

Healthcare & Life Sciences

Vital Signs

Strategic Insights for Healthcare Executives

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This Week's Industry Focus: Healthcare & Life Sciences IT

Industry Initiative to Reduce Complexity and Streamline Life Sciences Information Technology

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In a report issued in March 2004, the FDA "describes the urgent need to modernize the medical product development process - the Critical Path - to make product development more predictable and less costly...In collaboration with industry stakeholders, the FDA has taken the initiative to "coordinate, develop and/or disseminate solutions to scientific hurdles that are impairing the efficiency of product development industry-wide". The focus is on updating the "tools currently used to assess the safety and efficacy of new medical products" in order to accelerate the time that a medicinal compound reaches the patient, from the moment it is first conceived of to the time it reaches clinical testing.¹



LSIT CREATED TO EVALUATE AND ADVANCE GOOD INFORMATICS PRACTICES

Born from the same dissatisfaction with ineffectual and inefficient information technology solutions and processes in the life sciences, industry participants came together that same year (2004) to form a collaborative, industry-driven non-profit. Life Sciences Information Technology (LSIT) Global Institute was created to meet the growing need for an impartial third party to take the 30,000-foot view, LSIT has been established to pinpoint the current IT needs in the industry and to shed light on the best IT practices to meet those needs. Its unique position within the industry allows LSIT to not only evaluate existing practices but to take an instrumental role in guiding the use of IT in the life sciences of the future.

Life Science Drug Development Continuum

The adoption of information technology among pharma and biotech companies continues to increase steadily along all phases of the drug development continuum, shown in Exhibit I.

*"Recent basic science achievements promise significant payoffs in human health, but these potential benefits are threatened by low productivity - measured by the high costs and high risks of failure...often, developers are forced to rely on the tools of the last century to evaluate this century's advances."
FDA March 2004 report, Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products*

¹ The Critical Path to New Medical Products, Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products, March 2004, www.FDA.gov

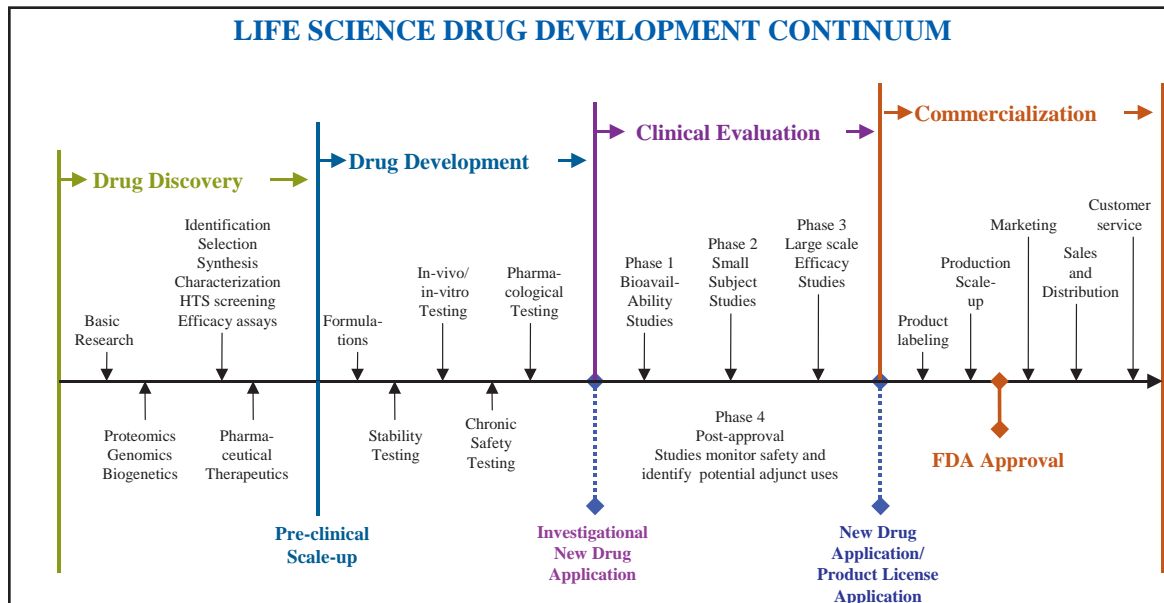


Exhibit I

COST OF CLINICAL EVALUATION AND RESEARCH SOARS

In 1993, the cost to bring one therapeutic drug to market averaged \$359 million, by 2005; the average cost had risen to almost \$1 billion, almost tripling in cost in just over a decade.

Reduced Tolerance for Risk Contributes to Time and Testing

The rapid increase in cost can be associated with a reduced tolerance for risk among industry participants as well as additional regulatory requirements that have been implemented in the past decade. The myriad possibility of drug interactions among an increasing number of drugs now on the market, require significantly greater levels of proof of safety and efficacy of drug candidates among test subjects. While drug interaction is important, the real possibility of adverse litigation has become a major impetus in the increase in additional testing being performed to identify as many side effects as possible prior to, and following, approval.

Complexity of Managing Multi-site Clinical Trials Contribute to Rising Costs

Pharma and biotech companies are truly global companies with research, drug development and clinical testing occurring in multiple sites across many countries. With most testing facilities still using proprietary standards, digital data exchange can be complex and cumbersome. Custom integration and format conversion costs are contributing to higher administrative and operational costs.

Explosion of Genomic and Proteomic Data Requires Sophisticated Computing Systems Contributing to Increased Cost at the Drug Discovery and Development Phases

The 2003 completion of the human genome-sequencing project created an explosion in knowledge about the basic building blocks of life and catapulted molecular medicine to the forefront of medical research. Together, high-speed gene sequencers, high resolution mass

- It takes an average of 10 to 12 years for a therapeutic drug to reach commercial status
- R&D costs to bring one therapeutic agent to market averaged between \$0.8 to \$1 billion in 2005
- Roughly 1 out of every 1,000 compounds evaluated will make it to clinical testing
- Out of 5 compounds tested clinically often only 1 or 2 will receive FDA approval

spectrometry and sophisticated computing systems technologies can generate over a peta byte (a quadrillion bytes) of data, making it possible for researchers to process thousands of genes and proteins in a day.

