

Bio·IT World

Indispensable Technologies Driving Discovery, Development, and Clinical Trials

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Best Practices

Profiles of Innovation in drug discovery, development and clinical research

Solvay Pharmaceuticals Enhances Worldwide Drug Development with SAS

ADAPTED FROM SOLVAY
PHARMACEUTICALS' 2005 BEST
PRACTICES AWARDS ENTRY

When bringing new drugs to market, time makes all the difference. Profits and brand recognition increase with faster releases, while development costs are minimized with early cancellations of underperforming compounds.

Solvay Pharmaceuticals, a subsidiary corporation of the worldwide Solvay Group of chemical and pharmaceutical companies headquartered in Brussels, Belgium, found that the key to expediting and globalizing the drug development process is in the successful sharing of data.

Solvay Pharmaceuticals needed global, secure access to clinical information — they needed to remove geographic boundaries and make information available to anyone who needs it, when they need it. Their obstacles to sharing data across the globe included accessibility, compliance,

and collaboration. SAS Drug Development helped overcome all three, providing data warehousing, analysis, reporting, and exploration.

Key to gaining the benefits of SAS Drug Development was a well-planned, well-executed implementation process to replace Solvay Pharmaceuticals' existing solution. A global team of integrated SAS/Solvay Pharmaceuticals employees, carefully planning and communicating with each other, were able to implement the new solution in nearly half the time it took to implement their previous solution.

Project Details

Accelerating drug development cycles is a primary goal of all pharmaceutical companies. Clearly, it benefits the companies that develop and market drugs by reducing development costs, but it also benefits patients by speeding time to market, delivering new therapies more quickly into the hands of those who need them.

Unfortunately, many companies lack sufficient means to share data across diverse global locations. As a result, they cannot support the collaborative research efforts that would enable them to achieve their goals. Such was the case for Solvay Pharmaceuticals before it implemented SAS Drug Development.

With more than 100 researchers around the world working in such areas as data management, statistics, and clinical and medical review, Solvay Pharmaceuticals needed a repository to provide global, secure access to clinical information used in developing its various compounds. By using SAS, Solvay Pharmaceuticals now effectively removes geographic boundaries to make information available to anyone who needs it, when they need it.

Implementation in Half the Time

Unhappy with an existing solution that was unable to address those needs, decision makers at Solvay Pharmaceuticals

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looked to other vendors. They chose SAS based on its stellar reputation and the positive experience employees had already had with the vendor.

To implement the new solution, Solvay Pharmaceuticals and SAS assembled an integrated global team from both companies. The team created an implementation plan and strictly followed the outlined processes, pre-testing for successful implementation and communicating frequently on design and configuration. SAS hosted the solution at its world headquarters, but held regular training sessions at Solvay Pharmaceuticals sites. The ensuing implementation took 45 percent less time than the implementation of the previous system — 10 months versus 18.

Key to the speed of the implementation was the flexibility and ease of using the technology as an application service provider (ASP) model. Providing maximum benefits with minimum impact on the Solvay Pharmaceutical team, the ASP approach freed Solvay Pharmaceutical's IT staff from having to install, upgrade, maintain, and support the new software and hardware systems, all while preserving the necessary documentation to successfully address an FDA audit. Moreover, there was no need to involve third parties who could potentially delay the process.

High security, including encryption of data and reports, and responsive 24/7/365 technical support ensure the data's availability — anytime, anyplace — and significantly enhance teamwork and collaboration among researchers spread across the globe. Indeed, interested parties (including external development partners) are able to access the application over a secure link to a protected facility.

With SAS, Solvay Pharmaceuticals

found a quick, easy, and complete solution for data warehousing, analysis, reporting, and exploration that transforms massive amounts of data into intelligence, which, in turn, expedites the drug development process.

Information Just a Click Away

The solution will provide users at all levels — from the vice president down — with customized information relevant to their own roles in the decision-making process. Executives, for example, might access broad measures, such as overall statistics on an individual study or the list of all ongoing Phase III studies for a particular compound. Researchers, in contrast, can access details as specific as demographics, laboratory data on a patient, safety information, or adverse event data. Whatever the data, they are readily accessible via the Internet.

Operating on a global scale can be difficult because people need to look at the same information — often at the same time. Using the SAS solution, researchers around the world will be able to query and explore the same data without the drag of time differences that slow knowledge sharing and discovery. Collecting data from around the world and deriving usable answers to queries once took months; now it can be accomplished in a week.

Solvay Pharmaceuticals is now positioned to become a truly global organization. Not only can its scientists bring together information from the company's research facilities in Europe and America, they can also easily work with outside development companies anywhere in the world. This ability to obtain timely access to common technical documents from clinical trials around the

world and regularly analyze the data enables them, for example, to make sure that no safety concerns exist in pockets or at far-flung locations. At the end of a study, too, researchers can better test for product efficacy. An important element to gaining early insight into a drug's safety and performance is the easy transfer of data back and forth, especially while the studies are ongoing.

Better access to complete and current data will translate into better knowledge of compounds on a global scale. Ultimately, these shorter times to market and decreased development costs mean improved earnings. Whether development is taking place in Europe or the United States, employees can now combine and share data — and learn from it — so they can successfully submit it for regulatory approval.

In contrast, the sooner a drug is determined not to be a good prospect, the more the company can save in terms of research costs.

Eventually researchers will use the software to combine drug studies on the fly as they are completed. Solvay Pharmaceuticals will then have an integrated database that will not only streamline decision-making and portfolio management but also offer insights into future studies.

But the results also stand to have a wide-ranging impact beyond Solvay Pharmaceuticals. More efficient processes and greater collaboration among researchers across the globe dramatically improve the likelihood that those researchers will play a central role in supporting the very processes that could deliver the next miracle drug, thus greatly increasing the speed of bringing that drug to the patients who need it. ●