

Whitepaper

A Unified View of Research and Trial Data

The Denodo Platform for the Pharmaceutical and Life Sciences Industry



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Unlock the Full Potential of All Data Assets to Drive Business Success

The pharmaceutical industry of today is faced with a combination of operational, regulatory, and informational challenges. Pharmaceutical companies must increase their productivity and reduce costs to maintain shareholder return, despite the fact that most research and development (R&D) expenses are invested in compounds that fail to make it out of the clinical development phase. Tighter FDA regulations (cGxP) are forcing companies to more vigilantly manage access to electronic records. And on the information front, pharmaceutical companies must manage a complex set of public and private partner relationships that require information sharing, a challenge that is exacerbated by mergers and acquisitions and by an explosion in the volume of 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, such as 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 product portfolio.

To support critical decision-making processes that drive everything from research and marketing activities to the management of clinical and manufacturing pipelines, companies 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 the 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. Inconsistent semantics and formats across data silos makes data
 access and usage 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.

Using the Denodo Platform, powered by data virtualization, organizations can integrate data from key sources and quickly provide a unified, corporate view. 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 Denodo Platform, powered by data virtualization, has been deployed successfully in the pharmaceutical and life sciences industry to help companies address a range of information management and integration challenges. Denodo has worked with pharmaceutical organizations and software partners to ensure that its products meet this industry's exacting demands and can provide solutions that help companies:



Streamline the drug discovery process by making information available across disciplines.



Use 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° 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 decision support. The following table summarizes the various disciplines and activities involved.

DISCIPLINE

ACTIVITIES

Chemistry

- Medicinal
- Synthetic
- Process
- Natural product
- Computational

Drug design Molecular modeling Structural elucidation Drug optimization Library design Pharmacokinetics Compound/library synthesis Natural product isolation

Biology

- Biochemistry
- Molecular biology
- Microbiology
- Physiology
- Pathology
- Genomics

Target identification Assay operations Data analysis Assay development In vivo study development Drug metabolism



Avoid being locked into any single vendor's proprietary data model or application. Instead, provide access that supports the reuse of vendor data by other applications. 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 websites 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 Denodo Platform enables a company to represent a wide variety of applications and data sources in a consistent manner with a common data layer, so research portals and other applications can access biological and chemical data without having to know 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 the reuse of vendor data by other applications. In addition, an organization can combine external data sources with proprietary internal data sources for the purpose of literature searches and other research activities. Denodo provides a more cost-effective and flexible solution for consistent data access across these systems. With the Denodo 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 data from multiple pre-clinical and clinical trials in order to reuse valuable data from prior studies. In today's world, with many data silos, the analysis of information across multiple clinical trials is typically difficult and time-consuming.

Research conducted across clinical trials is difficult to understand, due to the disparity in clinical trial data from one study to the next. The typical timeframe for gathering patient data for a targeted condition is 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 reprogrammed by the analyst, potentially resulting in duplication of effort.

With the Denodo 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, and family history) can be accessed across all clinical trial data, providing the appropriate translations and transformations as necessary. This approach greatly accelerates 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. With data virtualization, cross-study analysis can be executed in a matter of minutes and hours, rather than the days and weeks typically required for the process. Data virtualization provides a faster, less expensive way 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 the 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 such analyses resides in distributed modules including manufacturing asset databases, ERP systems, local sources of cost information, and local scheduling tools. 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, the implementation of ERP and CRM solutions such as SAP, Oracle, or Salesforce can involve many different systems and therefore can be much more difficult and time-consuming than for 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.

However, 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.

The unique metadata-driven approach employed by the Denodo Platform enables organizations to evolve their implementation of the unified view over time, in response to changing information requirements and in response to changes brought about by the implementation, upgrade, and migration of manufacturing systems.

Finally, the Denodo Platform can integrate information from subsidiary locations within a global pharmaceutical operation. In many cases, subsidiaries may be too small to justify implementing a complete ERP strategy, or their implementations may be deferred until others are complete. With data virtualization, 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, insurers, or public health agencies make the payment, and consumers often pay a portion of the retail cost. In the U.S. and other countries, 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 include channels such as help desks, field sales forces, and physician and clinician registries. Regulatory requirements, marketing strategies, and company image are all driving the need to integrate information relating to individual customers.

At the highest level, pharmaceutical organizations need to understand how activities across business units align with these objectives, how they are progressing, and what resources they are consuming.

