- My name is Tom De Potter. I work as an electrophysiologist in the cardiovascular centre in Aalst, in Belgium. Where I function as the associate director of the Cardiovascular Centre.

Please summarise the aim, study design and endpoints?

So CryoCure-2 is an open-label study that was designed to study the feasibility of a novel-ablation platform for treating atrial fibrillation, paroxysmal or persistent atrial fibrillation. CryoCure-2 was designed to recruit patients selected for an ablation procedure and monitored acute procedural efficacy, as well as clinical outcomes at one year, post-procedure. Ultimately, 79 patients were recruited into CryoCure-2. Being an open-label study, there is no comparator arm.

What were your key findings?

The key findings of CryoCure-2 were first and foremost that in terms of clinical efficacy, we were very happy to observe an 82% clinical efficacy at one year after a single procedure in terms of successful treatment of atrial fibrillation for the entire patient-cohort. And for the specific subpopulation of patients with persistent atrial fibrillation, which was the majority of the study population. We saw an 85% clinical efficacy rate. Furthermore, we saw in terms of acute procedural efficacy that the procedure can be done in a very reasonable amount of time. The average procedure duration was under two hours for the study cohort, which is, I think certainly impressive if you consider the first in man, nature of the study design. And if you consider the additional time that is typically needed for study purposes in such a trial. And perhaps even more importantly than the average procedure duration, was the observation that if we want to do additional ablation strategies, if we want to ablate additional targets outside the pulmonary veins, which we've called PVI plus in this particular study. The additional time needed to do so is very limited. Is in the order of additional minutes on top of the time you'll be needing to do the procedure anyway. Finally, in terms of safety, we're happy to report that we observed a very low adverse event rate. We observed the 1.5% adverse event rate, which was, which consisted completely of phrenic nerve injury, as we have seen in other cryoablation technologies and which resolved completely during follow-up.

How should your findings impact practice and influence further research?

The goal of CryoCure-2 has always been to replicate or approximate results that we've seen in surgery, in cryosurgery for atrial fibrillation. Using a percutaneous approach. And I believe our results have shown that the ultra-low temperature cryoablation platform is capable of achieving this ambitious goal. And we have implemented in clinical practice throughout our population this approach already. The ablation platform is commercially available in Europe as of today. But of course, next steps, scientifically speaking, are to validate our results in larger cohorts. And for this in Europe, a post-market registry is ongoing. In parallel with that there is a specific dedicated ID study ongoing in the United States, where we are also contributing to. Which is recruiting only patients with persistent atrial fibrillation to validate our results in a much larger multicenter setting.