HEARTio – Smarter Cardiac Triage
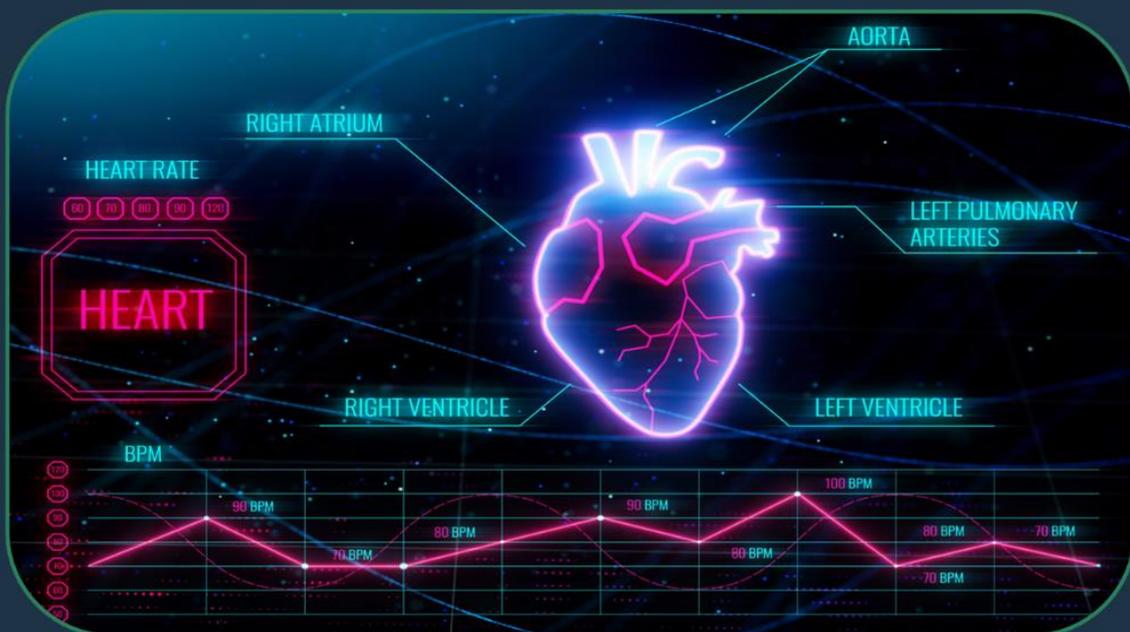

Faster more accurate cardiac triage to save lives, money, and time

Jeremy Cox, Founder CX-Create

Table of Contents

About this report

Based on interviews with Utkars Jain, co-founder and CEO, this brief report introduces HEARTio, (HEART INPUT OUTPUT, INC), one of a growing number of highly innovative companies supported by the Oracle for Startups program.

The company, founded in 2018, can make a massive difference helping emergency response teams, cardiologists, and clinicians rapidly diagnose and categorize the chest pains of incoming patients. The solution, ECGio, dramatically improves the triage process and minimizes the risk of misdiagnosis. Thus, ensuring that those at high risk of cardiac arrest are treated quickly while those whose chest pains are from less severe causes, like anxiety or indigestion, do not divert clinicians from time-critical cases.

HEARTio's solution is still in the clinical trials phase of development. It is hoped that reputable studies in partnership with the Cardiology Consultants of Philadelphia and early trials will provide a good evidence base for approval by the US Food and Drug Administration (FDA) approval of its AI-supported diagnostic platform - ECGio, running on Oracle Cloud Infrastructure (OCI). In November 2020, ECGio was granted Breakthrough Designation by the FDA to facilitate closer dialogue between the agency and the company.

The theme for this month is around startups in the healthcare sector and how they are innovating, changing the competitive landscape, and contributing to better health outcomes at a lower cost.

CX-Create is an independent IT industry analyst and advisory firm, and this report is sponsored by the Oracle for Startups program team.

