BIÇAKCILAR
Touching Lives One Device at a Time

MARKETWATCH

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Qure.ai leverages artificial intelligence to locate abnormalities in head CT scans

Qure.ai, a startup founded in 2016, has unveiled an AI-powered technology that can pinpoint anomalies like bleeds and fractures in head CT scans.

When a patient has head trauma, a CT scan is one of the first tests he or she undergoes. Though time is critical in these situations, a radiologist may not be able to read the scan fast enough. Qure.ai seeks to speed up the process by leveraging artificial intelligence to screen CT scans in under 10 seconds to find any abnormalities.

In a phone interview, Prashant Warier, cofounder and CEO of Qure.ai, outlined a few use cases for the technology. For one, it has relevance in the emergency care setting and can help prioritize certain cases.

The startup's tool can serve as a reviewer as well; in other words, it can measure the accuracy of a scan that has already been analyzed. Qure.ai also released the results of a study that took a closer look at its new artificial intelligence technology.

To train the AI, the company utilized 313,318 anonymized head CT scans and their clinical reports. Then, 21,095 of the scans were used to validate the AI algorithms. Plus, the tech's readings of 491 CT scans were compared to the readings of three radiologists, one of whom was from Mayo Clinic. The results showed Qure.ai's AI was over 95 percent accurate in locating abnormalities.

The findings from this study were published in a research paper called "Development and Validation of Deep Learning Algorithms for Detection of Critical Findings in Head CT Scans." Qure.ai has made a dataset of 491 AI-interpreted head CT scans and the interpretations from the three radiologists available for the public to download.

Making the information publicly available gives other AI companies the chance to validate their algorithms, Warier said. "It allows anybody to compare their performance to our performance," he added. In addition to recently launching its head CT scan capabilities, the startup also has chest, abdomen and musculoskeletal image interpretation tools.

Looking forward, **Warier summarized what he hopes the future holds for Qure.ai: "For us, success would be that we are able to influence patients' lives.**

In this issue…

Philips forms new alliance to introduce remote monitoring program

May 14,2018

Royal Philips has partnered with US-based academic health system Emory Healthcare to introduce a new remote intensive care unit (eICU) monitoring programme to enhance critical care and outcomes for high-risk patients in the country.

Based at the Royal Perth Hospital in Western Australia, the programme was pilot tested by Emory Healthcare in Sydney in 2016.

The critical care physicians and nurse experts under the programme are set to offer medical care to patients in the US from the Royal Perth Hospital by using Philips' eICU monitoring technology.

"It is intended to enable near real-time monitoring of patients remotely and early intervention through audio-visual technology, which can be used to communicate with local providers and advise on treatments."

Philips designed the technology as a virtual care model to deliver remote night-time critical care support to patients at Atlanta, Georgia, during daytime hours in Perth, thus minimising the night-shift work burden.

The solution employs smart algorithms to predict deteriorations in health.

It is intended to enable near real-time monitoring of patients remotely and early intervention through audio-visual technology, which can be used to communicate with local providers and also advise on the treatment.

Royal Philips ASEAN Pacific market leader Caroline Clarke said: "This partnership is enabling a crucial shift in the delivery of care, impacting clinical outcomes, where technology supports clinicians to deliver more proactive and timely care to patients across the globe.

"Access to highly experienced intensivists and critical care nurses is an ongoing challenge for hospitals internationally, and virtual care solutions, like the eICU programme, can help deliver much-needed expertise to areas where this is lacking."

During the pilot, the program is said to have demonstrated benefits in saving lives, as well as boosted provider satisfaction and cost savings by reducing the length of stay and inpatient readmission.

Biosense Webster treats atrial fibrillation with new catheter

May 10, 2018

Biosense Webster, part of the Johnson & Johnson family of companies and a specialist in the diagnosis and treatment of heart arrhythmias, has successfully treated atrial fibrillation (AF) in the first patient to participate in a study of its new QDOT MICRO catheter.

The study aims to evaluate the delivery of high-power, short-duration ablation with the QDOT MICRO novel radiofrequency (RF) ablation catheter, which has been designed to treat paroxysmal AF.

The catheter is a steerable multi-electrode device which has a deflectable tip designed to facilitate electrophysiological mapping of the heart and can transmit RF currents to the catheter tip electrode for ablation purposes. It also incorporates six thermocouple temperature sensors and three micro electrodes embedded in its tip.

The first patient participant was treated at OLV Hospital in Belgium, which is one of the eight centres in Europe to take part in the study that will be enrolling up to 50 patients. QDOT MICRO is only available for investigational use in Europe.

The company claims that QDOT MICRO is a next generation catheter and, in a world-first, it can deliver 90 watts of RF power in a four-second temperature-controlled catheter ablation session.

The catheter's optimised temperature control and micro-electrode technology is designed to provide more efficient and consistent lesion creation with advanced diagnostics, while also simplifying the technique and reducing total ablation time.

OLV Hospital associate director in the Cardiovascular Center, Department of Cardiology, Electrophysiology Section, Dr Tom De Potter, said: "The concept of high–power, short-duration ablation is novel and a potentially ground-breaking advancement for the industry. The new modality could result in improvements in clinical outcomes and procedural efficiencies and I look forward to further investigation."

De Potter is one of the study's clinical investigators and performed the first QDOT MICRO procedure.

