Adaptive LIFE SCIENCE

Adaptive Life Science is a specialist recruitment consultancy service for medical device manufacturers in Germany.

Rebecca Stevens
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Investing in People

Last month I had the pleasure to catch up with some of the team at Vara.

I welcomed Jonas Muff, CEO and Miriam Klemke, Regulatory Affairs Manager into the hot seat to talk about life in the MedTech start-up who are revolutionizing breast cancer screening. We discussed the growth plans for Vara, challenges facing the AI space and all things regulatory.

You cannot explain the team spirit at Vara – you just feel it.

Who are Vara?

Vara are a team of over 25 medical specialists, engineers, and entrepreneurs. Vara have built a machine learning powered platform for radiologists which reduces repetitive work and enables them to focus on cases which really matter.

Radiologists are held back by an increasing workload of normal exams. That's why Vara train machine learning models to flag these with very high confidence. Vara alerts the screening radiologist if they report an exam as normal when Vara has detected a suspicious finding. This alert prompts the reader to take a second look at the exam and shows them the region of interest.

You can find out more about Vara at the end of this Q&A.

Jonas Muff
Founder @Vara

Miriam Klemke
Regulatory Compliance for Medical Devices / AI Software

Rebecca: Can you tell us more about your journey, Jonas and how Vara was established?

Jonas: *I was the first employee at Merantix, an Artificial Intelligence (AI) venture studio. 4.5 years ago when we started, we knew there was huge potential for machine learning and AI to impact several industries in an overwhelmingly positive way – healthcare was one of these industries for tremendous potential.*

I built up the business of the Venture Studio before transitioning to Merantix spin-off, Vara in 2018, where I would lead the company as CEO. We saw the challenges in early cancer detection, and this was a problem we wanted to solve.

Breast cancer is the most prevalent cancer in women, and unfortunately 1 in 8 women will develop breast cancer in their lives. It is very curable if detected in its early stages, with patients having a 90% survival rate. Vara support radiologists to find suspicious mammography results, and spend more time focussed on the 3% of abnormal results, and not the 97% of healthy results.

We raised €6.5M in Series A funding in 2020, and Vara was the first AI software to receive CE mark for breast cancer screening automation. We have 10 live customers in Germany that are using the product daily, so the next step is to expand across the country and support more radiology teams to have access to the Vara platform. Then we can really start to revolutionize this field.

// We are finding fast solutions for pretty big problems sometimes.

Rebecca: What are the future plans for Vara?

Jonas: *The exciting part of being in a start-up is that some things are still undefined, and we still get to explore. Right now, we have a product on the market in Germany and our customers are satisfied.*

With our Medical Device Regulation (MDR) certificate we'll be able to use the harmonized standard to work with radiologist teams across Europe. The US market is on our mind, but you'll have to talk to Miriam about that!

On the technical side, we are always improving the product. We are closely observing the clinical data and developing further evidence in clinical studies to assess the positive impact of AI generally, and specifically on breast cancer screening. We even have the capability to expand the technology beyond mammography screening and into other pathological domains and other diseases, such as lung cancer or prostate cancer.

One long-term goal is to assess the impact Vara can have in emerging markets. Breast cancer screening isn't developed in these countries, so many women don't get a mammogram on a routine basis. It's a clear way we can support these underserved markets, the radiologists, and the patients.

Rebecca: What skills do you think are vital to success in a MedTech start-up?

Jonas: *Every MedTech company (including Vara) is, or should be, putting improving patient outcomes at the forefront. If you want to scale your impact (especially with VC money), speed matters. It's in our DNA when selecting talent, that we hire candidates who can manage the balance between clinical rigour and speed.*

Having personalities that don't just comply with regulatory processes but play an active part in shaping them in line with the company structure is vital. People who can navigate and are flexible to work at the intersection of high-speed growth and low-speed regulatory will succeed in a MedTech start-up. Before we hire anyone, we make sure people are comfortable in this environment.