Highlights:

- HEARTio's ECGio platform accelerates accurate diagnosis of chest pains
- Three co-founders started HEARTio while at the University of Pittsburgh
- ECGio – Smarter Cardiac Triage
- Oracle Cloud Infrastructure and the Oracle for Startups program prove their value to HEARTio
- If ECGio receives FDA approval, opportunities outside the US will also emerge

The business context for HEARTio

Key driver – accurate, fast diagnosis of the underlying causes of chest pains

Chest pains can be alarming and indicate a heart attack or dangerous issue with coronary arteries that might lead to one. They can also be caused by various other reasons, some relatively benign, like indigestion or a sudden anxious moment. When patients turn up at

emergency rooms in their nearest hospital, they may follow different treatment pathways depending on the immediate diagnosis. There is, however, not a single test to ensure the right pathway is followed. According to a study by Nawar E, Niska RW, Xu J. National hospital ambulatory medical care survey: 2005 emergency department summary. 2007 June 29, only 31% followed the correct pathway. Unsurprisingly, given concerns about potentially fatal outcomes, 65% received over-treatment, tying up resources unnecessarily, and only 4% under-treatment. Effective and reliable triage is critical to patient health and avoiding wasted resources, potentially invasive tests, and higher costs.

An electrocardiogram (ECG) is often the first test used to determine the health of the patient's heart and any abnormalities that might cause chest pain. However, to identify coronary heart disease from an ECG test with the naked eye is imperfect. It normally requires deeper analysis through a machine to uncover it.

HEARTio's ECGio platform accelerates accurate diagnosis of chest pains

What HEARTio provides with its ECGio cloud platform is to use artificial intelligence to help the clinician arrive at a more reliable diagnosis. ECGio identifies coronory artery disease in in the heart's arteries: the left main, the left circumflex, left anterior descending (LAD) artery, etc.

HEARTio's ECGio platform shows early signs of improved diagnosis at a lower cost than traditional tests. It may avoid the need for more invasive investigations where the underlying cause of the chest pain has nothing to do with the heart.

> We're committed to savings lives, reducing healthcare costs, and improving the Emergency Department experience for all.
>
> Utkars Jain, CEO HEARTio

HEARTio - the story so far

The beginning

Three co-founders, friends at the University of Pittsburgh developed the concept for HEARTio's eventual launch in 2018 while studying for their degrees. Utkars Jain, currently pursuing his Ph.D. in Bioengineering, came up with the idea while studying for a degree in Applied Mathematics and Neuroscience. He was fascinated with the potential of machine learning and artificial neural networks being applied in the medical field. His ideas were inspired by the loss of his grandfather following a misdiagnosed chest pain that had resulted from severe gastrointestinal bleeding. By the time this was discovered by doctors, it was too late.

Jain's friend and colleague, Adam Butchy, graduated with a degree in Chemical Engineering and Biochemistry from Villanova University and is also pursuing a Ph.D. in Bioengineering at the same Pittsburgh university. Shortly after the two started working on ML algorithms fed by ECG data, the two friends met Michael Leasure, who has his degree in Supply Chain Management from the University of Pittsburgh.

The three worked part-time on the ECGio platform after its launch in March 2018. The following year, they published their first paper in the Canadian Journal of Cardiology, gaining recognition and attracting seed funding, allowing them to accelerate the platform's development full-time.

Jain is the CEO and takes the AI lead. Butchy is responsible for short-term strategy and the long-term vision for HEARTio and regulatory submission, HIPAA compliance, clinical validation, and talent acquisition. Leasure focuses on day-to-day operations, meeting clients, and finance.

