In Vivo

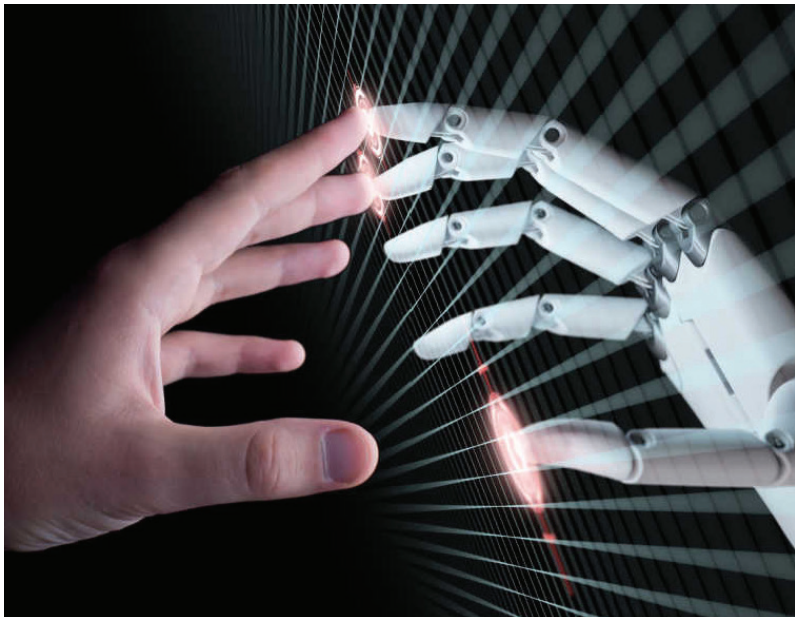
Informa Pharma Intelligence

Viz.ai: Precision Targeting Of Every Patient's Medical "Moment Of Truth"

Viz.ai: Precision Targeting Of Every Patient's Medical "Moment Of Truth"

By William Looney

Viz.ai is making artificial intelligence real and ready with an algorithm-based detection and diagnostics platform that is beating the clinical clock in fighting stroke. The start-up is now focused on positioning its joined-up AI software as standard-setter for broader patient engagement with big pharma on everything from participation in clinical trials to launching the next generation of high-touch specialty medicines.



In the health care business, where productivity is measured in patient lives saved, new technology breakthroughs from artificial intelligence (AI) ought to be a show stopper – so why is AI still stuck on the industry's to "do list" of coming attractions? Investments in AI lag other sectors and tend to be confined to rote tasks that do not transform clinical practice and bolster the bottom line.

Analysts cite several factors behind this boxed in approach to AI, including health care's conservative risk profile, especially with regard to patient privacy; siloed information management systems; discrepancies in the quality, scale and scope of health data, in which data "lakes" co-exist with data "deserts", and a still-evolving government regulatory framework for AI investments. AI and its complex algorithms depend on stability and consensus in each of these areas in order to render accurate clinical assessments for decision-makers, who in turn work within defined organizational parameters that companies have relied on for years. All this creates uncertainties that can negatively affect assumptions on ROI in the AI space.

Nevertheless, life science industry experts interviewed by *In Vivo* contend that momentum is shifting toward wider adoption of AI as a versatile business and research tool. Two factors are distinguishing the real winners in AI from the also rans. The first is having a business concept developed and executed by practitioners with direct knowledge of the day-to-day clinical landscape, where AI technologies will face the feasibility test almost immediately. Second is the ability of AI inputs to align with the entrenched internal mandates, procedures and business cultures unique to every health care organization. Failure of AI to get inside that operations "firewall" can sap its potential, simply for the reason that the technology isn't connected to the multi-disciplinary decision chains health providers increasingly rely on to expedite patient care.

