Insider Insights:
MedNet Solutions

CWWeekly's *semi-monthly company profile feature, Insider Insights, interviews executives of companies and organizations in the clinical trials space. Writer Ronald Rosenberg sat down with John M. (Rob) Robertson, president and CEO of MedNet Solutions.*

Q How has the company's growth in the last several years evolved from serving sponsors to a more focused approach with CROs and clinical services organizations that can become a bridge toward a better, cost-effective approach with sponsors?

A Historically, we have been a service company that focused on customizing our ENLIGHTEN product for each specific customer and each specific study. In that approach, our focus was to work directly with sponsors, because we really didn't have a tool CROs could use to build their own studies. This strategy allowed us to build a nice, solid profitable company over the last 12 years. However, it did prevent us from fully serving several other good parts of the market including the CRO side.

Our new iMedNet EDC product opened up that entire CRO market to us. Now we have a configurable study development tool that allows CROs and sponsors build their own studies. This approach reduces the cost of conducting clinical research. It really allowed us to forge mutually beneficial relationships with CROs that have been looking for an alternative to some of the higher priced, less flexible solutions out there.

Q MedNet's cloud computing (SaaS) approach with iMedNet EDC is focused on service-oriented solutions that CROs use on a contract basis—a goal that makes it both easier to use and robust enough so customers can accomplish more. What are the concerns you hear from potential customers who may be wary of making the switch?

A We feel iMedNet is a great solution for any type of CRO, from the biggest down to the under five-person CRO. You don't need to go through three weeks at a university to get trained on it. Simplicity of use is key and it's also a great value proposition, which makes for a great fit for the smaller CROs. It really allows anyone to use it for any type of study in any therapeutic area.

With our tool you don't need to be a computer programmer to build studies. You can be a clinical person and utilize our tool because it is so simple to use to build your studies. That is how we separate ourselves from the competition.

Q Beyond SaaS computing, what are the challenges in working with sponsors

and CROs that can help bring down their I.T. costs, as clinical trial costs continue to expand?

A Bringing down the costs is critical because it is so expensive to conduct these studies. What we've done is look at areas important to our customers, asking about their biggest challenges. One of their biggest needs is to reduce the time of study-builds. We do this in our system via reusable libraries, study-on-demand—which allows rapid study duplication—and ultra-configurability. So decreasing the time of study-builds is important, along with eliminating costly change orders and seamlessly sharing data among other

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systems such as lab and imaging systems, EMRs and EHRs.

The central idea is to capture the data in one place and share that information downstream. This can be done through systems that utilize advanced web services that can share that information. By following key standards we can eliminate the duplicate data entry that happens within clinical trials.

Better yet is to eliminate the need to share some data when it comes to eClinical systems by having one homogenous system that can serve as your EDC, your CTMS and CDMS. It just makes it easier and cleaner to not have multiple data entry points.

Q A major CRO concern is the rise and fall of many EDC and eClinical companies that initially gained attention but lacked the staying power to survive. Looking ahead, starting with SaaS, how do you see your industry addressing the CRO challenges of the difficulty picking a vendor at a time when the lines are blurring between EDC, CTMS and CDMS systems?

A We definitely have seen many EDC and eClinical companies come and go over the last 12 years, and I certainly don't blame CROs for being a little queasy about forming a partnership when they don't even know if the EDC company is going to be around when their studies end. We see three or four new EDC companies pop up every year. Either we see them at a trade show or hear about them. In many cases their use of the latest technology looks interesting. So that certainly can be confusing to CROs and the rest of the industry.

CROs first must determine what they need from a functionality perspective. There are myriad potential needs out there. Are they looking for just a basic EDC, or for a more advanced EDC that ties in study and site set up,

adverse event reporting, inventory tracking, payment management—all of those things. Some advanced EDCs can provide some CTMS and CDMS functionality as well.

The next question: What type of system

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>
> *John M. (Rob) Robertson, president and CEO, MedNet Solutions*

do they want? Do they have the resources in house to build their own studies, or do they want a turnkey solution and want the EDC company build it for them?

The truth is, while technology and functionality may have the look, cost and ease of use that are really important to the CRO and sponsor, other things are equally, if not more, important. Now you start to look at the company's experience and length of tenure.

The good CROs will go deeper into all areas of an EDC company. They'll dig deep into the SOPs, the overall quality system, the disaster recovery plan, the hosting facilities, the CAPA [Corrective and Preventative Action] plan, the validation plan, the testing philosophy, testing execution, the traceability matrix that goes with that and the audit history. We've been audited successfully over 80 times.

Key questions that should be asked include: Has this EDC company been audited? Who audited it? The FDA? Were there any major findings? Any 483s [a form for "inspectional observations" used by the FDA to document and communicate concerns]? Is there any other reason it didn't move forward with the company? Then they'll dig even deeper into the financials. They need to know if this company will be around—is it on solid financial footing? Does it have a history of making money? Is the EDC firm's future dependent on their business?

They need to look at all of these things to

make sure the EDC company is strong and will be around. If it looks good in all those areas, there's a good chance they picked a good partner.

Q With global trials, customers typically want speedy answers as part of good customer service for their clinical trial management systems. Given the ups and downs of meeting their requirements, how do you see "Live Chat" and virtual support centers used effectively to respond to customer issues?

A Clearly providing customer service is essential to providing a good user experience. We've used Live Chat, and it is one of the new and efficient support tools in our industry. It allows customers to quickly connect with support personnel and get fast answers to questions. It really allows them to save time and energy. While it may not answer all their questions, it is a great start. Sometimes you begin with the Live Chat, and it becomes apparent a phone conversation is necessary to solve the problem.

It's a good tool because not only is it helpful, but also it really fits into the workplace schedule. You can be using Live Chat while doing other things. That's why both we and our customers like it. Another advantage is that there is a written record of the conversation for quality purposes and review.

In virtual support centers, you can find online resources like frequently asked questions, video snippets and support forums on which you can post a problem. Not only will you have our staff answering these questions, but potentially other customers might provide answers. It is another great way to provide for 24-hour, 7-day-a-week help. We tie in key word searches on submitted topics, articles and other online resources so it is quick and easy to get answers. 🔗