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Technology Company

An interview with James DeSanti, CEO

PharmaVigilant, Westborough, Mass.

Tell me about your background and PharmaVigilant's founding.

I started my career at Johnson & Johnson in sales and marketing on the commercial side. I was trained at product launch and execution and then I transitioned into the vendor side when I became president of Walsh International, a very large data company in 84 countries. Walsh purchased prescription data and created databases that we would then sell to pharma companies as market share data. Pharma companies used this information for targeting for sales reps. The databases were very sophisticated and much larger than any databases used in clinical or R&D. There were millions of transactions per day. We sold Walsh to IMS Health, and I was restricted from working on the commercial side of the industry. That's when I started working for Phase Forward on the R&D side. I was amazed at the opportunities in terms of transitioning to electronic processes.

When I looked at the landscape in 2005, the year we founded PharmaVigilant, I recognized that the EDC [electronic data capture] market had been established and was on the right trajectory, but there were a lot of other technology components that were needed and not being addressed by the current vendors. We wanted to establish a company to fulfill those needs.

Year founded: 2005
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# of Clients: 26
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Tell me about PharmaVigilant's products.

The common thread through all of our products is that they are forward-facing products, meaning they're facing (interactive) the investigative site level and actionable (the front part of the actual clinical trial process). That actionability enables end users to interact directly with the systems and reduces the costs and increases the efficiency and accuracy.

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PHARMA VIGILANT

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Our primary product is our EDC component, InSpire, because the market is established. We've incorporated randomization, autocoding, a safety system, as well as all the feature functionality that you would find in all the leading products in the marketplace—complex edit checks, dynamic forms, dynamic visits, etc. EDC is the product that most companies buy from us first. With that comes a data warehouse. The data warehouse is important because it's not only a repository but has a very fast analytical tool. It does multiple trials, as opposed to most of our competitors' single trial reporting systems. But the biggest differentiator is that it can provide data on-demand. Clients can hit that button and down come all the data streams on their clinical trials in the format that they want—ODM, SAS or SDTM. So, whatever the client has determined, the company can now get that data set at no additional cost and no additional time. With the competition, you have to call to schedule an export and pay for it. We looked at pain points for the sponsors, which consisted of not getting their data quickly and paying for their own data twice, which didn't make sense to us. Our analytical tool in the data warehouse also allows sponsors to close out clinical trials quickly. It can be expanded on to not simply handle their clinical data but also monitor reports, lab data, etc. So, one of our goals as a company was to become more sponsor-centric to align with what the industry really wanted.

iVault rSDV is our product for remote sourced document verification. The technology has been deployed for more than a year now at sponsor companies in phase II and III trials—pivotal trials for submissions. The software takes up source document worksheets into an electronic environment so that you retain everything. At that point in time, you can do remote source document verification on any of the documents much faster because as soon as the EDC comes in and you have the worksheets, you can actually do the monitoring very quickly. This helps identify investigative sites that are having problems, speeds up the monitoring process and reduces the overall monitoring costs by about 50%. On large studies, the cost reduction can be significant, from the millions to the tens of millions of dollars.

I think sponsors want certain issues addressed, such as cost, speed and accuracy, and all vendors are going to have to transition their existing products and services in the monitoring area. It could change how business is done certainly and it could change the cost issue dramatically. You have a unique situation with remote monitoring in that you're actually reducing risk as well as reducing the cost. All the Tier-1 pharma companies are looking at this and running different stages of pilots. I discuss with them the key success points of these pilots so that at the end we can say, 'What's the scalability of it? How do I deploy it? How do I then bring it in?'

Another product is our iVault eTMF. We decided to create a product that would enable us to handle trial master files on an electronic basis to be able to see what is missing in real time, such as the informed consent from certain patients, and be able to get those documents quickly. So, eTMF has improved the accuracy and the ability to analyze the data sponsors have. Major clients would keep building dat bases but had no way to quickly access them. They had Documentum systems but those were repositories. By the time the documents get there, the trial is finished, so sponsors weren't getting any of the efficiencies they would get from a forward-facing system. That's another key piece we put in for submissions. With our product, sponsors can close out their trial master file at the same time that they close out their EDC.

What differentiates your products from other companies'?

You'll hear a lot about a product called SharePoint. From a technology stan point, this is a developer's toolkit from Microsoft. SharePoint is very co strained in terms of what you can do with it and doesn't bring in the robustness of what pharma wants, such as unlimited rights and roles. So, how do you deploy a limited toolkit across a global pharma company that's servicing 50 different subsidiaries in 80 countries when the product only has a limited number of rights and roles? Pharma has an insatiable appetite for flexibility, which is ingrained in the culture of the industry. Therefore, as a vendor, you need to address that and align with it. That was fundamental to the creation of the eTMF product. Being from the industry, I understand pharma's approach and how they deploy and market.

Another thing that differentiates us is our approach to service. We use dedicated teams per project that get high

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quality results within four weeks on average. We usually deploy with zero known defects, 100% on spec because our UAT [user-accepted testing] process is only a couple of days. The importance of having a high-quality delive able is that I can move my service and engineering teams every four weeks, whereas our competitors may take a multiple of that. I have more throughput per individual.

In addition, PharmaVigilant is a direct competitor against Phase Forward and Medidata, but we're covering more landscape than they do. If you take a look at the competition, they work primarily within EDC. We're branching out into warehousing, eTMF and monitoring. Our market potential, in terms of how we define the market, is greater than most of our competitors because we have defined the market more broadly. There are a lot more moving parts to what we do in terms of how we design the product. Flexibility is som thing we have that distinguishes us from older companies and is something that is ingrained in you early on when you work at a pharma company, as I have. The senior management at our competitor companies are not pharma people.

What changes do you expect to see in the clinical research industry?

All organizations are looking at how to improve their R&D processes. Technology will be a key component. Now, there's a mature market where the products and services are going to be more closely reviewed because you have educated buyers. I think the R&D side needs to be and will be run more like a business unit in the future. I think they will bring in practices they use in other parts of their business, which will increase efficiencies, accountabilities and the return on investments that they make. The efficiencies that pharma needs to get out of R&D can no longer be supported by cost savings from Third World countries.

If we come in with rSDV [remote monitoring component] to a major pharma company, that may be a $50- to $70-million savings per year while at the same time increasing the accuracy and quality of the data. They have to have savings in that order of magnitude to address the efficiencies of the organization.

What are your plans for growth?

I think we'll see substantial growth in the next several years as we ramp up. But also, we see the expansion of the modules regarding monitoring because, even though we're seeing a 50% savings with the use of the rSDV, we think we can accelerate savings beyond that. In addition, we want to make imports and exports very easy for the market to handle because right now they're clogged up with integration issues to the point of paralysis. Now is the time to re-fit.