CASE STUDY

Boehringer Ingelheim

SOFTWARE-AS-A-SERVICE APPROACH TO eCTD SUBMISSIONS

PROJECT SNAPSHOT

Client: Boehringer Ingelheim is a research-driven group of companies dedicated to the research, development, manufacture, and marketing of pharmaceuticals that improve health and quality of life. Headquartered in Ingelheim, Germany, the group operates globally with 137 affiliates in 47 countries and more than 38,400 employees.

In early 2007, the company sought a standard technology solution to comply with the January 1, 2008 FDA regulation for submitting electronic drug applications in the electronic common technical document (eCTD) format.

Boehringer Ingelheim chose eCTDXPress from ISI, delivered using a Software as a Service (SaaS) model. eCTDXPress is ISI's Web-based solution for creating eCTDs, managing eCTD lifecycles, and reviewing eCTD submissions.

Boehringer Ingelheim had a rapid system roll-out - deploying the solution in just under eight months - and enabling the company to achieve dramatic business efficiencies. Since first deploying ISI software for submissions five years ago, the company has cut at least two weeks from the submission cycle.

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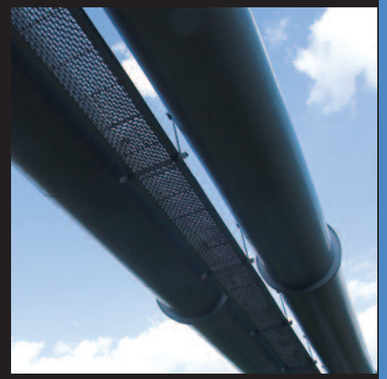
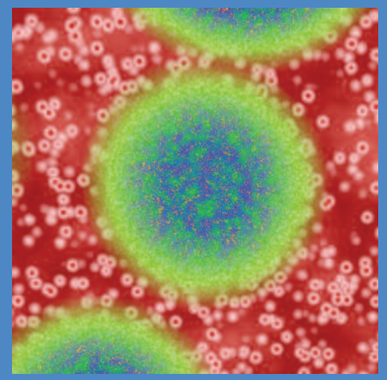
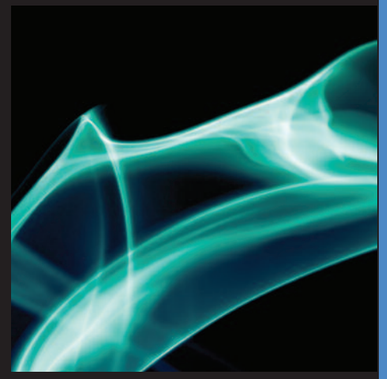






About Boehringer Ingelheim

Boehringer Ingelheim is a research-driven group of companies dedicated to the research, development, manufacture, and marketing of pharmaceuticals that improve health and quality of life. As one of the world's 20 leading pharmaceutical organizations, its business consists largely of human pharmaceuticals in the form of prescription medicines, consumer health care, and biopharmaceuticals as well as pharma chemicals and animal health.

Headquartered in Ingelheim, Germany, the group operates globally with 137 affiliates in 47 countries and more than 38,400 employees. The drugs it develops and produces must be ratified in Europe, Japan, and the U.S.

With this volume and scope of activities, Boehringer Ingelheim is a long-standing user of technology to optimise the quality, reliability, and efficiency of its administrative and information management activities. Boehringer Ingelheim uses Documentum for its document management and archiving activities, together with specialist solutions from ISI for management of electronic drug application submissions.

We had an established relationship with ISI and knew that the company, as one of the market leaders, would be around for a long time to come. But it was especially important to us to be able to implement an SaaS (Software as a Service) solution initially, and not all of the other players we considered were willing or able tooffer this option.

The Challenge

In early 2007, Boehringer Ingelheim realised it needed to take its electronic submissions activities to a new level in order to ensure compliance with new U.S. Food and Drug Administration (FDA) regulations due to come into force on January 1, 2008. The new regulations require that pharma companies must now begin to submit their electronic drug applications entirely in the approved electronic common technical document (eCTD) format.

This entailed choosing an appropriate standard technology solution across the group—na challenging task given the size and geographically dispersed nature of the organisation.

Crucial factors in the decision included:

- The solution needed to meet FDA specifications
- The supplier needed to have long-term stability and be able to survive any market consolidation
- The software and related services had to be provided on an outsourced, externally hosted basis (also known as software as a service, or SaaS)

This last criterion was critical. Boehringer Ingelheim had only given itself until December to successfully implement the new solution. This precluded using an in-house system that would require extensive integration and the creation of an entire team to manage and support the technology.

