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Everyone everywhere could only dream of a customer like this

By **ARUNDHATI PALMER**

In the business world, customer testimonials are gold especially for young startups hoping to open doors and grow.

They typically appear as one sentence kudos on the startup's or business's website or in press releases blessed by the marketing communications gatekeepers at both companies.

By design, those quotes from customers are planned and canned.

So it was quite a departure from the ordinary to meet Robert Huizinga, vice president of clinical affairs, Aurinia Pharmaceuticals during the J.P. Morgan Healthcare Conference in San Francisco earlier this month. Huizinga is literally over the moon about Philadelphia healthcare analytics firm Prevail InfoWorks that promises companies that it can run clinical trials better, faster and allow companies to stay on budget.

"In a previous life, I used a large, tech provider, and we would use their EDC (electronic data capture) systems, but the product was very unyielding in helping us find solutions," Huizinga said in an interview. "From an aggravation point alone, we love Prevail."

So why is it hard to run good clinical trials?

The goal is to have clean data and to get that data quickly, Huizinga explained. You have to get data from central labs, dosing data, safety and adverse event data, and clinical info for each patient. All of this data gets to the heart of the question — how is the patient doing and what is the safety profile of the drug?

The problem is that getting that data out of silos is difficult and then integrating it to get a good handle on how patients are responding isn't easy. It's a manual process. Huizinga recalls having to put various bits of a patient's data on pieces of paper to get a visual clue of what is happening to that person and answer calls from trial investigators. Which by the way happens constantly in an ongoing trial.

"For companies like us, especially smaller companies, we are always looking for a better way to understand does the drug have value in the disease that we are looking at," Huizinga said. "The better we get to quality data and the quicker we do so, the easier our jobs become quite honestly."

But this is the 21st Century and there is no dearth of companies that can properly analyze data, right? Wrong says Mary Schaheen, executive chairman at Prevail.

"There are other data visualization companies.

There are other analytics companies. But it would be Rob's [Huizinga] job and his team's job to aggregate the data in one place so that [the company] can put it in a fancy graph," Schaheen declared. "The aggregating, breaking through the silos, making it interoperable is the hard part, it's the heavy lifting. It's very easy to make a nice graph when it's all together."

Huizinga didn't miss a bit in echoing her.

"Right, right and we've all made these nice graphs when it's all together," he chimed in.

But aside from smoothing workflow, Prevail's analytics and reporting engine can actually help Aurinia to challenge assumptions that investigators make. [In Aurinia's case, it is developing a drug to treat lupus nephritis, a complex disease with really sick patients. Apparently, the Canadian company's trial testing the drug has been the only lupus nephritis trial globally to meet its primary clinical endpoint.]

For instance, when one investigator called saying he believes the patient has had protein urea, looking at the patient's complete visual profile from all the data captured and integrated, Huizinga said, it appears that judgment is incorrect.

The quality of the data has ramifications for how regulators view the company as well, especially whether the company understands how the drug works.

"So our job is constantly signal detection,"

he pointed out. "What happens to one patient in 300, will it happen to a 100 in 30,000?" he said. "So this kind of data methodology [that Prevail has developed] helps to understand the data better."

"You have better signal-to-noise ratio. You get rid of the garbage. You have a better understanding of what the drug does in that indication. That actually helps the FDA and helps them understand what the risk to benefit ratio is [of the drug]," he said.

In fact, Huizinga credits Prevail, which was used in the company's Phase IIb trial, as helping to expedite what FDA required for an ultimate approval.

"Based on the quality of the data for this one, we only have to do one more Phase III trial," he said. "So we actually shortened our development cycle because of this."

So pharma companies, especially smaller ones, should be beating a path to the Philadelphia company, right?

"Using Prevail, it's a no-brainer, Huizinga said. "It's a methodology for understanding your data better. We all see data but we rarely understand what it really means."

And here's the skinny on Prevail. The company was founded in 2005 and after some invested by management and strategic investors, it has grown on its own. The number of employees is just shy of 50 and the company's software has helped to run 250 trials, globally, according to Schaheen. She declined to provide revenue or profitability numbers.

Neither Schaheen nor Huizinga elaborated on the price of the analytics tool, although Schaheen noted that only two things determine price: the number of data integration sources and duration of use. The number of patients and number of patients do not matter.

"I think they are a very good price for what we get," Huizinga offered. "Everyone promised the world and they just all failed miserably and having used large providers, it just wasn't a good experience."

That must be like sweet music to any small vendor in any industry