



DIGITAL HEALTH'S CHANGING THE WORLD.

**BUT HOW DO YOU SCALE A DIGITAL HEALTH
BUSINESS? HOW DO YOU TAILOR YOUR
PROPOSITION TO THE MARKET?**

The current pace of technological development is exerting profound changes on the way in which people live and work. It's impacting all disciplines, economies and industries. As a Recruitment Specialist which has built a dedicated team to serve the Digital Health sector, we've had a front-row seat in witnessing the evolution of some of the most exciting Digital Health Start-ups.

It's abundantly clear that the future of healthcare will not be like the present. The Pharmaceutical industry faces the challenge of moving beyond the product into long-term integrated solutions, whilst other providers face the challenges associated with increased demand, a pressure to reduce costs, and a move to value based reimbursement policies.

Successful solutions to these most pressing challenges are often uncovered by disruptors who aren't setting out to improve a business process but rather, are looking to create a new way of doing business entirely.

Zest Scientific has supported some of the most exciting Digital Health disruptors, and it's clear that there isn't a magic formula for achieving the changes required by an ever changing landscape.

This paper does however seek to shed some light on possible options for emerging businesses. It picks the brains of leaders in the industry, and explores their views around the key topics of championing innovation, scaling, and adopting evolving customer needs, all whilst working to a very much emerging regulatory framework. It also goes on to ask how the demographic of 'Generation Z' – brought up around the technology on which Digital Health relies – will form the talent pool deciding the future for the industry.

As a result, it'll hopefully provide some useful, real-world insight as to how the landscape's being shaped from the individuals and companies who are themselves shaping it.

BALANCING INNOVATION WITH CORE BUSINESS NEEDS

Innovation lies at the very heart of the Digital sector, and business leaders face the challenge of creating environments where knowledgeable and creative talent can test innovative ideas, and perhaps also be 'set free' from the daily responsibilities of operating the existing core business. We asked Jason Freeman - Chief Treatment Design Officer from Oxford VR - how he juggles the demands of managing the core business requirements and finding time to focus on strategic innovation:

"Innovation is at the core of Oxford VR's business. VR for mental healthcare is a relatively new field. There is no playbook for success. This means being prepared to try a variety of approaches, learn lessons quickly, and adapt accordingly. As ever, recruitment is critical; we have been careful to hire people across the company who are comfortable in an agile, discursive, open environment. This is essential for any start-up, of course, but perhaps even more important given the relative novelty of mass-market VR technology and its application to healthcare. This doesn't mean that strategic innovation always happens automatically. As well as



hiring people with the right mind-set, it's essential to provide regular opportunities for those individuals to discuss candidly what we've done, where we want to go in the future, and how best to get there."

Jason's thoughts clearly lie in an ongoing flexibility when approaching a newly conceived industry. Julian Coe - Chief Operating Officer with Repositve – addresses the question from the end goal first: "Do the first revenue opportunities fit the strategy you envisaged and enable you to build that core business? If yes – great. If not – what is wrong, the strategic thinking or the opportunity? It is very difficult to turn business away but you may need to do that to develop your optimal core business."

Clearly then, there are some obvious indications that adaptability and flexibility is the way to balance innovation and the core business function in an ever changing field. This is however tempered somewhat though by the need to have some sort of vision as to what revenue opportunities and growth strategies are available.



VIEWING INNOVATIVE STRATEGIES AS SAFE HAVENS

Such an open and adaptable approach at a strategic level has traditionally had its own perceptions of attached risk, but what's clear is that the speed at which the Digital Health industry can change may well require it. How then do the companies with which we work create a culture where leadership view innovative strategies as safe havens, as opposed to the risky option?

John Cassidy - Chief Executive Officer for Cambridge Cancer Genomics - felt that this is a challenge in a reserved culture such as Cambridge: "We try to bring as much of the Silicon Valley ethos to Cambridge as we can and have adopted the 'two pizza team' [mentality]. We have small, well resourced, and autonomous teams who make faster decisions and tend to adopt an innovation-heavy hacker mentality."

Andreas Caduff - the Founder of Biovotion - also accepts that this is a very difficult challenge, and believes that the company needs to have robust foundations which can be used as the platform on which further innovations can be tested and verified: "In the case of Biovotion, we have concretely established a medically approved best in class wearable that can be seen as a kind of standard data collection tool. On that basis one can then experiment, explore and innovate using the data from the device."

