

JBoss ENTERPRISE DATA SERVICES PLATFORM FOR LIFE SCIENCES

DATA SERVICES ACCELERATE THE PROCESS

Today's pharmaceutical industry is faced with a combination of operational, regulatory, and information challenges. On the business front, companies must increase their productivity and reduce costs to maintain shareholder return, despite the fact that 75% of R&D expenses are invested in compounds that fail to make it out of the clinical development phase. On the regulatory front, tighter FDA regulations (cGxP) are forcing companies to manage access to electronic records in a more vigilant manner. And on the information front, pharmaceutical companies must manage a complex set of public/private partner relationships that require sharing of information, a challenge that is exacerbated by mergers and by the explosion of available data to manage, especially during the drug discovery process.

Much of a company's information is structured according to the functional silos of major business areas—research and development, manufacturing, sales and marketing—with a central corporate entity to manage the whole organization. These business areas function autonomously in many cases, and for a pharmaceutical firm, the number of silos grows with the many different therapeutic areas and brands in the company's portfolio of products.

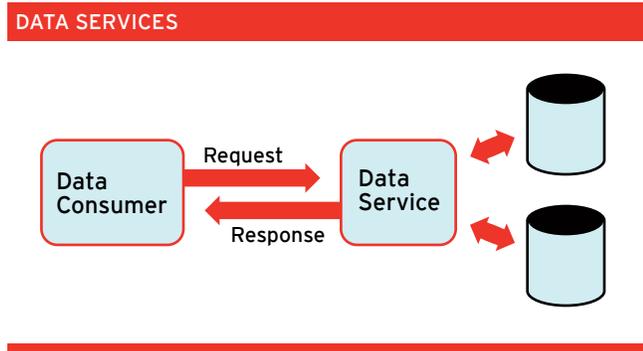
To support critical decision processes that drive everything from research and marketing activities to management of clinical and manufacturing pipelines, the company must be able to integrate information across these various silos. Many processes must be fed from heterogeneous sources

of distributed information—internally, from within the business unit, and externally, by other areas of the business and by commercial data sources. Timely access to this information can be a daily struggle. The number of projects that require integration of information at the enterprise level is growing rapidly, and organizations often cannot keep up with the demand. Organizations that do not address the challenge or that address it with stopgap solutions can fall prey to:

- **Data inconsistency**—redundant and inconsistent data stores are often created.
- **Limited access to required information**—inconsistency of data format/semantics across data silos makes access very difficult across application areas.
- **Expensive, risky projects**—projects that require integration between data silos are at best inefficient and expensive, or at worst have high failure rates.
- **Long implementation cycles**—evolving technology and data standards and disparate vendor platforms make new implementations, upgrades, and validation difficult.

While customer relationship management (CRM) systems and enterprise resource planning (ERP) systems have provided partial solutions, the larger goals of seamless customer data integration, effective business process management, and strategic product portfolio management require a level of information integration that is still elusive.

In a quest for greater efficiency and agility, companies are seeking better ways to harmonize information across business units. These firms realize that despite the unique nature of divisional data requirements and functional specializations, the organization that can master these information challenges will have a significant competitive advantage.



The JBoss Enterprise Data Services Platform has been deployed successfully in the life sciences industry to help companies address a range of information management and integration challenges. Red Hat has worked with pharmaceutical organizations and with software partners to ensure that our products meet this industry's exacting demands and can provide solutions that help help companies:

- **Streamline the drug discovery process** by making information available across disciplines.
- **Leverage valuable data assets** generated from previous clinical studies.
- **Provide consolidated views** of the manufacturing supply chain across multiple sites and ERP implementations.
- **Access a 360-degree view of customer relationships**, by bridging master customer data with the activities and transactions associated with each customer.
- **Manage the product portfolio** by measuring progress and costs against corporate objectives for activities that span business units.

