WHITE PAPER

The Pharmaceutical Challenge
Innovation and Efficiency an Unlikely Pair

LIAISON®

The Pharmaceutical Challenge

Innovation and risk have fueled the pharmaceutical industry since its inception. Manufacturers place their bets in the form of basic research, co-development, licensing and joint ventures. Hundreds of millions of dollars are required to take a promising formula to trial, where only a handful of the prospects will emerge as blockbuster drugs. The industry's focus on innovation has positioned U.S. pharmaceutical firms as world leaders until now, but the world is changing.

Intense competition for new drug discoveries, development, and revenue are forcing pharmaceutical companies to seek a competitive edge. Increased regulation, downward price pressure and increasing research and development (R&D) costs suggest that another, as yet unclaimed competitive advantage might be in order. This advantage? Efficiency.

After years of double-digit growth, and faced with a new economic reality, leading pharmaceutical firms have begun to look outside their industry for answers. Many firms seek process improvement solutions in the form of classic technology such as Enterprise Resource Planning (ERP) and Customer Relationship Management (CRM) systems. These traditional solutions have long histories in most manufacturing companies but are curiously absent in the pharmaceutical world.

In addition to ERP and CRM systems, real-time capable Enterprise Application Integration (EAI) and Business-to-Business (B2B) infrastructures are among the most common technologies to be implemented by the world's largest firms over the past five years. Thus far, the pharmaceutical industry has been slow to adopt these seemingly core technologies; it may also be best positioned to unlock their full potential.

Real-Time Infrastructure

Real-time infrastructures, enabled by EAI and B2B technologies, create an information network that links internal systems and external business partners in order to share critical information. For example, a pharmaceutical company might electronically connect its collaborative research partners in order to efficiently share information regarding joint R&D efforts.

These real-time infrastructures squeeze inefficiency out of processes by accelerating the delivery of accurate and up-to-date information to systems and people throughout the entire lifecycle of a product. Realtime information is a powerful concept that describes the continuous delivery of up-to-date and accurate information; it could be the key to pharmaceutical companies' ability to compete in the future.

Pharmaceutical Firms can take Real-Time Infrastructure to New Levels

The nature of real-time infrastructure makes it unlike many investments traditional companies make. An investment in this area is somewhat speculative; the return on investment (ROI) can be difficult to assess, making the decision to go forward problematic and even crippling for many companies. However, like the corporate wide-area networks, e-mail systems and voice mail systems

installed in the 1990's, a strategic investment in a real-time infrastructure may be demanded by collaboration partners, customers, and suppliers. It may simply become a baseline for doing business in the future.

Real-time information is a vision of a future state that will never fully be achieved. Moving closer to this envisioned state can have dramatic efficiency and time–to-market benefits. The pharmaceutical industry has an important and distinct advantage over other industries when embarking on the journey toward real-time information. By its very nature, the industry is somewhat idealistic and visionary in its approach to its core business; this has created a culture of smart, driven and creative people who are encouraged to take risks and achieve audacious goals.

While other industries have spent years trying to calculate the ROI on their e-mail systems and corporate web sites, pharmaceutical companies have the corporate culture to look beyond these justification-based measures and see the efficiency and competitive advantage inherent in real-time information. Pharmaceutical firms may not be the first to incorporate a real-time infrastructure into their business strategies, but could ultimately be the most successful in exploiting it.

How Real-Time Infrastructures will Change the Pharmaceutical Industry

To survive and compete, pharmaceutical firms must become more efficient. After years of covering R&D losses with blockbuster formulas and masking manufacturing and distribution inefficiencies with huge margins and mammoth sales teams, the industry has come to a crossroads. As one senior pharmaceutical executive recently noted: "Let's face it: all of the "easy" problems have been solved and variations on current drugs have been nearly exhausted. Something needs to change."

Drugs that remain to be discovered will cost more in R&D and be loaded with more risk then ever. Sales techniques of adding personnel and applying more aggressive techniques can only go so far. To combat this changing environment, pharmaceutical companies must protect their margins and focus on their bottom lines. They must control costs, speed time-to-market and become more efficient in all processes, from basic research to manufacturing and sales.