The Denodo Platform can be key for integrating 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. Data virtualization can provide a true "360° customer view" by using the information in the customer master and combining it with up-to-the-minute details on customer activity, by reaching across business intelligence, operational, and special-purpose systems.



Portfolio Management

At the highest level, pharmaceutical organizations need 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. Easier access to key data about project delivery against plan — including financial forecasts and resource utilization — would help to provide a timelier 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, data virtualization 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 to the files and spreadsheets where this information resides. Pipeline management using data virtualization offers the ability to assess new opportunities against existing project portfolios, as well as to provide insight into the management of resource bottlenecks, increasing the predictability of project plans.

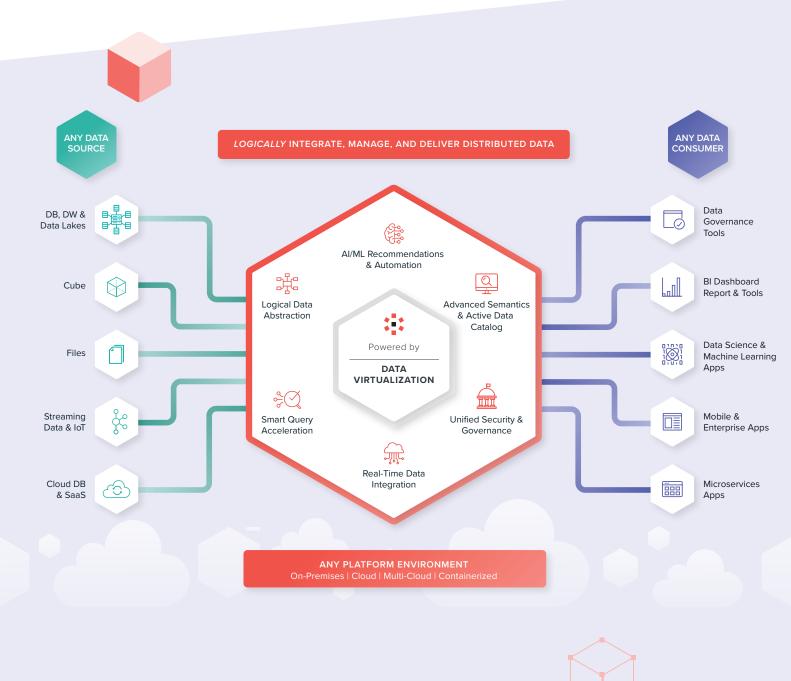
If you want to find out more about how the Denodo Platform helps pharmaceutical and life science companies, please visit our **Biotechnology and Pharma industry page** where you will find real-world customer case studies and testimonials.

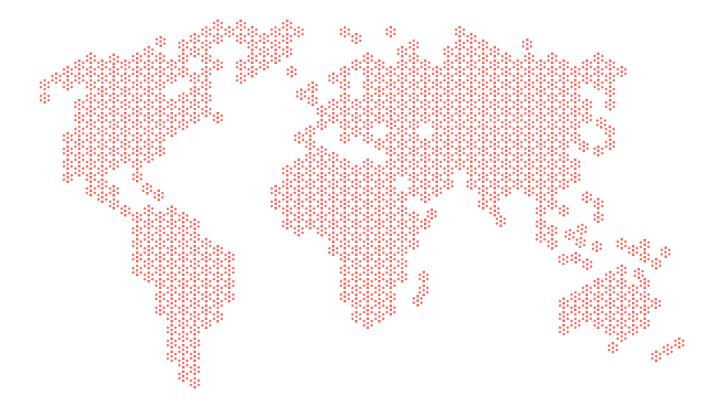




About the Denodo Platform

Every organization's data and related infrastructure is constantly evolving. As a result, enterprise data will always remain distributed. The Denodo Platform gives IT organizations the flexibility to evolve their data strategies, migrating to the cloud, or logically unifying data warehouses and data lakes, without affecting business. The Denodo Platform also accelerates data provisioning through reduced data replication, it enables consistent security and governance across multiple systems, and it gives business users the flexibility to work with their preferred applications. The only way you can accomplish this is through a logical data fabric powered by data virtualization. The Denodo Platform is the only solution that can meet this need.







Denodo is a leader in data management. The award-winning Denodo Platform is the leading data integration, management, and delivery platform using a logical approach to enable self-service BI, data science, hybrid/ multi-cloud data integration, and enterprise data services. Realizing more than 400% ROI and millions of dollars in benefits, Denodo's customers across large enterprises and mid-market companies in 30+ industries have received payback in less than 6 months.

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