IBM Life Sciences

IBM Life Sciences: Answering drug discovery, development, diagnostics and delivery challenges for life scientists worldwide

"IBM Life Sciences has had an astounding influence upon the life sciences industry since its founding in August of 2000. The Life Sciences group has taken on a spirit and drive completely unanticipated by the industry. The number of life sciences companies brought together via IBM Life Sciences umbrella of alliances is impressive to say the least, with the identities of these companies a virtual who's who in the life sciences universe."

– Frost & Sullivan
Life Science Infrastructure
Integration Award citation, 11/02

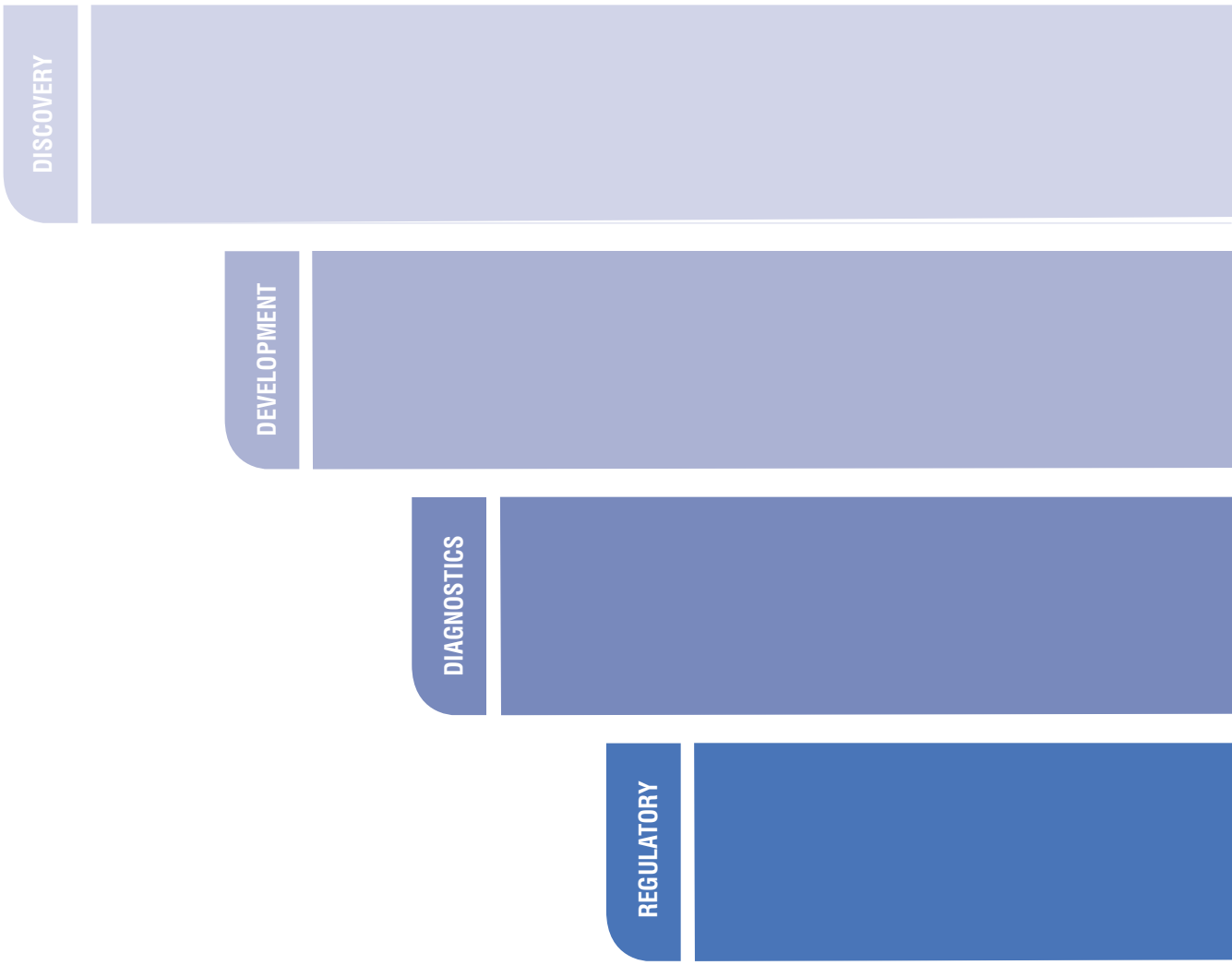
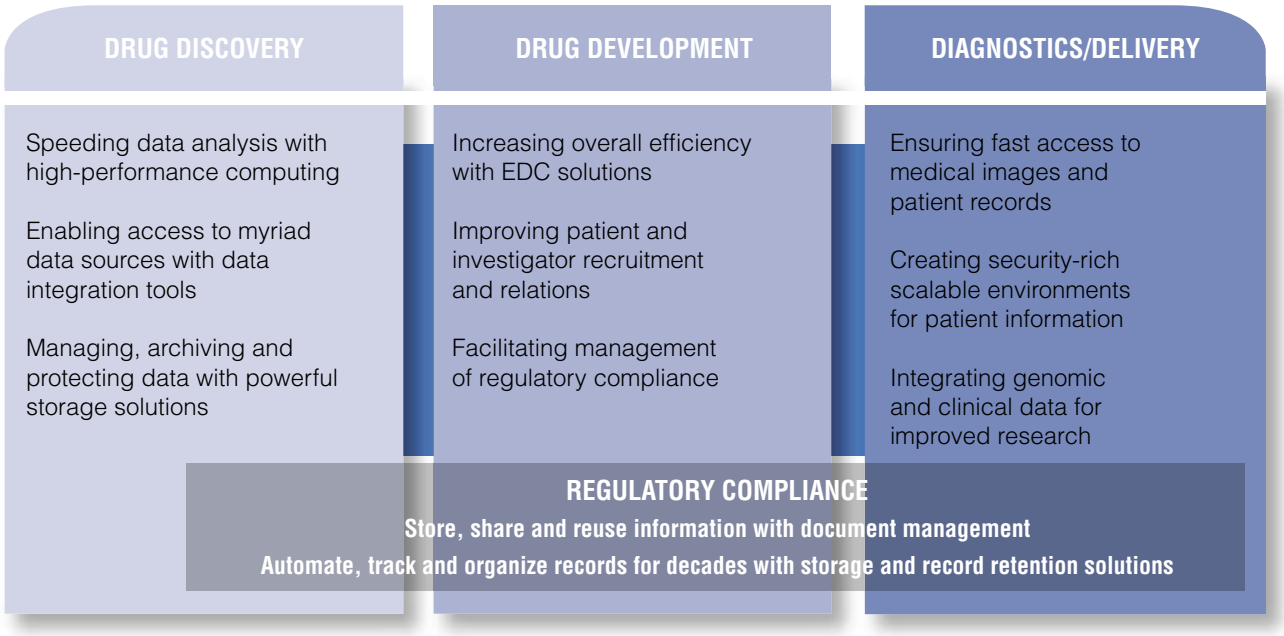
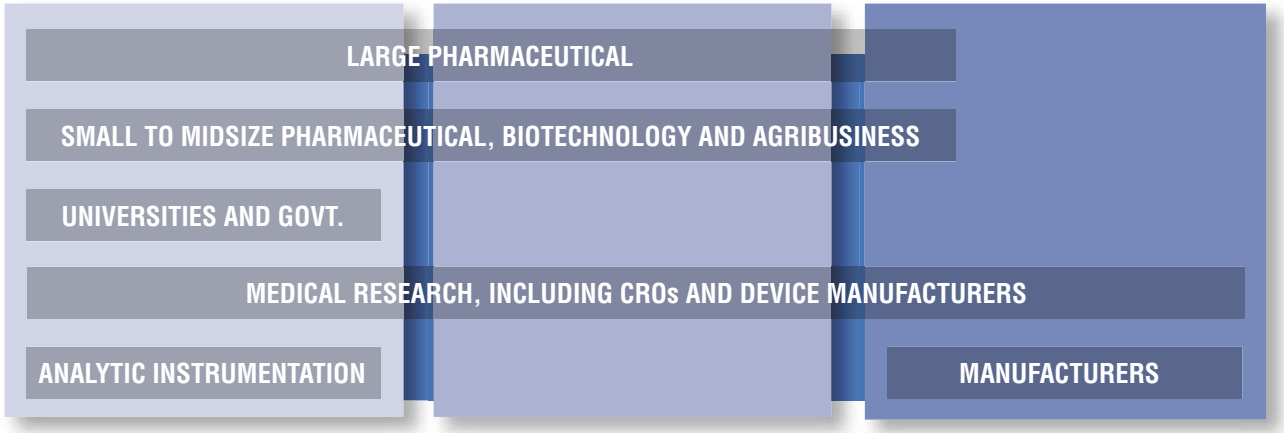


Table of Contents

IBM and its Business Partners answer life science challenges



Solutions for every phase of the drug discovery, development and delivery process



