

Friday, September 4, 2009

The efficiency remedy

Cancer researchers are working to streamline drug development to get medicine — and profits — flowing more quickly

San Francisco Business Times - by [Ron Leuty](#)

Before the bedside visit, before the prescription is written, even before the drug trials begin — the cost of a cancer drug, for the most part, is set.

But cancer drug-development companies and their trial collaborators at places like **Stanford University** and UCSF are trying to bring more efficiency to the earliest parts of the process. That could save the companies millions of dollars over the long haul, bring the institutions more business and carry better-targeted therapies to cancer patients sooner.

“Time is money,” said Alison Joly, vice president of clinical operations and program management at **Exelixis Inc.**, which is working with the **University of California, San Francisco**, on three cancer drug trials.

UCSF is in the process of broadening its Investigational Therapeutics Initiative — including everything from standardizing forms to accelerating the process of getting trial protocols approved — across its entire cancer center. The ITI’s 1½-year-old project-management approach has taken hold in the cancer center’s early-phase clinical trials unit as well as the breast cancer and prostate cancer units.

“There’s more accountability,” said Dr. Eric Small, who heads the initiative.

The effort has already reduced the time it takes to approve a Phase I protocol — through scientific, legal and financial reviews to the point of accruing patients — from 12 months to three or four months, Small said.

“We’ve done that now routinely,” Small said. “Twelve months is OK if it’s a 2,000-patient study, but in this new environment where we must respond and test drugs rapidly, that’s unacceptable.”

That saves money, Small said, but it also has the cumulative effect of better focusing later-stage trials.

Similar efforts to cut down the legal and scientific review bureaucracy are under way at Stanford and through philanthropic backers, like the **Multiple Myeloma Research Foundation**, whose research consortium has worked with companies like South San Francisco’s **Proteolix Inc.**

“It’s very bad for everybody when you put your effort into writing a trial and you can’t get it implemented for a year,” said Dr. Bev Mitchell, who last year took over as director of the Stanford Cancer Center.

It’s not all altruistic. With pressure building against higher drug prices — **Genentech**’s best-selling Avastin, for example, can cost more than \$90,000 to extend the lives of cancer patients only a few months — companies must find ways to cut costs out of their drug-development processes.

What’s more, experts say roughly half the drugs under

development are oncology. If only half of them actually win approval, the competition is tight and price may be a differentiating factor for lookalike drugs.

In that environment, drug developers must find winners and losers sooner.

“There’s a value in getting to the point of a go/no-go decision,” said Susan Kelley, chief medical officer of the **Multiple Myeloma Research Consortium**, which has helped standardize legal contracts and navigate protocols between several of its member research centers. “Maybe you can shift to a different patient population, use (a drug) in a different setting, in combination or not at all.”