Whole new fields have emerged to discover, explore, characterize and synthesize protein and genetic information and apply that knowledge to practical solutions. The real challenge to the medical research community will be decoding and interpreting how this knowledge can be converted into effective diagnostic and therapeutic agents.

BUSINESS STRATEGIES OFTEN AT ODDS WITH COHESIVE, COMPLIANT IT SOLUTIONS

Drug discovery and life science research has been in a state of flux over the past decade...by the early 2000s, massive mergers and acquisitions among participants in the pharmaceutical industry had resulted in 90 percent fewer pharmaceutical companies than there were during the 1980s. In addition to gaining economies of scale in R&D, the merger and acquisition activities resulted in an entire over-haul of the business model that large pharmaceutical companies had previously operated on.²

Although rapidly rising R&D costs have led many pharmaceutical and biotech companies to implement a number of cost saving measures, these measures have often been implemented at the expense of a cohesive, compliant data storage, retrieval and transfer solution.

- Acquisition and collaboration to boost potential drug candidate pipeline
- Increased use of outsourcing
- Implementation of compatible systems ultimately driven by need to reduce costs
- Expanding the uses of already commercially available drugs
- Electronic drug applications submissions
- Standardizing and integrating both internal and external IT systems

Acquisitions of smaller, innovative R&D-based start-ups gave existing companies a boost to the drug candidate pipeline. The difficulty with acquisition strategies has proven to be the need to integrate or replace the non-interoperable information systems that "come with" the acquisition. Separate infrastructures for the acquiring and acquired company require separate maintenance and administration and miss potential efficiencies resulting from a merger. These issues are often exacerbated when merging companies originate from different corporate cultures, countries or continents.

An increased use of outsourcing by the large pharma companies can reduce upfront costs by freeing up internal R&D resources but often increases administrative efforts and complexity putting significant demands for assistance on the Information Systems group.

The FDA approval of a process for receiving new drug application submissions electronically has contributed to the growing electronic capture and organization of information along the entire drug development continuum. To submit new drug applications to the FDA in electronic format offers the

*The challenge to researchers and scientists now is to determine how to read the contents of all these pages and then understand how the parts work together and to discover the genetic basis for health and the pathology of human disease ...Clinical opportunities for gene-based pre-symptomatic prediction of illness and adverse drug response are emerging at a rapid pace, and the therapeutic promise of genomics has ushered in an exciting phase of expansion and exploration in the commercial sector.
Source: National Human Genome Research Institute*

*"The explosion in the number of small to moderate sized biotech companies has been enormous in the past decade and fills a need that the larger pharmaceutical companies have difficulty in succeeding at."
Paul Laskin, Western Regional Informatics Director for Strategy and Portfolio Management at Pfizer*

² Excerpted from Frost & Sullivan's Strategic Analysis of World IT Spending in the Life Sciences Industry Study number B658-55 published January 2006.

promise of significant savings but it has not yet yielded these results for many pharma and biotech companies who still use an internal paper-based process.

*"With globalization taking place within pharma, non-interoperable systems will become an even bigger issue with outsourcing being one of the activities becoming more prevalent. Outsourcing adds another set of entities and relationships that need to be incorporated into the production and consumption of information across the life cycle of drug development. This issue is just going to get larger. There will be a strategic advantage to companies that are able to effectively resolve the non-interoperability issues."
Beth Kennedy, 25 years in the industry applying technology to solve life science problems.*

Although many industry participants are not in agreement with the following assessment, one document management solutions provider estimates that a significant percentage of the content of drug development documentation submissions sent to the regulatory affairs department of the research sponsor is rejected the first time due to incorrect formatting or missing information.

Unlike paper submissions contained in one very large document (50,000 to 70,000 pages), electronic submissions can be sent in a little at a time as the data are compiled. . Digitization and standardization of internal processes need to occur before electronic FDA submissions can provide significant cost savings. Additionally, a number of companies are exploring the value of continuous-submissions-over-time as a means of receiving faster FDA approval and gaining a possible commercial advantage of going to market faster.

However, many of the foreseen benefits of sending segmented submissions have yet to materialize as pharma and biotech companies scramble to systematize and integrate both internal and external IT systems. Individual departmental solutions, which traditionally have been siloed, must now produce data in new, electronically compatible formats, not only within an organization but also within its greater research sphere, encompassing its contract research organizations, testing labs, clinical evaluations, product labeling, scale-up and final manufacturing.

Ultimately the need to reduce costs will drive large and small organizations to harmonize their information systems. While it is true that data can be shared between departments via fax, e-mail, softcopy or hardcopy reports, the need for interoperability between information management systems is becoming critical.

Depending upon the scope (e.g. number of users, number of impacted sites, regulatory compliance), replacing stand-alone systems can run in the millions of dollars. A major project (a query platform for sharing all research data) recently completed at a global pharmaceutical company included in its scope over 2000 named users and a number of sites, but did not have regulatory concerns. Nonetheless, the total cost of the four and a half year project was over \$20 million. Conversely, a similar project with which I am familiar will focus specifically on one site and cost less than \$400,000. In both cases, the nature of the project is to replace multiple, disparate systems with an integrated one. Of course, financial cost is only one aspect of such maintenance; scientists spend an inordinate amount of time converting and distributing data in a way that will fit existing systems. Moreover, these rigid systems lead to noncompliance in data storage, retrieval, and ultimately sacrifice considerable investment and power in analytical tools for simple, yet flexible, decision engines. In total, the cost of multiple siloed systems may in fact be many times greater than maintenance alone, particularly when considering the sub-optimal decision-making and lack of learning that such environments promote.

