Going All-in on ePRO

The growing complexity of clinical trials has fuelled demand for ePRO solutions that ease the burden of trial participation for patients while building confidence in the quality and accuracy of data for sponsors. Now playing in the ePRO space, iCardiac is on a mission to bring together technology and flexible supply strategies to create a modernising force for today's global trials. John Sage talks to Journal for Clinical Studies about the fast-evolving market, its challenges and what the future holds.

1. What is your general outlook on the ePRO market at the moment?

Increasing protocol complexity has made compliance in clinical trials more difficult for patients, as well as making successful management a real challenge for sponsors. Simultaneously, a surge in global trials has seen emerging markets, such as China, evolve to become some of the most prominent regions for conducting clinical studies. These changes have demanded the creation of new technologies that eliminate the barriers of working across multiple sites and countries, and, in turn, have fuelled the growing ePRO market. We are at a very exciting time; the industry is calling out for more intuitive solutions and we are seeing significant growth opportunities for technologies that can reduce the burden of complying to clinical trials for patients while, at the same time, building sponsors' confidence in the quality of data being generated.

2. Why did iCardiac choose to move into the ePRO field and what does the company bring to the space?

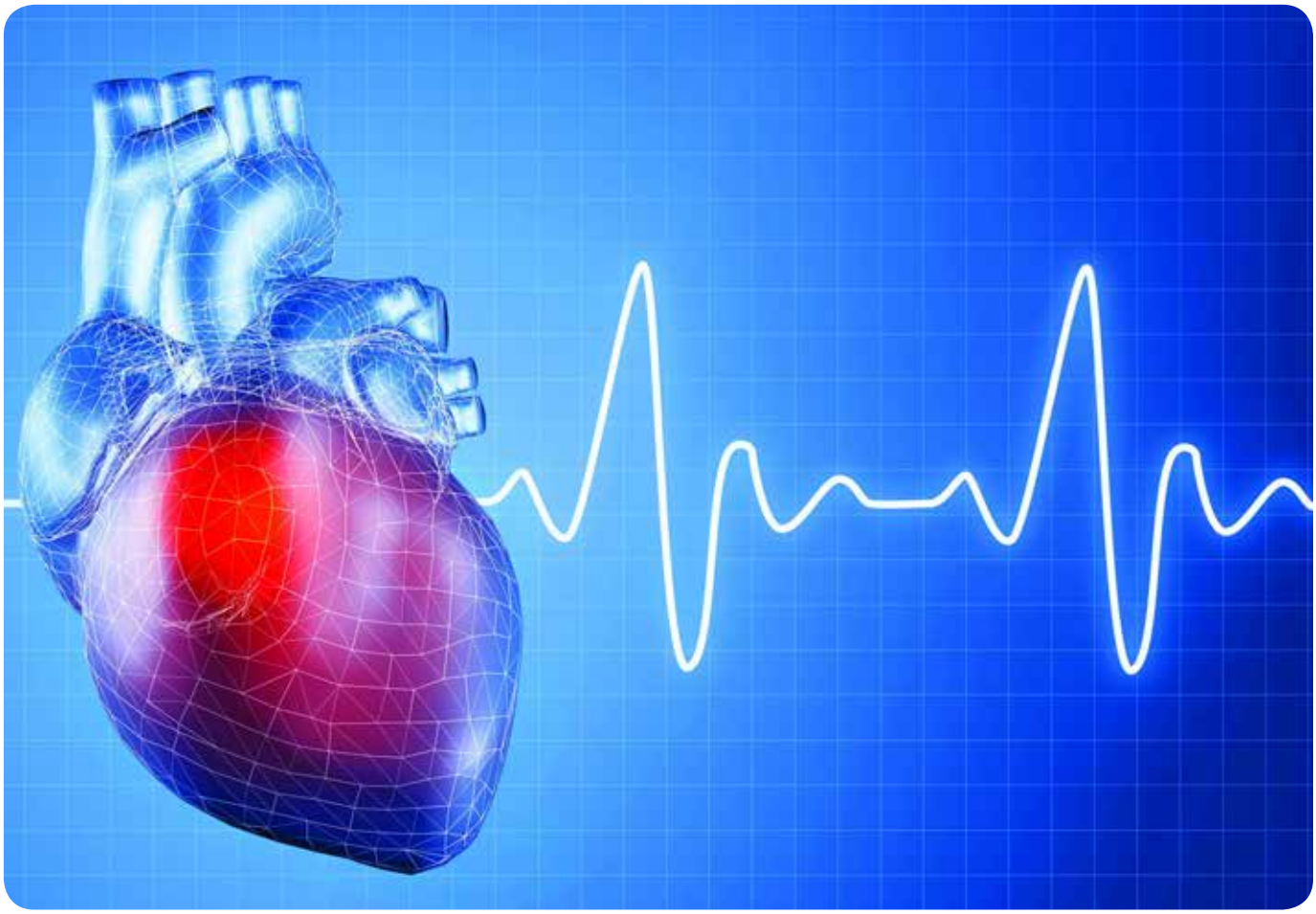
iCardiac has a strong fit in ePRO and our expansion into the field is a natural part of the company's evolution. As a business, we encompass deep, agile software development skills that enable us to bring leading-edge technology to the industry, while our expertise in international logistics and device management allows us to help clients optimise their device strategy in trials that are increasingly taking place across numerous different countries. Furthermore, we provide the superb on-demand customer support that is essential for the management of technology-based devices at research sites.

