

Getting a cancer drug to patients takes both scientific and business smarts

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What if an experimental treatment for an aggressive breast cancer had the potential to save women's lives, but nobody could use it because there was no money to develop and test it? With funding sources for research and development more scarce than in the past, it is not an unusual situation. It's a problem that Sourav Sinha, a Master's degree candidate at Rutgers' Graduate School of Biomedical Sciences, is working to tackle head-on.

Sinha is leading a team entered in the Breast Cancer Startup Challenge, a worldwide competition sponsored by the Avon Foundation, the Center for Advancing Innovation and the National Cancer Institute. The goal is to take a drug that shows promise in the laboratory – a powerful toxin created and patented by scientists at the National Institutes of Health – and develop a business plan to guide its development for potential use in patients.

"We have this unique opportunity to get a powerful treatment to [breast cancer](#) patients who desperately need it," says Sinha, who grew up in Holmdel, N.J., and aspires to be a physician as well as a research scientist. "I see this as a new, exciting avenue through which my team and I can make a meaningful contribution to health."

Bringing a drug to market is a much more daunting process than people might realize.

This drug is designed to kill individual cells altered by the

HER-2-positive gene mutation that is responsible for as many as 25 percent of all breast cancers. "The toxin is in a very early stage of development right now," says Sinha, "but if it works it will be huge."

That is where the need for a business plan comes in. The drug's inventors have shown it kills [cancer cells](#) in the lab, but in order for it to work in people, an intricate transport system is also needed to carry the toxin through patients' bodies and deliver it to diseased cells, while bypassing surrounding healthy cells.

Choosing the right mechanism requires an extensive knowledge of biochemistry. But it also demands business sense: to negotiate financial agreements with biotech companies that have expertise to construct the delivery system. Specialized components include synthetic antibodies that are specifically engineered to seek out HER-2-positive cancer cells, as well as "linkers" that would fuse the toxin to the antibodies – as a space capsule might be attached to a booster rocket – until just the moment when, inside the cell, the toxin detonates.

If the product ultimately works, each of these companies will see a share of what could be substantial profits. Those financial details, and many others, are essential parts of the [business plan](#), and need to be worked out now. Sinha and his team would then take the completed plan to venture capitalists and large foundations – which he hopes he and his team can convince to put up the capital needed to fund both the manufacturing process and the all-important human clinical trials that would follow.

Attacking HER-2-positive breast cancer may be just the start. If, as Sinha expects, the toxin can also be combined with different antibodies that seek out other cancers, Sinha says the drug has "nearly endless" cancer fighting potential.

"He is a very impressive young man," says Joseph Bertino, chief

scientific officer at the Rutgers Cancer Institute of New Jersey and a professor of medicine and pharmacology at Rutgers Robert Wood Johnson Medical School.

Bertino, whose own research focuses on targeted cancer therapies, is one of several Rutgers faculty members who have advised Sinha. "He has collaborators lined up," Bertino adds, "and I think he has a real shot at it." Sinha and his team have formed a company, OncoLinx LLC, to help advance their plans.

Sinha's foray into the business side of drug development is a sign of rapidly changing times. In the past, nearly all who earned doctorates in the [biomedical sciences](#) stayed in academia. But now, Bertino notes, "some of our best scientists are working with biotech companies and big pharma. It's important for them to understand what industry is all about, so we at Rutgers are trying to make sure it's part of their education."

Provided by Rutgers University

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