

## IBM SCOREs in Life Science

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### WHITE PAPER

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Alan S. Louie, Ph.D.  
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### HEALTH INDUSTRY INSIGHTS OPINION

The life sciences industry is one of the most highly regulated industries in the world. Over the past decade, there has been continuous growth in the level of regulation associated with GxP (e.g., good clinical practices [GCP], good manufacturing practices [GMP], and good laboratory practices [GLP]), U.S. Food and Drug Administration (FDA) 21 CFR Part 11, and EMEA Annex 11. In addition, the industry is also under increasing pressure to comply with provisions that originate outside what the life science industry historically defines as relevant regulatory authorities, such as the patient privacy requirements of the Health Information Portability and Accountability Act (HIPAA) or the fiscal and corporate governance requirements of the Sarbanes-Oxley Act (SOX). These regulations have implications for all IT systems, both transactional and informational, in addition to the corresponding clinical workflows that make up the clinical development life cycle.

The FDA has made significant progress in the adoption of the electronic common technical document (eCTD) as the standard electronic submission format in the United States. With eCTD submissions at the Center for Drug Evaluation and Research (CDER) growing at 122% between 2007 and 2008 (24,797 versus 11,175 submissions), it is clear that the FDA transition is well under way. Europe continues on schedule to strongly recommend eCTD-format electronic-only submissions by July 2009 and expect health authorities in all European Union countries to be capable of receiving eCTD-only submissions by the beginning of 2010. In looking to continue to move forward, we expect electronic submission to expand to include HL7-driven Regulated Product Submission (RPS) standards, which look to expand the eCTD approach across all regulatory submissions, including human therapeutics, medical devices, veterinary products, and food additives.

In developing the Solution for Compliance in a Regulated Environment (SCORE), IBM has introduced a revolutionary product innovation based on a service-oriented architecture (SOA) that leapfrogs incremental commercial improvements in document management to begin to fully manage and control information and workflow in the life sciences.

## IN THIS WHITE PAPER

With the introduction of SCORE, IBM offers life science companies a compliance-enabled solution that extends beyond document management capabilities. SCORE provides a framework for managing the life cycle of multiple content types, including documents, scanned images, and medical images, and ensures the delivery of that content within a secure, regulatory-compliant collaborative environment. Through the automation of critical information management, SCORE improves business processes and facilitates regulatory compliance across the entire life science value chain.

In this white paper, Health Industry Insights will examine how IBM SCORE is enabling two companies to move beyond simply managing documents toward the creation of a system that helps to manage information in context. The white paper includes the following sections:

- **Situation Overview**, which provides a review of the current market forces and recent trends in the information management market
- **Information Management: Maturity Model**, which presents a review of the market evolution of document, content, and information solutions
- **Case Studies**, which highlights the experience of two early adopters of IBM SCORE and the benefits the companies have experienced

## SITUATION OVERVIEW

To meet the challenges of managing the increasing volumes of information, many life science companies have embarked on a diligent review of their compliance strategies, methodologies, and associated costs. Solutions that could assist these companies in implementing a consistent approach to compliance using a records management metaphor were the early beneficiaries of considerable IT budget spending. But as these life science companies began to push the capability boundaries of these primarily document-focused (control and management) systems, they began to realize the potential for benefits beyond document management. The life science industry has come to realize that compliance is a measurement tool, not a strategic initiative. The strategic initiatives involve the establishment of transparent, dynamic, and service-based systems that can demonstrate compliance, just as the speedometer on an automobile dashboard informs the driver of speed. You don't stop the car to measure its speed.

Life science companies are struggling with solutions that allow them to capture critical documents and other sources of important data and then control them. The need to communicate more effectively with project team members, both internal and external, has remained largely unmet. Technology licensing, outsourcing, and partnership opportunities require a platform that truly supports auditable collaboration. This industry is starting to learn how to embrace change and evolve from a culture of concern about adherence to regulations toward the creation of a culture of confidence, increasing transparency across the organization.

