



CEO Interview: Doug Engfer - CEO - invivodata, inc.

Recently, **Q1 Productions** had the opportunity to sit down with Doug Engfer, Founder, President & CEO of invivodata, inc. to discuss the impact of Patient Reported Outcomes (PRO) on the life science industry, trends and recent successes with the utilization of enhanced technologies, as well as the growth and development of this exciting organization. For more information about invivodata, check out their website at www.invivodata.com; or come out and meet them at the upcoming PRO Conference to be held this April 24-25 in Washington, D.C.

Q1 Productions:

There is a tremendous discussion currently underway in the industry relating to the new FDA draft guidance documents on PRO. How do you think these documents will change the way that the industry collects and manages Patient Reported Outcomes?

Doug Engfer:

As you've pointed out, the PRO Guidance is a result of work that has been going on for a long time. I think the most significant aspect of the guidance coming out is the reinforcement of how important PRO Data are to drug development and making clear to the industry that FDA is looking at these. One of the reasons I feel it's been delayed has been the lack, until recent years, of truly high integrity methods to collect PRO data. It seems that FDA now has confidence that effective methods, practices and systems exist, which has freed them to provide this type of guidance to the industry. That said, the savvy folks in the industry have been pursuing more effective PRO methods over the last few years, and that's what has allowed companies like ours to get established.

The primary impact that the guidance is going to have is in reinforcing the importance of sponsors taking a thoughtful approach to the collection of PRO data. Companies have long had a lot of questions regarding the reliability of paper diaries. FDA has now put those questions onto paper, so to speak, and has indicated that they are paying attention to key areas like true patient protocol compliance, collecting data at the point of experience to mitigate recall bias and improve accuracy, and that instruments are appropriately developed and validated on the platforms. These are all activities that invivodata has been involved with since its inception and I think we're going to see a definite increase in the interest in the industry's interest to pursue the more reliable PRO data capture that's delivered through our electronic PRO offering.

Q1 Productions:

New technologies enhancing the collection of Patient Reported Outcomes seem to hold a panacea for the problems that the industry faces in terms of the collection and management of Patient Reported Outcomes. What do you see as the emerging trends in new technologies that will continue to assist and improve the utilization of PROs?

Doug Engfer:

One of the interesting aspects of patient reported data as distinct from data collected in clinic is that the technology is an enabler, but it's not the beginning or even end of the story. Fundamentally we're dealing with issues of human behavior here, volunteers who are generously providing us a window into their lives, allowing us to follow them around and sample what they are experiencing. Key to that, pointing back to the guidance, is getting the patients to comply with the protocol. Our experience is that in order to get patients to comply with the protocol, you need to manage the patient behavior. So even before you introduce technology, it is important to start with behavioral science and a deep understanding of what motivates patients, how they live their lives, and how you can and should interact with them in such a way that they are able to do what they need to do and still comply with the protocol. Further, technology must be introduced in an unobtrusive way so that you are indeed able to get accurate data collected in real-time, at the point of experience, in the real world. And so, managed compliance, based on behavioral principles, is job number one. Scientific principles must be instilled in any technology that is going to deliver truly high integrity PRO Data.

On that platform then, there are many exciting technologies – either already available or on the horizon -- that allow us to provide a more realistic picture of what's going on in the patient's life. Today the focus in PRO research is literally on the patient reported assessments, or interviews, that are conducted with patients, to obtain their impressions of how things are going. This is a significant part of the data stream but doesn't necessarily give researchers a complete picture. I think of this as providing a lot of snapshots. What we want to try to do is get as continuous a picture as possible, almost like a movie, of what the patient is going through. The first way of accomplishing this is through more dense sampling approaches that allow companies to capture patient behavior or experience more times during the day – while remaining unobtrusive, for both subjective and objective data.

Secondly, integrated physiological data, along with the patient reported data is very important. Today, within our SyncPRO™ architecture, we are integrating respiratory and blood glucose data from peak flow meters and glucose meters. This occurs within an open architecture so that it can be integrated with other physiological devices as well, providing a unified data stream of both subjective data and physiological data so that researchers can look at how they are interacting.

A third area that is further down the road, beyond physiological integration, is environmental data integration. Sensors in the environment that will help us understand temperature, allergen counts, and other factors that impact on given therapies. When thinking about temperature sensitive disorders, there are areas where the environment can trigger symptoms or can affect treatment efficacy. So again, we're moving toward having a complete picture of what the patient experience is all about.



“I think the most significant aspect of the guidance coming out is the reinforcement of how important PRO Data are to drug development and making clear to people that FDA is looking at these data, expecting companies to take a thoughtful approach.”

-Doug Engfer,
CoFounder, CEO
and President,
invivodata, inc.



On the operational side, from a more technical perspective, we're seeing activity in systems integration; that is, integrating our data with other data streams from other aspects of research, whether it is from in clinic data, lab data or so on, making sure that data are moving at the right times.

