

THE COMPUTERWORLD HONORS PROGRAM

CASE STUDY



LOCATION:
*Seattle, Washington,
United States*

YEAR:
2006

STATUS:
Laureate

CATEGORY:
Medicine

NOMINATING COMPANY:
Borland

ORGANIZATION:

Rosetta Biosoftware

PROJECT NAME:

Life Sciences Products Delivery

Summary

Revolutionary System Enables Drug Development and the FDA

Rosetta Biosoftware's primary goal is to empower researchers in drug discovery and development to conduct cutting-edge research for improving the quality of human life. To accomplish this goal, the company develops informatics solutions and provides services that enable research organizations to efficiently and effectively conduct life-saving discoveries and develop drugs. The Rosetta's Resolver[®] system, developed using the Borland Application Lifecycle Management (ALM) technology, offers life science researchers an analysis and data management framework for gene expression which can minimize costly and time-intensive downstream drug development. Life science research organizations that have licensed the Rosetta Resolver system include many of the top pharmaceutical companies in the world, as well as premier academic institutions and service providers. In August 2005, the U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER) licensed the Rosetta Resolver system for gene expression data management and analysis. The CDER will use the Rosetta Resolver system in the Voluntary Genomics Data Submissions (VGDS) program to analyze microarray data from sponsors, or any organization engaged in drug development. The VGDS program provides a means for sponsors to ensure that regulatory scientists are familiar with and are prepared to appropriately evaluate future genomics submissions. The CDER will use the Rosetta Resolver system to better understand, learn from and reproduce analyses conducted by pharmaceutical companies who voluntarily submit genomics data. In addition, they will perform independent analyses using the Rosetta Resolver system's microarray data management and analysis tools. The FDA's use of the Resolver system will enable the FDA to better understand the role genomics data submissions could play in the drug discovery process and enable them to understand the technology being used by drug companies to develop safer drugs more quickly. Likewise, it will put Rosetta Biosoftware customers who are participating in this program at the forefront of drug development submission if the FDA determines that genomics submissions one day be a mandatory component of submission.



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Introductory Overview

Rosetta Biosoftware develops products and solutions for pharmaceutical and biotechnology companies and service providers who are engaged in gene expression or proteomics research. Rosetta's flagship product, the Resolver system, is an entire framework for conducting gene expression data analysis and biomarker discovery. Biomarker studies that elucidate a biological parameter indicative of a disease state are at the heart of what Rosetta Biosoftware customers do, and both of Rosetta Biosoftware's products, the Resolver system and the Elucidator system adeptly enable customers to manage and analyze the large amount of data required for such studies. In the case of the Resolver system, Rosetta Biosoftware customers use the system in conjunction with their gene expression profiling or microarray studies. Microarray technology, in terms of gene expression analysis, allows scientists the ability to interrogate tens of thousands of genes at one time. The ability to perform gene expression profiling with such tools as the Resolver system has increased the industry's overall understanding of disease mechanisms and potential therapeutics. This knowledge has helped to improve the ability of pharmaceutical and biotechnology institutions to bring lifesaving therapies to market.

Gene expression data analysis is playing an increasing role in pharmaceutical and biotech drug development pipelines in areas such as toxicogenomics, clinical studies and molecular diagnostics. There is no question that genomics data opens new windows into understanding diseases and developing safer drugs more quickly. For example, Rosetta Biosoftware customers use the Resolver system throughout the drug discovery processes to determine and validate targets, discover biomarkers, prioritize compounds, pinpoint on- and off-target compound/treatment effects and determine underlying compound/treatment mechanisms of action.

Currently, the FDA is trying to better understand how these genomic data figure in a drug company's submission for a new drug. Therefore, in 2005, the FDA began requesting that sponsors who are part of a drug development program voluntarily submit genomics data when such data are normally not required under the regulations, as part of a new program called the Voluntary Genomics Data Submission (VGDS) program. The Center for Drug Evaluation and Research (CDER), which is responsible for the VGDS program, selected the Rosetta Resolver system as one of the technologies they would use to help support the VGDS program. Specifically, the CDER will use the Resolver system to replicate analyses performed by sponsors who voluntarily submit these data. Additionally, the CDER will use the system to conduct its own independent analyses.

According to the FDA, voluntary submissions of genomic data are a novel way to share information with the FDA. FDA and industry scientists alike would benefit from an enhanced understanding of relevant scientific issues, such as the types of gene expression profiles being explored by the pharmaceutical industry for testing, the test systems and techniques being employed, the problems encountered in applying these tests to drug development, and more. A greater understanding of the issues surrounding the use of these data may prevent delays in reviews of future submissions where genomics are an integral part of specific studies in a drug development program.

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Benefits

For the FDA, voluntary submissions today can benefit both the industry and the FDA in a general way by providing a means for sponsors (e.g., pharmaceutical companies and academic institutions) to ensure that regulatory scientists are familiar with and prepared to appropriately evaluate future genomic submissions. This understanding should expedite processes and lead to lower overall development costs, and possibly to reduced costs for consumers.

