

The innovative treatment getting to the heart of tricuspid regurgitation

# CROIVALVE

## Living with TR

For many elderly patients with TR, the only option they have is to manage their symptoms. Prognosis is poor – patients who have severe TR are four times more likely to die in the next year than patients without TR.<sup>9</sup> These patients are too frail for the open heart surgery that would be necessary to repair or replace the valve and so less than one per cent undergo surgery.<sup>10</sup>

The team at CroiValve are developing a non-invasive solution to fix the affected valve. An early challenge they faced was funding the important initial stages of pre-clinical testing and development. Viewing medical devices as high-risk propositions due to the long evidential and regulatory requirements, investors can be reluctant to take the risk.

**Over half a million patients** every year in Europe and the US suffer from TR and **most are elderly**.<sup>7</sup>

## A one-off life-changing treatment

EIT Health recognised the immediate value CroiValve would bring in an area of high unmet need and so awarded the team with funding and supported them in conducting the necessary clinical testing to generate enough data to demonstrate its potential to treat TR.

By introducing the start-up to new partners, with expertise in clinical testing as well as in areas that complemented their own team, such as cardiac tissue, EIT Health helped CroiValve conduct this testing required in an efficient and cost-effective way.

“EIT Health supported us through a range of testing, and have continued to support us.”  
– **Lucy O’Keefe**

## Benefitting patients, aiding doctors, improving lives

The support from EIT Health has enabled CroiValve to expand its team and secure further funding for developing the treatment.

The solution not only has the potential to improve and extend the lives of elderly patients who suffer with TR, but also to benefit healthcare systems. By being less invasive than open heart surgery and minimising symptom management, the procedure aims to reduce both the time patients spend in hospital and the number of repeat visits.

Human trials are the next step for CroiValve as the start-up edges closer towards taking the device to market.

“We weren’t sure how we would take CroiValve from an idea to a device. The support we’ve received from EIT Health has really allowed us to do that.”  
– **Dr Martin Quinn**

# spotlight

## EIT Health is committed to tackling the health challenges of an ageing population by supporting ground-breaking solutions for chronic conditions

Improvements in healthcare are helping Europeans to live longer than ever before.<sup>1</sup> In fact, it is expected that by 2100, almost a third of Europeans will be over 65 years of age.<sup>1</sup> But an ageing population means more people are likely to develop chronic diseases which can adversely affect their quality of life<sup>2,3</sup> and place significant burden on healthcare systems.<sup>4</sup>

Through our unique network of world-class healthcare organisations, EIT Health links entrepreneurial businesses with the knowledge and resources where needed to help fast-track their solutions to market. One example of such a solution is CroiValve, a start-up that is developing a device that aims to treat an otherwise chronic and debilitating condition.

## The story of CroiValve

Tricuspid regurgitation, known as TR, is a life-threatening condition prevalent among the elderly.<sup>5</sup> In patients with TR, the main valve between the chambers on the right side of the heart fails to work properly, causing blood to leak backwards.<sup>6</sup> This can lead to tiredness, appetite loss and swelling and also makes it harder to breathe, therefore significantly impacting a patient’s life.<sup>7,8</sup> Currently, the only option to treat this chronic condition is open heart surgery, which often isn’t suitable for elderly patients who may be too frail to undergo such a major operation. This results in many patients continuing to live with the condition and only being able to manage their symptoms which are debilitating and occur frequently. There is no option for these patients in treating the root cause.

Founded in 2016, CroiValve is developing a novel way to treat TR that goes beyond symptom management. The start-up has created a device that is designed to prevent the blood in the right ventricle of the heart from leaking backwards, by repairing the valve. It is implanted into the heart via a vein (a process known as transcatheter valve treatment) and therefore avoids the need for surgery. This means that vulnerable patients, who only currently have the option to manage their symptoms, could finally be treated.

As it’s less invasive than surgery, patients will spend less time in hospital as the recovery afterwards is quicker. Because the root cause of the condition is treated, it also means that patients won’t need to continue going to hospital to treat the ongoing symptoms, resulting in improved quality of life for the patients and reduced costs for health services.

CroiValve was awarded funding from EIT Health and introduced to multiple partners through the EIT Health network. This support enabled CroiValve to conduct extensive testing and validation of the device which is required to bring it to patients.

“Securing support from EIT Health was hugely transformational – without that, it certainly would have been a far more challenging journey.” – **Lucy O’Keefe, CEO of CroiValve**



EIT Health is supported by EIT, a body of the European Union

[1] Eurostat. Population structure and ageing, 2019. [https://ec.europa.eu/eurostat/statistics-explained/index.php/Population\\_structure\\_and\\_ageing#The\\_share\\_of\\_elderly\\_people\\_continues\\_to\\_increase](https://ec.europa.eu/eurostat/statistics-explained/index.php/Population_structure_and_ageing#The_share_of_elderly_people_continues_to_increase)

[2] Brennan P, Perola M, van Ommeren GJ, et al. Chronic disease research in Europe and the need for integrated population cohorts. Eur J Epidemiol 2018; 32: 741–749.

[3] eHealth Action Plan 2012–2020 – Innovative healthcare for the 21st century. European Commission; 2012

[4] Population ageing in Europe: Facts, implications and policies. European Commission. 2014.

[5] Prihadi EA. Tricuspid valve regurgitation: no longer the “forgotten valve”. E Journal of Cardiology 15(30)

[6] Medline Plus. Tricuspid regurgitation. Available from: <https://medlineplus.gov/ency/article/000169.htm>

[7] Mayo Clinic. Tricuspid regurgitation. Available from: <https://www.mayoclinic.org/diseases-conditions/tricuspid-valve-regurgitation/symptoms-causes/syc-20350168>

[8] Mercy Health. Tricuspid valve regurgitation. Available from: <https://www.mercy.com/health-care-services/heart-vascular/conditions/tricuspid-valve-regurgitation>

[9] Rostagno C. Heart valve disease in the elderly. World Journal of Cardiology 2019; 11(2): 71 – 83.

[10] Taramasso M, et al. The growing clinical importance of secondary tricuspid regurgitation. JACC 2012; 59(8): 703 – 710.