From a more clinical perspective, there is also a lot of process integration – understanding how to absorb these new tools into clinical operations in as seamless away possible so that as researchers, just as we try not to interfere with patients lives, we also minimize our interference with the caregivers. To the extent that investigative site staff have to focus on these other tools, they are taking time away from their primary role of care giving. This is an area where I think advances in technology as well as process integration can make things smoother still for the investigative sites.

QI Productions:

invivodata has recently announced continued record growth in 2005 – fueled not only by new business but also continued repeat clients. Share with us a success story of one of your clients:

Doug Engfer:

One of our early and long-standing clients, Amylin Pharmaceuticals™, focuses on diabetes; we have done work with them on their drug Symlin™, which they had approved by FDA early last year. Amylin had received an Approvable Letter from FDA, in which they were asked to run a very rigorous safety study around hypo- and hyper-glycemia. So Amylin chose to use our system to create a glucose monitoring network for the patients. Amylin, the investigative sites, and our ePRO system collected the necessary data, that FDA required, and Amylin got the approval they were looking for.

The way our system worked was that patients took their blood glucose readings on a schedule, and on this particular study, those readings were entered into the diary, along with additional information in terms of how they were feeling,, what they were eating, etc. All of this data was then uploaded, which enabled doctors to correlate the glucose readings with the other activities of daily living that the patients were going through, and were able to determine whether there were any hyper-glycemic or hypo-glycemic events related to the use of the drug.

The data all went through device that we deployed on a Palm handheld, which was then uploaded through a modem to the back end where the doctors and sponsor could view it on the web.

Also, interestingly, it created such a connection between the patients and the doctors that they asked to be able to continue to use the system even after the study was complete. They found that the interaction and the feedback between the doctors and the patients was elevated and enabled by the system. Patients also felt they were receiving better care, and the doctors felt they had a better idea of what the patients were going through. It was a real privilege to be involved in research like this. Symlin is the first new drug for Type I- Diabetes, since the introduction of insulin 70 or 80 years ago, so it was a major step forward for diabetes patients.

We really look forward to being able to do work down the road that is broader than clinical research, in areas like diabetes, where patients and doctors can use this kind of information and interaction within ongoing care.

QI Productions:

One of the greatest assets of your organization seems to be a solid scientific foundation, not just a great technology. What are some of the challenges you have experience in working together with both technology executives and scientists? How have you overcome these challenges?

Doug Engfer:

We really brought together the best of science, technology and clinical operations, all of which are essential to doing a good job within PRO data. I have to say that I think we had an easier time of integrating those groups here at invivodata, because they had worked together prior to the company being formed. Before we started this company, those of us on the technology side had worked together at my other company, the Windward Group. We did hire technology software development and helped companies build the products that they would then go out and sell. One of our clients was the University of Pittsburgh; Saul Shiffman and Jean Paty, my cofounders, wanted to migrate the patient reported outcomes system they had been using in their research since the mid 1980's to the Palm® platform, which we at Windward had helped Palm develop. So we started figuring out how to get scientists and technologists talking to each other – back in about 1995 or 1996. Looking back at when we did bring the groups together, the real key was in developing a common vocabulary, and what helped facilitate that were the scientists in the group had singled themselves out as not afraid of new technology. They embraced the technology and had developed the initial versions of the system on their own. So they actually brought half of the bridge with them in terms of the vocabulary; and on the flip-side, we at Windward really thrived on learning new problem domains and new spaces. In fact, if there was a challenge in front of us, it was trying to prevent our techies from wanting to turn into scientists, because they became so passionate about the work the scientists were doing. It all came down to employing mutual teaching – we accomplished most of this before starting invivodata, which helped us really hit the ground running.



Q1 Productions:

What has been the most fulfilling professional experience you have had in founding and growing invivodata?

Doug Engfer:

While at Windward we worked on a number of category defining products, FedEx Ship, QuickTime with Apple, Palm Computing, technology products for technologically adept people. It is a small segment of the population and so this has really been the first opportunity that I have had, and that most of our technology staff has had, to work on something that has a direct impact on people's lives. Every day this is both a humbling and motivating experience. It informs everything that we do, in terms of how we run the business, how deeply we care about what we do. The success stories, like when you hear about helping Type-I Diabetes patients deal with their chronic disease, certainly makes it easy to get out of bed in the morning and come to the office.

Q1 Productions:

You are also actively involved in your community – how do you find a balance between your professional and personal work?

Doug Engfer:

I think of this as more of a continuum of fulfillment rather than any sort of balance where you are trading anything off – I am able to derive tremendous personal and emotional fulfillment from my work as well as from my personal family life and the work that I do outside of that, and I think that is the key. Also, I have been fortunate that our family is engaged in much the same way. In many respects, when we are doing things out in the world, we are doing things together; or complementary to the extent that we're able to help one another on the work we are doing, whether it is in the arts or helping disadvantaged, abused children. So I don't really think of it as a balance, rather as a continuum of fulfillment.