Solution overview

ECGio – Smarter Cardiac Triage
Patients coming to the hospital with chest pains will usually be given an ECG for the initial diagnosis. The ECG data is then stored in a database. HEARTio's ECGio platform is automatically updated via an API and can return an initial diagnosis within a matter of seconds.
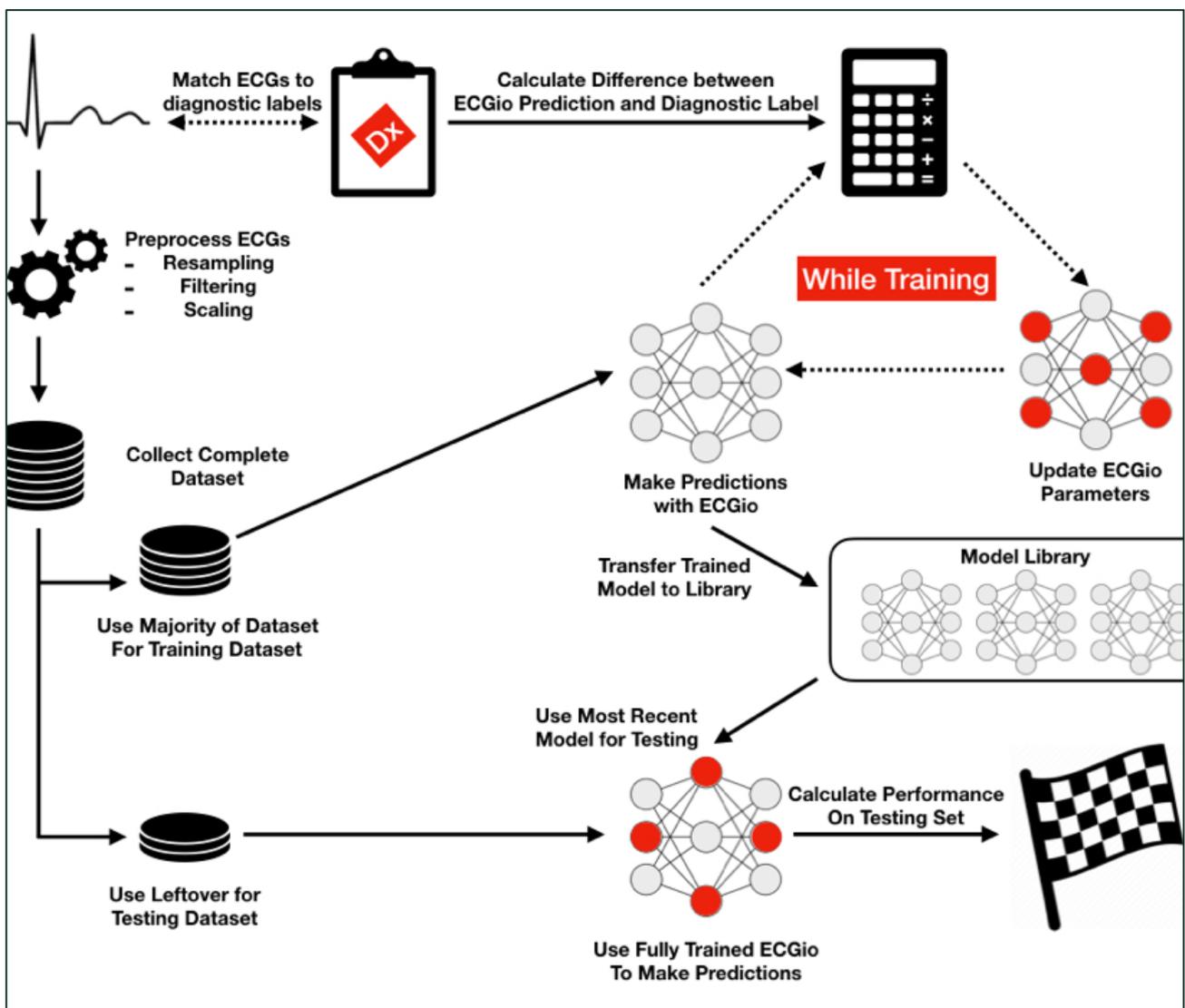

FIGURE 1 - HOW ECGIO WORKS. SOURCE: HEARTIO

Figure 1 provides provides an overview of how ECGio works and its machine learning models are trained by continuously ingesting additional data from ECGs.. ECGs provide the fastest test compared with other diagnostic techniques, which, are subject to interpretation and the

clinician's or cardiologist's level of skill and experience. By intercepting the ECG data via APIs, ECGio can rapidly provide a pattern match by comparing over ten million ECG data samples and using the AI algorithms in the platform that have been trained on the data.