More important, being an insider allows a reprieve from the competitor disruption that tends to appear once a new software tool finds its way to market. "Moore's Law on the pace of technology change requires investors to

ask just how deep is the moat that protects your market position from newcomers offering tweaks in the software, at less cost," Les Funtleyder, health portfolio executive for ESquared Capital Management, told *In Vivo*. "Occupying the insider position is a good defence against disruption because if your product is actually being used by the organization; and if you're doing it well, what's the case for change?"

VIZ.AI: A Medical Shorthand For Seeing Things Up Close

AI's transition from the "boxed in" mindset to something more "joined up" is encouraging more start-ups to step in. A prominent example is the rise of Viz.ai, a start-up founded in 2016 by a UK-based neurosurgeon Chris Mansi, and David Golan, an Israeli data scientist, to advance the detection, diagnosis and treatment of neurological, cardio and vascular disorders like stroke.

CHRIS MANSI, CEO VIZ.AI

Over the past five years, the two have built a single, digitally connected, AI-powered Intelligent Care Coordination (ICC) platform that uses deep learning algorithms to scan, identify, and triage patients presenting with these conditions. Its software allows for rapid, high-accuracy reading of a positive (or negative) cerebrovascular event, supplemented by a high-fidelity, 3D-capable mobile imaging technology engineered to work with computer tomography and other diagnostic screening tools ranging from the EKG to ultrasound and MRI. Once posted on the ICC platform, the scans and other relevant data can be assessed and updated simultaneously among members of a care response team at multiple locations, from health care practitioners at the front line to specialists in the surgical suite and operatives in recovery care. The result is the ability to bridge logistical gaps and coordinate and communicate seamlessly on behalf of individual patients.

Some Early Regulatory Breakthroughs...

Because the technology was new at the time, Viz.ai faced a regulatory process that was unprepared to evaluate the efficacy and risks of AI-based applications. It was a long iterative journey with the FDA but eventually, in February 2018, the company scored big with the agency's first-ever approval of a software-only decision support system for the two major types of stroke, based on deep learning algorithms. Since then, the Viz.ai system has gained FDA clearance for five additional disease indications, most recently in July this year, for subdural hemorrhage – a condition slated to become the most common neurological diagnosis by 2030.

Another regulatory landmark was the September 2020 ruling by the federal Centers for Medicare & Medicaid (CMS) to grant Viz.ai's AI software eligibility for add-on provider reimbursement due to clinical evidence of innovation in improving outcomes for stroke victims. Again, the decision was first of its kind in the digital med tech segment.

With these AI-assisted applications as the centerpiece, Viz.ai's goal is to reduce neuroimaging wait times, streamline the clinical decision workflow and ensure patients receive the right treatment, from "door to discharge." The ultimate payoff is a better outcome – for the patient, it's a more rapid recovery, fewer deaths and morbidities; for the provider, it's more efficient use of resources and, ultimately, lower costs.

At the beginning, some neurologists were skeptical about this new software tool. "When I first heard about the product, I didn't think it would make a difference in our workflow; it seemed to be external to our separate medical records, computer tomography and radiological viewing systems – which at the time was the basis for how we triaged patient care," says Chris Kellner, a neurosurgeon and Director of the Intracerebral Hemorrhage Program at New York's Mt. Sinai hospital. "Now, however, I see the ICC platform as the most impactful change in disease management over the seven years I've been in practice. With the Viz.ai app, I can view images within seconds, communicate directly with other members of the care team and decide on an appropriate triage response in sufficient time to make a difference to the patient. Everyone

is on the app and has simultaneous access to up-to-date information."

...And Some Good Timing With New Innovations In Medical Practice

Kellner also told *In Vivo* that Viz.ai came on stream just as the endovascular treatment of stroke was experiencing an unprecedented wave of innovation, after years in the research doldrums. "We finally had the evidence that if you can remove a blood clot quickly, through a procedure called thrombectomy, patients fare demonstrably better – a finding that for me stands as one of the most dramatic treatment effects ever seen in the practice of medicine. Viz.ai arrived and became a beneficiary of that change – now that we know time is of the essence for the survival of incoming stroke patients, we have the tool to do it."