DISCOVERY AND LEAD OPTIMIZATION

Drug discovery research is a complex, multidisciplinary process. Prioritization and other decision processes involved in target selection, project evaluation, and opportunity analysis in drug discovery and initial development require the analysis of information generated across several disciplines. Attributes can include biological properties such as experimental activity, in vivo and in vitro physiochemical properties, chemical structure attributes, genomic information, and unstructured information in the form of documented research discussions. As a result, drug discovery research requires cross-functional and cross-disciplinary data for operations and for decision support. The table below summarizes the various disciplines and activities involved.

DISCIPLINE	ACTIVITIES
Chemistry	Drug design
• Medicinal	Molecular modeling
• Synthetic	Structure elucidation
• Process	Drug optimization
• Natural product	Library design
• Computational	Pharmacokinetics
	Compound/library synthesis
	Natural product isolation
Biology	Target identification
• Biochemistry	Assay operations
• Molecular biology	Data analysis
• Microbiology	Assay development
• Physiology	In vivo study development
• Pathology	Drug metabolism
• Genomics	

Research conducted during the discovery phase of the process is often difficult due to the variety and complexity of data sources that must be combined. Both the biology and chemistry disciplines need to be combined in order to optimize the discovery process, and information generated from these disciplines and their associated activities is typically captured in separate application databases. When R&D sites are geographically separated, additional databases come into play. And research data is often required from external sources, typically available as public web sites or as purchased data sets from external providers. As a result, research scientists and analysts must access multiple applications during the course of their research, and today much time is spent finding, accessing, and reformatting data in order to feed one application with data from other applications.

The JBoss® Enterprise Data Services Platform enables companies to represent a wide variety of applications and data sources in a consistent, common data layer, so that research portals and other applications can access biological and chemical data without regard to the disparate formats and vendor APIs required. Using this approach, pharmaceutical organizations can avoid being locked into any single vendor's proprietary data model or application and can instead provide access that supports reuse of vendor data by other applications. In addition, the organization can combine external data sources with proprietary internal data sources for the purpose of literature searches and other research activities. Red Hat provides a more cost-effective and flexible solution for consistent data access across these systems. Using the JBoss Enterprise Data Services Platform, information aggregation and data searches take less time.

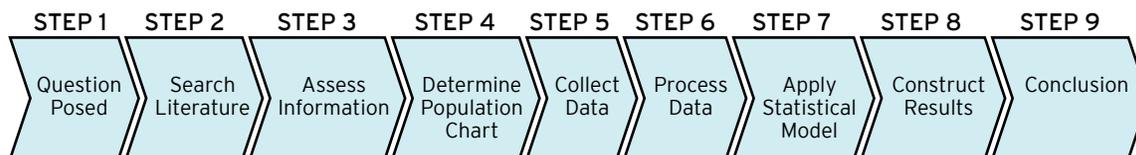
DRUG DEVELOPMENT

Drug development organizations are constantly striving to reduce the time and cost associated with developing and delivering new drugs to the market. One proven method for achieving time/cost reduction is to mine and analyze pre-clinical and clinical trial data from multiple trials in order to reuse valuable data from prior studies. With today's data silos, the analysis of information across multiple clinical trials is typically difficult and time-consuming.

Research conducted across clinical trials is difficult due to the disparity in clinical trial data from one study to the next. The typical time frame to gather patient data for a targeted condition is measured in days or weeks, depending on whether an analyst is personally familiar with any recent requests for similar research targets. If an individual research analyst does not recall any similar research being requested, then a new data extract module and a new statistical program would typically be coded by the analyst, potentially resulting in duplication of effort.