## **INFORMATION MANAGEMENT: MATURITY MODEL**

The use of solutions that permit life science companies to manage the massive amounts of information they require is changing rapidly. The pace of adoption is increasing quickly, and companies are realizing a wide range of benefits depending on their level of electronic data capture (EDC) adoption.

The following maturity model is extracted from Health Industry Insights research on information management in the highly regulated life science environment. This maturity model has been developed to explain the fragmented nature of the market and to provide a framework for companies to assess their needs and select appropriate information management solutions.

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### **Stage 1: Assuming Control**

In the past, document management systems (DMSs) were largely implemented as parallel systems that mirrored, but were not always fully integrated with, the workflows and standard operating procedures that define the document life cycle. The primary goal of these systems was to meet regulatory requirements for documentation of development and manufacturing processes. This parallel nature created significant task redundancy and data synchronization issues. The use of nonstandard user interfaces and lack of a standardized approach to data integration with other corporate systems further burdened the regulatory affairs and quality control groups, the primary users of those systems.

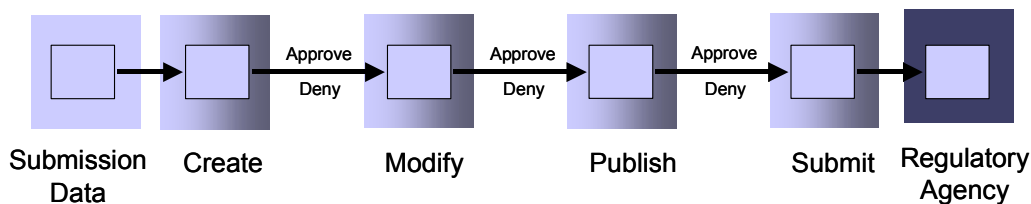
As a first step, many companies have identified document management as a crucial component in their migration from paper-based processes. But documents are only one source of content that must be considered and managed. To expand their markets into new therapeutic areas, for example, and effectively compete in more dynamic and adaptive studies, life science companies must be able to gain control over a growing number of nonpaper sources of clinical data. Submissions that include clinical data embedded in lab reports, complex imaging, and electrocardiogram (ECG) waveforms, for

example, are becoming common. At the same time, having to manage all this while operating in an environment of increasing pressure and complexity surrounding regulatory compliance is straining companies to their limits.

As depicted in Figure 1, the first implementations of electronic document control systems operated much like the paper handling processes that preceded them. The linear processes limited collaboration and made it difficult to send document edits or modifications to documents back to groups other than the original author.

**FIGURE 1**

Document Control



Source: Health Industry Insights, 2009

**Stage 2: Creating Content**

The success of document control solutions in providing life science companies with a "single version of the truth" elevated the status of these solutions from tactical to strategic. But the regulatory environment has evolved as well. The FDA's standardization around the eCTD within CDER and further plans to standardize around RPS across all parts of the FDA clearly demonstrate its commitment to more streamlined, simplified, and scalable submissions processes.

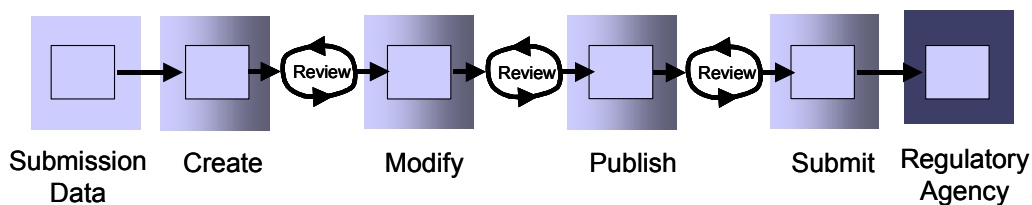
On the surface, eCTD would seem to complicate the submission process. But as submissions grow in complexity and encompass multinational filings, eCTD's additional structure provides superior scalability and improves the review process.