Viz.ai has certainly prospered. The San Francisco-based company has inked contracts for its proprietary ICC software platform with more than 1,200 hospitals and health facilities in the US, the UK and several other countries, tripling its revenues in 2021 over the previous year. Staff has grown to more than 400 worldwide, with a R&D unit in Tel Aviv and branch offices in London, Lisbon and Amsterdam.

More important, the company has established working partnerships with major corporate players like Medtronic plc, as well as the American Heart Association and the Society of Neuro-Interventional Surgery (SNIS). And with financial backing from mainstays of the high-tech VC community – Kleiner-Perkins LLC and former Google CEO Eric Schmidt were early recruits – the company has been able to generate some serious cash, including a $100m series D placement in April, which pushed Viz.ai's overall market value to $1.2bn – that's unicorn status, putting Viz.ai in the front ranks of AI leaders in health tech.

With its niche in the neurological zone firmly established, Viz.ai is now staking out new turf, with a growth plan centered on adapting its technology to other disease areas like cancer as well as in the larger – and hotly contested – playing fields of drug and device development, clinical trials and insurer/payer reimbursement. Can another helping of "eat you for lunch" software sate the appetites of big pharma?

More directly, will it work, at least enough to take the company to its ultimate goal as a publicly-listed company by 2025? It's a key question, especially in light of the more sober-minded assessment of risk now trending in the traditionally hyped-up world of high tech. "AI is emerging as the critical tool for pharma in making necessary transformations in clinical trials and market development," says Mason Tenaglia, founder of a leading consultancy on market access strategy and a long time observer of how technology and geopolitics shape pharma industry behavior. "The potential is there for the industry to help overburdened health systems diagnose and treat patients precisely, at the 'medical moment of truth,' in their care journey – how companies leverage AI-based technology will help determine whether they can meet the moment and succeed."

"The potential is there for the industry to help overburdened health systems diagnose and treat patients precisely, at the 'medical moment of truth,' in their care journey – how companies leverage AI-based technology will help determine whether they can meet the moment and succeed."

Mason Tenaglia

Building A Business Around AI: CEO Mansi Makes The Case For Going Big

To shed some light on where strategy meets the street, *In Vivo* recently sat down with Viz.ai co-founder and CEO, Chris Mansi, to discuss what's next for the AI work tool that has so far touched more than 200 million patient lives in the US and abroad.

***In Vivo*: How have your roots shaped your interests and affiliations – what drew you to medicine and the business of health care?**

Mansi: I am originally from the UK and was raised in a multi-cultural family, with roots going back to Sudan, Egypt and Ireland too. I am now an immigrant myself, having recently become a US citizen. I am never quite sure what to put down on all those forms asking about family background and origins.

I do know that I benefited from this diversity. It made me curious about the ways environment, culture, personality and the mind make each of us unique, which led me to medical school at Cambridge University and eventually to certification as a neurosurgeon. In surgical practice, I soon discovered that too many patients were coming to us too late. An early example was a young woman with head trauma from an accident who could have been saved had it not taken four hours to fix a diagnosis and get her into my surgery. The operation lasted 28 minutes and went well but too much time had transpired and she did not survive.

I was deeply affected by this event. I concluded that treating patients based on clinician adherence to an average standard of care had failed this woman. I realized we had to think bigger, scale up our approach to treatment and deliver consistently to a higher standard of clinical performance every time a patient presents with a neurological emergency. What that required was not just better data imaging to accurately detect acute stroke, traumatic brain injuries, aneurysms and other complex neurological events. We needed a time-sensitive decision management ecosystem that organizes the clinical workflow to expedite distribution of all case-relevant information to surgical specialists best positioned to treat the individual patient.

Transforming the clinical workflow sounds like the model for a business opportunity. As a practicing surgeon, did this require a change in persona? How did you make the move from the highly credentialed profession of neurosurgery to hands-on entrepreneur whose sole asset was an idea – to harness emerging AI technology to dismantle the institutional barriers that slow access to care for patients facing serious trauma?

