Intravitreal Injection Therapy (IVT – giving a shot of medicine into the eye) has transformed the treatment landscape of a number of previously blinding diseases, resulting in a dramatic increase in the number of ocular injections given every year.

But IVT has limitations, including patient discomfort, ocular bleeding, and the time constraints of treating the high volume of patients requiring anesthesia prior to injection therapy.

The Solution
University of Michigan Medical School team, Cagri G. Besirli, M.D., Ph.D., and Stephen J. Smith, M.D., has worked closely with Kevin P. Pipe, Ph.D., and Gun-Ho Kim, Ph.D., from the U-M Department of Mechanical Engineering to design the Cryo-Anesthesia Device. This device delivers ultra-rapid ocular anesthesia and vasoconstriction (blood vessel constriction) by flash cooling the surface of the eye at the injection site.

The Cryo-Anesthesia Device is a handheld instrument that utilizes thermoelectric cooling to provide rapid, precisely controlled cooling to the eye's surface, which helps greatly reduce the discomfort associated with ocular injections. It is designed to improve patient comfort, reduce side effects, and increase physician efficiency during IVT delivery.

This project was funded by the University of Michigan Translational Research and Commercialization for Life Sciences Program, also known as MTRAC. MTRAC works to “fast forward” projects that have a high potential for commercial success, with the ultimate goal of positively impacting human health.

MTRAC has been made possible by the Michigan Economic Development Corporation, the Michigan Institute for Clinical and Health Research, and the generosity of friends of the University of Michigan.
**New device delivers rapid, effective anesthesia**
to the surface of the eye, improving patient comfort and physician efficiency.

**Significant Need**
In contrast to current anesthesia methods that are time consuming with uncomfortable side effects, the Cryo-Anesthesia Device provides rapid anesthesia, improves patient comfort and physician efficiency, and significantly reduces the overall IVT time.

**Compelling Science**
A temperature regulating feedback loop maintains highly accurate temperature control, a timed lockout mechanism prevents excessive cooling, and proprietary, single-use sterile tips prevent infection.

**Competitive Advantage**
The Cryo-Anesthesia device uses thermo-electric cooling to provide rapid, precisely controlled cooling to the eye’s surface and provide adequate anesthesia in 30-45 seconds.

**MTRAC Project Key Milestones**

- Completion of device optimization and manufacturability assessment
- Delivery of three finalized devices for use in clinical and preclinical studies
- IRB approval and conduct two clinical trials with 40 patients in each trial
- Finish GLP toxicity data that can be presented to the FDA as part of the regulatory approval process
- Work to form start-up company

**Overall Commercialization**

- **Commercialization Strategy**
  - Form start-up company, continue to actively explore applications for this technology in other areas.

- **Regulatory Pathway**
  - Completing pre-FDA submission packet, anticipating the device will go through the de novo classification process. Also exploring the possibility of bringing the device to market outside the United States.

- **Engage Investors**
  - Seek venture and SBIR funding. Outside investment community has shown interest.

- **Intellectual Property**