Beyond the tasks required to author, route, approve, publish, and archive documents, the linear approach to workflow found in first-generation document management solutions can actually increase the difficulty in complying with regulations. Compound documents created by collaborative groups are becoming increasingly common. In response, life science companies have sought to deploy more collaborative solutions. These document management solutions typically hardwire workflow based on the document type. As a result,

collaboration is often restricted to the check-in/check-out review cycle of a single document instance. More open collaborative workspaces may be provided, but these review forums don't typically provide workflow support and are loosely monitored, making auditing extremely difficult. As depicted in Figure 2, document management solutions provide for increased collaboration between adjacent workgroups in comparison with a document control solution (Stage 1 example), but still rely overall on a single-threaded document-driven approach.

**FIGURE 2**

Document Management



Source: Health Industry Insights, 2009

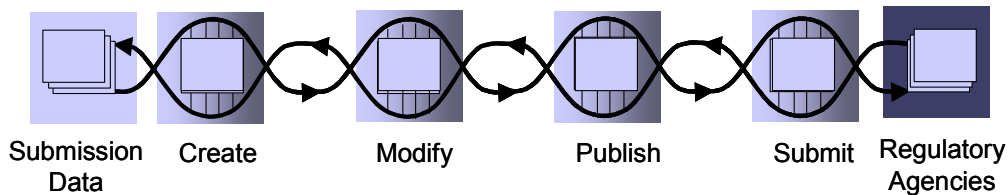
**Stage 3: Managing Context**

As life science companies attempt to reuse and repurpose data and eliminate data redundancy in their document libraries, an approach that focuses solely on content or document management has limited enterprise appeal. Solutions that hardcode or otherwise restrict workflow creation tend to limit the utility of document metadata as well. The value of such solutions, which were designed to support a single serial submission process, will be further reduced as the industry moves to rolling submissions and comprehensive drug life-cycle management. These solutions simply lack the ability to seamlessly integrate correspondence, task management, and auditing within the same application framework. Supplemental applications, such as project management, could provide some level of parallel or bolt-on functionality, but the result would be the construction of yet another collection of separate, discontinuous systems.

As product R&D and clinical development in particular become increasingly dynamic and adaptive, robust support of metadata offers a scalable approach to effectively deal with change. Figure 3 illustrates the evolution of document and data management from a single-threaded linear process to an interconnected continuum of information creation.

**FIGURE 3**

Managing the Context Continuum



Source: Health Industry Insights, 2009

**IBM SCORE**

As described previously in the Situation Overview and Information Management: Maturity Model sections, the pace of change in the information management market is increasing rapidly. Initially uncomfortable in such a fast-paced environment, many life science companies reacted to the deficiencies discovered in their processes by procrastinating or by plugging holes with technology whose selection was driven more by short-term convenience than a view toward long-term return on investment. The resulting sense of chronic future shock that pervades the industry would be easier to appreciate if you could see the trail of abandoned or marginally successful information management initiatives strewn throughout these organizations.

Today, companies are beginning to address the issue, abandoning their tradition of ad hoc technology selection of project-specific or functionally proprietary (silo) solutions in favor of extensible enterprise solutions that are service oriented rather than application or content focused. For their part, companies such as IBM are focusing on the development of solutions that not only address immediate points of pain but also are scalable, both in terms of performance and feature/function support for new or unforeseen needs.

IBM has taken a holistic approach to the development of SCORE. As a product instantiation of SOA, SCORE has been designed to behave more like a middleware solution than a DMS. SCORE not only can handle discrete documents but also can serve as a data management middleman of sorts, retrieving data from one application and passing it to another.

As a result, SCORE creates a repository-neutral overlay architecture that aims to reduce implementation time and cost as well as limit the overhead needed to maintain and validate the system and its contents. A typical installation of SCORE includes a series of templates, process-based workflows, and "accelerators," which function as data integration wizards. SCORE delivers a best practices approach to content life-cycle management that is available directly out of the box.