Brian Ellerman, Scientific Computing & Information Program Manager
Sanofi-Aventis

*"Different cultural approaches to systems, driven by the different silos of the organization, are the most difficult aspects of creating integrated systems in the life sciences. Perhaps more importantly, due to the siloed nature of business processes and management of the business, IT is also, by design, siloed. This leads to optimization of systems in that vertical silo, but does not provide horizontal optimization."
Geoff Odell, CIO, Genomics Institute of the Novartis Research Foundation*

LSIT ESTABLISHES SYSTEMATIC APPROACH TO INDUSTRY CHALLENGES

Taking its inspiration from the successful regulatory submission reforms initiated by the International Conference on Harmonisation (ICH), LSIT has taken as its mission the task of evaluating the needs and the best IT practices, across the drug development continuum, wherever they may be located, whether in the Americas, Europe, Asia or elsewhere.³

In collaboration with industry participants, associations and regional regulatory bodies, LSIT outlined twelve areas for IT review and evaluation of good informatics practices (GIP). Listed in the order of application along the drug development continuum and approval process, they are:

1. **Policies** - roles, responsibilities, compliance, quality, audits, lifecycle management
2. **Process** - requirements, service delivery, help desk, contracting, disaster recovery
3. **Architecture** - network and infrastructure, business applications, data management
4. **Infrastructure** - desktop, mainframe, server, network, telecommunications, storage
5. **Application** - planning, development, testing, deployment, maintenance, integration
6. **Data** - data and metadata management, standards integration, storage and interchange
7. **Validation** - application, database, security and integration testing, risk management
8. **Safety and Security** - data security, access controls, network security, alerts, biometrics
9. **Practice** - measurement, analysis, integration, resolution techniques and standards
10. **Projects** - scoping, staffing, managing, monitoring, reporting and closing projects
11. **Electronic Submission/Approval** - labeling, clinical documentation, sales and marketing
12. **Computerized Systems** - automated laboratory, manufacturing and distribution systems



LSIT reference body of 5 key communities coming together for building trusted systems in IT, GIP.

In order to initially prioritize research efforts, LSIT conducted an online survey between April and June 2005. Over two hundred senior life sciences professionals, from around the globe, responded to the survey. Not only did the survey bear out the dissatisfaction by industry participants with the current lack of a centralized reference body to define best practices in the industry, it also validated the desire by industry participants to identify and implement consistent IT practices globally as a means to reduce costs, accelerate regulatory approval and speed time to market.

In order of priority, the top four critical areas identified from the survey as the areas of greatest need are:

1. **IT security** (ranked as one of the most critical areas in need of attention by 94 percent of all respondents)
2. **Data management** (ranked as one of the most critical areas in need of attention by 94 percent of all respondents)
3. **Testing and validation** (ranked as one of the most critical areas in need of attention by 94 percent of all respondents)
4. **IT infrastructure operations** (ranked as one of the most critical areas in need of attention by 92 percent of all respondents)

In January 2006, LSIT established multi-pronged development tracks and working groups to research, analyze, and recommend the best practices related to each of the areas of need identified and prioritized in the survey. Working groups, composed of end users and IT

³The International Conference on Harmonisation (ICH) was established in 1990 with the express purpose of creating and standardizing regulatory submissions across the United States, Europe and Japan. Working with the FDA in the U.S., the European Medicines Agency (EMA) of the European Commission in Europe, the Ministry of Health, Labor and Welfare in Japan, the World Health Organization and each country's respective pharmaceutical associations, the ICH created a single, harmonized drug submission document, which was finalized and presented to the industry in November 2000. Its development of a Common Technical Document (CTD) for new drug submission, which provides industry-endorsed standards for proving medicinal efficacy and patient safety, was unprecedented. For the first time, pharmaceutical and biotechnology companies could conduct standardized in-vivo/in-vitro tests and clinical evaluations and follow the same application format for submission to the various regulatory bodies responsible for governmental approval within the U.S., Europe and Japan, rather than be forced to create and submit separate application documents. The CTD enabled medicinal therapeutic companies to reduce the time and cost associated with the drug evaluation and submission process. The recently accepted electronic CTD (eCTD) initiative was a natural extension of ICH's goal to "eliminate unnecessary delays in the global development and availability of new medicines".

professionals from the industry, will perform the following analyses and arrive at a suggested GIP over the course of 28 months. Each working group will do the following:

1. Study the needs of the life sciences industry with regard to the identified practice areas.
2. Select or develop practices that meet those needs and are tailored specifically to life science requirements.
3. Publish, in a public forum, the practices that have been identified for review by the larger life sciences community.

LSIT LEVELS THE REGULATORY, TECHNICAL AND TECHNOLOGY MANAGEMENT PLAYING FIELDS

LSIT's creation of a GIP Guidance Document will clarify standards, highlight existing best practices and indicate future functions/features necessary to provide and meet regulatory compliance, technical, and management needs. The GIP Guidance Document will give vendors and end users a playbook or map that streamlines and highlights the best practices available while identifying the potential standards and compliance issues involved.

The GIP Guidance Document presents Life Science Companies (pharmaceutical, biotech, device) hardware, software and service providers with a reference guide to solve the complex environment of IT standards, processes and issues that life science companies face.

- **Validation time and cost reduced, sometimes significantly.** Companies often go into 'overkill' repeating system validation processes, often more than once to be doubly sure, that systems are compliant and secure. The GIP guidance document will provide both the FDA and the company with a trusted, validated process ensuring a compliant solution while providing significant reductions in required validations.

- **More time and resources available.** The GIP guidance document will address in a single source, basic Security approaches, typical vulnerabilities, and specific good practices, providing assurance to the IT team and to regulators that basic practices are in place. As a result, pharma and biotech companies will have more time and resources available for addressing strategic or urgent priorities and new defenses.

