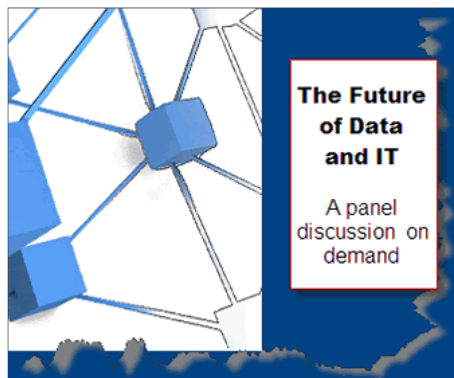


Inclinux has Better, Data-Backed Plan for Recruiting Sites, Subjects



By Deb Borfitz

March 16, 2009 | Identifying the best sites for a particular clinical trial just got a bit more precise. With the latest upgrade to its widely popular Critical Population Research (CPR) system, Inclinux, Inc. can now provide color-coded maps of disease prevalence down to the zip code level. The CPR database has also enlarged to include profiles on 40,000 additional investigators, many of whom do research outside the U.S.

So says Chris Sleat, chief marketing officer for the Wilmington, NC-based clinical trial enrollment solutions provider. CPR automates what just two years ago was accomplished by a team of data scouts assembled in a room over several days. Disease prevalence is typically the leading indicator for site selection and patient recruitment. But CPR can also factor in a multitude of other criteria that may be predictive of trial success, such as geographic barriers to trial participation or the availability of a site's study coordinator to accept a "warm transfer" from the enrollment call center.

The CPR database contains the names of over 100,000 investigators that have filed a 1572 with the U.S. Food and Drug Administration, although only about one-fifth of them are actively doing research—15,000 focused on phase II-IV studies and the remainder on phase I trials, says Sleat. Information on an additional 8,000 investigators was obtained from other venues, including similar filing systems in Europe and Latin America.

Investigator profiles contain a wealth of information, including how many studies have been run in which therapeutic areas and how recently, says Sleat. The information gets verified at least twice a year via telephone and email. In-depth site qualification questionnaires also get conducted face-to-face or via teleconference for specific studies.

Importantly, the CPR system can be used to assess site recruitment feasibility for protocols and potentially help in their redesign, says Sleat. "If we get to do that, our effectiveness in doing subject recruitment is [three times] higher." CPR can be mined for insights into the media habits of the targeted study population to further optimize recruitment campaigns, even if sites have been pre-selected. The database contains data from Neilson (television) and Arbitron (radio) ratings.

Numerous public and private databases, including the National Ambulatory Medical Care Survey covering uninsured patients, provide a foundation for the CPR system, says Sleat. To that, Inclinux adds sites and subject data based on primary research and actual experience with sites it has worked with regularly.

Inclinux customers include more than 70 mostly large pharmaceutical and device companies as well as multiple biotechnology companies and several clinical research organizations, says Sleat. Although it is thought of primarily as a recruitment company, it has been doing clinical site monitoring since CPR was automated in 2007. Monitoring services currently represent 15% of its study volume. "This year, despite the economy, we're doing well. Of our new business, we're working on four times the number of protocols that we were at the same point last year."

The reason, in part, is that Inclinux can provide trial-sponsoring companies with a "real plan" for acquiring subjects "rather than run a radio ad during drive time and hope for the best," says Sleat. "We come in with a plan and show them how we came to it." Pricing is based on performance. As a result, Inclinux relies less often on traditional, pricey media outlets than other modes such as social networking sites and community education and recruitment fairs.

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