



Focal Medical turned to Innovate Carolina for various modes of support, including help to protect the intellectual property arising from the technology's underlying research.

The prognosis for pancreatic cancer remains dim. Can energy-based drug delivery brighten the odds?

A startup with roots at UNC-Chapel Hill, Focal Medical, offers implantable technology to deliver drugs in higher concentrations to hard-to-reach tumor cells.

By Brock Pierce

When Tony Voiers walked into a conference room at the U.S. Food and Drug Administration in 2016 to discuss a new technology being developed by UNC-affiliated startup Focal Medical, he wasn't sure what kind of reaction the agency would have. But he hoped the large contingent of officials was a signal of the FDA's interest. Initial research indicated the technology could help shrink pancreatic cancer tumors at a scale never seen before. "I was personally very interested in the data that Focal Medical had, but the technology was so new and innovative that I really didn't know what the FDA would think of it—what clinical trials would look like for approval," said Voiers, who had just begun consulting with the startup. Voiers' intuition was right, recalling that the FDA "gave us very positive, tangible feedback on how we could move the technology forward."

The technology is an implantable medical device that uses an electric field to precisely deliver drugs in higher concentrations to targeted, hard-to-reach cells than is possible by pill or injection. It was developed via a collaboration between former UNC-Chapel Hill chemistry professor and serial entrepreneur Joseph DeSimone, PhD, and Jen Jen Yeh, MD, a distinguished cancer surgeon, who is a professor in the departments of surgery and pharmacology at the UNC School of Medicine.

Months before the FDA meeting, Yeh, who is co-founder of Focal Medical and works as the director of the Pancreatic Cancer Center of Excellence at the UNC Lineberger Comprehensive Cancer Center, told Voiers about the impressive research results her lab received using the technology to target human pancreatic tumors implanted in mice.

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Tony Voiers, Focal Medical CEO, and Dr. Jen Jen Yeh, Focal Medical co-founder. The duo are holding the company's implantable medical device.

As researchers, Yeh and DeSimone recognized the need for a technology that could deliver drugs to hard-to-reach places in the body. For example, Yeh says that when people swallow a pill or receive an injection, some regions of the body have too few blood vessels to effectively deliver the drug. "For hard-to-treat diseases, you often can't get your treatment of choice to the specific region because there are physical or other types of barriers," said Yeh. "With pancreatic cancer, there is almost a fortress around the tumor cells, so the vision for this device was to essentially collapse the fortress so the drug can get to the tumor."

The device was invented by Yeh, DeSimone and James Byrne, a former Carolina MD-PhD student whom Yeh and DeSimone co-mentored. Yeh said the technology, which is surgically implanted, uses an electrical field and works similarly to a magnet, in which the positive pole attracts the negative pole—a force of energy that is useful for directing drugs into tumors that are otherwise challenging to reach. "If we give the right drug the right charge, the device can essentially be used as a magnet to suck the drug into the right place," said Yeh. Targeted treatment is crucial because, even though the survival rate for pancreatic cancer doubled over the past decade, the odds still stand at only 12 percent.

After seeing drugs produce little-to-no shrinkage in pancreatic tumors via traditional methods, the team devised another way. They implanted human tumors, donated to research by pancreatic cancer patients, into mice. Still, even when injected

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into the mice, the drugs weren't effective—not until the team used its new technology.

Yeh said the "shockingly good results" demonstrated about 150-percent shrinkage when using the device compared to no shrinkage with traditional injection. "None of us had ever consistently seen tumor shrinkage, much less to that extent in this model, and it was incredible," she said.

To advance the company, Focal Medical turned to Innovate Carolina—UNC-Chapel Hill's university-wide team for innovation, entrepreneurship and economic development—for various modes of support. The startup worked with Innovate Carolina's commercialization office to help protect the intellectual property arising from the technology's underlying research. It received early guidance from Innovate Carolina's KickStart Venture Services team, while using the patent landscaping and market research service to assess the technical development path and marketplace. Focal Medical is finalizing plans with the FDA and, by summer 2024, expects to enroll patients in its first clinical trial for treating pancreatic cancer.

"We know for many cancers, including pancreatic cancer, that one shot on goal isn't enough: surgery isn't enough, and our current chemotherapy isn't enough. You have to tackle the tumor from many different directions," said Yeh. "This technology is huge for patients, because it gives us ways to help weaken the entire tumor system so that we can eventually cure the cancer."

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Focal Medical's implantable device uses an electric field to deliver drugs in higher concentrations and with greater precision to hard-to-reach cells than is possible by pill or injection.

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