- **Strengthens purchasing position.** The GIP guidance document can also assist in managing vendors and in acquiring new technology. Both end users and IT vendors will have a trusted, impartial, third-party source indicating the level of operational features and functions, systems integration, regulatory and validation requirements for vendors as set forth in the guidance document. Settling basic educational, compliance and interoperability needs allows end users to negotiate for greater functionalities, more targeted solutions, more efficient installations and to obtain contemporary IT solutions more cost effectively.

LSIT's playbook, the GIP Guidance Document enables life sciences companies to focus on driving compounds and devices from discovery to commercialization faster.

EVOLUTION OF GOOD INFORMATICS PRACTICES OVER TIME TO EMBODY ADVANCES MADE IN LIFE SCIENCES INFORMATION TECHNOLOGY

The task of each of the LSIT working groups will be to define the particular needs of the industry with respect to a specific topic, such as IT security. Identification and analysis of best practices will be conducted by examining existing operating conditions as well as future needs. As a result, the proposed best practice solutions will represent a continuum of solutions. Not only will the proposals identify the elements needed in the existing best of class solution(s) they will also identify elements necessary to succeed in next generation technologies.

LSIT Paves the Way for Life Sciences Information Technologies of the Future

Drug development is at a crucial turning point. Pharma and biotechnology companies can no longer gain competitive advantages using

yesterday's information technologies. Technology advances including high-speed sequencers, laboratory and clinical information management systems, local-area- and wide-area-networks, portable devices, improved application functions, faster processors, new content addressed and virtual storage, digitization, IP convergence, and rapid data compression, multi- and parallel-processing expansion technologies and contextual search create significant technology challenges for life sciences IT.

As they analyze current practices being used to meet a specific application, system or process, the working groups will also be addressing the impact that over arching industry and technology mega-trends may have on the future requirements for a given IT solution. Examples of some of trends that will impact future life sciences IT solution sets include:

1. The adoption of model-driven platforms versus individual instrument interface-driven systems
2. The move from discrete informational systems to networked-web-based solutions
3. The incorporation of industry specific meta-data taxonomies, such as the Semantic Web, to unify data distribution, storage and retrieval

Other trends shaping the creation and use of IT solutions within life sciences and impacting IT-based best practices are discussed below.

Ability to manage, mine and leverage data - the information explosion has made the ability to manage, mine and leverage data a critical element in accelerating drug development in the future. The successful sequencing of the human genome, made possible through the development of advanced high-speed DNA sequencers and information management systems, has created an information explosion. A massive amount of data are now generated daily. Whereas labs used to conduct one or two gene sequences per week they can now process up to 30,000 genes, in the same time frame, using high-throughput instrumentation.

The **future IT challenge** is not only to create a secure, regulatory compliant laboratory information management systems (LIMS) capable of handling this informational load, but also to create taxonomies and pathways that can provide an interactive communication layer. In the future, analysis provided by LIMS could in fact self-populate standardized drug development forms that then create a digital report for attachment to electronic regulatory submissions. In addition, the integrated LIMS would automatically self-populate a number of pertinent drug and biological databases with the results and analysis, providing access about critical findings to researchers throughout an organization or a research specialty.

Accessibility to the right information - accessibility to the right information at the right time can accelerate and compress the discovery, pre-clinical and clinical evaluation phases of therapeutic development. The way data are created, stored, retrieved and managed within a company or within a research community must become more flexible and adaptable for ease of access across multiple databases, both within a company and within a research specialty.

The following diagram (Exhibit 2) illustrates the web of biological databases from which one Life Science organization wants to be able to mine data from. The **challenge to the IT industry** is creating a solution that allows secure data access, data mining and integration capabilities among diverse, but pertinent databases, both internal and external to a company.

"Data management remains the single most pressing problem in our industry. Information scientists struggle daily with making sense of the overwhelming masses of data produced during the drug development process. Entire organizations are reshaping to include data management departments or groups. This in many ways mirrors the origins of information system departments, with the centralization of user experts into formal groups followed closely by the emergence of process standards."
Brian Ellerman, Scientific Computing & Information Program Manager

"Non-interoperability between systems is really about the inability to share the 'right' information. The real issue is accessibility to the right information at the right time within the context of the scientific question being asked."
Beth Kennedy, LSIT working group member

