

OKLAHOMA HEALTH RESEARCH CONFERENCE

Scientists discuss steps getting product to market

Oklahoma Center for the Advancement of Science and Technology holds 32nd Health Research Conference

Once a year, the Oklahoma Center for the Advancement of Science and Technology (OCAST) gathers scientists from across the state who are currently receiving funding from its health research program in a sort of show-and-tell educational event.

Recently, about 100 OCAST-funded life science researchers assembled at the Samis Family Education Center on the Oklahoma Health Center campus for OCAST's 32nd Health Research Conference. The event featured a keynote presentation from Dan Clark, president of Oklahoma City-based Linear Health Sciences.

Co-founded by Clark and Oklahoma City physician Ryan Dennis, Linear Health Sciences developed a patented device known as the Orchid Safety Release Valve (SRV), which prevents dislodgement of IV catheters in hospitalized patients. It is estimated that approximately 14 percent of all IV catheters are accidentally dislodged, which requires re-sticking patients and creates higher risks of infection.

"Our device is designed to mitigate that," Clark said. "The concept is quite simple. If you've ever seen someone drive away from a gas station with the hose still in the car, the hose rips away from the terminal, but no gas is spewing from the terminal and no gas is coming out of the car.

"We did the same thing, but we did it for your veins."

The Orchid Safety Release Valve has drawn interest from both potential hospital users and investors alike.

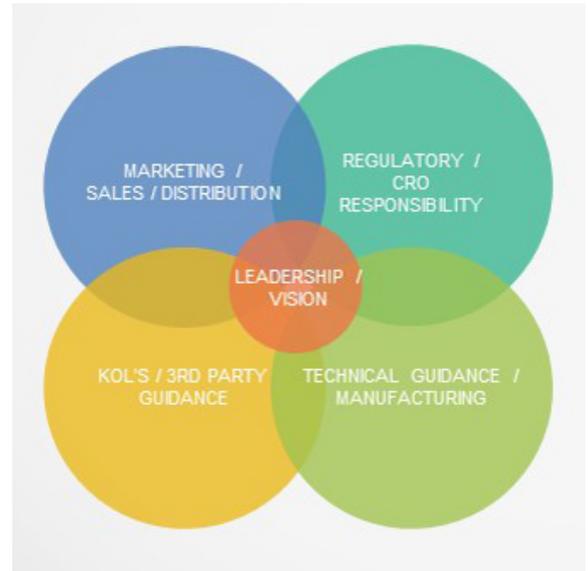
Linear Health Sciences attracted early seed investment from i2E Inc., a partner with OCAST in what has come to be known as the Oklahoma Innovation Model of supporting entrepreneurs and innovation across the state.

"We see a really big opportunity here," said Carol Curtis, i2E's vice president and director of investments. "If we can improve patient outcomes through the device, but also capture a good portion of the market, it's a win for investors as well as patients, physicians and the health care system."

Clark's presentation to his audience of scientists focused on how Linear Health's founders learned from their experiences as they negotiated the challenging regulatory pathway.

"The context of our device is not difficult to understand, but to put it into practice, all the way from design inputs and strategy to validating those inputs to traceability across all the different elements, that was tough," he said. "We became students again."

Linear Health has submitted what is known as a 510(K) application to the Food and Drug Administration, which is a premarket submission to demonstrate that its device is safe and effective. The company is relying on the



expertise of contracted outside experts to help it navigate the regulatory challenges of advancing its medical device.

Clark's advice to his audience of scientists hoping to advance their own concepts centered on utilizing contractors and external resources to manage the regulatory challenges that will confront them and shape their decisions.

"While you are designing your own experiments, your regulatory path is going to dictate what experiments and what understanding of methodologies is required to get there," he said.

Clark said Linear Health anticipates FDA regulatory clearance of its device early next year, after which the Orchid Release Safety Valve should soon reach early adopters waiting to put it to use.

[See the story in the 10-29-19 Oklahoman](#)