This was not an adjustment for me. I started thinking about building businesses from the time I entered medical school. I actually launched two small companies – both focused on medical education – while I was undergoing my neurosurgical training. Entrepreneurs and surgeons actually have one thing in common: the need to improvise. Whether your actions are driven by the market or what happens in the operating theatre, the incentive to get it right is immediate and compelling. We've taken that grounded, continuous learning mindset to heart at Viz.ai. We were a newer entrant – not the first – in deploying AI for evaluative software applications in health care, but due to the careful tie-in between our technology and actual clinical conditions, Viz.ai today stands out as the largest player in the field.

Has luck been a factor in your success?

Luck is part of life. What matters is being well prepared to take advantage of it. To expand my horizons, I left the UK 10 years ago and enrolled in the BioDesign and MBA programs at Stanford University. There I met my Viz.ai co-founder David Golan, an Israeli data scientist in post-doctoral research who had recently been laid up by a suspected stroke and thus had some life experience in interacting with neurosurgeons like me. Our backgrounds differed, but we bonded over his surprise that while knowledge of AI data integration platforms was abundant in Silicon Valley, no technology had yet been developed to narrow that critical care delivery time span for patients facing a neurological emergency.

From that we developed a business proposition: to develop an algorithm-based "deep learning" tool to .screen, identify and confirm specific acute neurological conditions to reduce time to treatment and improve patient outcomes. The important point is had we not met, I doubt the concept behind viz.ai could have gelled. Our complementary experiences – as a front-line neurosurgeon and a data scientist with deep insights on advanced process engineering – enabled us to develop the right tools and technology within the parameters of everyday clinical practice.

How do you build a business around AI? Are there any lessons to be learned from applying this technology within large, complex institutions?

AI has vast potential, but its successful application to real world challenges in the clinic must be guided by principles. At Viz.ai, we rely on several fundamentals. First, in designing and deploying our decision support software, understanding the patient perspective always ranks at the top. We seek up-front patient engagement in clinical research as well as with the radiologists and others that evaluate patients and monitor outcomes at the point of care. Second, the treatment pathways that drive those software algorithms must be based on clinically validated evidence. And third, we will use the Viz.ai platform not just to help patients, but to improve institutional standards of care and eliminate disparities in access to technology. Raising standards is especially important as we grow: since we launched the business in 2016, more than 1,200 US hospitals rely on this software to direct patients to the right treatment, quickly and accurately, in diverse clinical settings primarily in the neurologic, cardio and vascular domains.

One lesson we have taken to heart is not to overstate the complexity of these new technologies. Although AI can be transformational in its effect on clinical workflows, the way it works as a machine learning instrument is actually quite simple. In our case, AI has allowed us to introduce software that performs to a high level of accuracy on tasks that previously required expert human intervention. Its value rests not in being better than the experts but by bringing more reach and focus to clinical assessments in emergency situations, working without interval, the same way, every time, at a level of accuracy that doesn't depend on the constraints that come with being human. It also gives radiologists and other health professionals more leeway to contribute at the higher end of diagnosis and practice.

The effects are self-evident: a big improvement in patient outcomes. Within a minute of the AI-trained software making an identifying assessment from a patient's scan, the neurosurgical specialist is alerted and can go to work on the patient to induce a cerebral or coronary reperfusion in enough time to prevent cell death and loss of vital organ functionality. In my field, any delay in the timing of these interventions can mean the difference between life or death, or between a return to normal life or being institutionalized in a nursing home. So the value proposition is pretty stark – and simple to explain from a clinical standpoint.

What about pushback from the radiologists or other practitioners that might see the Viz.ai software as a threat to their professional status?