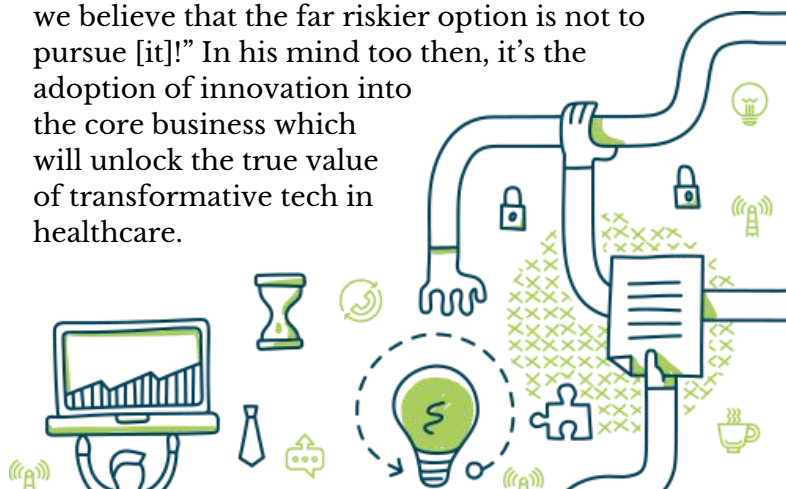
Jason (Oxford VR) believes it's also largely down to a holistic hiring strategy, not just the senior leadership team's ethos and aspirations: "Everyone must be able to cope with, and thrive in, a fluid, fast changing, risk-taking environment. With the right people, a culture of innovation is much easier for leadership to establish."



This fluidity in business strategy is likely what's attracted so many outstanding professionals to the Digital sphere, not least owing to the refreshing creativity such an approach provides commercially. Primarily though, and as a result of the ability to experiment with more innovative processes, the prospect of improved outcomes for patients is increased too.

Such is the case for Valentin Tablan, the Senior VP of Artificial Intelligence for Ieso Digital Health. For him – having forged a career within the development team of Amazon's Alexa - the necessity for adaptability to bring about innovation is echoed. "[For] organisations active in the healthcare industry, the relentless pursuit of innovation is the key to effecting change, to achieving competitive advantage, and to making a positive difference in the lives of patients. At Ieso, we have made a solid investment in innovation with the creation of an in-house multidisciplinary research lab that combines skills in clinical science, artificial intelligence, and software engineering. This allows us to stay competitive, to feed a continuous pipeline of new products, to add improvements to the existing ones, and to make progress on the path towards our mission to defeat mental illness.

Rather than seeing innovation as a cost, or a risk, we believe that the far riskier option is not to pursue [it]!" In his mind too then, it's the adoption of innovation into the core business which will unlock the true value of transformative tech in healthcare.



EMBRACING CLINICIAN AND USER INPUT

The commercial landscape has changed as organisations explore options to create competitive differentiation. Global drug makers are undertaking internal restructuring measures to prepare themselves for the digital transformation of pharmaceutical research, and the adoption of artificial intelligence for drug discovery. Disruptive tech is trying to create new markets and position their offering in undefended territory. From a product development perspective we wanted to examine how customer needs have been adopted when building a product or service which focuses on competitive differentiation:

Valentin Tablan (Ieso Digital Health) believes it's important to take a mixed approach which recognises customer needs, but doesn't inhibit the potential scope of new ideas: "Keeping innovation teams grounded in the needs of the customer is both necessary and risky. It is necessary because you need to build products that have a place in the marketplace. It is also risky because it can limit the horizons of the R&D efforts, focussing too much on the short-term, and missing out on the next disruption. The solution we take at Ieso for this conundrum is to make sure that we maintain a good mix of risk profiles in our projects portfolio. At all times we are working on near-to-market projects, that will deliver within the next 12 months; as well as on moon shots that may deliver big within the next five years, or that may not deliver at all. A key element is to always keep the door open for new project ideas that may arrive from any member of the organisation, or from any one of your partners."

Andreas Caduff (Biovotion) champions a collaborative approach in product development, highlighting the need to explore elements from different fields or functions. This approach thereby allows for a more complete examination of wider market needs, which a customer in isolation may not identify alone: It's "always helpful to have the luxury of clear customer needs that can be translated into concrete specifications for a product."