Scalable solutions tailored to address the needs of a range of life sciences companies

The knowledge, technologies and experience to enhance drug discovery and development

The State of Drug Discovery and Development

As the constraints of developing blockbuster drugs increase, companies engaged in drug discovery and development are entering a new era and experiencing the strains of diverse technological, scientific and business challenges. In response, each of these organizations—whether pharmaceutical, governmental, academic or commercial—is seeking new ways to:

- Accelerate the research and development process to discover more promising leads sooner and to identify failures faster
- Glean knowledge from increasing amounts of scientific, clinical and market data
- Integrate disparate data and applications to create a collaborative environment across scientific and business disciplines
- Take full advantage of current and future technologies, legacy data and applications through the use of open standards
- Facilitate compliance with regulatory bodies
- Improve overall clinical and diagnostic decision support

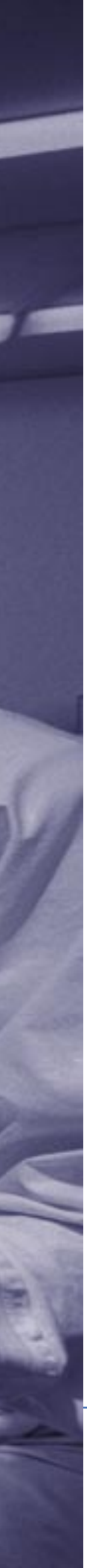
Underlying these challenges are two critical issues. First, the scope of research and development has widened. Data generated by genomics, proteomics, high-throughput screening and other automated analysis methods promise to help scientists understand disease states at the molecular level and uncover more potential lead candidates.

Second, enormous amounts of research and clinical data and compute-intensive applications are straining IT infrastructures. Current systems simply weren't designed to manage such volumes of data, integrate the applications and provide the realtime multi-user access required to accelerate the discovery and development of new treatments. These systems lack the means to streamline the collection of clinical data for submission to regulatory bodies as well as the greater capacity needed to protect, store and archive the data for the length of time required by regulatory authorities.

The need for a new approach—and a new infrastructure

Regardless of their size, leading life sciences companies are taking a systems approach that expands beyond the study of a single gene to examine how entire biological systems react to illness and affect an individual's response to a drug therapy. Reaching this level of understanding requires significant changes in the computational models scientists use and the hardware and software required to test those models. Biochemical models, complex data queries and protein-folding simulation, for example, all demand robust, flexible technologies that enable companies to capture, analyze, manage and store ever-increasing amounts of data.

The key to realizing the benefits of a systems-based approach to drug discovery and development is a more integrated, flexible and efficient infrastructure that allows companies to better manage and store ever-increasing amounts of data with minimal disruption; that links data and applications across functions for enhanced collaboration and efficiency; and that streamlines and automates workflows and processes across the organization. For example, electronic data capture helps ensure more accurate and timely data, while reducing costs and streamlining the clinical trial process.



IBM Life Sciences & IBM Business Partners

Building relationships to further life science solutions

Working with a network of global Business Partners, IBM Life Sciences addresses today's unique data and compute-intensive challenges with offices in more than 100 countries and thousands of consultants around the world. IBM Life Sciences and its network of global Business Partners deliver integrated solutions that help companies tackle their specific concerns, from growing their drug pipelines, to attracting and working with clinical and research partners, to accelerating the adoption of new technologies.These solutions include:

- *Global consulting services to assess IT and business process needs and support solution design and implementation*
- *Data integration to extract data from multiple sources*
- *Collaboration tools and services*
- *Robust infrastructure and high-resolution workstations to support access to medical images throughout the enterprise*
- *High-performance computing systems for analyzing and managing scientific workloads, performing computational modeling and simulation and accessing, querying and mining databases*
- *Modular storage technologies*
- *Security and data management to protect intellectual property and help ensure patient privacy*
- *Solutions and services to facilitate regulatory compliance*
- *Access to an unparalleled network of innovative software, hardware and service providers*

IBM and its Business Partners take a comprehensive view of the drug discovery value chain, offering both enterprise and point solutions to address the specific needs of each customer. In addition to solutions for drug discovery, clinical development and point-of-care diagnostics and treatment, IBM and its Business Partners offer solutions and services to help companies assess, create and implement processes that facilitate compliance with regulatory bodies. Every solution is designed to integrate with a customer's existing applications and infrastructure, leveraging and protecting their investments in technology.