If efficiency and continued innovation are keys to the pharmaceutical industry's ultimate success, the following "efficiency killers" must be addressed:

- **Inefficient Collaborative Information Flows Between Partners, Licensees, and Supply and Distribution Channels**. This limits firms' ability to quickly engage with partners and conduct secure, collaborative communications. Multiple business processes require this capability - from basic research to recruitment for clinical trials.
- **Poor Regulatory Compliance Information Flows:** Manual processing, non-standard systems and changing requirements lead to delayed approvals. Pharmaceutical companies must communicate electronically with the Food and Drug Administration (FDA), U.S. Securities and Exchange Commission (SEC), and Environmental Protection Agency (EPA), to name a few.
- **Incomplete Supply Chain Visibility and Tracking**: This problem allows counterfeit drugs to enter the supply chain. It also creates costly excess inventories, slow or overreaching recalls, and price arbitrage opportunities through levels of distribution.

Collectively, these "efficiency killers" can be dramatically improved with the implementation of a real-time infrastructure that improves standardization of information and information flows, delivers more accurate and up-to-date information, and links all interested parties and systems.

Realizing the Real-Time Infrastructure Vision

In practice, a real-time infrastructure is deployed with an architecture made up of a few core technologies and deployment options, each with a specific purpose and application. This real-time infrastructure can then be leveraged inside and outside the enterprise, with partners, customers, and suppliers throughout the supply chain.

Enterprise Application Integration (EAI)

EAI refers to the linking of applications within an enterprise. Typically, companies consolidate and coordinate their existing legacy systems and databases while migrating to a new set of applications which exploit new technologies.

Business-to-Business (B2B) Integration

Business-to-Business integration allows firms to automate business processes that involve parties outside the company. Firms might automate functions connected with suppliers, partners, and customers.

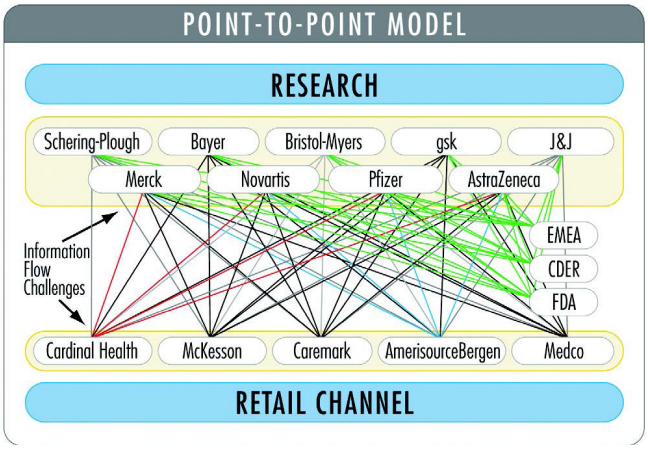

FIGURE 1

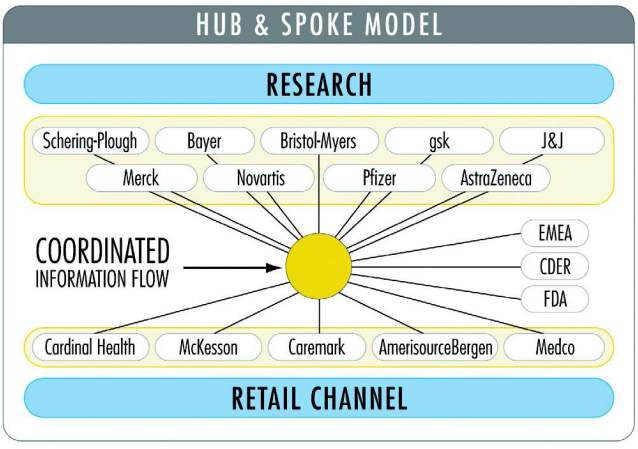

FIGURE 2

Point-to-Point Implementation

The point-to-point model involves of a series of direct connections between two unique end points, as shown in Figure 1. Initially, this model is generally the simplest real-time architecture for both internal (EAI) and external (B2B) infrastructures. However, as the number of point-to-point connections grows the complexity of the infrastructure increases dramatically. Also, multi-step communications which involve more than two end points generally emerge, further increasing the complexity of the model. As a result, the point-to-point model is typically utilized for limited, small or specific applications.