Using the JBoss Enterprise Data Services Platform, a consistent set of clinical trial data can be exposed via a set of clinical trial data services. A common set of patient cohorts (e.g. age, gender, race, disease conditions, family history) can be accessed across all clinical trial data, providing the appropriate translations and transformations as necessary. This approach greatly expedites the data collection and data processing steps. In addition, these data services can expedite the literature search step, by seamlessly tying together an organization's internal content management systems, internal structured databases and applications, and external research repositories. The end result is that with the use of the JBoss Enterprise Data Services Platform, cross study analysis can be executed in a matter of minutes and hours, rather than the days and weeks typically required for the process. The JBoss solution provides a fast-

CROSS-STUDY CLINICAL TRIAL DATA REQUEST



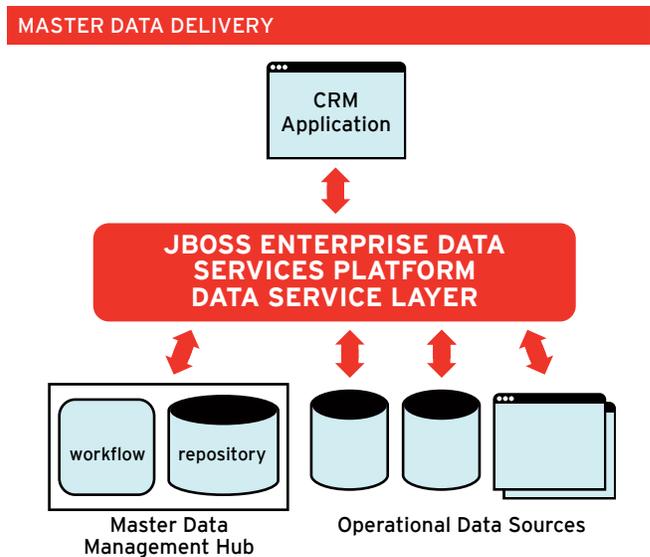
The workflow for a cross-study clinical trial data request for a particular hypothesis. Once a data request comes in, a manual search for literature is performed. Relevant protocols are then examined for their contents to determine if they meet the specific need. Selected protocols are identified for further processing where additional data is obtained from disparate clinical trial data sources. Data is then processed for statistical modeling applications. Ultimately, a conclusion is reached, and depending on the conclusion, either new research is started or results are published.

er, less expensive means to support analytics and reports that need to access the wide range of different data types captured in clinical trials. Unlike other approaches to this problem, which often rely on hard-coding data transformations in applications, a data services approach provides a way to reconcile semantic differences and integrate information from multiple studies into a single logical view.

SUPPLY CHAIN

Like any manufacturing industry, the pharmaceutical sector has a manufacturing supply chain that requires integration of information regarding manufacturing assets, distribution channels, manufacturing and transportation costs, warehousing capabilities, and financial targets. Overall pipeline management and many sub-process analyses require dynamic access to data across the manufacturing enterprise. Information for these analyses resides in distributed modules including manufacturing asset databases, ERP systems, local sources of cost information, and local scheduling tools, to name a few. For the pharmaceutical business that is challenged to produce a variety of products for a dynamic market, effective integration of these data sources is critical to business analysis.

As the number of products and formulations increases, the need to manage the manufacturing process more efficiently also increases. Because of the independent nature of the different operating units within a pharmaceutical business, implementation of ERP and CRM solutions such as SAP, PeopleSoft, or Siebel can involve many different systems and therefore can be much more difficult and time-consuming than in other types of businesses. The major driving force behind these projects is the real need for a unified view of the business across functional and geographical boundaries. But, given the complexity of the data sources, it might take years to create a cross functional view of information relating to products and related financial and operational data. Utilizing the JBoss Enterprise Data Services Platform, organizations can integrate data from key sources and provide a unified view from the corporate perspective much more quickly. The unique metadata-driven



Master Data Delivery. JBoss Enterprise Data Services Platform can combine master data with data from other systems and deliver tailored views to diverse applications through SQL or Web service interfaces.

approach that the JBoss Enterprise Data Services Platform provides enables organizations to evolve their implementation of the unified view over time, in response to changing information requirements and to changes brought about by the implementation, upgrade, and migration of manufacturing systems.

Finally, the JBoss Enterprise Data Services Platform can provide the capability to integrate information from subsidiary locations within a global pharmaceutical operation. In many cases, subsidiaries may be too small to justify implementing the complete ERP strategy, or their implementations may be deferred until others are complete. With the JBoss Enterprise Data Services Platform, information for these sites can be transformed and combined with information from centralized systems, creating a complete, consistent, and unified view of the company.