To be successful, join a start-up like Vara for the right reasons - you should want to help patients. You should be pragmatic and comfortable with growing pains. We are finding fast solutions for pretty big problems sometimes.

> ***You get to have a major impact and your voice will be heard, so make sure you are ready for your team to hear it!***

Rebecca: AI is revolutionizing healthcare, but what do you see as the barriers to success?

Jonas: *AI's promise is to automate human work, and therefore it has a lot of potential, because there is no one human an expert in all areas. AI has the capability to automate a lot of that work. It's a win/win for the company (solving a problem), healthcare provider (cost saving, efficiency), and the patient (better outcomes). These are the legitimate interests of AI, broadly speaking. However, AI cannot make independent decisions. Someone still must be accountable and liable – it cannot automate all human work.*

Healthcare technology reimbursement requires assessment procedures and multi-centre clinical trials to prove that the technology is safe. It's a necessary process, but at the same time, if the automation potential of the product is limited, the revenue potential is limited. Customers will only pay a certain price for a solution. Therefore, as a MedTech AI company, you go through the assessment process which costs a lot of time and money, but it needs to be worthwhile.

We have to push the boundaries of AI, but still make sure the product is safe and profitable.

Rebecca: What attracted you to join Vara?

Miriam: *Jonas has passion and drive and the whole team feel this. It was inspirational during the interview process and a team I knew I wanted to be a part of. We have a common goal – the team want to implement AI into healthcare, and everyone is driven to improve the whole system for society. I've been working in Regulatory Affairs for a long time but deep in my heart I am a Medical Scientist. Working with Machine Learning and AI, connecting it to healthcare really is a dream for me.*

Rebecca: What do you see as the biggest challenge in MDR for AI MedTech companies?

Miriam: *Especially in the software section, MDR Classification Rule 11. Some even say it's the 'regulatory nightmare' because of the huge amount of resources, paperwork, and time to up-classify devices to the new regulations. There are increased costs and time management concerns because of the bottlenecks with Notified Bodies. Some companies have to invest in a position they never had to before, like the PRRC.*

In the area of Artificial Intelligence, a lot will stay unregulated, and this is a huge grey area. Making the transition to higher regulatory requirements for software is tough, and then you must balance this with the grey area of AI.

Rebecca: You transitioned from a 5,000 person company to a start-up – what was the biggest challenge for you?

Miriam: *Definitely the speed and flexibility of mind. At one of my previous companies, they were highly regulated and planned projects several years in advance. In a start-up you are setting and adjusting the priorities of projects on a monthly, weekly, daily basis.*

The benefit though of working in a start-up is that you work as a team to solve problems and still manage to complete time-critical projects. It's agile working and interactive. As a Regulatory Affairs professional, you have to interact with every stakeholder whether they are internal or external. I have to be at the centre of this communication and coordinate it – I like to have this visibility as it makes me better at my job.

> ***You can't be a small wheel inside a big machine.***

Rebecca: You're working broadly across RA/QM/Data privacy – how do you manage your time?