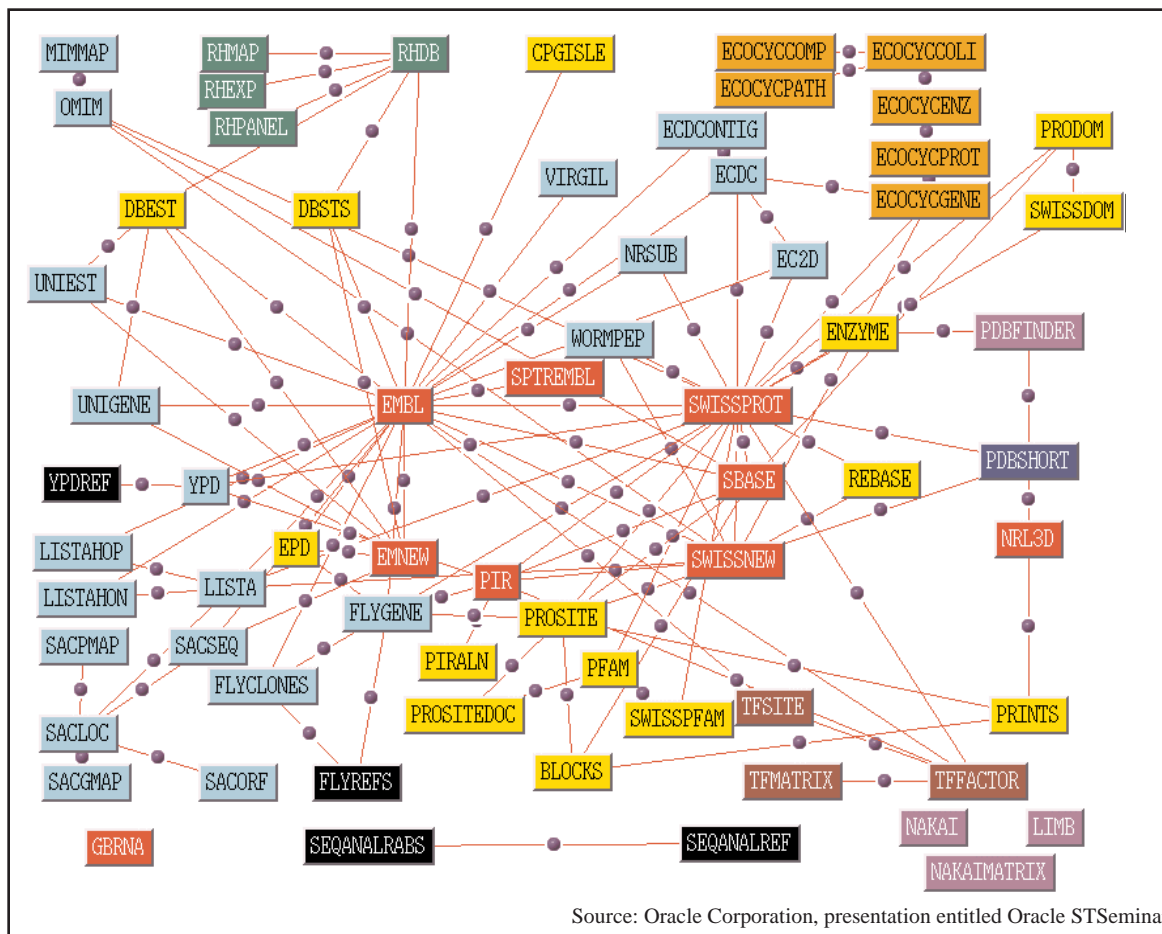


Exhibit 2

Accessibility is not just about integrated systems - the various stages of the drug development continuum create and use information differently. The questions of interoperability and accessibility ultimately lead to human motivation and behavior. Does an IT solution also address ways to help different departments within a pharmaceutical or biotech company interact more easily? How can the Life Sciences industry and IT vendors work together to create more universally functional solutions, that meet departmental needs, but take a comprehensive approach? Beth Kennedy, a LSIT working group member, summed up the issues as follows:

A pharmlarge biotech is a fabric made up of many different organizations and functions that have different motivations. A good example is the profile of a highly regulated function (clinical) in a pharma and the profile of its IT staff/systems vs. a non-regulated function (discovery) and the profile of its IT staff/systems. They have different standards, protocols, methodologies, software lifecycle process and staff skill set.

Purchasing decisions within Pharma continue to be made at a variety of levels. A Pharma CIO has very different customers with conflicting needs. Decision-making has often depended upon the department. It is much easier to make a decision in a silo, where an individual has complete control, then to get agreement across departments. There's an increased need to look at information in a holistic manner across several disciplines

"Tell me everything about this target"

"Tell me everything about this compound"

Producers (biologists) and consumers (chemists) of the information have different motivations. How do you provide incentive to a biologist to capture information in a way that makes it easier for the consumer (chemist)? The benefit is that the information is more accessible to others 'upstream'...

Creating integrated systems is all about consensus from a 'team'. New types and sources of data are always becoming available. Creating a holistic solution can help resolve redundant and inconsistent data issues and provide agreement on what is the 'golden source' for information.

Flexibility and ease of use needed when incorporating interoperability - the need for data sharing prompts interoperability. Usage may suffer though if the solution is inflexible or too difficult to use. Flexibility must be made easy to use; otherwise it takes the end user away from their real task. Brian Ellerman, Scientific Computing & Information Program Manager at Sanofi-Aventis, and a LSIT working group member, summed up the issues as follows:

Excluding the creation and use of sophisticated Excel macros, which can qualify as a discrete system and very often are the "glue" that hold departments and local business units together, considerable effort does go into the development of customized, interoperable systems, and this is most notable where information must be shared among sites or global departments.

One of the most difficult aspects of creating integrated systems in a life science environment is the need for flexibility in information systems, particularly among discovery units. Unfortunately, information systems' roots can be traced to standardized, repetitive processes (such as accounting) that could be easily modeled in software and then supported through iterative development. Thus a key weakness of many commercial off-the-shelf products is the assumption - intentional or otherwise - that business processes can either be standardized or reworked in order to fit the software. In life sciences, however, much of the innovation (and challenge for scientists) comes from straying from the typical paths. Ironically, the most flexible systems - and those that would appear on paper at least to fulfill the most requirements - are almost always also the most complex, and therefore utilization suffers greatly. The most flexible piece of software is of little value if no one is able to use it!

Another challenge is data format incompatibilities. Tying multiple applications together requires that either the user or the software be able to store data in a format that the next application in the chain can use. More often than not, the burden is placed on the scientist to know and understand the myriad data formats, and to spend precious time away from the bench performing such mundane and easily automated tasks.

WHY LSIT AND WHY NOW?

Why does the industry need an organization like LSIT and why now? LSIT was formed as a direct result of the needs expressed by industry participants. As a result, LSIT placed industry participants at the core of its organization to create the specific GIP solutions most needed by the industry.

Using a question and answer format, industry participants, who are also LSIT working group members, address why the industry needs LSIT.

Q: How will the creation of good informatics practices help build solutions and support recommended standards?

