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Lilly Creates Standards for Technology Adoption

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Large pharmaceutical firms, as a rule, neither implement data-analysis software as an enterprise solution nor rigorously assess whether or not they get the expected return on that investment. **Eli Lilly & Company** is doing both in partnership with **SAS**, helping to earn

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it this year's Best Practices Award in the Clinical Research category.

Lilly has been using an internally developed "adoption and migration scorecard" to track progress toward desired outcomes since it began deployment of SAS Drug Development last year, explains Jason Burke, worldwide director of health and life sciences at SAS. The performance metrics include the proportion of users with accounts, the number of "trouble tickets" issued and resolved, successful user logons, and system performance against a projected ramp up of data loads through the system.

SAS Drug Development is a software solution for aggregating and collaborating around clinical information in the context of statistical analyses and in a manner that's compliant with federal regulations, says Burke. It will impact up to 500 SAS programmers at Lilly, including statisticians, statistical programmers, and data managers. More than 350 of them are already registered users.

The project's value to Lilly is not just in modernizing a 25-year-old mainframe architecture, but in creating an "industry standard," says Todd Sanger, director of global statistical sciences at Lilly. "All along, we wanted an application that could be sold to everybody. There's no competitive advantage to being the only one to use this tool. It facilitates partner-

ing with other companies, CROs (clinical research organizations), and the Food and Drug Administration."

As SAS sees it, Lilly has given the industry an example of how implementations of this sort "ought to be done, including the right kind of project management, process re-engineering, and training" as well as disciplined progress tracking, says Burke. "You can't improve what you do not measure."

Sanger agrees, adding that Lilly "worked with SAS to improve the product, implemented it as a group, and tested it beforehand. The implementation process itself was a best practice. We had upper management support from day one and the expectation that this would not be voluntary." It's important that project management and deployment implementation teams "come together to realistically model what's important for the organization to get out of the project." The metrics serve as a flag that "something is wrong." Diagnosing the problem is a separate step.

Performance metrics are tracked weekly as a way to monitor usage, says Sanger. Since October 2007, roughly 90% of all trained users have had accounts set up with SAS Drug Development, showing little lag time between training and system availability. Logon by users was lower than anticipated only during the start-up phase be-

cause of existing work completed using the old platform. There has been a mostly steady drop in the number of issues raised by users. Recently, a section was added to the scorecard detailing how 6,000 gigabytes of data are migrating from the old to the new database.

Completion of global adoption of SAS Drug Development ends with Japan in October, says Sanger, but use of a corporate scorecard will continue indefinitely. With future FDA submissions, Lilly may also allow the agency to directly access clinical data in SAS Drug Development, "so we have total transparency with our processes." Lilly expects annual productivity and efficiency savings of \$11.3 million starting in 2010, which appears probable based on the metrics gathered to date, says Sanger. Additionally, Lilly expects to save \$2.7 million per year by retiring its legacy data-analysis system.

Burke notes that SAS has extracted as many lessons from the experience as Lilly, helping it "guide customers down this path to ensure implementation success." The companies were able to "transcend" the traditional vendor relationship model to forge a true partnership. They meet quarterly to discuss progress and collaborate on new ideas. "As part of this working relationship, Lilly is providing ongoing input on future requirements and capabilities for SAS Drug Development." •

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