A broad range of proven solutions from a single source

IBM high-performance computing infrastructure provides the ideal foundation for the innovative, proven applications of IBM Business Partners. Solutions from IBM and its Business Partners integrate easily with existing systems and scale as needed, allowing customers to purchase point or enterprise solutions and to fully leverage their existing technologies. IBM Business Partners offer a range of solutions and services, including:

- *Clinical genomics*
- *Data analysis*
- *Data integration*
- *Data management*
- *Devices and diagnostics*
- *Document and records management*
- *High-performance computing*
- *Informatics*
- *Knowledge management*
- *LIMS*
- *Security*
- *Ontologies*
- *Scientific instrumentation*
- *Visualization*
- *Strategic outsourcing*
- *Workflow/business processes*

Drug Discovery

Moving to a higher level of productivity and performance

Traditionally, the process of drug discovery has been labor intensive and empirical, and serendipity has played a role in the identification of new drugs or new therapeutic indications for existing drugs. But the human species contains roughly 40,000 genes, which can be translated to 60,000 to 100,000 proteins[1] or more. Analyzing this data, interpreting it and then forming and testing new compounds requires significant computational and storage power. A high-performance infrastructure is particularly important for the discovery phase, where:

- *Analytical techniques such as high-throughput screening, mass spectrometry, liquid chromatography and DNA sequencing require the analysis and integration of data from a wide range of instruments and databases*
- *Modeling and simulation tools such as molecular dynamics, docking, quantitative structure activity relationships, ADME/Tox and quantum chemistry help researchers identify promising candidates while eliminating poor options early*
- *Laboratory Information Management Systems (LIMS) organize quality testing regimens and new product development activities and are beginning to play a larger role in increasing lab productivity*

Together with its Business Partners, IBM offers solutions that can help increase productivity, lower operating costs and enable the management of large numbers of samples and data points. For example, 4SC AG, a Munich-based biotechnology company, relies on Linux cluster technology from IBM to power its Virtual High-Throughput Screening Technology (vHTS). vHTS calculates the biological activities of millions of molecules on the basis of protein structure, homology modeling or the biological activity of existing compounds. With Linux cluster technology, 4SC is able to screen databases for 1.5 million molecules with flexible docking algorithms in just one hour.