A: Brian Ellerman, Scientific Computing & Information Program Manager at Sanofi-Aventis, and a LSIT working group member. XML or SOA standards do help to solve certain problems, but are not panaceas. The Semantic Web (OWL/SWRL/RDF/SPARQL) seems to hold the most

- *Nine out of ten survey respondents felt that consistent IT practices would accelerate regulatory approval**

- *Nine out of ten survey respondents agreed there was a critical need for a global, centralized reference base for IT professionals in the life sciences**

- *77 percent of the survey respondents felt there is a definitive need for an organization like LSIT to develop industry-specific best practices**

- *76 percent of the survey respondents believed that open, freely available Good Informatics Practices (GIP) guidelines would significantly improve business processes and regulatory compliance**

* Critical Need for IT Guidelines in Life and Health Industry According to New International Survey of Top Industry Execs, June 29, 2005, LSIT Global Institute, www.lsit.org

promise, though vendors are only now releasing products based on these standards. With time, it is quite possible that solution providers will be able to develop highly collaborative, integrated, and scalable solutions by following semantic Web standards. Even so, it will still be incumbent upon the data consumers within the industry to develop and follow better data practices, particularly because no technology - no matter how sound or sophisticated - can save people from themselves if they are not willing to be saved; they must be committed to spending time curating their data and developing new and better ways to organize it. In many ways, it is much like owning a home: one can purchase a home and never care for it and, with time, it will fall into ruin. Or, with proper maintenance, it can last a lifetime or even longer.

A: Beth Kennedy, Life Sciences IT Consultant, and a LSIT working group member. Like anything in life this is a complex issue whose solution is a combination of approaches. Standards are key, but another area to understand is where integration needs to take place. It really is at the consumer-level. Therefore looking at tools, protocols and standards around the presentation of information within the context of the question being asked is important. Pharma will always produce large amounts of information (data, images, text) on a variety of technologies. The creation of best industry practices would be instrumental in helping the life sciences industry create an understanding and agreement on difficult solutions such as:

- Real-time integration via presentation layer
- On demand access to data
- Allow multiple multiply entry points for consumers of data
- Tools that make data independent of its source (hardware, software); using services technologies

A: Paul Laskin, Western Regional Informatics Director for Strategy and Portfolio Management at Pfizer, and a LSIT working group member. We struggle with two thoughts here; Standards and Guidelines. The FDA frequently publishes guidelines. Companies attempt to interpret those guidelines and implement their own in-house developed "standard" interpretation. While guidelines set the framework within which solutions are deployed and are critical to establishing the boundaries for acceptable implementation, guidelines are open to interpretation; an interpretation that is dependent upon an organization's appetite for risk. Having industry best practices for software solutions could reduce the variability in interpretation and provide a more robust implementation solution set.

A: Bill Branan, IT Management Consultant and LSIT GIP Guidance Document leader. The question this brings up is what are the most important universal design objectives for software? Scalability is important...integration is important in horizontally integrated industries (pharma is getting there), and collaboration is important to large businesses that have complex product development processes (pharma qualifies). Standardization is clearly an aid to, if not a prerequisite for meeting these objectives. However, standards that are not flexible in implementation, or that raise implementation costs significantly, are not useful because the implementation effort can cancel out the gains made from integration, collaboration and scalability. Where standards are truly useful is in allowing software companies and in-house developers to create lower-cost tools and services that can be easily incorporated into an information systems architecture, or in creating system interoperability that streamlines and integrates processes. Used in this way, standards help achieve the selected design objectives.

Q: What does it mean to someone in the industry to have a reference body evaluate, test, rank and create an approval of the best practices being used in the industry?

A: Brian Ellerman, Scientific Computing & Information Program Manager at Sanofi-Aventis, a LSIT working group member. Using the home ownership analogy, a compilation of best practices is like a How-To book you get from a home improvement store. Sometimes you may choose to perform the work yourself, other times you may want to hire an expert. But at least by having such a resource, you can make

an informed decision about the project and determine an approach. Further, it could help companies in evaluating solution providers, much like SEI's CMM does for software development; it is not the only means for evaluating, but it at least provides a baseline from which to start. As for product development, it is far more difficult to say. A comprehensive, end-to-end compilation is ambitious to say the least. But life sciences, as we have already observed, is an ever-changing field, and such a source might quickly become outdated or, worse still, inapplicable to some of the more dynamic areas of drug development. Thus, any such endeavor must be accompanied by a dedicated and motivated group of stakeholders as well as an effective and well thought out plan for the compilation's upkeep. I cannot speak to the overall effect on time to market, but certainly if the information systems that support the business can be better integrated (and ostensibly developed faster), it seems quite plausible that the pipeline would benefit significantly through better decision-making, better application integration, less time spent on inefficient data-related tasks, and higher overall data quality.

A: Paul Laskin, Western Regional Informatics Director for Strategy and Portfolio Management at Pfizer, a LSIT working group member. The key is to have solution provider, user community and regulatory body acceptance on the value of best IT practices. The challenge will be to maintain these best practices in a very dynamic IT environment. If these best IT practices existed, (www.itil.co.uk has many of these already) then putting in place best practices becomes infinitely simpler.

A: Bill Branan, IT Management Consultant and LSIT GIP Guidance Document leader. If you mean would it help if you had best practice guidance that was targeted to the life sciences industry and focused on compliance with FDA's risk-based regulatory guidance processes, clearly, streamlining IT validation gets products to market faster.

*"Currently the head of each siloed technology organization within a pharmaceutical or biotech company is tasked with keeping track of all of the technology changes, IT development and compliance. Currently software integrators play a part in this, but ultimate accountability is still within the company."
Geoff Odell, CIO, Genomics Institute of the Novartis Research Foundation*

INFLUENCE THE FUTURE

Although a relatively young organization, LSIT already has an impressive industry representation among its various working groups and its board. Established by leaders in the industry to simplify and streamline life sciences information technology, LSIT provides the forum for information officers, professional end users and vendors to come together to influence and create the vision of the future.

LSIT's universal appeal carries weight in the industry. Composed of a host of well known industry contributors, LSIT's most recent workshop brought together more than 30 dedicated participants from pharma/biotech, systems solution providers, as well as leading industry reference bodies such as GaMP and CDISC. In addition, its systematic, well thought out approach to the industry's IT challenges and its potential to create a lasting impact in the industry continues to bring new members aboard, with the FDA being one of its most recent collaborators.

