

Pharmaceutical companies, innovation is closer than you think – if you have the right relationships

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A CLOSE 'CIRCLE' OF FRIENDS: THE STORY OF NEWTON & HALLEY

If it hadn't been for Edmund Halley and a wager of forty shillings, one of the greatest innovations in human understanding might never have happened.

In 1683 in a café near Oxford, Sir Christopher Wren offered two scientists, Edmund Halley and Robert Hooke, a wager of forty shillings to the man who first devised the formula for the orbit of celestial bodies.

Hooke immediately answered that the planets followed the inverse square law, but when the other two gentlemen asked for proof, Hooke demurred. Halley, on the other hand, became consumed with finding the answer.

Fortunately, he had heard of a crazy professor at Cambridge named Isaac Newton who might just know the answer.

When Halley put the question to the professor, Newton replied that the orbits of celestial bodies followed the inverse square law. "An ellipse."

Halley was ecstatic. Newton's answer corroborated Hooke's and, even better, he said he had figured out the formula years ago. Newton proceeded to search among his papers for his notes, but he couldn't find them.

In *A Short History of Nearly Everything*, Bill Bryson declares, "This was astounding – like someone saying he had found a cure for cancer but couldn't remember where he had put the formula."

Eventually Halley convinced Newton to recreate and publish his notes. Newton did so, and the result was the *Principia Mathematica*, which is recognized today as one of the most important scientific publications of all time.

What does this have to do with innovation in the pharmaceutical industry today? Everything. Innovation is often thought of as a Flash of Genius or a moment of Eureka.

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– Bill Bryson, *A Short History of Nearly Everything*.

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The complexity of these relationships grows exponentially with each one, and securing companies' precious intellectual property is more important – and difficult – than ever in our global, online, collaborative environment.

But people who innovate for a living know that it is the result of building and mining many complex relationships between people and ideas. It may have been Newton who arrived at the answer, but it was Christopher Wren who set Halley on the quest, and Halley who realized the extraordinary value of Newton's discovery and convinced him to publish his findings.

(Incidentally, Halley also had to front the money to publish the book, the Royal Society having just spent their entire budget publishing a book about fish. Genius is rarely recognized in its time.)

Like Newton, Pharmaceutical companies are not making the best use of their knowledge. In an industry turning on its head, they, too, need to search through the deep recesses of their institutional memories and start building relationships between their knowledge and knowledge partners to foster a culture of intellectual discovery and collaboration, and lead the transformation of the industry, rather than suffer through it.

AN INDUSTRY IN MOTION...

It almost seems as though the world is conspiring against the pharmaceutical industry: patents are expiring, pipelines are shrinking, most experts agree that the Blockbuster model is more bust than block, drugs are removed from the market due to unforeseen risks, regulatory agencies are stricter than ever, healthcare providers are pushing to drive down costs, investors are skittish and, if that isn't enough, Al Gore wants us to know that the earth is heating up.

To paraphrase Newton's first law of motion from the Principia Mathematica, an industry in motion tends to stay in motion, unless it is acted on by an external force. And there are

certainly a lot of forces acting on the pharmaceutical industry.

Pharma companies are responding to their changing industry by trying to adapt. They are trying mergers, joint ventures, investment in new technologies, acquisitions, divestitures, outsourcing, open-sourcing, and public private partnerships. All of these have their place, but none has proven to be a panacea; perhaps there is no such thing.

One thing that is clear is that business as usual today is a lot more complex and fragmented than it was yesterday.

To begin with, pharma companies have billions of dollars worth of data within their own servers and hard drives, but they can't draw on that value because they haven't been able to create relationships between the data. This problem is compounded by the information coming from an increasing number of acquired, merged or partner companies, academic institutions, contract research organizations, regulatory agencies, and other outside knowledge sources. The complexity of these relationships grows exponentially with each one, and securing companies' precious intellectual property is more important – and difficult – than ever in our global, online, collaborative environment.

If pharma companies are going to succeed at innovation and long-term, transformative change, they need to start orchestrating these increasingly complex relationships – between knowledge, people, and organizations – to nurture, rather than stifle innovation.