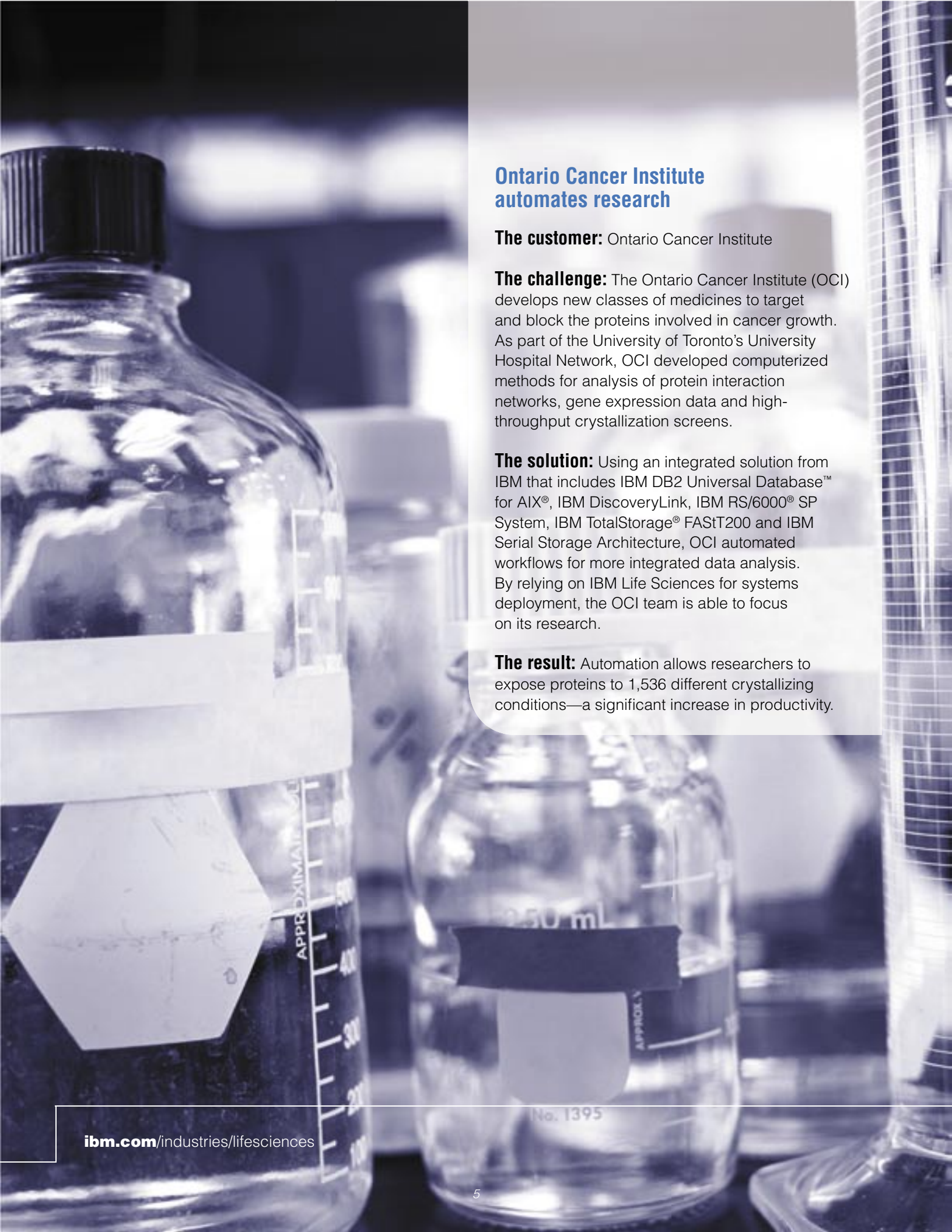
The ability to ask new questions

Drug discovery begins with questions: What proteins are encoded by the roughly 40,000 human genes? In which biological pathways are they expressed? Which of these proteins are appropriate targets? Currently, the information needed to answer such questions exists in specialized data sources distributed across organizations and around the world.

IBM DiscoveryLink® is a middleware solution that provides integrated access to discovery, clinical and regulated data sources. DiscoveryLink dramatically increases R&D productivity by creating a virtual database. With a single query, life scientists can access multiple data sources, asking new and complex questions that can't be answered with data from a single source. For example, when integrated with SRS, a data and analysis tool and integration platform from LION bioscience AG, DiscoveryLink makes it possible for researchers to easily extract and track data from more than 500 public and private databases, including GenBank®, MEDLINE®, SwissProt™ and others.

DiscoveryLink is powered by the proven technology of IBM DB2® Information Integrator, which allows analytical tools, portals, data integration solutions and other applications to access diverse data. Even with disparate sources such as Oracle® databases or Microsoft® spreadsheets, or across different operating systems, DB2 Information Integrator enables life scientists to access a broader range of scientific data.

[1] *Pharmaceutical Clinical Development: The future of clinical trials—How genomics, proteomics and technology are changing the clinical development process,* IBM Life Sciences, June 2002.



Ontario Cancer Institute automates research

The customer: Ontario Cancer Institute

The challenge: The Ontario Cancer Institute (OCI) develops new classes of medicines to target and block the proteins involved in cancer growth. As part of the University of Toronto's University Hospital Network, OCI developed computerized methods for analysis of protein interaction networks, gene expression data and high-throughput crystallization screens.

The solution: Using an integrated solution from IBM that includes IBM DB2 Universal Database™ for AIX®, IBM DiscoveryLink, IBM RS/6000® SP System, IBM TotalStorage® FAStT200 and IBM Serial Storage Architecture, OCI automated workflows for more integrated data analysis. By relying on IBM Life Sciences for systems deployment, the OCI team is able to focus on its research.

The result: Automation allows researchers to expose proteins to 1,536 different crystallizing conditions—a significant increase in productivity.

But enhanced access to data alone isn't a panacea. That's why IBM also offers a set of innovative solutions and tools to reduce discovery time and costs. For research organizations with groups working in multiple locations, IBM InsightLink™ helps researchers leverage relevant data and insights outside normal workgroups. This unique middleware solution uses an open standards-based design for integrating annotations into familiar applications. Supporting a wide variety of data formats, it features flexible annotation templates (or structures) based on applications and user roles and enables researchers to capture and store relevant notes and insights for use in future experiments, enhancing knowledge sharing throughout the organization. Researchers can also conveniently review and consolidate the work from multiple teams and manage decision processes and workflows.

IBM collaboration solutions help organizations develop a customized, portal-based discovery environment to access data, locate expertise, work more effectively with team members and implement best practices for research processes. With collaboration solutions, organizations can make more efficient use of resources, reduce rework and increase efficiency across the enterprise. They can also extend R&D beyond the organization through the use of on demand technologies—especially relevant in a time of mergers and alliances.