According to the FDA, for the participating sponsors, voluntary submission to the FDA of genomic data offers a number of specific potential benefits:

- It creates an opportunity for early informal meetings with FDA pharmacogenomics experts
- It offers flexibility in review and meeting process
- Sponsors receive and benefit from informal peer-review feedback on issues and/or questions
- Sponsors gain insight into current FDA thinking that may assist in reaching important strategic decisions
- It offers time- and cost-savings by familiarizing both parties early with novel approaches avoiding future delays in review
- It provides an opportunity for sponsors to impact FDA's thinking and help build consensus around future standards, policies and guidances

The Importance of Technology

Rosetta Biosoftware's customers increasingly rely on tools such as the Resolver system to enable faster and safer drug discovery. Rosetta Biosoftware's customers and now the FDA in its use of the Resolver system in the VGDS program must have confidence in the accuracy and reproducibility of the analysis results produced by the software. This confidence is needed not just in the software, but in Rosetta Biosoftware's methods for developing and validating the software. The development and validation methods must be well-documented and reproducible, and must support the creation of high-quality software.

To support these needs, early on, Rosetta Biosoftware realized it needed a comprehensive application lifecycle management (ALM) solution one that integrated and documented requirements creation and management, source code control, requested changes, and validation. In addition, the life sciences industry rapidly changes as information technology is applied to more areas of research. Rosetta Biosoftware must be able to deliver quickly new features and functionality that meet the rapidly changing software needs of its customers. Therefore, Rosetta Biosoftware's development methods needed to follow suit. On the one hand, they must be well-defined, predictable, well-documented, and capable of producing high-quality software. On the other hand, they must also be lean and agile, enabling Rosetta Biosoftware to quickly adjust to the changing industry and to customer needs.

Rosetta Biosoftware relies on Borland's complete ALM solution to achieve these ends. Specifically, Rosetta Biosoftware is deploying the ALM solution to better manage critical software development processes, including:

Requirements Management: Rosetta Biosoftware leverages the tightly integrated and customiz-



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able Borland® CaliberRM® technology to automate its specific requirements processes and to track requirements from elicitation through final delivery. For example, after business, technical, functional, and operational requirements are entered into the Borland CaliberRM repository, stakeholders across the organization can collaborate more effectively, including quality assurance team members who can immediately begin building test cases to ensure requirements meet specifications, so that Resolver system releases and upgrades are high-quality and delivered on time. Using Borland CaliberRM to define, prioritize and track requirements throughout the project lifecycle, the Rosetta Resolver development team is better able to respond rapidly to ever-changing requirements without jeopardizing project success.

Configuration and Change Management: A robust platform for coordinating and managing the entire software delivery process, Borland® StarTeam® promotes team communication and collaboration within the Rosetta Biosoftware development team through centralized control of all project assets and time stamping. With Borland StarTeam, every member of the Rosetta Biosoftware development team is able to rely on a single repository for integrated requirements management, change management, defect tracking, file versioning, threaded discussions, and project and task management for all of its development projects. Rosetta Biosoftware also enables its customers to leverage the ALM solution to automatically enter escalation and enhancement requests for the Resolver system, and then dynamically extract web pages to view the progress of their change requests.

For internal use, the Borland StarTeam repository is being used to house a variety of Rosetta Biosoftware documents, from policies and standard operating procedures to project specific documentation history, customized forms, and more. Borland StarTeam delivers version control and change management capabilities to effectively manage these documents to regulatory compliance standards.

Visual Modeling: The Rosetta Biosoftware team is using Borland® Together® to help bridge the gap between business and IT stakeholders using a common set of visual best-of-breed modeling languages to help define the next release of the Resolver system. With support for business process modeling, data modeling, application modeling and visualization, and comprehensive audits and metrics for both models and code, the visual modeling technology helps the Rosetta Biosoftware development organization accelerate the delivery of its high-quality software solutions.

Rosetta Biosoftware is also working with Borland Consulting and Borland Education Services to ensure the successful rollout of the Borland ALM solution.

Originality

Voluntary Genomic Data Submissions are a novel way to share information with the FDA, and this program with FDA's Center for Drug Evaluation and Research (CDER) is the first of its kind.

At the current time, most pharmacogenomic data are of an exploratory or research nature and FDA regulations do not require that these data be submitted to an Investigational New Drug application or that complete reports be submitted to a New Drug Application or Biologic License Application. However, voluntary submissions are becoming more prevalent as a result of this voluntary program.



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Success

Our has exceeded its goals and is fully operational. There is no limit to the number of people who have benefited from our project.

Difficulty

For Rosetta Biosoftware, the difficulty was in elucidating a perfect balance between having well-defined, predictable, and well-documented methods and methods that also enabled Rosetta Biosoftware to act quickly when customer needs changed, based on the dynamic nature of the industry.

Rosetta found this balance by working closely with customers, Borland, and external expertise to implement the ALM system in its organization and to ensure high quality throughout its development process.