It can often be observed that examining all elements can lead to product offerings that allow the customer to truly transform through a capability that they on their own would not have requested initially. To put it simply, it is then the vision of the company to develop something which goes beyond the next step to have that competitive differentiation."

Sukhbinder Noorpuri, the CEO of i-GP ensured that both User Groups and Clinician voices were heard during the creation of their platform positioned to provide virtual GP consultations: "We had an experienced medical board who helped create the questions and patient flow on our platform. We continue to review our system in



Explaining further to us, Edward demonstrated how he provided a range of solutions which showed improved outcomes in the clinic, but simply didn't transfer into everyday use; the important lesson: "The Patient and Caregiver are interconnected and we obsessed about this."

We went through a number of off the shelf platforms and eight iterations of custom hardware before identifying what makes a difference.”

Oxford VR addresses the question from the perspective of the stakeholders, as well as utilising the data gained from clinical exploits which John Cassidy emphasises as being important. Jason Freeman summarises: "Every product we develop is produced in collaboration with stakeholders. We are a clinically led company, and where appropriate we supplement the expertise already in the company with that of Scientists and Clinicians from Health Services and Academia. Patients / users are always involved in the development process, providing input on designs, trying iterations of the software, and ultimately participating in pilot studies and randomised controlled clinical trials."

Tempering the emphasis on Key Opinion Groups, John Cassidy recognises that whilst their engagement is important, they do not necessarily represent your average user and input from patient groups is difficult as they aren't used to seeing the data. "We are actively involved with patient advocacy groups and we have some of the more active patients to come into the office and discuss their journey. This is great for reminding everyone what we are working toward, and for asking some of the more nuanced questions about the practical aspects of precision oncology."



ALIGNING REGULATORY REQUIREMENTS

Regulatory requirements are just that: requirements. Andreas Caduff (Biovotion) emphasises clearly the danger of not addressing this at the outset and applying a retrospective approach to regulatory alignment:

“Once the [customer needs] vision is translated into a concrete action plan it is then really important to have a regulatory view as well as other standard requirements fully reflected in the products functional specification. The same goes for cybersecurity and data privacy, both elements need to be core parts of a system architecture and functional specification from the very beginning as well. I see this as a relevant challenge for a number of organisations as it is often thought to be put on as an add on once things have been made.”

In agreement, Jay Lakhani recognised from the outset that regulatory alignment needed to play a central role in Visulytix’s development plans. “We ensured that regulatory requirements were at the heart of the discussions taking place in our software engineering scrums, data science, and business development meetings.”

It’s clear though that as the sector continues to gather pace, the legislative or regulatory bodies are being forced into a position of playing catch-up. By their nature, it takes a while to put an adequate regulatory process in place, and whilst there is an established framework for more traditional forms of healthcare, this structure is by no means tailored for disruptive tech. As such, defining what pathways should be taken for compliance when working with Digital Health products is not always particularly easy or clear, and certainly has less precedent than other therapies.

Whilst there has been a gradual inclusion of software and Software as a Medical Device regulations, it wasn’t until December 2017 that the US Food and Drug Administration (FDA) released a final ‘Software as a Medical Device (SAMD): Clinical Evaluation’ guidance document and on the same day, published draft guidance on clinical decision support software. Put simply, for the majority of solutions which are currently being brought to market, product development started way before the regulatory pathway for it was in place.

To tackle this conundrum, Edward Cox (Dthera Sciences) highlights the value of adopting tailored approaches when dealing with Product development and Regulatory authorities. For example, whilst one may pursue disruptive development aggressively, a much more measured and collaborative approach is required when dealing with regulatory authorities: “If you’re one of the first wave of a first wave, you are building the bridge out in front of you. We benefitted from taking a communicative approach with the FDA who provided excellent support and guidance.”

Regulatory bodies are not there to stifle new and beneficial solutions and as Andreas Caduff (Biovotion) and Jay Lakhani (Visulytix) clearly state, their approvals are a requirement for success. One should try to build the requirements into the development process but if the framework isn’t there, collaboration is key. By adopting an open stance for example, Edward ensured that Dthera explored fluid regulatory resolutions.

This can be an uncertain process though, so as he says: “Where possible, do not reinvent the wheel!”