A new class of technology, called Contextual Knowledge Environments (CKEs), is finally giving knowledge-intensive industries, like the pharmaceutical industry, the ability to do just that.

KNOWLEDGE RELATIONSHIPS

Do You Know Where Your Data Is?

There are a lot of Isaac Newtons and Edmund Halleys running around the halls of pharmaceutical companies. Some of the brightest people in the world work at pharma companies, and they have insights and breakthroughs on a daily basis. Where does all this genius go?

Some of this knowledge goes into scientific reports and official documentation; some is discussed in meetings and recorded in meeting notes; and a whole lot of it goes into email. A 2009 Deloitte report estimates that employees spend about 25% of their workday on email, and another report estimates 37% of their time goes to meetings. For Big Pharma, this represents billions of dollars of intellectual capital that is created, consumed, and lost in the terabyte-wide jaw of corporate email servers and hard drives, never to be seen again.

The sheer amount of tacit and structured data produced by the pharmaceutical industry is

staggering, and growing at an alarming rate. But pharma companies don't benefit from all this rich information because most of it is orphaned between hundreds of disparate technology systems, thousands of employees, and an ever growing number of partners.

Even if far-flung data is reunited, it is not enough. A lump of data is, as Figure 1 suggests, a bit like a lump of spaghetti and meatballs: it's messy and probably not the best source of wisdom. Data must be understood in context to reveal relationships. This is what transforms chaotic data into actionable knowledge.

If companies are willing to spend a billion dollars developing a drug that is more likely than not to fail before it reaches the market, doesn't it make sense to spend a few million dollars to ensure they are using their knowledge as effectively as possible to increase the probability of its success? For most pharma companies, this is a hidden gold mine of opportunity that already exists within their walls. The key to transforming lost data into accessible knowledge is the key that will unlock innovation.

What you Don't Know You Know

"Knowledge depends on two, less glamorous cousins that go by the names of 'data' and 'information,'" says former Chairman & CEO of Eli Lilly, Sidney Taurel. "When health-care data and information are not available, or when they are poorly organized and understood, then health-care knowledge is greatly diminished... At best, some of us are seeing pieces of the whole, but the totality of insights that could emerge from this treasure chest of information is being denied to everyone. The inescapable conclusion is rather painful to admit: We do not know what we know about health care."

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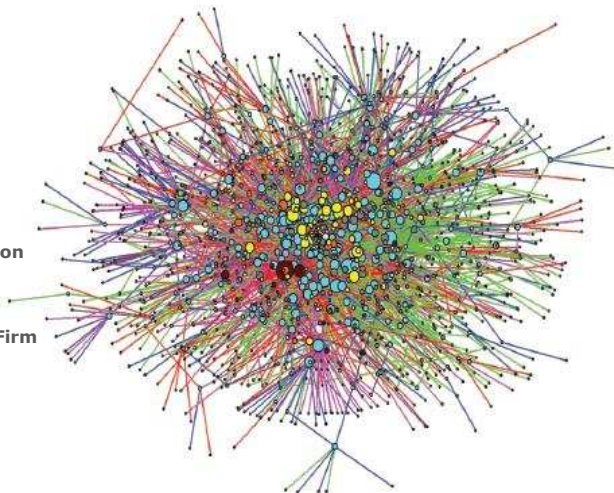
"The inescapable conclusion is rather painful to admit: We do not know what we know about health care."

- Sidney Taurel, former Chairman & CEO, Eli Lilly

The good news is that all pharmaceutical companies know much more than they think they know.

Internal Functional Area Ties
Red = R&D
Green = Finance
Blue = Commercialization
Magenta = Licensing

External Influence Ties
Cyan = Drug / Biotech Firm
Orange = PRO
Brown = Regulators
Yellow = Pharma
Gray = VC Firm



Powell et. al (2004) "Network Dynamics and Field Evolution: The Growth of Inter-Organizational Collaboration in the Life Sciences." American Journal of Sociology. Reprinted with kind permission from the University of Chicago.

