

to a lot of time spent scrolling through unnecessary information. "Those definitions can be found in the protocol, or presented elsewhere," said Clewlow. "By getting rid of them in the electronic version, the CRF is actually 75% less in size." Adopting features that electronic offers and not just replicating the paper process is another factor of the EDC journey.

A final note to the bookmark, hyperlink process for the Patient Data Reports collected for submission. Clewlow noted that version 4.5.3 has all the bookmarking and hyperlinking capability needed. "Previously, it took easily a month to do the scanning and treatments for a paper-based trial. That in itself pays for the upgrade," says Clewlow.

"Two years ago, the EDC market leaders may have had better products and features," said Clewlow. "But now Oracle's latest version compares well to them."

Retina Implant AG

www.retina-implant.de

Category: Medical device start-up

Executive: Anuschirawan Hekmat, PhD, vice president of quality management & regulatory affairs

Headquarters: Reutlingen, Germany

EDC Goal: Move from paper-based CRFs to eCRFs on a Web-based system

Current EDC Solution: OpenClinica

Number of Employees: 10

For this medical device start-up, its first foray into EDC began with a six to nine month evaluation period of about 12 EDC products. In the end, Retina Implant AG decided on OpenClinica, an open source software with open standards. "I thought it was the easiest for a start-up. We could use open source and host it ourselves on our server," explained Anuschirawan Hekmat, PhD, vice president of quality



management & regulatory affairs at Retina Implant AG. "We could build, modify repeatedly, and use our own CRFs. Ease of use with OpenClinica was the major feature."

Not to mention the cost of hosting fees. For Hekmat, numbers of \$50,000 USD a year to host its EDC system seemed more in line with the big pharma companies and their larger budgets. For the German medical device start-up, the money spent on purchasing a Web server, hiring an IT consultant to set up OpenClinica, and investing in future training seemed more practical.

Last summer, Retina Implant started using OpenClinica for its latest trial, which is comprised of 11 studies. Currently, five of those studies have acquired subjects and are up and running with the OpenClinica CRF process. Randomization of study subjects are done outside OpenClinica, as it doesn't have this feature. So far, Hekmat is appreciative of the flexibility of the

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Hekmat believes the flexibility to create, edit, and upload the CRFs to the sites is crucial in the European medical device world, which is predicated on incremental proof-of-concept studies. In 2003, Retina Implant AG was founded with the goal to place the first fully functioning electronic retinal prosthesis for visually handicapped and blind people. "In the United States, the IDE is based on the model and the design is frozen. Then they test it in trials. With our retinal product in Europe, we test it in one patient at a time. It is in controlled use and we do the changes in pilot trials and make changes quickly, but in a controlled fashion using a process validation and qualification model" explained Hekmat. "With our product, people who were totally blind are able to see a white plate on a black

tablecloth. But it won't stop there, we want them to be able to read a large print newspaper." For Hekmat, the versatility to obtain clinical data is what is going to get the company to that point with its subjects.

Hekmat describes the use of OpenClinica as "self-evident." "For the sites, it's easy to set up the trials. One form follows the other and proceeds from there. It is obvious to set up the case report forms," says Hekmat.

Rapid data analysis by viewing eCRFs in real-time is also a plus. The data is exported into Excel, which factored into Hekmat's decision for OpenClinica. He wanted an application that would be easily integrated with other applications, and believes the Excel avenue offers that. The rest of the studies at Retina Implant are currently paper-based, and will be moving over to the eCRFs soon.

Hekmat recently took some training classes at Akaza Research's Cambridge,

MA, facility, although he maintains it is possible to use OpenClinica without training. He believes the online support manual and SOPs offer the installation recommendations needed to get it up and running easily. However, he also said that there is the potential to run into problems if you don't use a specialist to set up the system.

Akaza Research provides the open source software and provides support, training, and consulting services to users of the free software. Ben Baumann, director of business development at Akaza, says that it is the smaller biotechs, sponsors, and CROs, as well as academia, government, universities, and cancer centers that are registering to download OpenClinica at www.openclinica.org. "The price point is accessible," said Baumann. "It allows them to be more competitive to do research when they have their own systems."—*Lisa Henderson*

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