According to Dr. Hanns-Georg Leimer, head of the Global Document Management Solution Center (GDC) at Boehringer Ingelheim GmbH in Germany: Says Dr. Leimer: "ISI was a good match with our users' requirements, and of course we had an established relationship with ISI and knew that the company, as one of the market leaders, would be around for a long time to come. But it was especially important to us to be able to implement an SaaS (Software as a Service) solution initially, and not all of the other players we considered were willing or able to offer this option."

In addition to meeting all of Boehringer Ingelheim's other criteria, only ISI could offer the company the requisite flexibility.

The Business Case

The teams at Boehringer Ingelheim appreciated that they were able to outsource the solution for the time being meant we were able to set up the system in a validated way, with full, expert technical support; bug fixing; and end-user support.

Given that Boehringer Ingelheim's core competency lies in drug development, not in supporting large software systems, this approach made good business sense. Leaving it to the experts has paid dividends for Boehringer Ingelheim. The project started in April 2007 and was delivered on time, by December 2007. "This was a very impressive collaboration," Gilbert Kampfner, Managing Director of ISI Europe says. "We didn't have to keeping pushing back the timelines; everything was right on schedule."

The chosen solution implemented by Boehringer Ingelheim—eCTDXPress—is ISI's Web-based solution for creating eCTDs, managing eCTD lifecycles, and reviewing eCTD submissions. The application satisfies both regulatory agencies' and industry sponsors' requirements for reviewing, compiling, publishing, and archiving multi-region eCTD submissions. eCTDXPress lets users separate technology from content, which improves productivity and speeds up time to market.

In addition to meeting the authorities' requirements, standardising the software and eliminating paper output from the applications process will help Boehringer Ingelheim meet its business objectives of reducing heavy costs associated with drug development, by shortening R&D and regulatory lifecycles, accelerating speed to market.

Blockbuster Benefits

Boehringer Ingelheim chose the SaaS solution not only because of the system's guaranteed, rapid availability, but also because the solution enabled Boehringer Ingelheim to cut internal support costs by approximately 40 percent. This resulted in considerably lower overall cost and investment than an in-house solution.

Since first deploying ISI software for the support of electronic submissions over five years ago, the company has cut at least two weeks from the submission cycle. For a blockbuster drug worth 1 billion euros a year, a two-week time-to-market market advantage is worth a lot.

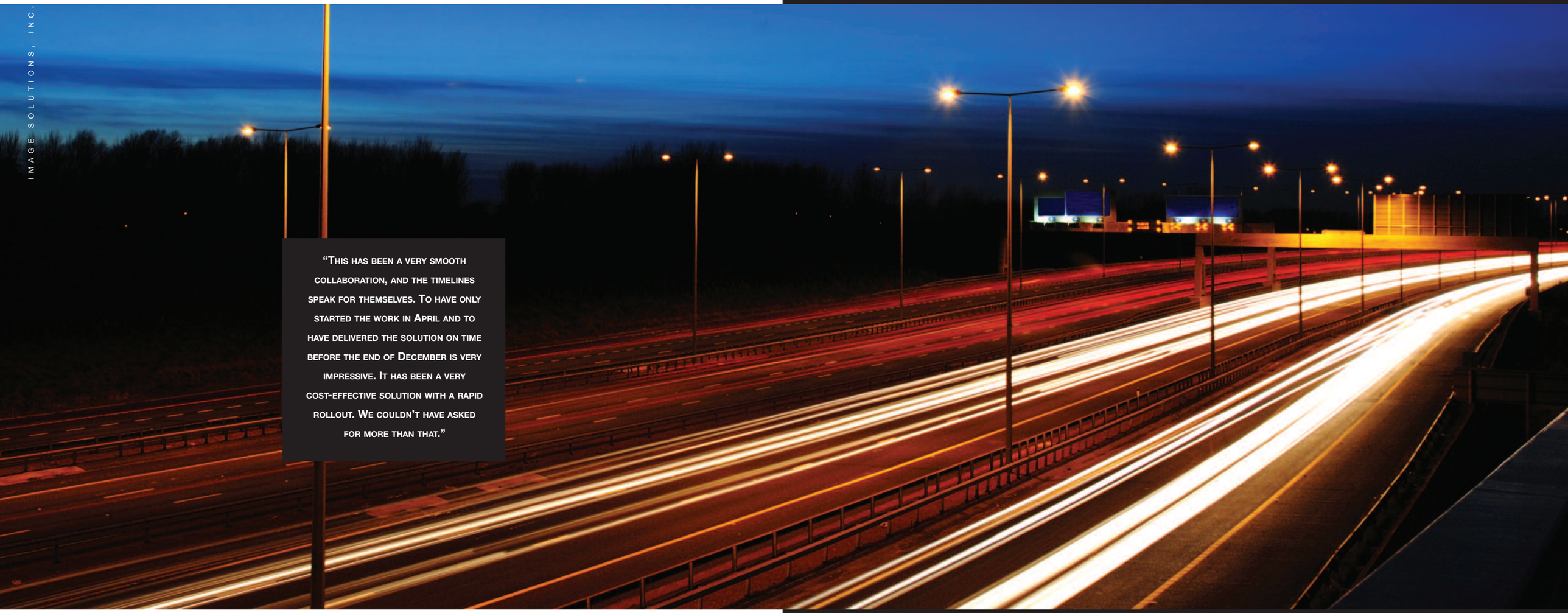
According to recent research by the Tufts Center for the Study of Drug Development in the U.S., each day that gets shaved off the development process typically saves $37,000 in out-of-pocket development costs and results in an additional $1.1 million in daily prescription revenue for an average-performing drug.