Powerful, open systems

IBM also enables life scientists to address critical questions through a range of open systems such as IBM @server® technologies. IBM @server is a powerful family of servers that offer self-managing and self-optimizing features as well as the power to handle complex tasks—such as mapping proteomic information or performing data mining to identify patterns. Providing a truly open environment based on UNIX® and Linux, IBM @server systems include the pSeries®, running on AIX/L® (UNIX) and the xSeries®, running on Linux and Microsoft® Windows®.

An integral component of any IT strategy is reliable, security-rich, disaster-tolerant storage. IBM's TotalStorage® systems include storage networking, software solutions and disk, tape and optical systems for backup and recovery. Together they provide a reliable storage infrastructure designed to be modular and scalable. Networked storage allows for the efficient management of data-intensive applications, while backup is performed to ensure ongoing access to intellectual property. All of IBM's networked solutions ensure that data is accessible and manageable from a single point of control.

The research database that IBM and MDS Proteomics are developing is an ideal example of the power of IBM technology and partnerships. This public database of protein analyses will be available to pharmaceutical researchers, universities and other scientists via the Internet. And it will be used to help scientists better understand the interactions among proteins that trigger chemical reactions in cells and cause diseases such as cancer, AIDS and depression. The database will be housed on a supercomputing infrastructure that includes clusters of IBM @servers running Linux and UNIX and high-performance data management and storage systems. MDS Proteomics software will accelerate the process of analyzing enormous amounts of data collected from mass spectrometers in North America and Europe.

Drug Development & Clinical Trials

Ensuring data quality and access

IBM and its Business Partners can help address the challenges of increasing efficiency and throughput with the use of electronic data capture (EDC), improving investigator relations and patient recruiting and improving the management of clinical trial data and documents to enable regulatory compliance.

Improving efficiency and throughput with EDC

The first step to transforming clinical trials is through the use of EDC, which is already providing more accurate data, reducing errors and protecting the integrity of the trial process. Through the development of services and technology solutions that increase productivity and throughput, IBM and its Business Partners provide EDC solutions for improving and automating the trial process. These collaborations combine IBM infrastructure and implementation experience with industry-leading EDC applications from companies such as Phase Forward and eResearch Technology, resulting in customized solutions that improve efficiency and ensure the quality of documentation.

IBM offers these EDC services on a variable cost basis, enabling organizations to take advantage of clinical development applications and services without significant up-front costs. Ideal for biotechnology firms interested in extending their capabilities from discovery into clinical development, IBM EDC solutions provide a cost-effective, efficient way to move compounds into the testing phase. These services cover all aspects of clinical development, including process design, investigator support and ongoing evaluation of emerging technologies and industry standards.

Aventis boosts participation in post-marketing surveys

The customer: Aventis Pharma AG

The challenge: Aventis Pharmaceuticals, a subsidiary of Aventis Pharma AG, sought to increase the participation of oncologists in post-marketing surveys of Campto, which is used to treat colorectal cancer. Participation had been dropping due to slow feedback, which frustrated oncologists who had taken the time to register and reduced the amount of data available to Aventis researchers.

The solution: Aventis relied on an IBM Wireless e-business solution that included a graphical user interface, business logic and communication protocols and personal digital assistants—making it easy for oncologists to add, edit and send drug and patient-related information to Aventis.

The result: Aventis reduced participation time, provided participants with regular, timely updates and collected more relevant data about Campto.

Improving patient recruitment

Even clinical trials based on the most streamlined, automated processes can be delayed by inefficient patient recruitment. In the past 20 years, the number of patients required for a new trial has tripled, and today over 50 percent of trials are delayed due to patient recruitment challenges. Although investigators are a crucial part of the process, most participate in only one study. And estimates predict an investigator shortfall of 15 percent by 2006. In response, IBM offers the Investigator Relationship and Trial Management (IRTM) solution. This set of services and applications uses business processes such as customer relationship management (CRM) and proven IBM technologies to help collect investigator information, deploy enabling technologies, establish best practices and improve the productivity of Clinical Research Associates (CRAs) and overall experience for investigators. By bringing together contact center and CRM tools, portal technology, collaboration tools, distance learning capabilities and reporting functionality, IBM IRTM speeds start-up time, automates routine tasks and integrates relevant business processes, giving investigators and CRAs the ability to view and track progress in near realtime.

Faster access, more comprehensive management

Every clinical trial must adhere to regulatory requirements, a mandate that can now result in hundreds of binders of data. IBM and its Business Partners provide solutions that help organizations meet regulatory requirements by protecting patient privacy and ensuring the identification of every user.

For example, to improve documentation and facilitate compliance, IBM and Documentum, Inc. offer IBM Regulatory Content Services for Life Sciences, a preconfigured and affordable document management solution that enables management of all documents required to compile a compliant dossier.

