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EP Vantage Interview – CardioDx looks to Europe

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Although CardioDx has met with great success both in trials and with investors since its genomic test for coronary artery disease, Corus CAD, was launched in 2009, so far this has been confined to the US. But the private Californian company tells *EP Vantage* that it is now seeking to move into Europe, where the cost-effectiveness of its technology could help it find a niche in austerity-minded healthcare systems.

CardioDx claims that the test can reduce the number of the expensive – and often unnecessary – catheter-based procedures that tend to be the first tests used to evaluate patients with chest pain. The US government seems convinced: Corus CAD gained Medicare coverage as a means to test for blockages in the coronary artery this August. CardioDx is now working on persuading providers of private insurance to fund the diagnostic too.

Dead end

Patients with chest pain must be tested to determine whether they have a blockage in the coronary artery. This is usually done using a myocardial perfusion scan, in which the patient is injected with a radiolabelled tracer and the heart is imaged using a gamma camera. The process is time-consuming, expensive and, according to CardioDx's chief executive, David Levison, overused.

Mr Levison tells *EP Vantage* that 90% of cases of chest pain aren't associated with a major blockage in the coronary artery. "We send too many patients, in the US and around the world, down a cardiac pathway that turns out to be a dead end, and then we've got to backtrack to find out the real cause of their chest pain," he says. He points out that, as well as the procedure being expensive, the gamma radiation used can also be harmful.

Corus CAD works by assessing gene expression. It detects the regulation of 23 genes in each patient and gives them a score out of 40, also taking account of their age and gender. The higher the number, the more likely they are to have a blocked coronary artery. "We've designed a test that can be used early on, when the patient and physician first interact," Mr Levison says. "It can tell the physician whether the patient has a low risk of having a blocked artery or a non-low risk. We can rule out about half the patients – they don't need to go down that cardiac pathway."

The technology is currently only available in the US, but this is set to change. "We are in the early stages of selecting additional markets to launch the test in and you'll probably see us do that in the next three to six months," Mr Levison says.

Processing

The test is run on a blood sample that is processed at CardioDx's CLIA-certified laboratory in California. "All the samples come back across the US via FedEx into our facility here. If the blood sample was drawn, say, on a Monday, it would show up here on the Tuesday and we would have the results back with the clinician typically on Wednesday afternoon," Mr Levison says.

This is another area in which the company's proprietary technology, in this case processing and handling of the blood samples, comes into its own. "Unlike DNA, which is stable for millions of years, RNA, which is what we measure, is highly unstable and starts to degrade as soon as it leaves the patient. So the process of handling the sample from the site where it's drawn all the way into our labs involves a lot of proprietary know-how that we developed," Mr Levison says.

The company will have to make new arrangements for sample processing if it does expand into Europe. Mr Levison says he is considering two alternatives: either couriering the samples across the Atlantic to its lab, which would lengthen turnaround time, or partnering with a lab in the UK to run the samples.

Cost

The move could also affect the cost. In the US, the test's list price is $1,195 – far more expensive than simple blood tests such as that for cholesterol, which clock in at around $15-50 a pop, but cheaper than some other gene expression tests.

“Genomic Health has a test for breast cancer patients to determine who should get chemotherapy – that has a list price of $4,000,” Mr Levison says. “And XDx has a test of almost that same price in the cardiac space, looking at whether a heart transplant has been rejected. Those are both gene expression-based, they use about the same number of genes, and are priced significantly above ours.”

The company closed a funding round this summer, raking in $58m, and is funded for several years. Sales of Corus CAD are starting to kick in, and will ramp further if the insurance companies bite.

CardioDx has shown that it can save the healthcare system and insurance companies money by avoiding the expensive cardiac diagnostic imaging – this is what helped the test obtain Medicare coverage. And Mr Levison gives a hint of what might come should CardioDx push into the UK: when he visited the UK to investigate launching Corus CAD, he says, “they were very interested at NICE”.

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