Vice president for Johnson & Johnson Cardiovascular Specialty Solutions in EMEA, Gabriele Fischetto, said: "For over 20 years Biosense Webster has pioneered the development of atrial fibrillation treatment. QDOT MICRO continues our commitment to deliver solutions that help clinicians heal more hearts and has the potential to increase the standard of treatment for paroxysmal atrial fibrillation."

AF affects 14 million people across Europe, the Middle East and Africa. The condition places a burden on healthcare systems with up to 2.5% of total healthcare expenditure associated with the disease.

Why the Device Landscape Continues to Face Significant Hurdles

Over the last few years, FDA approvals have taken significantly longer than any other markets so it delayed new product launch in the U.S. Gradually, however, the FDA have improved timelines through new measures bringing about greater productivity. On the other hand, the European regulatory process has become more complex than ever.

Traditionally, the EU has been viewed as a faster way to get to market, however, the new product registry in Europe is expected to increase delays by 20-40 percent, greatly impacting EU-based companies. To reduce the unpredictability of timelines, it's vital sponsors learn how to obtain a CE mark.

Medical Device Innovation

Additionally, emerging technologies are continuing to revolutionize the industry, but its ultimate impact on clinical trial processes are yet unknown. Medical device companies are adapting and modifying their behavior as seen in the way sponsors use electronic medical records to manage big data.

There is a wealth of tech-based software that doesn't require approval as they do not enter the human body. Therefore it is much cheaper to develop and easier to bring to market. From this point of view, looking at the software regulation for the future is essential. While the extent to which wearable products are regulated is yet to be clarified, the industry will soon reach a crossroads as it decides how best to regulate them.

Funding Challenges

Another factor that remains a pertinent issue in the industry is acquiring funds. Funding has always been challenging for small medical device companies, in particular. With clinical trials becoming more and more expensive, the regulatory knock-on effect impacts sponsors greatly. Furthermore, as clinical trials require more time, costs begin to mount placing undue pressure on a company's resources.

Therefore, streamlining costs in product development is always the issue for medical device companies.If sponsors don't have enough money for the development stage, they can't produce proper data to bring the product to the market. Even though the global investment environment is difficult, the med device industry must take steps to ensure it can compete by adopting new approaches.

Spiraling Health Care Costs

Lastly, the clinical reimbursement of medical devices in the U.S. is becoming increasingly difficult year on year. According to experts, the U.S. has about 1150 private payers with rising health care costs showing no signs of abating. As a result, insurance companies are far more hesitant to provide coverage, meaning obtaining reimbursement presents significant barriers to trial sponsors. The financial constraints this creates is reaching its tipping point, almost akin pouring water into a glass as it overflows.

However, as regulations governing reimbursement evolves, the hope among those within the industry is that there is light at the end of the tunnel.

Disruptive Changes in the Medical Device Industry

Monir El Azzouzi, Johnson & Johnson, Plant Quality Senior Manager, shines a spotlight on some of the latest innovations to impact the medical device industry

Did you expect the future look like this when you were a kid? If you were from my generation, you'd say there are still no flying cars, or biometric scanners that let you enter your home. However, if you take a closer look you'll find many technological advancements have indeed been made. Do you remember when smartphones were reserved for business use? Or when many forms of cancer were almost incurable? From that point of view, we can see there has been a lot of progress. But what about medical devices? Let's review two aspects of it, exploring the progress made in terms of products proposed as well as technological innovations.

New way of Manufacturing Medical Devices

Additive Manufacturing

On the aspect of disruptive changes we can also talk about new ways to manufacture medical devices. This is not specific to the health care industry and it's called "Additive Manufacturing." Now, some might ask "What is Additive Manufacturing?" and I would use the more common words to define it – 3D printing. This technology is revolutionizing the way our plants are working. Many projects are starting with it and we should see in future if this is only a new gadget or whether it will become more widely used. On the history of 3D printing, this methodology is not new and was mainly used for rapid prototyping. But nowadays, you can have real parts manufactured and implanted on patients.

One of the interesting aspects of 3D printing is the fact you can use many kinds of raw material, such as aluminum or stainless steel. Even polymer can be manufactured while using human cells to build an artery. In terms of possibilities, we have a new world in front of us as 3D printer manufacturers are really imaginative in the way they serve their customers. At the same time, our regulators noticed this change and are creating some rules. The FDA issued guidance for the industry called "Technical Considerations for Additive Manufactured Medical Devices," and after a quick read, it's really helpful to know what is expected. Nevertheless, I think we will continue to hear about this new technology. You will maybe see in future hospitals having these machines and only receiving 3D printer files from manufacturers to print their design. For those thinking this will be like the cheap home 3D printer, they should really see what kind of machines are used. They are large 3D printers with greater results. We still see on TV or on the Internet that you can create 3D printed prosthetics at home as 3D printer files are available for free. Some of you will say this technology is already working in our hospitals. For example, in radiology departments, one of its usages is to print a lifelike tumor of a patient to have a better visual of it. It certainly looks better than a CT-scan. Immediately, the surgeon can take it in hand, feel it and get more familiar before the operation. I suppose this reassures the patient's surgeons can see what's making them sick.

Conclusion

As you can see, the medical device industry should not think it is old fashioned. If you want to be more competitive, be aware of all the latest technologies and products that are coming to market. The interesting aspect of those disruptive changes is the fact our regulators are following them and issuing guidance and new regulation to put rules in place. This is good news as many deviations can come from industries that would use a dated regulation and apply them to new technologies. This would not be beneficial for the patients.