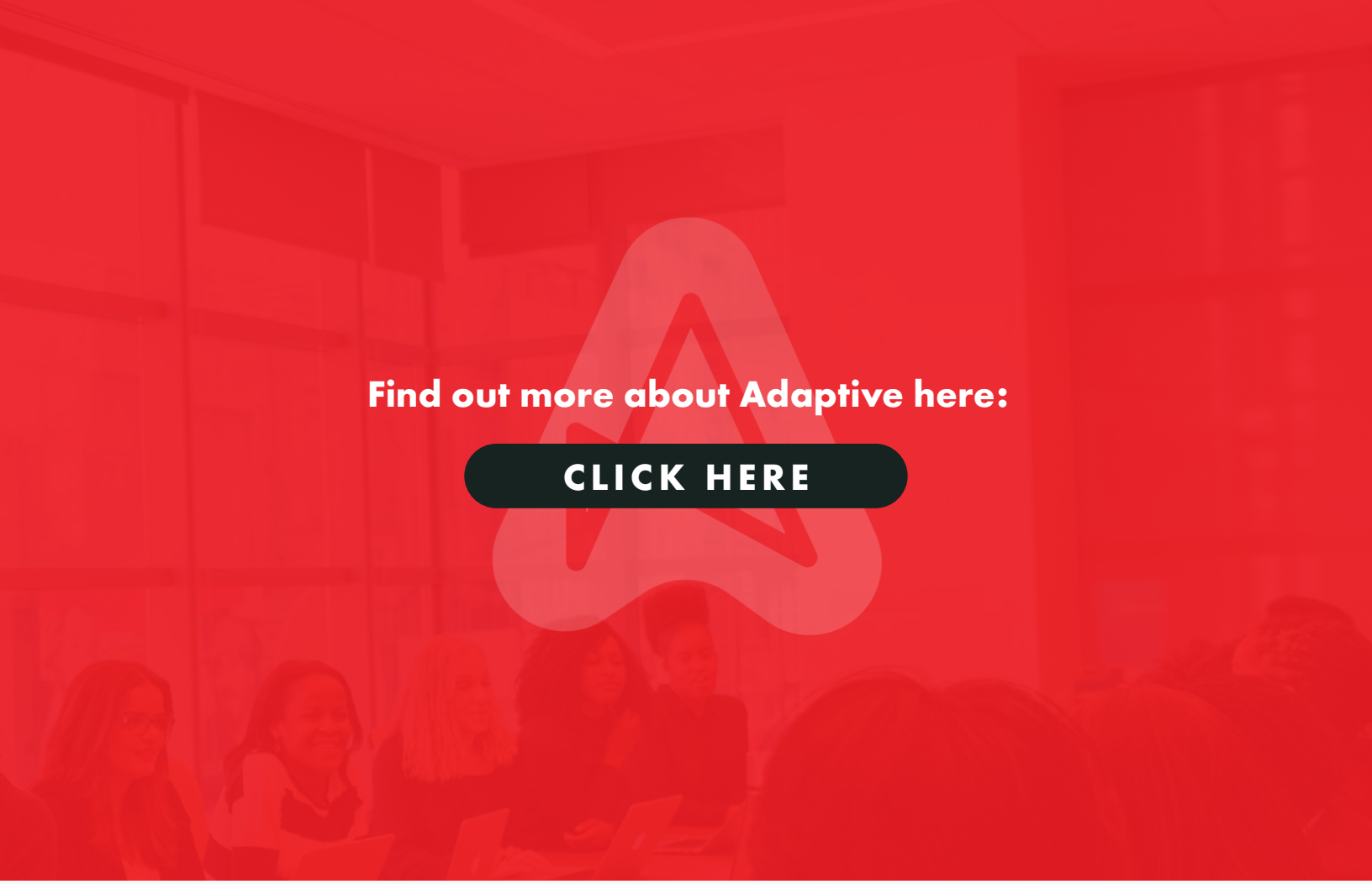
Miriam: *I'm a big fan of lean management, agile working and Kanban. I had to unlearn and relearn a lot about project management. I must keep track of tasks on a daily basis to identify red flags and bottlenecks. Part of my job is to identify problems asap and communicate them to the team, to ensure we still achieve the weekly sprints.*

I try not to overregulate my own day – my diary is time blocked with reoccurring weekly tasks, but I have to be flexible to assess the project priorities.

Rebecca: What would your advice be to anyone thinking about a transition to a start-up? Tell us the good, the bad and the ugly.

Miriam: *My biggest advice - You have to love what you do because you will need to be dedicated with your time and energy. You have to work with a high level of responsibility and an autonomous working attitude. You will need to love discussions and meetings, being challenged, and challenging yourself. You get to have a major impact and your voice will be heard, so make sure you are ready for your team to hear it! You can't be a small wheel inside a big machine. I love that I get to work with my CEO so directly and be part of the future growth and vision. I never had this before.*

You cannot explain the Team spirit at Vara – you just feel it.



