CEO CFO

PHARMA VIGILANT

Issue:
February 18, 2013

CEOCFO Magazine - The Most Powerful Name In Corporate News and Information

PharmaVigilant is using Software and Technology to Revolutionize the Clinical Trail Industry by Providing a Streamlined Client Application Covering the Full Spectrum of Clinical Development through to Electronic Trial Mast Files

Healthcare
e-Clinical Provider

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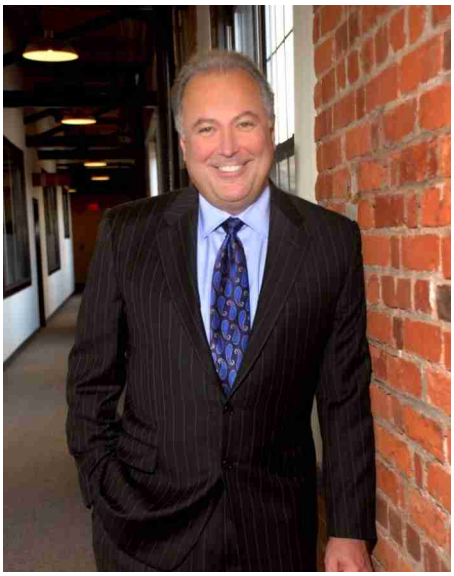

James DeSanti
CEO

BIO:
James has over 25 years experience in the pharmaceutical and software industries. He started his career at Johnson and Johnson, involved in Sales & Marketing (product development, and launches). He was later named President of Walsh Americas, with operations in the USA, Canada, and Brazil. James has extensive international experience, starting and managing companies in North America, Europe, and South America. He has been involved in over 400 clinical trials and nine clinical technology transfers in the pharmaceutical, biotech, and medical device industries.

About PharmaVigilant:
PharmaVigilant was started in 2005 with the intent to revolutionize the clinical trial industry. Our goal was to acquire and develop software products and companies that could significantly improve the Research and Development processes within the Pharmaceutical industry.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. DeSanti, what is the concept at PharmaVigilant?
Mr. DeSanti: PharmaVigilant is a technology company that supplies solutions to the pharmaceutical industry, biotech industry, and medical device industry, in support of clinical development. Primarily, we provide a streamlined client application that covers the full spectrum of clinical development, from the beginning stages of a trial, feasibility study, through to electronic Trial Master Files. These are used for regulatory submissions and segway into the actual collection of the clinical data within Electronic Data Capture (EDC) system. Then move right through the analysis phase to data warehousing, randomization/drug accountability and remote monitoring.

CEOCFO: Do most of your customers take advantage of the full range or depth of services or is it more pick and choose what they need at any given point in time?

Mr. DeSanti: It depends on the specification of the client, actually, and that sometimes corresponds directly to the size of the client. The larger companies, the "big pharma companies" will identify quickly the value of an integrated solution. They will tend to take the full spectrum of products within the solution, and they will move very quickly to maximize the use of that product as well. Smaller companies may take different pieces of the product to supplement applications that they have already in-house. Even in most cases, what we see in the industry is that it does not even utilize the full technology that is available today. We see that there is a technology gap, in the usage of products in terms of what is available, as well as the companies that use them.

CEOCFO: How do you close that gap both from PharmaVigilant and from an industry perspective? How do you get people to understand what is available and that it makes sense?
Mr. DeSanti: It is an education process. Once clients utilize a product, their knowledge of the technology spikes. Then they start to use more and more of it. As an example, you will have organizations that start a pilot program or they may do a number of trials with us. As they go through that cycle, the more they utilize different aspects of the technology. Organizations may start off within an Electronic Master File or EDC. As they go into subsequent trials they may start bringing in the remote monitoring. Then they may bring in randomization and Drug accountability, which will track all drug supply for an organization.

CEOCFO: How do you reach potential clients?
Mr. DeSanti: It is a multitude of ways as direct sales; calling directly on the pharmaceutical companies. We also go to seminars, trade shows, as well as indirect marketing through partners.

CEOCFO: Why should companies choose PharmaVigilant as opposed to many of your competitors?
Mr. DeSanti: We are more innovative in terms of the technology and how it is used. Our organization really is comprised of people from the sponsor side of the industry. We spent years working in pharmaceutical companies. I myself was with Johnson and Johnson. We understand what the needs are of the sponsors, and we craft our solutions accordingly in terms of trying to maximize their efficiencies from a standpoint of reducing time in clinical research, reducing costs in clinical research, getting data to them so that they can access and make decisions a lot faster. What we bring to the table is really a higher degree of innovation.