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## **Configure to Fit, Not Custom Code**

The SCORE middleware solution focuses on replacing customization common in DMSs with configuration options built into the application. By leveraging the flexibility and features of that middleware platform, SCORE provides an interface layer that sits on top of the DMS and is preconfigured to the business environment without the need to write custom code within SCORE. It provides tools for collaboration and integration (e.g., a Web portal), links to online discussion group applications, and interface "accelerators" for building connections to LIMS, ERP, MES, and other systems that commonly coexist with document management in a regulated environment.

SCORE supports regulatory requirements while allowing configurable options for the terminology and business processes employed by a user organization to store and access the information. The configurability options are designed to speed the implementation process and reduce total costs. Although configurability is by no means a new feature in software, this approach to regulatory requirements is gaining greater acceptance in the marketplace. As life science companies rationalize their IT infrastructure, SCORE has the potential to become a true enterprisewide solution. Isolated data or workflows that prevented efficient information flow between multiple divisions or lines of business, such as clinical development, regulatory submissions, finance, or manufacturing, for example, can be integrated with SCORE to achieve greater operational efficiency.

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## **Best Practice Templates**

So that SCORE could provide immediate value to its customers, IBM has pursued a design goal that fulfills the majority of document management needs straight out of the box. During our review of the product, IBM held that the out-of-the-box functionality and configurability options delivered in the base product typically should meet a minimum of 80% of the largest companies' needs. IBM's position is supported by interviews conducted by Health Industry Insights with two companies using SCORE. Both companies are detailed in this white paper.

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## **Validation**

IBM's SCORE solution for pharmaceutical industry document management is designed to implement cumbersome regulatory requirements with relative ease and simplicity. IBM asserts that the SCORE template speeds the implementation and lowers the cost of document management while increasing data quality.

One of the most compelling aspects of compliance-focused solutions is their validation capability. SCORE handles documentation in compliance with 21 CFR Part 11 and GxP requirements and includes a prepackaged documentation solution to accelerate the validation process. Other solutions offer similar features, but the flexible workflow tools built into SCORE take validation to a new level of utility. With SCORE, users can take externally created documents, such as submissions standards, and validate them. Once validated, these documents can be incorporated directly into SCORE as updated templates in the library.

Over the long term, the approach offered by SCORE can dramatically simplify implementation, integration, and validation of document management solutions in the pharmaceutical, biotech, and medical device industries.

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### **SCORE Feature Summary**

The latest version of SCORE was released in November 2007. It is in production at companies around the world, including in Belgium, Germany, India, the Netherlands, Portugal, Spain, Switzerland, and the United States.

This version provides the following capabilities:

- Integrated regulated document management and submissions management
- Full document life-cycle and eCTD life-cycle management, from creation through submission
  - Planning, tracking, and monitoring of the document life cycle
  - Status dashboards
  - Workflow management at both eCTD and node levels
  - Full life-cycle audit trails
  - Recognition of country-specific eCTD requirements (which are regularly updated as these requirements evolve)
- Compound document assembly, eCTD assembly, communications and correspondence management, and registration status tracking
  - Improved portal interface that facilitates greater user productivity
  - Autosuggest feature that automates the placement of components based on document metadata, speeds assembly, reduces errors, and shortens assembly time



- Unique cross-reference tools for Microsoft Word and Adobe Acrobat
  - Allow cross-references to be added during the authoring and review cycles, eliminating the rush to add large numbers of cross-references during the final assembly of a submission
  - Maintain cross-references as new versions of documents are created
  - Improve accuracy by allowing users to check the cross-references during the creation, review, approval, and assembly of documents and submissions
- Communications and correspondence management
- Submissions planning and tracking
- Multilanguage support (currently includes Brazilian Portuguese, simplified and traditional Chinese, Dutch, English, French, German, Italian, Japanese, Korean, and Spanish)
- Support to run in an SOA environment, including Web services interfaces to ease integration with other applications

## **CASE STUDIES**

The following case studies illustrate the results experienced by early adopters of IBM's SCORE.