That can happen only when you haven't communicated the merits of an AI-guided technology that improves diagnoses and saves lives. When the medical professions realize the technology helps them do their jobs better in treating patients, the pushback goes away. The notion that there is a generalized AI capability able to replace the insights of an experienced radiologist is a major stretch – we are nowhere close to that. You'd have to develop 500 algorithms to match what radiologists already do day-to-day, in their heads. Independent study data shows that the financial benefits of our technology come from its impact on patient outcomes through increased information flows that filter back to the clinic in the form of improvements in diagnosis and treatment along with fewer side-effects and shorter patient stays. We actually enable the "high touch" staffing side of care rather than detract from it.

These improvements are critically important in light of the productivity crisis facing health care today. One of the major drains on productivity is the response of health systems to major conditions like cancer, stroke and heart disease, which are frequently detected or treated too late. Right now, the estimate is that only 20% of patients in US hospitals get the right treatments, in enough time to make a positive difference in the outcome. If our service can raise that number by, for example, coordinating information flow to move stroke victims quickly into the right treatment, then patients do better, with lower rates of death, disability and rehabilitation. From a financial perspective, it results in a greater ROI and ability to absorb costs.

What were the early hurdles you faced in establishing the business and contracting with customers?

The biggest challenge was perfecting our initial Viz AI ContaCT algorithm-based software technology for stroke triage care so it could pass muster with the Food and Drug Administration (FDA). There would be no marketing rights for the product without evidence proving that the

product would work as intended, in the real-world clinical setting. It had to be accurate, every time. We had to create an accessible data signaling system to guide clinical staff toward rapid diagnosis and a situation-appropriate avenue of treatment, for multiple complex conditions. We had to test that system in different settings, evaluating customer work flow and organization, including the approach taken with different electronic health record [EHR] protocols.

A key factor behind the win was relying on my daily routine as a neurosurgeon to model our product. The technology reflected what I would have wanted had such a system already been in place. Would it overcome situations like me being awakened at 2 a.m. and having to make an on-the-spot decision about an emergency stroke patient? I'd value a tool that allowed for speed and convenience in evaluating all information at hand. To get that, you'd have to solve for the "hub and spoke" organization of most medical care today, with specialists like me at the hub while care-givers in a support role occupy the spoke. So we spent a huge amount of time learning about the work flow priorities of radiologists and others who operate computer topography equipment.

All this was achieved in our first 18 months as a company. The FDA label we secured in February 2018 is a milestone in medical device regulation: it was the first AI-assisted computerized triage and notification software system cleared by the FDA. It took a while, as the FDA realized after some debate that it needed to place us in de novo review, as an entirely new category and pathway to certification.

We backed that approach, even though it added to the challenge of drafting the right protocol for our clinical trials – with no precedents, everyone involved was forced to improvise. It took time but it added to the cachet of our approval because the category is now the standard under which nearly all AI-based technologies are introduced to market in the US.

Was there a particular measure that earned you the confidence of regulators in setting the standard for evaluation under this new category of medical device?

It was our articulation of how risk vs. benefit might best be applied in the context of a care coordination software model oriented through algorithms reliant on AI. As far as official regulatory guidance was concerned, this was uncharted territory. FDA staff were open to any input we could provide, especially in coping with false negative or false positive readings generated through the algorithms.

We were able to demonstrate that false negatives are the norm today in every hospital that lacks the enhanced AI algorithm-based capability to detect situations requiring swift clinical intervention. Sadly, the risk threshold is such that losing some patients is entrenched as the standard of care. The Viz.ai technology addresses both ends of the problem. False positive readings detected by the algorithmic scan simply requires the operating clinician to take a closer look and conclude no immediate deployment of high-touch, high-cost resources is required. A true positive revealed through the Viz.ai software is even more risk abating and cost-effective, saving precious time for interventions that forestall loss of brain function, disability and death, allowing patients to resume healthy productive lives.

Most important, we've backed this up with studies showing an average 40% reduction in disability among patients in facilities that relied on our product. Overall, we now have evidence to prove reductions in time to treatment, shorter lengths of stays in hospital and rehabilitation, and better patient outcomes based on solid, quality-of-life criteria.