CEOCFO: In December you introduced a groundbreaking Batch Uploader. Is that typical of the innovation you have been speaking about?
Mr. DeSanti: It is very typical of the innovation because the Batch Uploader, as an example, is a way to pull data and information directly from any site in the world in volume with minimal training on the parts of the sites. It is really something that is to commoditize the process of extracting data, and putting it into a cloud so that it can be worked on 24/7 anywhere in the world. It is this ability to have the sponsors control the data, which is really going to give the ability to scale and reduce costs globally. As long as the data remains at the site, it is almost hostage to the cost structure that is going to be surrounding it.

CEOCFO: How is business?
Mr. DeSanti: We see a bright light in 2013. There was a dormancy in 2011 and 2012. The industry is starting to move again.

CEOCFO: Do you find that most companies today are outsourcing the technology part or is that still trying to be done correctly in-house?
Mr. DeSanti: That is a traditional cycle where they outsource it until the sponsors do not get what they want or the technology on the outsourcing partners fall behind what is available in the industry. Then they start bringing it back in-house a little bit and then it goes back out again. The technology really is an ebb and flow cycle within the industry, always has been. If you really take a look at outsourcing partners, for example, it is a huge investment for them to change out technology. They are not necessarily the ones getting the benefit, unlike the sponsors, so they tend to have a lag time that is quite significant from a standpoint of the technology that is available to the market, to the technology that is actually implemented in the market.

"The issue is technology on the commercial side of pharma companies is quickly evaluated and integrated based upon the business case."- James DeSanti

CEOCFO: What are some of the more unusual features that you are able to track? What are some of the things that people might be surprised that you are able to control with your application?
Mr. DeSanti: One is the use of I-Vault, as an example, allows us to extract the data from the sites globally. Once we get that data out of the site, we then can actually do incredible things from a scaling standpoint in terms of even entering the data within just 48 hours or having the data monitored within 72 hours. What we have done with large clients, "the big pharma companies", the data, from the time it is taken out of the site is actually entered into the Electronic Data Capture (EDC) system. Then monitored within five business days or less, contractually This provides cleaner data to the clients on a scale that they are not used to, or that other companies really cannot manage on a day-to-day basis. Faster data allows quicker and better decisions. It allows you to make decisions whether to move forward with continuing on, expand the study potentially, or actually to make a decision and shut it down quicker. This saves a lot of money as well for sponsors.

CEOCFO: As government regulations change do you need to make changes to your software or is that something the client is more involved with doing?
Mr. DeSanti: No, we actually have to make changes to that all the time. This is because the companies rely on us to make sure that our products are compliant and in alignment with regulatory agencies. Regulatory agencies are really pushing for transparency. Transparency via technology aligns both the regulatory agencies and the sponsors. With transparency, you get insight into data, as well as the audit trails. We are constantly looking to ensure that we are aligned with the regulatory agencies. That really absorbs a significant amount of responsibility for the sponsors.

CEOCFO: What surprised you most as you have developed the company and as it has grown?
Mr. DeSanti: The issue is technology on the commercial side of pharma companies is quickly evaluated and integrated based upon the business case. From a business standpoint, individuals on that side of the commercial side of the isle are trained at reducing cost, and maximizing profits constantly. On the R&D side, the focus on that is not as great, and that slows down the use of technology. One of the biggest surprises I have had is that pharmaceutical companies, which are used to looking at innovation, actually are not as quick to adopt technology, even with the metrics available to them.

CEOCFO: What is ahead for PharmaVigilant?
Mr. DeSanti: Ahead of us really is the final stage of piecing together a fully integrated solution form actually the beginning of a trial start to the end. Although other companies have cobbled together integrated solutions it is not the same as having one product

that literally moves it across the whole spectrum. This is providing us a significant advantage from a standpoint of access, analysis of the data, and the movement of the data, as well as the submission of the process. Because what we are able to do and prove to organizations now that savings on large pharma is not going to be in millions of dollars, but in tens of millions of dollars on an annualized basis. This is quite significant, and this will actually reduce the human footprint from a standpoint of the simple data collection and data review processes and allow the industry to really refocus that human capital in other ways that are probably more meaningful to them.

CEOCFO: Why should investors and people in the business community pay attention to PharmaVigilant?

Mr. DeSanti: Because PharmaVigilant could provide them with the catalyst for change and innovation that could absolutely transform their cost structures within their organizations. If you look at remote monitoring, as an example, that we utilize our I-Vault products for, this is a cost savings for a major pharmaceutical company of anywhere from fifty to a hundred million dollars per year in terms of introducing this technology. It is quite significant from a standpoint of the numbers that you may actually save, and redeploy into other clinical programs.

CEOCFO: Final thoughts?

Mr. DeSanti: One of the things that we are doing is we will be launching our CTMS system within the next several months, which will further enable our clients to take advantage of already imbedded information within our system so that they can actually take managing their clinical trials to the next level.

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