This solution is designed for fast implementation and deployment and supports the development of GXP-compliant documents to meet FDA, European Medicine Evaluation Agency (EMEA) and Japan's Ministry of Health, Labor and Welfare regulatory requirements. Developed by Documentum with IBM Business Consulting Services, IBM Regulatory Content Services for Life Sciences is an enterprise content management system that can be configured for virtually any life sciences organization, from a growing biotech to a large pharmaceutical company.

With its deep background in the implementation of clinical development solutions, IBM can help organizations in a number of ways, including hosting, infrastructure implementation and deployment solutions, as well as help desk services to support investigator sites worldwide. For example, clinical development portals based on IBM WebSphere® technology provide easy access to diverse applications, the ability to integrate multiple applications and the flexibility to adopt new technologies as needed. And IBM Business Consulting Services is available to help implement solutions for electronic data capture, data management, Web hosting, systems integration and eClinical strategies that range from patient recruitment and data collection to enabling rolling regulatory submissions.

Streamlining access to information for improved operations and patient care

Insights gleaned from the analysis of clinical and biomedical research not only lead to new medicines but also form the basis of a new and compelling direction for diagnostics and delivery of patient treatments: information-based medicine. With the goal of improving treatment outcomes, information-based medicine supplements existing medical and clinical practices with insights and information gathered from diverse clinical research data. By using this data, practitioners of information-based medicine seek to improve the accuracy of diagnostic decisions and help providers select the best possible treatments for patients.

To progress toward an information-based approach, organizations will need to centralize clinical and R&D information for near realtime data access. For example, in the case of medical imaging, powerful desktop workstations and secure, robust storage solutions help ensure the transfer of film images and paper-based medical records to electronic files—and enable fast access to patient information across the organization and at the point of care. In particular, the IBM IntelliStation® Workstation with T221 flat panel display is a cost-effective solution in a high-power, color LCD monitor—providing high-quality images for improved diagnosis and patient care.

In addition to superior medical assessment workstations, IBM and its Business Partners offer the scalable infrastructure and innovative software needed to support the move to electronic records and enable patient privacy and regulatory compliance. IBM and Business Partner BRIT Systems recently worked with the Great Plains Regional Medical Command, a network of army hospitals, to implement a Picture Archiving and Communication System. This PACS enabled instant access to medical images in a security-rich environment.

Another example can be found in clinical genomics, where the integration of genotypic and phenotypic data helps improve research efforts. In this instance, IBM and deCODE genetics, Inc. are working together to advance information-based medicine by integrating their respective technologies. deCODE genetics is dedicated to identifying the genetic causes of common diseases such as stroke, heart disease and Alzheimer's, which result from the interplay of multiple genes and environmental and health factors. Using its unique genealogy database, deCODE's genetics discovery programs have been based on the Clinical Genome Miner Discovery™ software environment. By integrating this environment with IBM technologies, IBM and deCODE offer a comprehensive solution that applies genetics to the improvement of drug discovery and healthcare.

Mayo Clinic and IBM develop patient database for genomics-based research

The customer: Mayo Clinic

The challenge: To develop a plan for a comprehensive life sciences resource that allows access to individual as well as aggregated patient medical records—and eventually genetic information—for medical research purposes.

The solution: The first phase of the project entailed building an information infrastructure on IBM platforms to bring together clinical data that can immediately support a variety of research projects, such as epidemiological studies of selected disease categories, while protecting the confidentiality of individual patients. This infrastructure enabled investigators to identify patient data—including demographics, diagnoses and results of tests performed—on consenting research populations for further clinical study at Mayo. The goal of subsequent phases will be to incorporate patient-related genomic and proteomic data to support basic, translational and clinical research that leads to enhanced patient care.

The results: The system will run on IBM @server pSeries using AIX and facilitate access to data on more than 4 million consenting patients—allowing Mayo Clinic's investigators to draw meaning from both phenotypic and genotypic data, including genomic information from public and private databases and retrospective studies of millions of archived patient records.

Facilitating compliance through the entire discovery and development process

Today, regulatory approval can require multiple clinical trials and take years, while patients wait for drugs that will alleviate their symptoms—if not cure their illnesses. While early and ongoing communication between life sciences companies, the FDA and other regulatory bodies is key to improved regulatory processes, comprehensive documentation is an important step in shortening the time needed to approve a new medicine.