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### **Scenario 1: Gaining Consistency, Speed, and Streamlined Workflows at a Global Medical Device Company**

#### ***Company Overview***

A global medical device company with headquarters in Germany and operations in multiple countries has been using SCORE since 2005. Like other successful global life science businesses, this company has grown organically as well as through acquisition. As a result, many of the company's operations are organized around a distributed model. The company maintains centralized management and several horizontal or shared services departments, including information technology and quality management, which span the company. However, for practical operational management, each product-centric division maintains a high degree of process autonomy.

The company currently has 200 active users of SCORE, primarily in the global quality management department, who are responsible for the majority of authoring, editing, and publishing of the documents managed in SCORE. These users, along with users from other functional groups, are located at the company's corporate headquarters.

## ***Global Deployment***

The company consists of employees dedicated to division-specific operations as well as employees from global departments such as IT and quality. IBM SCORE was deployed first at the company's headquarters and then expanded to its divisions. Each of these divisions maintains its own instance of SCORE, exchanging documentation as necessary across the company, and shares template libraries and workflows maintained in a global library.

Users from quality management, with the support of IT, serve as SCORE's ambassadors at each location. The company plans to eventually support 1,500 users, including 500 active authors, over these multiple instances of SCORE.

## ***The Selection Process***

It is not surprising that a German medical device company would employ a systematic approach to the selection of a compliance-related application. But what may surprise many is the rigorous analysis the company employed before vendors even saw an RFP. Realizing the strategic importance of this application and its long-term value, the company spent a great deal of time gathering the input, functional requirements, and support from a wide range of potential system users throughout the company.

The company selected SCORE after an exhaustive review of its existing solution and evaluations of several other commercially available solutions, including EMC Documentum. The company stated that the following five criteria ultimately drove the selection of SCORE:

- User feedback (suitability to task)
- Pricing
- Product features
- Technology vision
- Functionality

The following are some of the functional benefits the company has realized through the use of SCORE:

- All regulated documents reside in a single system, thus reducing the administrative overhead for managing these documents.
- Ability to support multiple, but related, workflows provides centralized control of all workflows related to the document creation, review, approval, and publishing process.

- Ability to create compound documents ensures that all appropriate relationships are maintained between documents and allows for easier navigation and review of related documents.
- Process automation enables seamless publication of released documents, providing greater efficiency and reducing errors.
- Significant off-the-shelf functionality enables the organization to rapidly implement IBM SCORE to improve document processes.
- Extensible architecture, including robust API support as well as support for SOA and Enterprise Service Bus, specifically SAP NetWeaver, allows information residing outside of the SCORE repository to be accessed and included in the document process. (Note: It is also possible for other applications to pull metadata or documents from SCORE or initiate SCORE workflows. SCORE can also update information from other applications.)
- Robust role-based user security provides flexibility and greater efficiency in assigning security rights to users across the organization.
- Support for change management allows an organization to systematically implement and audit the change process.

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## **Scenario 2: Standardizing Image Management at a Global Pharmaceutical Company**

### ***Solution Overview***

A global pharmaceutical company based in the United States selected SCORE as its clinical development solution for management of imaging data in conjunction with managing data collection at its many clinical trial sites and imaging core labs. With its primary goal of managing and accelerating drug development, the company was looking for a common solution that could be provided to all trial sites to allow for standardized collection, storage, and access to imaging data collected during company-sponsored clinical trials. Recognizing that clinical trial imaging makes up only a very small portion of site activities, the company hoped that the SCORE solution would be broadly adopted by the trial site and available to all current and future clinical trial efforts (both the company's own future efforts and clinical trials performed by other companies). The system is designed to be "agnostic and scalable" so that it could be used in nonclinical imaging studies or clinical trials where the outcome measure can be modeled as a nonradiological image, such as an ECG, a molecular profile, etc.