Opportunities to influence the future of an industry, an industry intrinsically intertwined with the health and well being of individuals around the globe, must be judged in relation to their potential for change. Created by industry leaders to solve difficult questions, LSIT is gaining momentum and is on a trajectory of change. Poised to dramatically streamline life sciences informatics practices, LSIT offers industry participants a forum to influence the direction of the future.

For further information about LSIT please visit www.LSIT.org or contact Anette Asher, Executive Director, via e-mail at anette@lsit.org or by phone at +1.858.759.4750.

Company Spotlight: Teranode Corporation

Company Profile

Founded in 2002,
Teranode Corporation



made its successful debut into the market with the introduction of an innovative, laboratory information management system (LIMS). Teranode's laboratory informatics software dramatically shortens deployment cycles, integrates multiple instruments, automates experiment designs across a cohesive platform, streamlines project workflow and reporting and manages the data in a unified database.

Strength of its Management Team

Headquartered in Seattle, Washington, Teranode is a privately funded and operated company. Teranode is the brainchild of a local team of industrial and academic scientists and technologists. With more than a century of combined experience in the industry, Teranode's executive management team is a canvas of talent, synergistically combining strong cellular and computer engineering backgrounds. Neil Fanger, PhD and Zheng Li, PhD provide the scientific backbone while Eric K. Neumann, PhD and Murthy Srinivas architect the highly unified, distributed platforms that make Teranode's laboratory management systems seamless. Joseph Duncan, Larry Arnstein, Matthew Shanahan, John Ohrn and Yoram Lapid provide seasoned executive level operational support for a fluid and successful venture.

Mission

Bringing a wealth of physical and virtual in-silico modeling/testing and distributed computing expertise to the table, Teranode's mission is to capture the convergence and evolution of bioinformatics to create state-of-the-art bioinformatics that are flexible, cost-effective and user-centric.

Awards and Recognition

Since its inception, Teranode has introduced a number of pioneering contributions to the industry. Recently recognized for its innovation and leadership in the industry, Bio-IT World awarded Teranode it's Best of Show Award in the Informatics Tools and Data category for its XDA 2.8 application platform. Speaking on behalf of Bio-IT World, John Russell, executive editor, summed it up best when he said, "these [Best of Show] awards recognize the products that are fueling tomorrow's discoveries."

In 2005, Teranode was also the recipient of Frost & Sullivan's Technology Innovation Award for its success in the U.S. laboratory information management systems, in recognition of the company's leadership, technological acumen and breadth in high-end LIMS services used in the life science industry.

Notable Technology Contributions

Teranode was the first provider to apply a distributed, object management architecture to laboratory management systems. Its Teranode Design Suite (TDS) and Teranode Model Server (TMS) modules offer customers a robust informatics platform that supports multiple designs, continuously, eliminates the need for ongoing reprogramming and dramatically reduces traditionally long deployment cycles and vastly improves data mobility.

Teranode's experiment design automation (XDA) software is its next generation offering to the industry. Its XDA solution incorporates its

TDS and TMS modules into a unified, network accessible database with its deployment of its Teranode Portal Server (TPS) module. Unlike other, more traditional database approaches, Teranode's XDA solution is a unified, Web-based, enterprise-wide platform.

With the introduction of its XDA 3.0 release, targeted for a summer release in 2006, Teranode will become the first informatics provider to incorporate Semantic Web technology into its schema. Much as the extensible mark-up language (XML) is to the Web, resource description framework (RDF) is a meta-data structure or layer that sits above traditional XML hierarchies. Using science-based classifications or ontologies, Teranode's version 3.0 release uses the Semantic Web taxonomy and RDF meta-language to quickly and easily access experimental data output by anyone on the network from any server or data repository.

Applying an RDF meta-structure to experimental data is an information technology (IT) function that a company's IT administrators can switch on quite easily. Much like the use of XML hierarchies by the Google search engine, Semantic Web standards allow researchers to dramatically shorten the time and effort previously needed to access relevant experimental results, apply analytics and create comparative reporting charts. Not only does this solution accelerate data research, it dramatically reduces (and in many cases will eliminate) the need for expensive customized interfaces between disparate databases.

Existing Customers

Teranode's technology solutions are not only being adopted by an increasing number of pharmaceutical, biotechnology and life sciences research organizations, including such notable companies as Pfizer, AstraZeneca, Amgen and GlaxoSmithKlein, but its informatics platform is also finding applications within leading academic institutions (MIT), government facilities (NIH) and clinical testing facilities (Fred Hutchinson Cancer Research Center).

Conclusion

True to its mission, Teranode continues to lead the life sciences informatics industry forward. First to offer its customers a model-driven, automated LIMS, Teranode's latest release brings the industry out-of-the-box thinking and applies a much needed technology solution to the difficulty of data accessibility and data mobility.

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Reimbursement & Regulatory News

Recent FDA Approval Announcements:

