



**Nurture growth with technology solutions that transform  
how you work and speed time to market.**



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### Executive summary

As the life sciences industry evolves in fast-forward mode, businesses must adapt to a barrage of changes. Today, scientific advances promise exciting new results, such as earlier treatment and prevention of diseases. And new economics shape the industry, driven by factors like price-containment pressures and personalized healthcare. Only with the right IT foundation can you cultivate your core strengths and empower your business to succeed. IBM Middleware Solutions for Life Sciences help deliver an on demand operating environment — flexible, resilient and responsive processes and systems that enable you to achieve rapid time to market. By helping you move rapidly and predictably from discovery to development, enhance collaboration within and outside of your organization and optimize existing IT investments, IBM Middleware Solutions for Life Sciences help you use IT as a tool for strategic marketplace advantage.

### Thriving in a season of change

There's a season for everything — but in life sciences, seasons have become shorter, with boundaries blurred. New diseases like SARS can enter the scene virtually overnight. Pharmaceutical companies' windows of patent exclusivity shrink. Biopharmaceutical research shifts from molecular actions of small compounds to biologic-based diagnostics and therapeutics. As personalized healthcare gives patients more control, the industry uses costly marketing tactics to sway the purchase of new drugs. And as generic drug companies eat into the revenues and profits of traditional pharmaceutical giants, insurance and government payers maintain price-containment pressures.

Against this backdrop, scientists strive to discover, develop and bring to market new drugs. Small teams manage increasingly complex clinical trials with growing volumes of patient information. Organizations look for ways to recruit and retain top investigators, then leverage their experience in future trials. IT departments struggle to securely store staggering amounts of process documentation and data records. And doctors and scientists around the world dedicate themselves to improving treatments through information-based medicine.

### Recognizing your new business needs

Traditionally, life sciences computing resources supported distinct business processes such as those for chemistry, biology, informatics, toxicology, biostatistics and clinical trials management. Isolated organizations owned specific data — and did not share it across systems or organizational boundaries. But as new technologies and advances in genomics and proteomics sciences evolved, lines between traditional business silos began to blur. Organizations demanded increasingly intense computational and data storage requirements. New IT systems were needed to link intellectual assets, biology and chemistry knowledge with patient-specific data residing in multiple global sites.

To succeed in this era of information-based medicine, pharmaceutical and biotechnology companies, academic and government labs and medical research centers must build IT systems aligned with a whole new set of business priorities. Your information infrastructure must be tightly integrated and accessible across and among enterprises. You should be able to share data in real time and work collaboratively across a diverse value chain of stakeholders. You must be able to secure information, protect patient privacy and use data ethically. All as you maintain strict compliance with multiple industry regulations.

*“In order to quickly identify patients at risk and select potential clinical trial participants, we constantly seek out new solutions. Taking advantage of IBM’s data integration services and life sciences expertise along with the Affymetrix GeneChip technology could lead to revolutionary ways to target cancer treatment.”*

— William Dalton, MD, Ph.D., and CEO, Moffitt Cancer Center

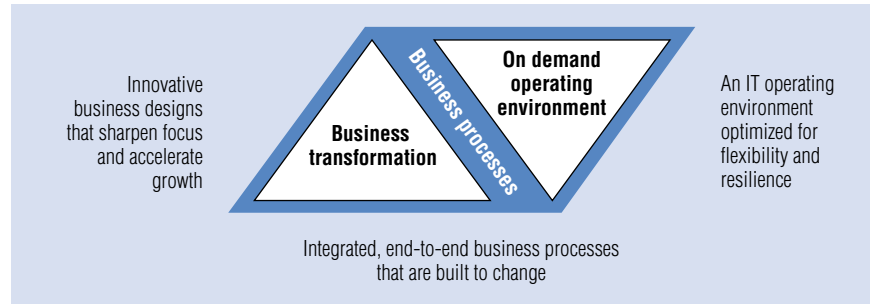
### Embracing IBM technology to become an On Demand Business

To be truly successful in the new life sciences landscape, your organization must operate as an On Demand Business. That means having a modular computing foundation built on open industry standards so you can adapt quickly and flexibly to any situation at hand — during discovery, development or delivery cycles. It means adopting a new way of working that lets you approach opportunities and threats

holistically, rather than through fragmented processes and business silos. To create an On Demand Business, your organization must be:

- *Focused on its core competencies through business units that can manage risk and address regulatory pressures as well as highly specific customer needs.*
- *Responsive to competitive threats and changing market conditions.*
- *Variable with a corporate culture that adapts quickly and easily to changes like those resulting from mergers and acquisitions.*
- *Resilient so that you can deploy the right science and technology today – and tomorrow.*





*An on demand operating environment*

### Delivering a technology foundation designed for your needs

With help from IBM, you can build an on demand operating environment that delivers impressive returns. By taking an approach to discovery and development that helps you get high-quality compounds into trials and on the shelves quickly. By adopting a solution for development that speeds time to market, minimizes process delays and builds on technologies you already have rather than starting all over again. By learning new ways to view, manage and store compound and clinical data across the enterprise. And by simplifying compliance with government regulations.

