



Leading Supplier of Clinical Trial Management Software Provides Industry's First Fully Integrated Solution Using the Microsoft .NET Framework and Visual Studio.NET



Published: January 2002

With the help of Web services deployed through the Microsoft .NET Framework and Visual Studio.NET development environment, DataLabs CTMS is helping to streamline the management of clinical trials for leading pharmaceutical companies. DataLabs also is streamlining its own development environment with the help of fully integrated cross-language programming and debugging and a smooth transition path from Visual Studio 6.0 to Visual Studio.NET.

If you were asked to come up with ideal technology for software programming in the pharmaceutical industry, you could hardly do better than Web services. That's the way Scott Thompson sees it, based on his experience building software that fully integrates the management of data, documents, and projects for clinical drug trials. Thompson, vice president, Enterprise Division, at Southern California-based DataLabs, considers Web services instrumental in helping to simplify maintenance and enhancement of systems in which code must be exhaustively validated to meet stringent trial-management-system standards set by the U.S. Food and Drug Administration (FDA).

"A whole system can be updated with a change to one or more of its Web services, and those are the only parts of the system that will need revalidation," he explains. "What a contrast to the traditional approach—where you replace ten lines of code and you have to revalidate ten thousand."

Web services—designed, developed, and managed by DataLabs developers with the help of the Microsoft .NET Framework and Visual Studio—form the core of Thompson's company's flagship product, DataLabs CTMS (Clinical Trial Management System). The first fully integrated trial-management product in the biopharmaceutical industry, DataLabs CTMS is designed to lower drug-development costs, reduce time-to-market, increase efficiencies, and enhance the quality of research. Although it is a relatively new product, DataLabs CTMS been embraced by no less an industry presence than Merck, which is using the product's framework to consolidate data from hundreds of clinical trials being conducted worldwide and involving tens of thousands of patients.

Solution Overview

Customer Profile

DataLabs specializes in integrated Internet-based applications for the biopharmaceutical industry and has introduced the first fully integrated management solution for clinical-trial data, documents, and projects.

Business Situation

DataLabs needed to enhance its flagship product, DataLabs CTMS, to meet the demanding requirements of the highly validated pharmaceutical environment.

Solution

Benefits

A solution enabling customers like Merck to consolidate and normalize cross-trial data quickly and easily for bringing medications to patients and generating revenues that much sooner, and a programming environment leveraging the language skills of all developers and easing the transition to next-generation capabilities.

Software and Services

Microsoft® Windows® 2000 Server
Microsoft .NET Framework
Microsoft Visual Studio.NET®
Microsoft .NET Enterprise Servers
BizTalk™ Server 2000
Exchange Server 2000
SharePoint Portal Server
SQL Server 2000
Microsoft Message Queuing 3.0
Microsoft Office XP
Microsoft Project
Microsoft Project Central
Microsoft Visio

Microsoft Consulting Services

Scenario

Business-to-business and business-to-employee

The Importance of Timely Cross-Trial Data

The scope and complexity of large, long-term clinical trials, along with the fact that trial data is generated in a variety of formats, presents the most fitting challenge to the versatility of Web services, according to Thompson. "In the past, studies would proceed for months or years, and then Merck would normalize the data and put it into its cross-trial database," he says. "But with the core staging and management capabilities of DataLabs CTMS, Merck can normalize and review cross-trial data while the studies are in progress so analysts can apply business rules consistently and merge studies easily for extended analysis. This makes the results of some studies available earlier than originally scheduled, and if the results are highly favorable, a new medication can begin benefiting patients and generating revenue that much sooner. If the results are unfavorable, the trial can be ended early so that patients can be switched to another medication or trial."

As Thompson goes on to explain, Web services have offered powerful capabilities for the heavily distributed approach that is characteristic of the Merck trial-management environment. "Such environments typically have multiple firewalls that must be 'pierced,' and Web services provide a highly robust and secure solution for this that does not require direct access to code or DLLs on the other side of the firewall," he says. "For many of the same reasons, Web services are ideal for exposing critical interface activities, such as patient enrollment and delivery of trial data, without the overhead of a data connection or DCOM call."

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Vice President, Enterprise Division
DataLabs

A Powerful and Versatile Programming Environment

DataLabs initially developed CTMS using an n-tier model with Microsoft Active Server Pages, Visual Studio 6.0 (primarily Visual Basic and Visual C++), COM+, and SQL Server 2000. Then, when Microsoft introduced the .NET Framework and Visual Studio.NET, Thompson and his colleagues recognized what they considered an excellent environment for incorporating Web services into their application.

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To upgrade the DataLabs CTMS code, which was largely written in Visual Basic 6.0, to Visual Basic.NET, DataLabs enlisted the services of six developers, two full-time and four part-time, for about a month. The development environment was enhanced, Thompson says, by the "mix and match" language capabilities offered by Visual Studio.NET. "Developers could work in the language they knew best, or the language best suited to a given function, and debug various components as if they were written all in one language. In one case, we implemented cross-language calling between some Visual Basic.NET code and Visual C#.NET code with just two lines of code. This is thanks to the Common Language Runtime, which was not available before Visual Studio.NET."

Smooth Transition Path

Thompson emphasizes that it's not just developers working in diverse languages who can code and debug their components and applications faster and more easily in the Visual Studio.NET



environment. Any developer who is expanding his or her skill set can also benefit. "For example, a new developer can start out by learning Visual Basic for Applications for customizing Microsoft Office functionality," he points out. "They can transition easily to Visual Basic.NET and there, they can work seamlessly among client front-ends, Web-based Active Server Pages applications, middle- and data-tier components, and even SQL Server Stored Procedures. This is a far easier training path than what might be available in an Oracle/Java environment, where developers must learn multiple languages and dialects before they can begin to do serious work."

The smooth transition path also streamlines development in general. "Since interoperability is so strong between Visual Studio 6.0 and Visual Studio.NET., we can migrate pieces of the application at our own pace and in an orderly fashion," Thompson says. "We can fully leverage our legacy code base without any disruption in business operations."

For example, one task in migrating DataLabs CTMS from Visual Studio 6.0 to Visual Studio.NET involves exposing dozens of legacy COM objects—which return clinical-trial data such as patient enrollment, quantities of data processed, or documents awaiting signature—on a digital dashboard for easy access by internal and external users alike. "Without having to change the back-end Visual Studio 6.0 components, we just put a very light Web services wrapper on each of the COM objects, and suddenly they became available to anyone who needed the information, at Merck or at the CRO."

Thompson and his colleagues at DataLabs are looking forward to making increasing use of Visual Studio.NET and the Microsoft .NET Framework. "Because of our success with Visual Studio.NET and the smooth transition path provided from earlier versions of Visual Studio, all the developers at DataLabs are now using Visual Studio.NET in some capacity," he says. "Ultimately we plan to migrate all DataLabs CTMS code to Visual Studio.NET in coordination with the evolving launch of that technology."

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