scientific, intellectual, and even humanitarian dimensions. I think professional societies can play a very important role in actualizing this potential," says Sabritt. He adds, "SCDM, for example, has an irreplaceable part in establishing clinical data management as a professional discipline with a voice of its own, and with a vehicle for acknowledging excellence and promoting standards of good practice. DIA, in addition to its specialized offerings, has a worldwide scope and multidisciplinary breadth that present wonderful opportunities to connect what one does with a