

## Insider Insights: PHT Corp.

CWWeekly's semi-monthly company profile feature, *Insider Insights*, interviews executives of companies and organizations in the clinical trials space. Writer Ronald Rosenberg sat down with Philip Lee, president and CEO of PHT Corp.

**Q** Over the last few years PHT has grown to become the e-diaries market leader in electronic Patient Reported Outcomes (ePRO), participating in more than 400 clinical trials over the past decade, some of which led to 14 new drug submissions and 11 regulatory approvals. With the globalization of clinical trials, do you expect greater growth overseas than in North America? In what areas has PHT seen the most success and the most problems for ePRO?

**A** We've seen the adoption of ePRO grow across the board. ePRO in North America is doing just fine, but our international business is growing more rapidly, especially in India where we have done a whole host of trials, as well as in China and Japan and all over western Europe. We have rolled out ePRO to 70 countries and translated our ePRO technology into 80 different languages and dialects. For India we had to do eight or nine different dialects, which was a lot of work.

At a high level we've seen ePRO adoption growth in almost every single therapeutic area. Many of our studies are in pain. When a subject in a trial must provide information about how they feel in evaluating the effects of a drug ePRO becomes very important.

We have also seen an uptick in COPD studies, in which you have to integrate spirometers [devices that measure the volume of air inhaled and exhaled]. Patients have to blow into it to measure lung function and we had to integrate our technology with these medical devices for collecting data to gain a much better feel for how the drug is affecting various subjects.

There is no therapeutic area that is difficult. However, what we have found challenging is the global aspect of these trials. That is, translating these diaries to different languages, shipping these devices all over the world, getting them through customs, being able to support sites 24/7 and being able to handle different types of telecommunications.

**Q** Although few disagree that hand-held diary devices are superior to paper-based diaries, other than initial cost how big



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*Phillip Lee, president and CEO  
PHT Corp.*

is the overall ePRO market, and what is PHT doing to make sponsors and sites that use paper-based diaries more comfortable in adopting e-diary technology?

**A** We estimate the ePRO adoption rate among us and the other three major

**Headquarters:** Charlestown, Mass.

**Total Worldwide Employment:** 240

**Description:** A provider of electronic patient reported outcome (ePRO) solutions that have been used in more than 400 clinical trials by 100 biopharmaceutical clients. LogPad System, a handheld wireless electronic diary, and SitePad Tablet deliver the voice of the patient in more than 80 languages and dialects. End-to-end ePRO solutions from eDiary design and deployment to help desk support and full study data archiving.

**Officers:** Philip Lee, President and CEO  
Stephen Raymond, Ph.d., Founder,  
Chief Scientific and Quality Officer  
John Arcari, Chief Financial Officer

**Offices:** 4

**Operations:** in homes and sites in 65 countries

**Clinical trial studies:** 100, of which 80 launched this year

**Year founded:** 1994 as PHT, which stood for Personal Health Technologies

**Website:** [www.phtcorp.com](http://www.phtcorp.com)

e-diary companies is 25% to 30%, which means that 70% to 75% are still paper diaries. So there is a huge market opportunity. With sponsors who contract with us, about 50% of our business is based in the U.S. and North America, 40% in western Europe and the rest in Japan, China and India.

The beauty of ePRO technology is that we have made it extremely easy to use. Paper diaries force the user to read the instructions and skip certain questions, so there is a lot of instruction embedded in it. With paper diaries you can have errors, such as pregnant men and illogical answers. Users of our ePRO devices see every question in a large font and generally choose from three or four choices. Depending on the choice you select, it branches exactly where you need to go. Plus the handheld device is meant to be used with your finger or

Insider Insights **PHT Corp.** (continued)

with a stylus. It's really quite easy to use.

Patients can learn to use our handheld devices in 15 minutes. We try to make sure that the wording of the questions is understandable by a seventh grader or younger. That's important so you don't ask questions that they can't answer, the vocabulary is too complicated or it has drug terms that don't make sense.

A year ago, we introduced a rental model for the devices instead of having sites buy them, which reduces their barriers to ePRO. Renting the devices reduces their costs by 30%.

**Q** How do you view the major issues in using hand-held devices versus interactive voice, versus web response in capturing and managing patient information?

**A** There are advantages and disadvantages to every approach, so it really depends on the study. For example, the regular telephone is ubiquitous and inexpensive so anyone can participate in a trial. But the downside to interactive voice response is that if you get a long questionnaire, it could be very burdensome. If you had four or five response choices and each question was long, you would have to listen for a very long time and you may not remember the first response. For simple yes/no responses, I think it is a very good technology.

The hand-held is much better if you have branching logic where you've got questions, you've got visuals and you have a visual analog scale. NetPRO, which is web-based data capture and will be our newest product offering, will allow subjects to use their PCs at home or

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their smart phones to answer diary questions. So this gives trial participants the best of both worlds. The upside of the Internet is that it's pretty ubiquitous in the western world, the costs are low and we're shipping devices all over the world, so it's a little bit simpler.


**Q** What are the business and technology challenges you face with ePRO in non-Western European countries?

**A** For our business, we implemented an ERP [Enterprise Resource Planning software that manages internal and external resources] system so all of our sponsors know exactly where the hardware is and when it's coming back. In technology, we're developing

a portal to make it easier for sites and sponsors to get the kinds of reports they want. So it will be more user friendly with graphs and pictures that allow site coordinators to do a variety of things. What we have now is a two-dimensional report, like a spreadsheet with rows and columns, in which each row is the patient and each column is a piece of data.

So now think of Excel, in which you are able to take that data and graph it, create charts, aggregate, do sums, do filtering. That's what we're developing—something that is much more dynamic and allows the user, whether it's the sponsor or the site personnel, to really slice and dice and make it more meaningful. That's the purpose of data. Right now it's more flat, like a listing.

**Q** As biopharmaceutical companies look to trim costs by outsourcing parts of their business to CROs, how has this major change in clinical trial management affected PHT?

**A** We benefit from this trend because we are basically an eCRO, as we do data collection and data management for PRO type data. So it really has helped us a lot. The more that pharma outsources, the more we have the opportunity to be part of that equation. And what drives a CRO to use ePRO versus paper diaries is the sponsor telling them to go with e-diaries. Pharmaceutical companies need to focus on their core competencies, which is drug discovery, not IT or PRO data collection. But we can do that and let them do what they do best. 

**PHT**  
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