This provides a low-cost solution without any special training of onsite clinicians. More accurate tests such as Calcium Scores, Myocardial Perfusion Imaging, and Fractional Flow Reserve – Computed Tomography can be used; however, they are time-consuming and rack up the costs involved.

Current position

Trials & validation studies

Following an initial six-month validation process in partnership with highly regarded Cardiology Consultants of Philadelphia in 2020, the study has since been extended. The high-scale validation is expected to conclude in 2022 and provide additional momentum for FDA approval.

Advisory support from recognized experts

While Jain, Butchy, and Leasure continue to fine-tune the AI algorithms and work with the Cardiology Consultants of Philadelphia, they also have an advisory team of experts to act as mentors, challenge their thinking, and provide guidance for commercializing ECGio once FDA approval is granted.

- **Dr. Russ Salakhutdinov, Ph.D.,** is a UPMC Professor of Computer Science in the machine learning department at Carnegie Mellon University. His specialism is deep learning, probabilistic graphical models, and large-scale optimization, and Google, Microsoft, and Samsung fund him.
- **Dr. Veronica Covalesky, MD,** is the President of the Cardiovascular Institute of Philadelphia. She is an Adjunct Clinical Assistant Professor at several hospitals in Pennsylvania and completed her fellowship in cardiology at Hahnemann University Hospital and the University of Pennsylvania.
- **John Marous** – former president and CEO of Tandem Life, led the development and initial commercialization of the Tandem Heart system.

HEARTio has several strategic partnerships to help it develop and commercialize its solution:

- **National Science Foundation's Innovation Corps** – which offers research and commercialization support.
- **Nvidia Inception Program** – providing technical resources and advice for startups.
- **University of Pittsburgh Innovation Institute** provides guidance on commercialization, licensing, and entrepreneurship.
- **Oracle for Startups program** – discussed below.

The validation trials, expert advisory support, and the FDA Breakthrough Device Designation bode well for the future. According to the FDA, the first criterion for receiving the Breakthrough Device Designation: *The device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions.* Providing smarter cardiac triage meets that criterion.

Current go-to-market

In advance of FDA approval for general clinical use throughout the US, HEARTio's route to market is via clinical trials and validation, in partnership with the University of Philadelphia and Cardiology Consultants of Philadelphia and others. Once approved, take-up of the ECGio solution is likely to be rapid.

Clinicians will benefit through faster and more effective triage, enabling them to focus on victims of chest pains caused by severe and underlying heart conditions. The improved testing sensitivity will significantly reduce erroneous patient discharging. Medical costs will diminish, and unnecessary testing will be avoided. Patients with non-cardiac-related conditions will get peace of mind that the conditions causing the pain are not life-threatening. If dangerous but not caused by heart conditions, they can be quickly diverted to the relevant medical team. Payors can reduce their cost exposure by avoiding unnecessary testing and receiving better outpatient monitoring.

Future direction

What to expect

The ECGio AI algorithms have been trained by the data from 10,000,000 ECG readings from over 500,000 patients. AI in clinical environments must meet a very high bar of transparency. Therefore, as the ECGio platform ingests more data, refinements require constant monitoring to avoid rogue outputs resulting from self-learning adaptations. The scale of this monitoring is likely to increase substantially, and therefore it is expected HEARTio will expand its team of AI and cardiology experts.

While the solution is easy to use and does not require specialist training for emergency teams, inevitably, the level of remote support required will grow substantially. Word of mouth will rapidly increase demand once the FDA approves the ECGio platform, and HEARTio will need to tackle the growing support challenge. This may require partnerships with organizations that have the relevant domain expertise.