Through its Regulatory Compliance Consulting Services, IBM provides compliance strategies, diagnostic assessment and program implementation services—all with the goal of improving documentation and communication to speed the approval of new drugs. In addition to facilitating compliance with FDA regulations, IBM also offers services to enable compliance with regulations set out by the European Medicine Evaluation Agency and Japan's Ministry of Health, Labor and Welfare.

Preserving, restoring and securing clinical data

Regulatory bodies require long-term storage of clinical data. To help organize, store and retrieve relevant clinical documents and reports, IBM offers the IBM Corporate Information Asset Manager for Life Sciences. Designed to help organizations accommodate regulatory requirements concerning data management, maintenance and submission, this integrated solution delivers rapid access to dossier information throughout the retention period, enables accurate reconstruction of data for inspection or review and helps secure the value of legal information and intellectual property. The Corporate Information Asset Manager includes a range of IBM database and storage technologies as well as expert services from IBM Business Consulting Services to assess each client's data management, infrastructure and implementation needs.

In addition to compliant content management, IBM provides solutions that authenticate electronic signatures and ensure that only authorized individuals access research, clinical and medical records. Together with its Business Partner Daon, IBM offers an advanced, scalable identity management system that uses physical characteristics (biometrics) such as fingerprint, iris and voice. Daon's biometric authentication and identity management systems help companies meet a host of security and regulatory requirements for nonrepudiation and data protection more easily and efficiently. And DaonEngine uses IBM cryptographic systems to ensure the safety of each biometric template.

To learn more about the IBM vision of the future, download *Pharma 2010: The Threshold of Innovation from IBM Consulting Services* at http://www-1.ibm.com/industries/lifesciences/doc/content/resource/insight/940902121.html

To find out more about solutions from IBM and its Business Partners, go to: http://www-1.ibm.com/industries/lifesciences

Information-based medicine enabled by information technology

The one-two punch of information overload and inefficient systems is challenging the pharmaceutical and biotechnology industries. The only way to leverage recent advances in genetic and proteomic research is by investing in services and technologies that enable new ways to identify and develop drugs.

Such a dramatic change in direction can't be accomplished overnight—or alone. Life sciences companies of all sizes need technology partners with the experience, industry knowledge and commitment to help them transform the drug discovery and development process. With its proven technologies, global consulting services and extensive network of life sciences Business Partners, IBM is ideally suited to help organizations prepare for the future of medicine.

IBM believes that the future is information-based medicine. Advanced tools and systems such as modeling, simulation and high-performance computing will enable the industry to model how drugs act in whole body systems, in organs and at a subcellular level; to design accurate trials; and to conduct adaptive trials, where information acquired during a trial can be used to modify the course of the same trial without compromising its statistical validity.

To help pave the way for a profitable future based on personalized medicine, IBM Life Sciences offers focused solutions, including:

- *IBM Business Consulting Services—offering extensive industry knowledge and international experience to help clients transform research operations, build and leverage customer relationships with e-business solutions and develop strategies for growth*

- *Integrated Technology Services for Life Sciences—focused on developing solutions for data integration and management, computational and knowledge management challenges*

- *Strategic Outsourcing Services—working with Business Partners to implement solutions for electronic data capture, data management, Web hosting, systems integration and eClinical strategies that range from patient recruitment and data collection to enabling rolling regulatory submissions*

Today, IBM Life Sciences and its Business Partners offer an unparalleled range of solutions designed for every phase of the drug discovery and development process. But this is only the beginning. As targeted medicines become a reality and as information technology helps reduce the time it takes to bring new medicines to market, IBM will work with its Business Partners and customers to continue answering the changing needs of life sciences companies with the solutions they need to develop safer, more effective treatments.

About IBM

The goal of IBM Life Sciences is to rapidly bring IT technology to customers and Business Partners in the fields of pharmaceutical research, biotechnology, genomics, health, and other life sciences industries. IBM is a proven leader in data integration, supercomputing, high-performance storage, e-business and information technology services.

Long-term projects at IBM Research Centers and the IBM Deep Computing Institute foster collaboration with life sciences companies—bringing domain expertise and innovative technologies to the development of life sciences solutions. IBM actively collaborates with leading hardware, software and service providers whose domain knowledge, products and resources can help build valuable solutions for our mutual customers.

For more information

To learn more about IBM Life Science Solutions and our Business Partners, visit **ibm.com**/industries/lifesciences or contact an IBM Life Sciences specialist at LS@us.ibm.com.

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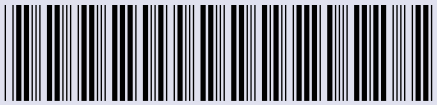
Printed in the United States of America
03-04



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