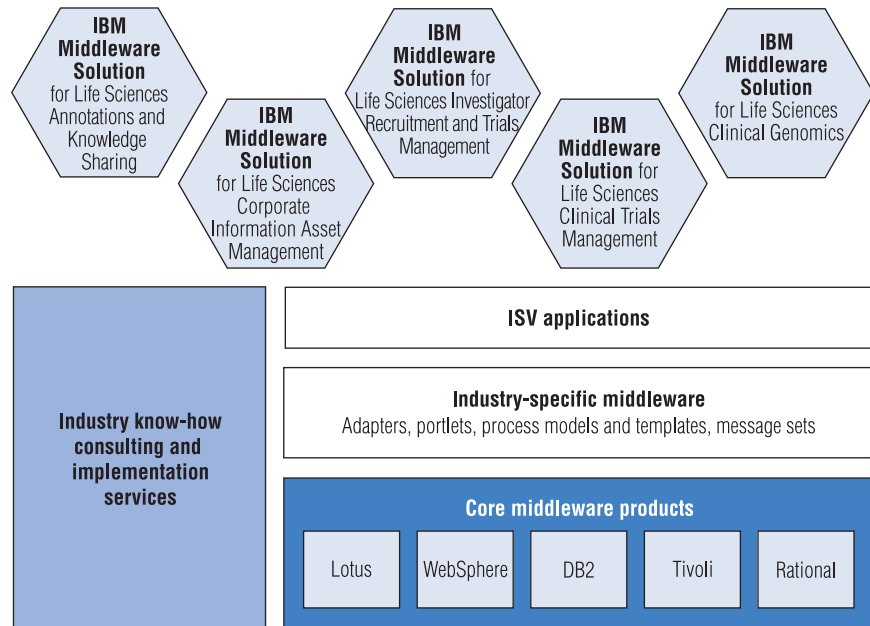
*“I think building new and more powerful data accessing, mining and analytical capabilities will have a huge impact on our efforts to understand brain behavior and to diagnose and treat diseases such as Alzheimer’s that degrade behavior and cognition.”*

— Bruce Miller, MD and Director, UCSF Memory and Aging Center

### IBM Middleware Solutions for Life Sciences

IBM has five middleware solutions to help optimize specific life sciences processes. These solutions can help increase drug discovery innovation and diagnostic efficacy and accuracy. Enable fast, low-cost clinical trials and regulatory compliance. Decrease time to peak sales and provide groundbreaking data mining and analysis for federated clinical, phenotypic and genomic data. Ultimately, the solutions can help you deliver personalized, effective medical

care for patients. IBM Middleware Solutions are customized combinations of IBM core middleware and industry-specific middleware that, when combined with application software from IBM’s network of independent software vendor partners and industry-specific services, enable customers to build an on demand operating environment.



Overview of a middleware solution

#### ***IBM Middleware Solution for Life Sciences Annotations and Knowledge Sharing***

The IBM Middleware Solution for Life Sciences Annotations and Knowledge Sharing enables researchers to create, store and share valuable insights “on the spot” from a variety of commonly used applications. Using IBM InsightLink as an annotation solution, you can easily capture researchers’ insights and create a collaborative environment that promotes knowledge, expertise and idea sharing. Users across the enterprise can quickly and easily search the annotations database and view contextual insights alongside related research data, helping avoid redundant work and dead-end research avenues. The result? Efficient discovery and fast time to market. Maintained in a secure storage environment, these annotations, impressions and ideas become intellectual property and part of your permanent research record.

#### ***IBM Middleware Solution for Life Sciences Corporate Information Asset Management***

The IBM Middleware Solution for Life Sciences Corporate Information Asset Management gives you a way to securely store and process documentation and data records while minimizing your risk of noncompliance. Use this records management environment for storage, search and retrieval, long-term archiving and disaster recovery. The solution enhances access to and searches of records and data objects stored in disparate systems and applications. It can also integrate some of your information assets into a single archival repository. By creating a secure storage system for data, documents, intellectual property and other research assets, the solution helps establish an auditable process that can verify compliance with government archive and storage regulations.

## Mayo Clinic speeds search times from months to seconds

### Business challenge:

Scientists from the Mayo Clinic struggled to effectively analyze vast stores of critical patient and research data residing in a variety of locations and formats.

