

Addressing a large unmet clinical need with the power of partnership

Background

Ischemia Care is a rapidly growing diagnostics company based in Ohio (US) that is engaged in the development of blood testing for ischemic stroke to enable rapid treatment of complex and chronic conditions. They created a first-of-its-kind assay that could use RNA expression to understand stroke at the molecular level. Their goal was to launch the first clinical diagnostics product using RNA expression to prevent strokes, the fifth leading cause of death in the United States, by leveraging large amounts of existing clinical and biological data, managing chronic conditions, and improving access across the stroke care continuum.

Challenge

Commercializing this new assay posed many challenges. Ischemia Care needed to identify and acquire the right instrumentation, ensure regulatory approvals were received, and have a secure supply of raw materials with established delivery dates that could address their evolving needs.

Partnership

Ischemia Care connected with the Thermo Fisher Scientific Genetic Sciences OEM and Commercial Supply team (OEM team) at the beginning stages of their portfolio commercialization planning process. In order to get their assay to market at speed and scale, Ischemia Care required multiple types of support, including identifying the right products to use, minimizing the risk of price fluctuations, and ensuring peace of mind.

The OEM team began by leveraging their years of industry experience and prior support of Ischemia Care in the selection of products and instruments that address the needs of their innovation. They then worked with Ischemia Care to ensure that their chosen product(s) could be granted the relevant commercial-use rights.

Since stable pricing is an essential part of a successful commercial plan, a contract that locked in long-term pricing was created. This contract allowed Ischemia Care to continue the development of their assay without the concern that inflation would adversely affect their cost of goods during the contract period.

Not having to worry about their supplier delivering on the agreed-upon contract objectives allowed Ischemia Care to focus on what they do best: innovating. The OEM team provided assurance that Ischemia Care would consistently receive the high-quality products—utilizing numerous quality control testing protocols and standards—required for the development of their assay. This helped enable confidence in the process, since Thermo Fisher would manage the supply chain hurdles.

As a result, Ischemia Care designed their assay using Applied Biosystems™ microarray technology. A joint [press release](#) highlighting this ongoing relationship was developed to promote awareness of this partnership.

Partnership outcomes



Protection from market price changes



Entry to market at speed and scale



Potential reach of 1.2M tests annually

Summary

The partnership between Ischemia Care and Thermo Fisher's OEM team helped Ischemia Care further their advances in interventional and preventative stroke care. Their goal is to use advanced molecular testing to address the unmet clinical need of an estimated 1.2 million patients (annually), improve patient outcomes, and potentially reduce cost of care. The OEM team plans to continue supporting the evolving needs of Ischemia Care.

About Genetic Sciences OEM and Commercial Supply

If you are working to develop molecular assay products for commercial sale, contact our Genetic Sciences OEM and Commercial Supply team. We work globally on projects of any size, in support of our clients' commercialization goals.

There are many challenges during the product development journey. Partner with us for the quality, security of supply, customization, and specialized experience you expect from the world leader in serving science.

The Genetic Sciences OEM and Commercial Supply team at Thermo Fisher Scientific offers a comprehensive portfolio of products, services, and support to help you achieve your goals on time and on budget.

Learn more about what Ischemia Care does at ischemiacare.com and about our OEM and commercial supply capabilities at oem.thermofisher.com