SALES AND MARKETING

The concept of customer in the pharmaceutical industry is unique and extremely complex. Those who buy and use pharmaceutical products, the actual patients, are in fact consumers of the product, but they typically play no part in the selection of or payment for the product. The product is selected (prescribed) by the physician; employers or insurers make the payment, with consumers paying a portion of the retail cost. Pharmaceutical companies sell the bulk of their branded products to a limited number of wholesalers that, using the definition employed by other industries, would be considered the pharmaceutical customers. The relationship with the wholesaler, though critical, is not the source of sales growth or opportunity, so it is difficult to consider wholesalers the true customers. Meanwhile, the sales activities of pharmaceutical companies are primarily oriented around the physician and intended to demonstrate the value of their product so that the physician might choose to prescribe it. The physician is the principal driver of sales, but neither takes possession of the product nor handles payment. Even so, many would consider the physician to be the pharmaceutical organization's primary customer.

Given this complexity, the sources of the different types of pharmaceutical customer data are diverse. Customer information includes both external, purchased data sources and data from internal customer systems. Much of the external and/or purchased customer data has different data structures, different characteristics for the attributes of the data, and different ways of identifying the customer. To add to the challenge, the same attribute or identifier can be defined using a different set of business rules and implemented using different data types depending on the source. Internal customer systems supporting various sales and marketing channels all create and manage key pieces of customer information, and include channels such as help desks, field sales forces, and physician/clinician registries. Regulatory requirements, marketing strategies, and company image are all driving the need to integrate information relating to individual customers.

The JBoss Enterprise Data Services Platform can be a key enabler for integration of customer information, working in conjunction with existing CRM and customer-master vendors' systems. Typically a customer master would maintain the master list of customer identities, as well as any potential customer hierarchies and cross-references from the master identifier to system-specific identifiers. The JBoss Enterprise Data Services Platform can provide a true "360-degree customer view" by leveraging the information in the customer master and combining it with up-to-the-minute details on the customers' activities, by reaching across business intelligence, operational, and special-purpose systems.

PORTFOLIO MANAGEMENT

At the highest level, the pharmaceutical organization needs to understand, in relation to corporate objectives, how activities across business units align with these objectives, how they are progressing, and what resources they are consuming. Currently this task involves the laborious collection and roll-up of relevant information from diverse systems. These efforts typically take place on a quarterly or yearly basis, leaving little opportunity for fully informed course adjustment during the year. More facile access to key data about project delivery against plan—including financial forecasts and resource utilization—would help to provide a more timely view into progress against objectives. In addition, the integration of clinical information would support the optimization of project strategy as it relates to the management of a research portfolio. Unlike spreadsheet-based approaches to portfolio management, the JBoss Enterprise Data Services Platform provides real-time visibility into the current status of product development activities across all disciplines. It does this by accessing the databases and vendor applications that are the systems of record—the "single version of truth"—with regard to research and clinical projects. Where such databases and applications do not exist, it provides access into the files and spreadsheets where this information resides. Pipeline management using the JBoss Enterprise Data Services Platform offers the ability to assess new opportu-



nities against existing project portfolios, as well as provide insight into the management of resource bottlenecks and thereby increase the predictability of project plans.

FOR MORE INFORMATION

JBoss Enterprise Data Services Platform is part of the JBoss Enterprise Middleware family – a powerful group of open source middleware solutions that can help make your IT infrastructure simple, open, and affordable. For more information on the JBoss Enterprise Data Services Platform, visit jboss.com/products/platforms/dataservices. For more information about how JBoss Enterprise Middleware products can help you create a more intelligent, integrated enterprise – including case studies of successful implementations – visit redhat.com/promo/integrated_enterprise.

To learn how Red Hat can address your specific goals and requirements, contact your Red Hat representative.

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