### Solution:

- IBM built a data warehouse and developed an industry-specific data query abstraction tool
- IBM DB2 Universal Database™ and IBM WebSphere® Application Server

### Business benefits:

- Completes queries in seconds
- Integrates access to medical data and access to genomic and proteomic data in the future
- Supports durable queries that can adapt to change in physical data schema
- Manages query and result sharing

### *IBM Middleware Solution for Life Sciences Investigator Recruitment and Trials Management*

A key to successful drug development is to enhance efficiency, effectiveness and speed of clinical trials by empowering trials investigators. The IBM Middleware Solution for Life Sciences Investigator Recruitment and Trials Management creates an integrated, portal-based environment that gives investigators better access to colleagues, information and education regarding trials and trial outcomes. The solution minimizes administrative activities and gives investigators an active, rewarding role in trials management. It can

also give your organization a complete view of investigators, sites and trial progress to help you keep investigators informed and satisfied. Leveraging proven best practices and technology components, the solution can help you identify the most productive investigators and recruit those most appropriate for specific trials. In turn, you can make the most of investigator expertise and enhance patient recruitment and retention.

### *IBM Middleware Solution for Life Sciences Clinical Trials Management*

For complex clinical trials, challenges abound — hard-to-access information, multiple interfaces, process delays and inconsistencies. The IBM Middleware Solution for Life Sciences Clinical Trials Management meets the challenge of increasingly complex clinical trials by promoting efficiency and

cost-effectiveness. The solution helps you manage time-critical information, documents, budgets and schedules about investigators, patients, clinical trials staff and related trial components. All in a secure environment that allows geographically diverse trial participants to communicate effectively.

### *IBM Middleware Solution for Life Sciences Clinical Genomics*

The healthcare and pharmaceutical industries have been buzzing with the promise of targeted, personalized medicine since the inception of the human genome project. Advances in science, technology and IT accelerate the delivery of research discoveries into clinical practice. To realize this vision of information-based medicine, you need a solution that will allow you to capture, integrate, manage and mine genotypic and phenotypic data to gain a molecular understanding of disease. The IBM Middleware Solution for Life Sciences Clinical Genomics provides an environment for capturing and

integrating clinical information with high throughput research data to identify and validate novel therapeutic targets, conduct focused clinical research and ultimately revolutionize the way to diagnose and treat diseases. The environment helps protect information like intellectual property and sensitive patient records from unintended use as well as adhere to regulatory requirements. With this solution, you can capture clinical patient data to be reused during directed drug development research. You can also drive new drug development projects to market fast by rapidly identifying new targets, revolutionizing and increasing speed of clinical practice and making fast, informed portfolio decisions.

### Components of IBM Middleware Solutions for Life Sciences

At the core of IBM Middleware Solutions for Life Sciences is industry-specific middleware components like IBM WebSphere Business Integration Adapters and IBM WebSphere Business Integration Collaborations. These middleware components combine with core capabilities from IBM's five software brands and pervasive technologies, including:

### Protocol Manager solution for clinical trials from IBM and Winchester Business Systems

#### Goal:

Create a clinical trials management system (CTMS) to streamline trials and bring new drugs to market fast with minimized costs and increased return on investment.

#### Solution:

- Combines capabilities of IBM Lotus Notes® software with IBM's proven life sciences business process expertise and IBM Premier Business Partner Winchester Business Systems' specialized industry knowledge
- Provides modules for electronic document management, patient recruitment, budgeting, resource utilization and more

#### Business benefits:

- Helps avoid cost and time overruns by tracking trial progress and expenses in near real time against schedules and budgets
- Gives small business an economical way to implement top CTMS technology
- Helps streamline all facets of the clinical trials process
- Supports compliance with FDA 21 CFR Part 11 regulations on electronic documentation

- *IBM DB2® software – Database and data management solutions to help you access, store and analyze data more effectively*
- *IBM Lotus® software – Tools that let you capture and apply essential knowledge and collaborate in real time*
- *IBM Rational® software – Advanced software and system development tools to speed software development cycles*
- *IBM Tivoli® software – Intelligent management software to store, protect and provision your resources*
- *IBM WebSphere software – e-business software for transaction management and business integration*
- *IBM pervasive technologies – Wireless and mobile solutions that deliver access anytime, anywhere*





IBM Middleware Solutions for Life Sciences also offer proven consulting and implementation services with resources from:

- *IBM Business Consulting Services, with thousands of worldwide consultants*
  - *Strategy and change services geared to business and operations, technology and organizational change*
  - *Integration services*
  - *Business process reengineering*
- *IBM Global Services – IBM Life Sciences Integrated Technology Consulting Services*
  - *Data integration and management*
  - *Computational and knowledge management*
  - *Hosted and application management services*
- *IBM Software Services*

### **Change the way you work — and the outcomes**

To match the pace of evolution in life sciences, you need a technology partner with the experience, industry knowledge and commitment to help you transform the drug discovery and development process. IBM can help you optimize the way you conduct R&D. Unite fragmented processes and develop a dynamic organization. Collaborate internally and externally with suppliers, partners and customers, making informed decisions and responding to threats and opportunities fast. By adopting new discovery and development models, you can gain strategic advantage over uncertain competitors and seize unparalleled opportunities to shape the future of the life sciences industry.

### **For more information**

To learn more about IBM Middleware Solutions for Life Sciences, including case studies and more detailed information about solution components, call your sales representative or visit **[ibm.com/software/industries/lifesci](http://ibm.com/software/industries/lifesci)**

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