Hub-and-Spoke Implementation

The hub-and-spoke architecture, as seen in figure 2, often requires more planning and infrastructure design than point-to-point solutions. The systems architect should understand information flows and business processes that must be supported, then design flexibility into the "hub". Hub-and-spoke models are more efficient and scalable for medium- and large-scale implementations and are generally preferred by systems engineers.

Under the hub-and-spoke model, technology solutions are often delivered as services, reducing the cost and risk of multiple large software implementations. Additional benefits include a common platform for managing standards and keeping current with the changing needs of the industry. Traditional Value Added Network (VAN) providers and Application Service Providers (ASPs), like Salesforce.com, have validated the benefits of using a hub-and-spoke model for solution delivery. Recently, large companies like IBM and HP also embraced this approach through their "On Demand" and "Adaptive Enterprise" computing initiatives (respectively), and Microsoft and others have quickly followed suit.

Complete Real-Time Infrastructure

The hub-and-spoke architecture may also include ASP or hosted applications designed to enhance the realtime infrastructure. Figure 3 describes standard services provided by real-time infrastructure to business and collaborative applications.

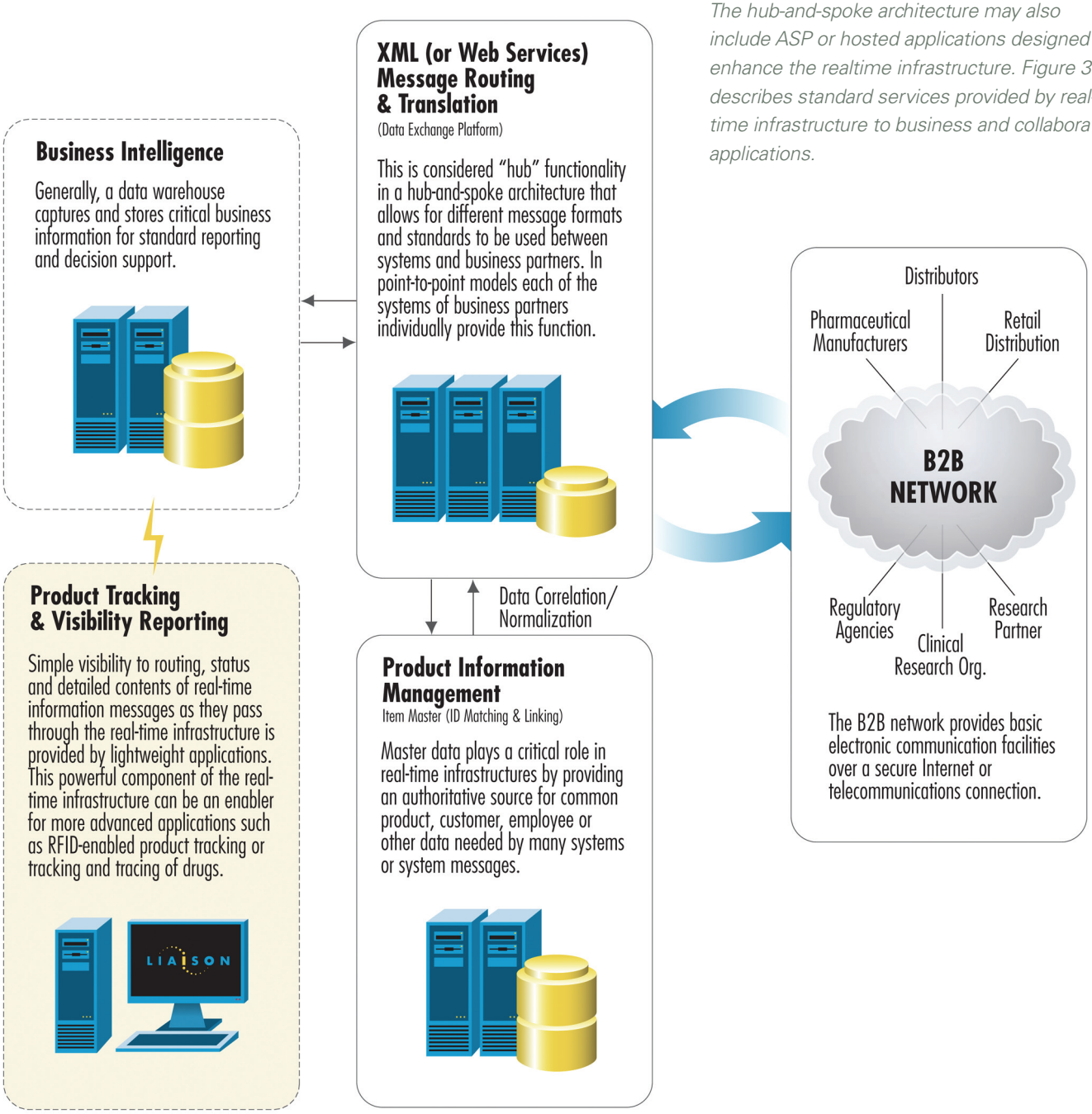

FIGURE 3

Hub-and-Spoke Solutions - Examples

Many industries have deployed hub-and-spoke models for B2B messaging, ASP applications, and collaboration. In general, these are mature industries with traditional investment guidelines strictly based on ROI or economic value added (EVA) tools. The table below shows that these vertical hub-and-spoke infrastructure services have gained significant momentum and business model validation.

	History	Adoption
ANX	Founded in 1996, the ANX Network was originally built and operated for use as a collaborative commerce solution for the automotive industry and was sold to SAIC in December of 1999.	As of September 2002, more than 1400 companies including several leading automotive original equipment manufacturers and nearly 90 percent of the North American automotive Tier 1 supply base use the ANX Network to perform a wide range of e-business functions.
Elemica	Elemica is a network for the global chemical industry, developed by 22 of the leading chemical companies in the world for the benefit of the entire industry.	As of 2003, Elemica reported 154 trading partners connect to their network for a total of 650 trading pairs. Elemica added logistics services and other supply-chain applications for the chemicals industry.