SELECTING INVESTORS

There's a point along every business' road to success where external funding is required. How do you choose though between Seed Investors or Angel Investors, or perhaps Venture Capitalists? Age old investment questions will likely feature: What do you want the investors to provide for you? What is the timeline for their investment? etc.

Of course these questions will influence your decision, but in Digital Health a slightly different approach might be necessary. Not all businesses have the luxury of being able to pick what they perceive as 'smart investors', but it's evidently important to our panel that you select based on some shared principles, largely owing to the recency of the industry's emergence.

When Edward Cox (Dthera Sciences) joined their project, his objective was to solve a crisis first and build a business second. Edward believes that given the sector is still in its infancy, identifying investment partners who are extensively dialed into this area will inevitably be particularly challenging. For that reason, their selection was based on identifying common goals: "We largely selected partners based on integrity and [asked the question internally:] are they passionate about changing the treatment pathways for this disease?"

That being said, investors remain an extremely useful tool for scaling businesses when the right ones are picked. John Cassidy (Cambridge Cancer Genomics) recognises that CCG have been fortunate enough to have been in the privileged position of being able to select the investors with whom they'd like to work. "Y Combinator [an accelerator in California] were transformative for us, their network companies includes some of the hottest Start-Ups in the valley and the partners have lots of relevant experience we can draw on. We also had a Private Cancer Clinic invest very early on. This was amazing as we have direct access to lots of Clinicians and they are aligned with helping is succeed. In general we like to take capital from funds similar to us – small, agile and ready to roll their sleeves up and get involved."



LAYING THE PLATFORM FOR THE NEXT WAVE OF TALENT

The Digital Health space is well aligned by its progressive nature to mimic the wider societal trends forced by developing generational gaps. Whilst still in its infancy, Digital Health has adopted collaborative working practices, open-plan offices and workplace messaging systems – all of which are particularly appealing to a millennial talent pool. If we look to the future, similar paradigmatic shifts are on the horizon.

The next generation of talent will come from those born from the mid-90s, commonly referred to as 'Generation Z' or 'Gen Z'. Gen Z could quite possibly be the most independent generation we've ever seen. They've grown up in a climate where Google could instantly answer their questions, and YouTube walked them through a variety of do-it-yourself projects.

On top of the feeling of meaningful purpose which talent is often attracted to the industry for, this generation will most likely seek the same convenience – and resultant independence – which they have in their personal lives in their working life too.

The Digital Health sector has already shown itself to be progressive environment for millennials, and given its capacity for change, it has a fantastic opportunity to present a compelling case that its platforms will provide the brightest minds with the ability to make a meaningful difference.

As our panel noted however that the attraction of independence to Gen Z would render an extension of the same offering made to millennials (close team working etc.) a huge mistake. The question is ultimately: what new steps can we take to appeal to the new market?

Jay Lakhani - the CEO of Visulytix - recognises the need to create a culture which provides freedom and purpose: "[Typically] Gen Z employees have an expectation of a high amount of freedom in their work and opportunities to tackle challenges in new and innovative ways, [...] using the latest technologies. Our working environment is tailored to match this expectation with each of our team members being not only allowed but encouraged to find new ways to go about their work."

John Cassidy (Cambridge Cancer Genomics) mentions again that bringing the Silicon Valley ethos (minus the fake grass...) to Cambridge helps, and has incorporated a range of activities so as to create a more informal working culture. This in turn provides an added benefit to the sense of purpose the sector brings more generally: "We go for company meals, attend events around Cambridge and have even hosted Mario Kart tournaments in the office. We also have a fully stocked 'refreshment' fridge which definitely eases the toll of evening meetings!"



WHAT COMES FIRST WHEN SCALING, THE PEOPLE OR THE PROCESSES?

Solutions to real problems get funding, and investors are willing to back big ideas with potentially big returns. Our network has navigated the choppy waters of scaling a start-up, and we wanted to examine what comes first – the people or the processes?

Sukhbinder Noorpuri (i-GP) acknowledges that both elements are required for scaling, but leans towards the importance of recruiting the right people: “If you can develop a great team you create more opportunities which in turn usually leads to a more successful business. An agile and united team will deliver company goals.”