Viz.ai's Intelligent Care Coordination (ICC) platform has expanded to include rapid AI-assisted detection, diagnosis and treatment support in triaging seven different conditions. Given the company's latest fund-raising success with investors in April, what new growth opportunities are you targeting to take Viz.ai to the next level?

Our successful $100m series D round in April gives us the scale to invest in R&D to broaden the reach of our proprietary software technology. We intend to add more algorithms to the platform, making it more robust and sophisticated in interpreting data, and adding numerous other diseases to the list. This could cover extending our neurological capabilities to include autoimmune conditions like multiple sclerosis (MS). We will add to the variety of AI-based procedures we rely on as part of the case triaging process. Another goal is deploying our ICC model to the

cancer space. All told, we plan to execute these objectives over the next three years, across a global network of more than 3,000 hospitals and facilities (currently at 1,200) using our products – tripling the number of customers we have today. That's our goal.

Drilling down a bit, we want to establish logistical partnerships with big pharma and device companies to better target and speed their drug and device development, from expanding indications or clearing new compounds for regulatory approval. The value-added comes from novel, customized algorithms we can build to interpret data from a clinical trial and identify solutions that move things forward, faster. We are already working with major players like J&J and Medtronic; partnering deals with other big pharma are in the works and will be announced over the coming months.

The potential from using AI and machine learning to raise productivity against longstanding industry vulnerabilities is vast. We can accelerate screening of human candidates for clinical trials, across age, gender, race and geographies. Trials are like finding a single needle in a haystack; our AI software is able to cycle through a thousand such haystacks in less than a day. And because the hospital facilities worldwide that now use this technology has a patient being evaluated every 30 seconds, on average, that gives our partners an immense pool of recruits for their trials. We hope to cut that time even further as our technology evolves.

Likewise, Viz.ai can build with the sponsor a customized AI machine-learning algorithm to look for treatment effects, or to detect, analyze and evaluate the viability of patient inclusion and exclusion criteria – even anticipate and control for protocol compliance problems at trial sites. And we are there for the next step: taking the trial drug through to FDA clearance and into the marketing space, where our algorithm could be positioned to perform post-marketing surveillance work through the Viz.ai intelligent care coordination software, at the hospitals that contract with us. As a comprehensive, end-to-end service package, it represents a very strong value proposition for big pharma, particularly in the specialty launch space.

Finally, we see the same kind of "wrap around" approach involving large insurers and other health care payers, answering their need for AI data technologies that improve the consistency and standardization of work flows and data assessment. It gives them higher levels of efficiency, and better grounding in how much you have to spend in meeting the needs of their covered populations.

Do you anticipate Viz.ai continuing as a software technology company rather than a more traditional maker of medical devices?

Yes. We are not a hardware company. Nor do we expect our products to work by themselves. The high rate of adoption of the ICC platform is due to our singular focus on customer service at the ground level. We place customer relations people on site who ensure the workflows don't degrade, getting more clinicians using the platform – making sure customer engagement is the highest it can be. Hence while we won't be investing in hardware, our software is complemented by a significant high touch customer service component. It's hard human capital and that's not cheap.

As a practicing neurosurgeon who is also a technologist proponent of AI, what do you see as the impact of these disruptive new tools in shaping options for patients a decade from now?

AI is going to enable a hyper-specialization in medical practice. A neurologist will have many colleagues who focus on cognitive disease in the form of various sub-types of Alzheimer's, for example. Aided by technologies like AI, the science will expand, more will be known about subtle variations in disease states and more patients will present for treatment than what is available today. All of this will be enabled by a democratization of what is currently the "ivory tower" of specialty medical practice due to the kind of information networking and care integration tools we are developing here at Viz.ai. It means a patient in rural Mississippi, where specialty care is limited, will be able to benefit from real time decisions taken by an expert team at Mass General hospital in Boston. This in turn will further accelerate the consolidation in health care service infrastructure we are seeing today.

Published 31 August 2022