

On Site: Industry Headlines MyClin Offers Virtual Communities for Sponsors, CROs, Sites to Stay Connected During Trials

At the investigator meeting prior to the start of a clinical trial, principal investigators and their staffs sit together to hear the sponsor explain the protocol and to ask questions. Everyone socializes over snacks or a meal, connecting faces to names and discussing the ins and outs of the trial.

Then they all return to their respective sites and their communication drops to almost nil — perhaps an occasional phone call and likely not with any of the people they met at the meeting, but rather some other contact employed by the sponsor or fellow site.

That’s why James Denmark started myClin. “We really wanted to capture the sense of community that happens toward the end of the investigator meeting and carry that forward,” he said.

MyClin, which went live in March, is something of a mix between LinkedIn and Facebook for all parties working on a particular trial. The drug sponsor, which purchases a myClin subscription, uploads all documents that sites and other service providers working on the trial need to access. Those working on the trial become lifetime members (at no cost to them) and set up their own profile pages to gain access to the online community for the trial. There, they can easily see the protocol or any updates or newsletters associated with the study posted by the sponsor.

What makes myClin different from a basic portal, though, is its open forum section, on which members can post questions about matters great and small. “One site might post something like, ‘Where can I get dry ice in New Hampshire on a Sunday?’ and the only party who might know that is another site coordinator,” said Denmark. Others might have questions about the protocol. The sponsor, or others working on the trial, can reply.

Kath Goin, associate director and clinical trial manager for Endo Pharmaceuticals — which currently uses myClin communities for eight of its trials — said having everyone together in one virtual community brings all parties closer to the science.

“I went on a site-initiation visit with a monitor recently and the site was pounding the monitor with technical questions about the protocol, pointing out a loophole in the inclusion/exclusion criteria,” Goin recalls. “In the past, that monitor would have had to make his way back to the office and go back through the chain of command to get the answers, and it would have taken a lot of time. But he was able to put the questions on myClin and within 24 hours the scientists had answers for all to see, which helped all the other sites.”

Each post on myClin has the person’s photo next to it, which is a key feature, explained Denmark. “You’d be surprised how much people’s attitudes change when they can see a picture to connect with a name. They’re so used to the sponsor being some black box at the end of a phone number. This really breaks down the barriers and opens channels of communication. Your identity in myClin is you — not a drug company or site. I think that really changes the dynamics of working together, breaking down the hierarchies and letting everyone have their own identity.”

Goin agrees. “It puts a face on all of the people who work behind the scenes, humanizing the experience,” she said. “These sites have to work with so many sponsors and the

sponsors work with so many sites. This shows who's actually sitting around the table and what their role is."

All of which fits in very nicely with the current push for investigator-site relationship enhancement, said Denmark. Yet, he acknowledged some drug companies might actually prefer that their employees remain faceless and nameless.

"A number of sponsors, we know, are not going to buy into this approach," he said. "But Endo gets it. Philosophically, they embrace the transparency of it and want there to be an open channel between the science and those working on the trial."

The target audience, said Denmark, is small to medium biopharmaceutical companies, particularly those with a vested interest in staying with a compound through most of its life cycle. MyClin — which has different tracks for various types of vendors — is most useful for sponsors who are outsourcing to many companies for each of its trials, said Denmark. "The sponsors who outsource to many vendors have to talk to so many people it's hard to keep it all straight. They, more than other sponsors, run into these tiers and layers and communication breakdowns. We're trying to remove the layers and make everything flat."

In order for each study community to remain a closed and private system, the sponsor is responsible for granting and revoking membership to each specific trial community. "You can become a member of myClin just by signing up, but to get into a study community the sponsor needs to invite you in," said Denmark. "We also give the sponsor tools to audit membership of its community."

MyClin handles encryption, unique usernames and passwords, session expiry, password lockouts, terms of service, and privacy policy for each community.

MyClin's platform has been in use by clients since September 2009. Its first client to use the latest version is Endo. Denmark's founding business partner in 2008 was Eileen Daniel, who left to work in clinical operations for Endo and helped introduce the myClin concept to Endo. In the eight trial communities myClin currently hosts for Endo, there are 350 site users at more than 90 organizations. Sponsors, said Denmark, pay a monthly subscription that covers one or many trials; they aren't charged by the number of users or amount of traffic.

Denmark, who has 25 years in technology management, with 17 of those in the clinical research field, is talking to other sponsors and CROs about the concept. At the end of the year, he said, version 2.0 will come out with more start-up activation features and private areas for one-on-one conversations, which the communities currently don't offer.

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