When asked about expanding beyond the US, Jain said that it would depend on the different regulatory requirements in other countries. The FDA is considered across the world as the gold standard, so we can expect countries like the UK to move rapidly once FDA approval is forthcoming.

Oracle Cloud Infrastructure and the Oracle for Startups program prove their value to HEARTio

Michael Leasure was aware of the Oracle for Startups program, and the team agreed to contact Oracle in 2020. They were initially attracted by the low-cost terms of migrating to the Oracle Cloud Infrastructure, and the security and scalability of OCI were also reassuring. They did not expect the level of attention and support they received from the Oracle for Startups team. As Jain said, 'they really made us feel that we were a priority.' He was also very pleased with how Oracle increased its visibility by providing analyst briefings and social media support in the form of blogs and video interviews.

CX-Create's viewpoint

If FDA approval is received, opportunities will also emerge outside the US.

As mentioned earlier, the limiting factor for HEARTio will be the ability to scale up support as demand proliferates following FDA approval. We expect HEARTio to overcome the challenge through extended partnerships and investment.

HEARTio has already shown that it is adept at forging partnerships with academia and commercial organizations to help accelerate progress. Once the FDA has approved ECGio, HEARTio will likely receive offers from significant investors that can be used for both product development and scaling up support. Oracle is investing in the healthcare market. In December 2021, Oracle jointly announced an agreement to acquire Cerner, a leading provider of digital information systems used within hospitals and health systems, to enable medical professionals to deliver better healthcare to individual patients and communities. Oracle also has one of the most advanced customer service applications that HEARTio could utilize to ramp up its support capabilities.

Beyond the US, we expect HEARTio to win clients in other advanced economies. The NHS in the UK would seem an obvious candidate. The Medicines and Healthcare products Regulatory Agency (MHRA) was the first such agency to approve the Pfizer BioNTech vaccine to fight against the current Covid-19 pandemic.

HEARTio's future success will depend on the FDA's approval, which will depend on HEARTio's pivotal study that will be doen after the next validation study. It is hoped that its success in 2022 with the latest validation exercise will further lead towards that goal.

Summary details

Table 1: Fact sheet

Solution name	ECGio	Solution category	Healthcare
Key industries	Healthcare	Geographies	US
Deployment model	PaaS	Licensing basis	SaaS
Size of organizations served	Large and medium	Go-to-market model	Direct
Number of employees	3	Key partnerships	National Science Foundation's Innovation Corps, Nvidia Inception Program, University of Pittsburgh Innovation Institute, Oracle for Startups program
URL	https://www.heartio.ai/	HQ	1 Big Idea Center,30 Thackeray Ave Pittsburgh, PA 15213 United States

Appendix

Further reading

- [Aindra Systems - democratizes healthcare in India](#)
- [PRORADIS - shortens distance and time improving patient care in Latin America through innovation](#)
- [Skin Analytics - helping moore people survive skin cancer](#)
- [Sensei Ag - .improving human nutrition](#)
- [Sensei Retreats – takes a science-led approachto health and wellbeing.](#)

To explore more startups supported by the Oracle for Startups program, follow this [link,](#) and under categories select Startups and Scaleups for innovation, sub-category: Oracle for Startups.

About CX-Create

Jeremy Cox founded CX-Create Limited in January 2021, a former principal analyst at Omdia (formerly Ovum) focused on customer engagement strategies and platforms.

He is recognized by major CX vendors, clients, and former colleagues as a leading thinker in customer experience and engagement. Formative experiences in the 1990s at IBM convinced him of the critical importance of understanding the business world from the outside in. These insights were put to practical use in his former roles as a principal CRM consultant at KPMG Consulting and as an independent consultant supporting public and private sector organizations.

Our mission

CX-Create's mission is to help enterprises and the vendors and startups that serve them remain relevant. The company's primary focus is to track and understand the constantly evolving customer experience world and share those insights with clients. Continuous innovation is also an essential component of persistent customer relevance, directly and indirectly, which is why we are enthusiastic about startups and the Oracle for Startups program.

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