Along similar veins, Jason Freeman (Oxford VR) strives to create structures which don't stifle creativity and – as he has echoed previously - ensure that the business can react quickly to new market opportunities: “Processes need to be flexible, user-centered, and appropriate. Ideally, they emerge semi-organically from among the people who use them. And they don't unduly restrict the kind of agile approach that's so important for an early stage company like Oxford VR. However, unless you find the right people, no system or process is going to work. People drive the evolution of effective processes.”

There's no question for Jay Lakhani (Visulytix): any start-up should always put its people first, as processes are always going to need to change and adapt: “We need to remain agile to be able to deal with unforeseen challenges and placing too much of an emphasis on rigid processes will make that difficult. Great ideas come from the talent we have on-board so the smartest option is to consider them first.”



SUMMARY

The Digital Health Revolution is gathering significant momentum, and it's particularly evident from the C-suite which contributed to this Round-Table that there certainly are common traits which allow businesses to keep pace with their market.

In order to drive competitive differentiation through innovation, leaders often adopt strategies that incorporate fluidity to the core business function. This in turn not only makes the core business more flexible - and thereby less susceptible to shifts in the competitive and ever-changing landscape - but also drives innovation and positions their companies as being adaptable in new, undefended territory. Our panel universally accepted that people are the key to driving disruption, and business processes evolve organically as a result of having the right team. Putting it simply, Julian Coe (Repositive) didn't hesitate:

"People – easy choice. Which people and how many – not so easy."

This answer will come from the decisions implemented at a strategic level. Companies must create an environment which builds a team capable of supporting both 'moon shot' innovation goals, and also a good mix of shorter-term development projects. In so doing, they can allow for commercial sustainability, whilst also tapping into ideas which will change the landscape of healthcare as we know it.

It cannot however be underestimated the importance of ensuring regulatory compliance, and more importantly, building it into the development process from the outset. Whilst avenues are available to take under existing frameworks, our panel made it clear that the best approach to authoritative bodies remains a collaborative one.

They're not trying to impede or frustrate development (they themselves need to develop too after all) but honesty and guidance is required by both parties pursuing it.

As for where the disruptive teams of the future will come from, it will likely be from the independence and purpose seeking 'Gen Z'.

Arguably, few other sectors can provide the same level of tangible purpose which Digital Health does; it's outcome-based care, personalised medicine, intelligent wearables and digital medicine solutions (Chip-on-a-pill) are all aligned to be game changing next-gen technologies. For Gen Z, there'll likely be few other industries boasting the same potential for a sense of fulfillment.

It's not just about long-term visions of a better world though, it's also about creating an environment in which future talent will want to work. Whilst the market has shifted to incorporate the collaborative working and imported 'silicon valley ethos' attractive to millennials, it must now change again, and is presented with a fantastic opportunity to leverage its position as a sector focussed on the technology with which Gen Z has grown up.

If it can offer the independence and problem solving opportunities they'll likely desire, it has the potential to become the 'career destination of choice' for tomorrow's talent in Healthcare.



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About the Author:

Matt has over 15 years' Recruitment experience working within the wider Healthcare sector, and has been at the forefront of the Digital Health market's emergence, partnering with some of the most innovative start-ups in the industry.



WITH THANKS TO OUR PARTICIPANTS

Oxford VR is built on the ground-breaking work of Daniel Freeman, Professor of Clinical Psychology at Oxford University and Consultant Clinical Psychologist, Oxford Health NHS Foundation Trust.

Oxford VR takes a cognitive therapy approach, basing therapeutic techniques on a tested theoretical model of each problem. The automated therapy is therefore tailored for each condition, with its efficacy demonstrated in clinical trials.

When VR is done properly, the experience triggers the same psychological and physiological reactions as real-life situations. And that means that what people learn from the VR therapy can help them in the real world.



Jason Freeman
Chief Treatment Design Officer
Oxford VR
oxfordvr.org



Repositive was founded by Fiona Nielsen who, after experiencing cancer in her family first hand, recognised the distance between research and readily available treatments. Given her background in genomic data, Repositive was born to bring data and clinical applications closer together.

Repositive are enabling biopharma undertaking preclinical drug discovery for cancer treatment to discover, understand and purchase the optimal cancer models. They're already the world's largest source of these models and are trusted by the industry which spends more than \$100M p.a. on preclinical cancer research required in undertaking translational research projects.