Largely for this reason, Boehringer Ingelheim made the decision early on to focus its eCTD submission capabilities on major submissions—particularly, new chemical entities. This year, that decision will affect three major products, involving three submissions in the U.S. and two in Europe. Dr. Leimer notes. "The benefit of having a common format across Europe, the U.S., and Japan is substantial, reducing the workload considerably."

Software as a Service

Software as a Service (SaaS) is a software application delivery model deployed as a hosted service and accessed over the Internet. Users pay a rate based on usage. The service provide deploys the application and keeps it running by testing and installing patches, managing upgrades, and monitoring performance.

Among the benefits of a SaaS model to a pharmaceutical company are lower cost of ownership, which eliminates the risk and cost associated with a large-scale software acquisition; ability to test a new application before purchasing; and relatively easy rollout. With cost savings offered by SaaS, investment earmarked for large-scale IT infrastructure projects can instead be diverted to R&D.



"This has been a very smooth collaboration, and the timelines speak for themselves. To have only started the work in April and to have delivered the solution on time before the end of December is very impressive. It has been a very cost-effective solution with a rapid rollout. We couldn't have asked for more than that."

The Future

For the moment, using the externally hosted, managed service (or SaaS) model, the eCTD software is being run from data centre facilities in New Jersey in the U.S. This is fine for now, but Boehringer Ingelheim recognises that in the longer term, this could hold back the group from gaining additional efficiencies that will become possible when the group begins to integrate eCTD functionality more closely with its internal document management system.

So far, Dr. Leimer couldn't be more pleased with the way the project has gone. "This has been a very smooth collaboration, and the timelines speak for themselves. To have only started the work in April and to have delivered the solution on time before the end of December is very impressive. It has been a very cost-effective solution with a rapid rollout. We couldn't have asked for more."

About Image Solutions, Inc.

Founded in 1992, Image Solutions, Inc. (ISI), is a proven market leader in providing submission solutions, process services, and consulting for life sciences companies as a way to improve clinical and regulatory processes that bring new medicines to market. ISI was among the first professional services firms to deliver electronic submissions to the industry and has since delivered more than 1,500 electronic submissions and nearly 750 eCTD submissions. ISI serves the top 50 pharmaceutical and biotech organizations as well as the top companies in other regulated industries. ISI is a privately held company with headquarters in Whippany, New Jersey, and has operations throughout the U.S., Europe, and Asia. ISI also remains committed to giving back to society and sharing its success with others by donating 10 percent of annual net profits to more than 20 recognized charitable organizations. For more information, visit the company's Web site at www.imagesolutions.com.

The Americas

East Coast

U.S. HEADQUARTERS
Image Solutions, Inc.
100 South Jefferson Road
Whippany, NJ 07981
Phone: 973.560.0404
Fax: 973.560.0240
E-mail: info@imagesolutions.com

Image Solutions, Inc.
245 First Street, Suite 1800
Cambridge, MA 02142
Phone: 617.444.8554
Fax: 617.444.8405
E-mail: info@imagesolutions.com

West Coast

Image Solutions, Inc.
1250 Bayhill Drive, Suite 305
San Bruno, CA 94066
Phone: 650.624.5400
Fax: 650.624.5500
E-mail: info@imagesolutions.com

Image Solutions, Inc.
12707 High Bluff Drive, Suite 200
San Diego, CA 92130
Phone: 858.350.4234
Fax: 858.794.1450
E-mail: info@imagesolutions.com

Europe

Image Solutions Europe GmbH
Frankfurter Strasse 63-69,
65760 Eschborn,
Germany
Phone: +49.0.6196 77 625 0
Fax: +49.0.6196 77 625 25
E-mail: infoeurope@imagesolutions.com

Asia Operations

Image Solutions, Inc.
FL.16, Regent International Plaza,
NO.53 plus 1 WeiDi Road,
Hexi District, Tianjin 300201
People's Republic of China
Phone: 0086.22.58371088
Fax: 0086.22.23550282
E-mail: infoasia@imagesolutions.com

Toll Free: 800.827.5827 | www.imagesolutions.com

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