E2open	E2open was founded with the mission to simplify and fundamentally change the economics of Multi-Company Process Management. Their focus is on the electronic and consumer products supply chains.	As of 2004, more than 30 major supply-chain hubs and over 2500 trading partners connected to the E2open network.
IVANS	Twenty-one insurance companies founded IVANS in 1983 as an industry network. IVANS, which initially stood for Insurance Value Added Network Services, provided a focal point for conducting business in the insurance industry electronically.	IVANS membership includes more than 500 participating firms and more than 100,000 users including property and casualty companies, agents, international reinsurers and brokers, third-party administrators, industry groups and associations, financial services, and life, health, and managed care organizations.
Liaison Technologies	Established in June of 2000 by five leading forest products companies to provide e-commerce solutions to the industry leveraging shared technology infrastructure solutions. Currently offers real-time infrastructure services across multiple industries.	Over 125 customers with nearly 2500 trading partners across several industries. 3.2 million transactions processed in 2003 and 25+million transactions are projected in 2006. 2.1 million products have been processed using the Liaison Content Director product.
QRS	QRS was founded in 1988 with the goal of automating paper-based transactions among retail trading partners to reduce costs and errors. QRS is not an industry consortia but a very successful industry-focused solution provider.	QRS grew to 8000+ customers by 1999 with over 73 million UPCs in their catalog. QRS was a public company with a market cap of $87 million in May 2004. QRS has been acquired by Inovis.
SITA & Equant	Founded in 1949 by 11 airlines, SITA's primary aim was to bring together the airlines' existing communications facilities so that all users could take advantage of the cost efficiencies of a shared infrastructure.	Serves over 730 members, comprising 588 airlines, all major computer reservation systems, including airports, aerospace companies, airfreight organizations and governments worldwide.
1SYNC (formerly Transora)	Founded in March of 2000, 1SYNC is a combined effort of 56 companies in the CPG retail industry. With a combined investment of $250 million, 1SYNC is one of the worlds largest B2B portals.	Shifted focus to data synchronization solutions and completed 78 implementations that account for 76 percent of all of the items in the UCCnet global registry. Recently merged with UCCnet to form 1SYNC.