Julian Coe
Chief Operating Officer / Chief Financial Officer
Repositive
repositive.io



CCG is using blood draws to guide smarter cancer therapy & shorten the time required to know whether treatment is working or not. This gives a clinician more time to alter treatment and reduce unnecessary side effects experienced by the patient.

Through simple blood draws, CCG can also identify relapse an average of 7 months earlier than standard practice. Over time, this continuous monitoring of treatment effectiveness will power better predictions of the best therapeutic strategy.

CCG's mission is to use advances in machine learning, AI and big data analysis to power a new type of cancer treatment regimen. Ultimately, CCG will ensure that each patient has the right treatment to beat their cancer.



John Cassidy
Co-Founder and Chief Executive Officer
Cambridge Cancer Genomics (CCG)
www.ccg.ai



Biovotion, based in Switzerland, is a leading wearable physiology monitoring company and provides integrated solutions with connected hardware and value-added monitoring services.

Their solutions integrate medical grade quality and reliability with ease-of-use and design of the consumer markets. The Digital Health solutions provided support users in keeping a healthy lifestyle, improving healthcare treatment outcomes, and aiming to reduce cost of health provisions.

Biovotion's wearable solutions have been awarded with multiple international, prestigious prizes and high-caliber endorsements, including an XPrize



Andreas Caduff
Founder
Biovotion
www.biovotion.com



Ieso Digital Health uses AI to revolutionise the way mental healthcare is provided. They use data to derive a deeper understanding of therapy than was ever possible before, and use these insights to improve how they provide therapy, driving up outcomes for their patients.

Their platform allows their therapists to deliver cognitive behavioural therapy (CBT) to patients in real-time through written conversation online, using a secure virtual therapy room. Therapy is confidential, discreet and accessible from any connected device at any time or location convenient to their patients.

Ieso delivers exclusively evidence-based, quality controlled clinical models, using breakthrough technology and clinical data science to continuously learn what works in the relentless pursuit of better outcomes for patients.



Valentin Tablan
Senior Vice President for Artificial Intelligence
Ieso Digital Health
www.iesohealth.com/en-gb



i_GP provides a service designed around patient convenience. They saw the need in the market for a quick and effective way for patients to get in touch with the primary care practitioners and utilised available technology to provide that platform.

Their service offers an innovative virtual care solution to the 60 million minor illnesses which are treated by the NHS every year. Utilising branching logic based on NICE guidelines, architected within image enhanced proprietary software, the i-GP Platform is a world first in its design and offers the highest level of online care.

Having joined the Digital Health Accelerator 2018, i-GP is now partnering with the NHS to offer patients their world-class product.



Sukhbinder Noorpuri
Founder and Chief Executive Officer
i_GP
www.i-gp.uk



Dthera Sciences is a leading digital therapeutic company specializing in neurodegenerative diseases. The San Diego based, publicly traded company is working to improve the lives of seniors and individuals suffering from neurodegenerative diseases, as well as those who care for them.

Dthera is developing DTHR-ALZ, a medical device that has been granted Breakthrough Device designation by the FDA for the mitigation of the symptoms of agitation and depression associated with Alzheimer's disease. To the company's knowledge, DTHR-ALZ is the first product to receive Breakthrough Device designation for the treatment of Alzheimer's disease.

If granted approval by the FDA, DTHR-ALZ would become the first non-pharmacological prescription treatment for the symptoms of Alzheimer's disease, and the first medical device of any kind for the treatment of Alzheimer's disease.



Edward Cox
Chief Executive Officer
Dthera Sciences
dthera.com/



Visulytix specialises in the development of powerful AI systems which augment the workflows of clinical decision makers. They improve the patient journey by detecting sight-threatening conditions and reducing costly false positives.

Their AI-powered software is called Pegasus and acts as a Retinal imaging analysis tool designed as a single solution to both Fundus and OCT. Specifically, it searches for features which can be indicative of Diabetic Retinopathy, ONH pathologies, Wet or Dry Age-related Macular Degeneration, Diabetic Macular Edema and General Macular Anomalies.

Further to Pegasus, Visulytix has established a successful consultancy function. 'Visulytix Black' focuses on delivering bespoke deep learning based image analytics to customers from proof of concept to full product solutions.



Jay Lakhani
Chief Executive Officer
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