Date	Company	Product or Device	Function	Designation
5-May	Lonza Biologics Inc (Portsmouth, NH)	ORENCIA (abatace)	Provides relief from the signs and symptoms of rheumatoid arthritis	Approval by FDA for a Supplemental Biologics License Application (sBLA)
5-May	Irvine Scientific (Santa Ana, CA)	Blastocyst Vitrification Kit	Innovative preservation technique to cryopreserve eggs and embryos	US FDA Clearance
4-May	Hologic (Bedford, MA)	Hologic Discovery(TM) Dual Energy X-ray Absorptiometry (DXA) system	Abdominal Aortic Calcification (AAC) test now approved as a predictor of cardiovascular disease	US FDA Clearance
4-May	Bioniche Life Sciences Inc. (Belleville, Ontario, Canada)	Urocidin	Alternative treatment in non-muscle invasive bladder cancer	FDA Fast Track designation following Clinical Phase III approval
3-May	deCODE genetics (Reykjavik, Iceland)	DG03 I	Phase III clinical trial to test leukotriene-based compound as a heart attack preventative	FDA Special Protocol Assessment (SPA) granted
3-May	MGI Pharma, Inc. (Minneapolis, MN) and SuperGen, Inc. (Dublin, CA)	Dacogen (decitabine)	Approved as a treatment for all forms of refractory anemias, myelomonocytic leukemia and other myelodysplastic syndromes (MDS)	US FDA Clearance
2-May	Myriad Genetics, Inc. (Salt Lake City, UT)	MPC-0920	Phase I trials to begin to test potential predictable anticoagulant used in the treatment of thrombosis	FDA Investigational New Drug (IND) Approval
1-May	Cephalon, Inc. (Frazer, PA)	NUVIGIL (armodafinil)	For use to treat patients suffering from excessive sleepiness	FDA new drug application (NDA) pending final product label approval
1-May	Imaging Diagnostic Systems, Inc. (Fort Lauderdale, FL)	CT Laser Mammography	Clinical trials to establish CT Laser Mammography as a supportive diagnostic in the detection of breast cancer	FDA non- significant risk (NSR) device study approval
1-May	Novartis Group (Basel, Switzerland)	Diovan HCT (valsartan/hydrochlorthiazide):	Higher dosage treatment for high blood pressure	FDA approval of higher dosages
1-May	AstraZeneca (Wilmington, DE)	NEXIUM (esomeprazole magnesium)	Treatment for gastroesophageal reflux disease in children	FDA approval granted

Recent Centers for Medicare & Medicaid Services Coverage Announcements:

Friday, May 5, 2006

The Centers for Medicare & Medicaid Services (CMS) announced that the State Health Insurance Assistance Programs (SHIPs) will receive an additional \$500,000 to help people with Medicare who reside in rural areas obtain drug coverage by May 15th when the 2006 enrollment period ends. The funding also provides for counseling for the next annual open enrollment period, and to identify and enroll people in rural areas who might be eligible for the Medicare Prescription Drug Coverage low income subsidy that provides additional savings to beneficiaries. This funding is in addition to nearly \$925,000 included in the \$29,269,885 in grants previously awarded to the SHIPs on April 1, to support rural beneficiaries.

Tuesday, May 2, 2006

The Centers for Medicare & Medicaid Services (CMS) issued a final rule designed to assure appropriate payment for services by long-term acute care hospitals (LTCHs) to severely ill or medically complex patients, while providing incentives for more efficient care for Medicare beneficiaries. Under this final rule, Medicare payments to LTCHs are expected to be \$5.3 billion for rate year (RY) 2007.

Monday, May 1, 2006

The Centers for Medicare & Medicaid Services announced Payment Increase, Policy Changes for Inpatient Psychiatric Facilities. Inpatient psychiatric facilities (IPFs) will receive an average 4 percent increase in Medicare payments, beginning in July. The higher payments, for discharges occurring July 1 or later, will be under a final rule announced today by the Centers for Medicare & Medicaid Services (CMS). This increase includes the effects of market basket updates resulting in a 4.5 percent increase in total payments for Rate Year 2007, July 1, 2006 to June 30, 2007. The market basket shows how much the costs of goods and services used by a particular industry have changed over time. Within this average, government-operated psychiatric hospitals receive the largest share of the total increase. The final rule also includes several changes in payment policies for these facilities.

The Frost & Sullivan Healthcare Group specializes in closely monitoring the healthcare marketplace to provide critical information, opportunities, and strategic recommendations for market participants. Our global team of highly skilled industry analysts and consultants are educated and experienced in a variety of healthcare market sectors, and maintain well-developed, long-standing relationships with key industry participants. Leveraging these assets, the team provides clients with comprehensive industry knowledge, including detailed coverage of market, technology, economic, and customer-focused trends and forecasts.

The Frost & Sullivan Healthcare team offers extensive coverage of the following markets and sectors:

Drug Discovery

- Proteomics
- Protein Markets
- DNA & Protein Microarrays
- Research Consumables
- High Throughput Screening
- Bioinformatics
- SNP
- Pharmacogenomics
- Mass Spectrometry
- Gel Electrophoresis
- Laboratory Information Systems

Medical Devices

- Cardiovascular Devices
- Orthopedic Devices
- Home Care
- Surgical and Infection Control Products
- General Medical Devices
- Hospital Supplies and Products
- Wound Care/ Management Products

Clinical Diagnostics

- Molecular Diagnostics
- Immuno-chemistry
- Point-of-Care
- Cell Culture
- In Vitro Diagnostics
- Genetic Testing
- Infectious Disease Diagnostics
- Cancer Diagnostics

Medical Imaging

- Core Imaging Modalities
- Imaging Agents
- Imaging Software
- PACS & Imaging IT
- Digital Imaging

Pharmaceuticals & Biotechnology

- Oncology
- Drug Delivery
- Biotechnology
- CNS
- Contract Manufacturing
- Contract Research
- Ophthalmics
- Chronic Diseases

Patient Monitoring

- Cardiac Monitoring
- External Defibrillators
- Multi-Parameter Monitoring
- Glucose Monitoring
- Blood Pressure Monitoring
- Temperature Monitoring
- Pulse Oximetry
- Remote Patient Monitoring
- Patient Monitoring IT
- Sleep Apnea Monitoring

Healthcare & Life Sciences IT

- Electronic medical records
- Data and storage management
- Emerging wireless technologies
- Acute Care Information Systems
- CPOE
- Enterprise clinical information systems
- Claims management through IT
- RFID in Healthcare
- RHIOs

CUSTOMIZED SERVICES

Growth Consulting - Clients may leverage our unique combination of market expertise, global presence, and relationships with key industry players for customized research, business strategy, consumer analysis, and organizational development projects. Clients get powerful and practical solutions to address their unique challenges and develop winning strategies for growth.

Customer Research - Clients gain insights into their customers behaviors and attitudes, find out what end users think of their company, and how their products should look and feel in the future. These analyses are designed to assist you in formulating and applying effective product marketing strategies across your product and service lines.

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