Standardization

Standardization implemented as part of a real-time infrastructure will generally show efficiency improvement for companies with multiple solutions providers or patchwork point-to-point solutions. Standardization is similar to the rationalization of telecommunications providers, which for many companies led to significant long distance and data network savings.

Standardization also allows companies to reduce the number of communications protocols, message formats and transmission methods used. Cisco Systems made standardization a reality in the world of data communications by providing the multi-protocol router in the early 1990's. This software was put in place to solve the problem of supporting many different communication standards such as AppleTalk, IPX/SPX (a Novell communications protocol), DecNET, SNA (IBM's Systems Network Architecture), Banyan Vines, OSI, and more. Within five years, most of these protocols had been reduced to obscurity and TCP/IP was the dominant communications protocol. This standardization significantly reduced the complexity of the technical environment and reduced support, hardware and software costs by as much as fifty percent. TCP/IP is now the standard foundation of future real-time infrastructures. To fully realize the real-time information vision, EAI and B2B messaging must progress toward XML standards.

ACORD	ACORD, the Association for Cooperative Operations Research and Development, is the insurance industry's non-profit standards developer, a resource for information about object technology, EDI, XML and electronic commerce in the United States and abroad.
CDISC	CDISC (Clinical Data Interchange Standards Consortium) is an open, multidisciplinary, non-profit organization committed to the development of industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development.
CIDX	CIDX (Chemical Industry Data Exchange) is a robust trade association standards body focused on realizing transactional efficiency throughout the global chemical industry supply chain.
papiNet	papiNet is the global initiative to develop, maintain and promote the implementation of standard electronic transaction standards to facilitate the flow of information amongst the parties engaged in the buying, selling, and distribution of forest, paper and wood products.
RosettaNet	A self-funded, non-profit organization, RosettaNet is a consortium of major information technology, electronic components, semiconductor manufacturing, telecommunications and logistics companies.
SAFE	SAFE (Secure Access For Everyone) is a standard to provide electronic identity credentials for legally enforceable and regulatory compliant electronic signatures in the bio-pharmaceutical industry. It is intended for both business-to-business and business-toregulator transactions.
1SYNC (formerly UCCnet)	UCCnet was established as a not-for-profit subsidiary of the Uniform Code Council, Inc., the global standards organization, to serve its stakeholders. UCCnet Data Synchronization and the associated standards are focused on the retail industry including but not limited to CPG. Recently merged with Transora to form 1SYNC.

Once companies standardize EAI and B2B XML protocols, standard document formats and business processes are required for XML document choreography. Efficiency savings in this area are likely to exceed that of standardization of communications protocols previously discussed. More importantly, it will greatly increase opportunities for real-time electronic collaboration.

Summary

There is a case for change within the pharmaceutical industry today. Real-time infrastructure can be a fundamental IT building block to enable this change. Furthermore, the pharmaceutical industry has a unique culture that can be leveraged to exploit real-time infrastructures to gain competitive advantage where other industries have been held back by traditional thinking about IT investments.

Real-time infrastructure consists of both EAI and B2B technologies, each of which can either be deployed in a point-to-point or a hub-and-spoke architecture. Increasingly leading companies are considering provisioning of real-time infrastructure as a service versus a technology, and several industries have worked cooperatively to create real-time industry solutions offered as services. In conjunction with real-time infrastructure services and solutions, industries have defined enabling XML and security standards to help facilitate real-time information.

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