3. Describe your business philosophy in 10 words.

Great technology matters; but people and unsparing service matter most.

4. How are patient-reported outcomes (PROs) used in clinical research? Why are they so important?

Patient perspective plays an important role in drug development and is a vital component in demonstrating and measuring the benefits of a new drug on healthcare outcomes. PROs are the ideal technique to capture patients' perceptions on their quality of life, on how they feel, and how they are functioning in their daily routines. This is especially relevant in the respiratory space where the drug pipelines are mainly focused on improving the



quality of life for chronic obstructive pulmonary disease (COPD), asthma and idiopathic pulmonary fibrosis (IDF) subjects.

5. What are the challenges associated with collecting home-based patient-reported outcomes?

The collection of data across different demographics is definitely a major challenge when it comes to home-based reporting. ePRO devices must be designed for ease-of-use by subjects in older demographic groups, especially in the respiratory space. The device must be highly intuitive for the user so it blends into their daily routine, and training of subjects is also critical at the time of deploying any ePRO device. Every patient must know how to correctly use the technology and recognise the importance of compliance. Additionally, any data that is dependent on the subject performing the test correctly, such as home spirometry, requires a higher degree of training and data monitoring to ensure the subject population can maintain acceptable compliance levels.

6. What are the challenges with collecting patient-reported outcomes outside the US?

There are numerous advantages of using ePRO to support global clinical trials of every size and level of complexity, however, without a watertight device supply strategy for global trials, sponsors are likely to run into difficulties as a study progresses. Global logistics management and wireless network management are always going to be key to enable maximum enrolment speed. At the same time, competitive enrolment and changing site start-up plans can create incredibly short lead times to have devices available at sites when needed. These scenarios require nimble supply and resupply capabilities on a global scale. Working with vendors who can assist sponsors to implement a practical device supply strategy will be paramount in ensuring the proper management of logistics, while controlling the cost of using an ePRO strategy.

7. What is causing the rapid growth and advocacy of capturing PRO data electronically?

Speed of data monitoring is approaching true real time, while time-stamping is enabling investigators to monitor compliance with a study's protocol at any time during a study. Rapid feedback loops on compliance monitoring enable the study CRA network to quickly observe low compliance levels, and take corrective steps with sites. This is allowing investigators to adopt a more risk-based approach to monitoring, employing targeted activity where needed to ensure that patients adhere to study requirements. Furthermore, electronic capture also helps eliminate transcription errors into the electronic data capture (EDC) system that are common with paper-based methods, improving overall data quality and accuracy.

8. When it comes to ePRO, are there still obstacles that the industry needs to overcome?

Limiting subject populations and the potential of this to introduce bias is still a problem for many of today's clinical trials. Bring your own device (BYOD) initiatives are working to overcome these obstacles by making cost-effective, real-world data collection, practical.

9. What are some of the hot topics affecting ePRO and how does iCardiac plan to address these?

As already mentioned, ePRO technologies are helping drive the industry's surge towards risk-based approaches to monitoring, with ePRO playing a significant role in the effort to support patients who need it most. By delivering technologies that are intuitive and easy-to-use, while also seamlessly fitting into patients' everyday lives, iCardiac's solutions not only eliminate the burden on patients, but provide sponsors with an overview of compliance to their protocol, as well as a more detailed insight into investigator site performance. At the same time, access to real-time data is fuelling more responsive study designs, which is one of iCardiac's key offerings to our customers. Immediate access to information on compliance levels, and a rounded view of the data being generated in a trial, means that sponsors can adapt their study designs as needed.

John Sage serves as Sr Vice President, Respiratory and ePRO of iCardiac Technologies, and joined iCardiac in July 2015 through the acquisition of the clinical trials business of nSpire Health. Prior to the acquisition, he served for three years as the leader of the clinical business of nSpire. Prior to nSpire, Mr Sage held senior leadership positions with Johns Manville, a Berkshire Hathaway Company, and General Electric. Mr Sage holds a BSc in Chemical Engineering from The Ohio State University.