

A CenterWatch Publication

Profile: Technology company

KIKA Medical, Boston, Mass., and Paris, France

An interview with Linda Beneze, CEO

Interview conducted at the DIA EuroMeeting in Berlin

Tell me about the background of KIKA Medical.

We were founded in France in 1997 to deliver medical images to French hospitals. The two founders had a relationship with French cardiologists and wanted to find a better way of delivering images. In 1998, they began combining the imaging with EDC [electronic data capture]. They developed the technology for EDC to make the process better than the old RDC [remote data capture]. We have had a web-based product from the beginning. We have been a U.S. company for about two years. We do about 60% of our business in Europe and 40% in the U.S. We have conducted 180 clinical trials with about 70 customers, with the split also being 60-40% Europe-U.S.

Tell me about Veracity.

We launched our new product, Veracity™, in June. It's a new platform that we completely built from the ground up. We built it on a transactional file system, so it's CDISC-ready. It's in the ODM [Operational Data Model] format, which gives us a lot of flexibility and a lot of potential out in the marketplace. Veracity offers a unique functionality

with the ability to take any image or any kind of file—MRIs, EKGs, JPEG files, lab files—and integrate it right into the CRF. There are very few companies that offer a product that can do that, which is why many customers choose us—along with our ability to offer safety adjudication online with the images. Typically, you find only 10% of the data in the eCRF. We have found that the key is to get all those other data assets into the client's database and give it visibility.

Eventa, which was the predecessor product, also enabled the imaging to be integrated with the CRFs, but what Veracity does is take a lot of what the biopharmaceutical companies have been asking for and enable those functionalities as well. For example, we use a web services architecture. That enables us to interact with other third-party systems. We don't have to have the entire end-to-end clinical trial management system. We can have a good EDC system with the imaging capability and then the option to interoperate with IVRS [interactive voice response systems] or ePRO [electronic patient-reported outcomes] or any other kind of systems, such as safety, that might have already been built because of Veracity's web services architecture. That is important because integration with other systems to date has been hard. Because of

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Employees: 54

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Veracity's architecture, it isn't. The interoperability is certainly attractive for CROs because they've already invested in other systems and don't necessarily want to use everything that we provide, just certain pieces.

The other thing that Veracity provides is user empowerment. Our system is unique because we can sort and filter on any data field in the CRF and create on-demand reports. Most other systems have eight to 10 pre-programmed reports to work with. Ours can sort and filter on anything in the entire casebook and create graphs, charts, etc. The user interface is customizable for that particular user's needs. So, if you're a monitor, you may not need to see all the fields that most other systems might put in the front end of their system. It's very easy to customize to customers' needs, which is very attractive.

How have the industry's needs changed during the past 10 years?

I started out in medical devices, spending 15 years there. One thing about medical device and pharmaceutical customers is that they invest a lot in

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KIKA Medical (continued from page 1)

their R&D but they hadn't, until about 10 years ago, invested in their clinical IT for clinical trials. Everything was done on paper. What shocked me was when I would go into a board meeting and the regulatory person would have piles of binders for one clinical study. I certainly wouldn't want to be the person who had to go through all that data. When I left the medical device market in 1999, I went to work for Phase Forward. Ten years ago, the customers were less sophisticated and less educated on what it took to implement an EDC trial. In the last 10 years, there has been so much learned, especially from meetings like DIA and a willingness to share information amongst users. The providers have gotten better at delivering EDC, and the customers are more sophisticated and better educated today. Customers know what the challenges and pitfalls are, and they are better resourced and better prepared to implement an EDC offering than 10 years ago.

What services do you offer around your Veracity product?

KIKA Medical definitely plays a consultative role. It's important for our customers to really understand the process of implementing an electronic

clinical trial because it's not like implementing a paper trial. We need to have a clinical understanding of what they're trying to do in order to implement the technology in a way that enables them to achieve the scientific benefit that they're trying to achieve. Our largest trial to date is 20,000 patients with over 200 million data points. We have another trial that just finished enrolling 3,000 patients. We have done some very large cohorts, and when you have that size patient population using your technology, you need a good service offering. One of the things we did was hire a new clinical director, someone who has a lot of experience. He is involved in every trial both at the pre-sales stage to understand the protocol requirements and at the kickoff meeting to make recommendations on how to implement the technology in a successful manner. I have also brought in a vice president of professional services who has made sure that we are really ready to deliver to our customers. Our clinical and scientific experience are key. Over the years, we have had a very strong success rate in the cardiovascular arena, particular because of our imaging capability. More recently, we have been expanding into orthopedics, oncology, gastroenterology and others.

What are your plans for further growth?

We want to make sure we serve the customer appropriately in the geographies where they are located. We are well-positioned to serve global customers because of our longstanding global presence. We have our R&D in France, but we have professional services teams in both the U.S. and France. Our plan for growth this year is to grow more in the U.S. Our goal is to bring our ratio of customers to a 50-50 level between Europe and the U.S. We have been growing our Boston office, and we'll continue to grow in Paris and get the balance that we need for where our customers' needs are. KIKA is an exciting company, and we have an exciting technology. We've proven ourselves over the years, yet offer the flexibility and the accessibility to the data that other technologies haven't provided in the past.