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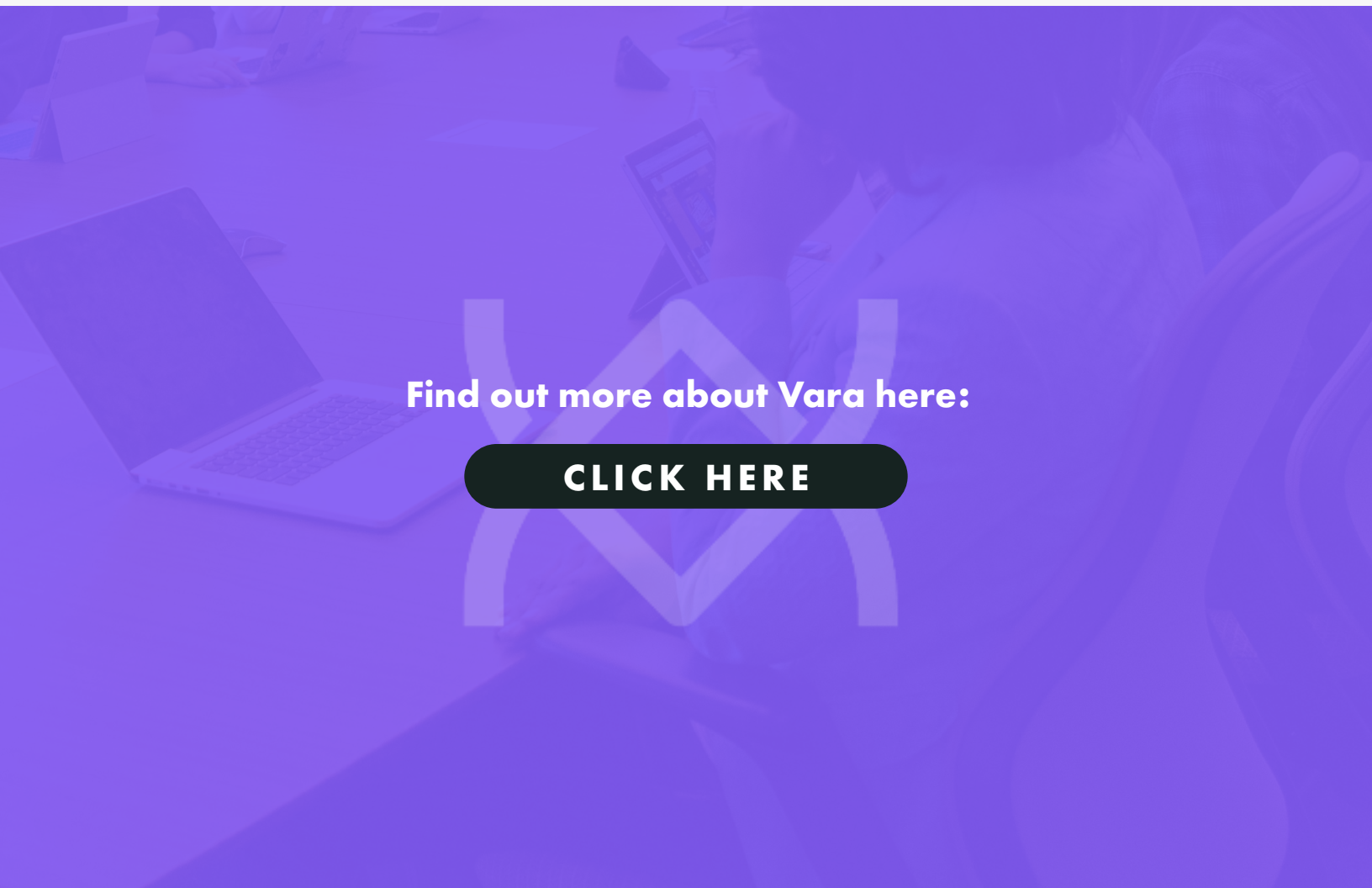

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