In looking to establish a broad precompetitive image management platform, the company is seeking to achieve a number of goals. For example, the SCORE solution over time will eliminate the need to produce and ship DVDs of imaging data collected at investigator sites,

then analyzed by CROs, and included in new drug submissions by the pharma sponsor. By doing so, quality issues can be addressed promptly and data "missingness" detected in hours instead of weeks. With the increasing need to submit imaging data in support of drug submissions, the SCORE platform, in conjunction with standardized storage formatting, is expected to directly streamline collection and access to trial imaging data, enabling more efficient analysis of multisite imaging data. Over the long term, the potential for faster retrospective analysis of imaging data becomes possible, based on ready access to archived study data collected using the platform.

### ***Product Deployment***

While still in pilot evaluation, SCORE has been implemented at several clinical trial imaging sites and two contract research organizations that specialize in imaging. In advancing from an initial rollout in January 2007 to updated medical imaging management versions in August 2008 and December 2008, the company has worked closely with IBM to improve application functionality and workflows and is actively using SCORE in some of its current clinical trial efforts. As the initial pilot effort to systematically manage biomarkers within the organization, successful management of imaging data by SCORE could lead to expanded use with other biomarker data within the company.

As with most, if not all, pilot studies, complications arose with the implementation of SCORE. In this case, significant project complexity was uncovered that has limited acceptance among some users to date. Since the source of some issues was the company's own internal IT infrastructure and not SCORE itself, the organization as a whole remains committed to SCORE. Although it is too late in the development process to change approaches, SCORE's recently added application-on-demand hosted solution option has been recognized as an alternative that could have averted many of the issues that have been encountered.

### ***The Selection Process***

After a comprehensive effort to identify program requirements, a sophisticated internal scorecard was developed as the basis for comparative analysis of prospective product solutions. Requests for written proposals were solicited using this scorecard to evaluate potential solutions. Several product finalists were identified and subsequently evaluated. As a result, IBM's SCORE emerged as the highest rated solution. As the pilot evaluation continues, SCORE appears to be a promising solution capable of achieving all of the company's image management goals. At the culmination of successful pilot efforts, the company is committed to providing the SCORE solution to all of its clinical trial participants with the goal of making SCORE a key part of the de facto standard platform for clinical trial image data management.

## **Benefits of the SCORE Solution for Clinical Trial Image Management**

The following are some of the functional benefits the company expects to realize through the use of SCORE:

- Provide plug-and-play capability with other image management components that become standards (For example, the Medical Imaging Resource Center of the Radiological Society of North America is developing a tool to automatically deidentify digital images from commercial picture archiving and communication systems [PACS].)
- Track and trace all clinical trial imaging documents and data, which enables faster analysis and assembly of results and also allows faster analysis of larger volumes of historical data, if required
- Provide trial sites with an extensible tool for image management that is applicable to needs well beyond clinical imaging trial applications (e.g., proteomics studies).
- Standardize image data management and storage over multiple clinical trial sites to reduce the administrative overhead of managing the data
- Provide researchers with easy and secure access to completed study data for future retrospective analyses, as new analysis algorithms become available
- Effortlessly collect imaging data from and monitor clinical trial progress of a wide range of participants without placing additional IT management burdens on those participants (Note: It is also possible for outside experts to review images from their offices, saving both travel time and expenses.)
- Quickly implement (with simple modifications) significant off-the-shelf functionality at new clinical trial sites, thus reducing the time and cost of acquiring clinical trial data

## **FUTURE OUTLOOK**

IBM's SCORE solution for pharmaceutical industry aspires to provide a simple means to fully manage and control document-based information in this tightly regulated environment. Its configure-to-fit implementation design reduces the need for custom coding, speeds implementation time, and lowers the cost of document management, all while simultaneously improving overall data quality. Available as either a standalone solution or a hosted service offering, SCORE is designed specifically to bring control and improved operational efficiency to a wide variety of life science companies virtually out of the box.

Health Industry Insights believes that the market is primed for the features and functionality detailed in this white paper and available in SCORE. To ensure the continued adoption of SCORE, IBM continues to make significant investments in product development and services that support key areas of deployment, such as document migration and data integration with legacy and homegrown systems.

This ensures that the benefits available in SCORE are relevant to life science as well as other companies operating in highly regulated environments that lack an existing document management solution. IBM has addressed the market for companies looking to invest in information management solutions that not only provide the state-of-the-art functionality found in SCORE but also extend that functionality to existing legacy document management systems.

## LEARN MORE

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### Definitions

- **21 CFR 11:** Title 21 of the FDA's Code of Federal Regulations, Part 11; the section of CFR that contains regulations pertaining to the FDA and specifying regulations pertaining to the electronic storage and transmission of data
- **CDISC:** Clinical Data Interchange Standards Consortium, the standards organization formed from industry institutions, vendors, and other interested parties for the purpose of developing data interchange standards to support the clinical trial industry (Standards have been established for the storage and exchange of data relating to the content of case report forms, operations, regulatory submissions and analysis data, the representation of study protocols, laboratory data, and nonclinical information associated with clinical trials.)
- **CRO:** Contract research organization, a third party that conducts outsourced research, mainly drug development and clinical trials, on behalf of trial sponsors, including pharma and biotech companies
- **CTD:** Common technical document, the internationally agreed-upon format for the technical component of a drug application, as determined by the ICH (Although the content of the technical document is still country specific, this common format has led to significant improvements in the process for multicountry drug approval.)
- **eANDA:** Electronic abbreviated new drug application, the electronic format for a new generic drug application

- **eCTD:** Electronic common technical document, the second-generation electronic format for submission of the CTD (The eCTD has five modules that make up a portion of the 20–22 sections of the eNDA. Its format is that of CDs containing PDFs with an XML-based table of contents that is used to organize and link the document's many sections. The eCTD's XML-based organization enables the use of rolling dossiers for regulatory submissions.)
- **EDC:** Electronic data capture, a method for using computers and other devices to electronically capture and store data generated during the conduction of clinical trials
- **eNDA:** Electronic new drug application, an electronic-format new drug application
- **FDA:** Food and Drug Administration, the government agency that oversees the regulation of prescription drugs, biologicals, and devices marketed in the United States
- **GCP:** Good clinical practice, the FDA-defined and -enforced process for conducting clinical trials
- **HHS:** Department of Health and Human Services, a cabinet-level federal department in the United States responsible for the FDA, Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), and other health-related government agencies
- **HIPAA:** Health Insurance Portability and Accountability Act, which provides for transfer of health insurance between periods of employment, extension of coverage during gaps of employment, electronic data interchange standards, and security of personal health data
- **HL7:** Health Level 7, a nonprofit ANSI-accredited standards development organization dedicated to creating standards for the exchange, management, and integration of data that supports patient care services in the healthcare industry
- **ICH:** International Conference on Harmonization, the international organization governed by representatives from pharma in the three main drug-consuming regions — the United States, Japan, and the European Union — that sets international requirements for the CTD, preclinical, and clinical trial processes (These international requirements may or may not be adopted by individual countries following publication by the ICH.)
- **SDTM:** Study Data Tabulation Model, the data standard for the preparation and submission of clinical study results to the FDA

- **SOP:** Standard operating procedure, a business or manufacturing process that is closely documented and repeated according to the standards laid out in the documentation in a regulated environment
- **Sponsors/trial sponsors:** The pharmaceutical, biotech, and medical device companies that are the source of financing for clinical trials, whether they conduct them by contracting with individual investigators or by outsourcing these responsibilities to a CRO

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### **Related Research**

- *The Clinical Development Archipelago and the Rise of an Information Economy* (Health Industry Insights #HI210484, February 2008)
- *Technology Accelerates Drug Development — or Does It?* (Health Industry Insights #HI205975, March 2007)
- *IBM's SCORE Solution: A Rapid Implementation for Document Management* (Life Science Insights #LSI1005, March 2005)
- *Worldwide Regulatory Compliance Issues in Life Science* (IDC #32690, December 2004)

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