Figure 1: Spaghetti Data: without proper context, a lump of data is like a lump of spaghetti and meatballs: meaningless.

The corollary to this – and the good news – is that all pharmaceutical companies know much more than they *think* they know.

Very little of the gigabytes they produce daily is readily accessible the next day, so it is almost as though it doesn't exist. But it does.

Pharma companies produce enormous amounts of valuable data that sit static and forgotten in reports and databases, generating no further value than the trial for which they were generated. The potential value of such data is tremendous...

These gigabytes comprise both tacit and structured data, both of which are necessary for innovation: tacit data aids the intuitive hypotheses and educated hunches, while the structured clinical and non-clinical data can narrow down which substances are likely to succeed and which will fail.

The lost tacit data of a pharma company includes important decisions, solutions to recurring problems, patterns that can lead to new concepts, best practices, finding the key to the next blockbuster drug, or avoiding the next drug recall.

Contexts are the relationship matchmakers of knowledge... they form relationships with other data, and thus become part of the company's 'living brain.'

The structured data that goes into databases and official reports has a short shelf life too. Pharma companies spend billions of dollars on complex clinical trials, producing enormous amounts of valuable data that sit static and forgotten in reports and databases, generating no further value than the trial for which they were generated. The potential value of such data to predict future trials is tremendous: meta-analysis conducted across a broad range of molecules and studies related to them can reveal potential new blockbuster drugs, or expose potentially toxic effects that will, in the future, bust a potential blockbuster. This is a huge, untapped opportunity for pharma companies to make better decisions and yield higher success rates from their pipelines.

Contextual Knowledge Environments can help companies transform the day-to-day data of a company into actionable knowledge – and even more, into the 'living brain' of the

company. When pharma companies are able to unify all the data from emails, meeting notes, documentation, reports, scientific studies, and other sources of unstructured and structured data, contextualize it into relationships of information, with the option of searching and navigating within those contextual relationships – then they will know what they know.

What You Don't Know You Don't Know

Equipped with the knowledge of what they do know, pharmaceutical companies can gain visibility to what they don't know. They can then focus their resources on filling gaps in knowledge that are standing in their way of innovation. They can invest intelligently in their skill pool through training or hiring and in their knowledge base through research, in-licensing, acquisitions, or partnerships with complementary companies.

From Data to Knowledge: Context is Crucial

Even if it is centralized, data is often confusing, misleading, and unintelligible. Spaghetti and meatballs, as it were.

When data is understood in context, however, it is transformed from 'spaghetti and meatballs' into something entirely different: knowledge.

Contexts are the relationship matchmakers of knowledge. When data is anchored to contexts at the outset – when an email or document is written or when a decision is made – they automatically form relationships with other data, and thus become part of the company's 'living brain.' Suddenly, intelligence is born. Connections between seemingly unrelated studies can shed new light and lead to innovation.

“This is one of the great opportunities of pharma R&D. We generate terabytes of data, but the ability to creatively analyze it and extract the embedded knowledge is very much lacking.”

Predictive analytics: used creatively, yesterday’s dust-gathering data can help fill this year’s pipeline with more successes and fewer failures.

By prioritizing sleeper hits over promising duds, they are essentially reducing the time to market of a successful drug by months or years.

“This is one of the great opportunities of pharma R&D,” says an industry expert on innovation. “We generate terabytes of data, but the ability to creatively analyze it and extract the embedded knowledge is very much lacking.”

Best-in-class CKEs not only allow employees to see all the emails, documents, and data associated with a given context (and within each user’s security access), but they allow them to explore new patterns of relationships through context-based searches and a new capability called Orienteering. Orienteering is the ability to discover zones of interest and explore various new pathways that might not otherwise have been apparent.

Leading technologies also have the potential to be truly intelligent, adaptive, even brain-like, with an Amazon.com-like ability to predict and adapt information that is relevant to users’ ‘favorite’ contexts, thus revealing knowledge they may not even have known existed.

These capabilities finally allow companies to glean from their data the billions of dollars that they are worth. For the first time, companies can truly know what they know.

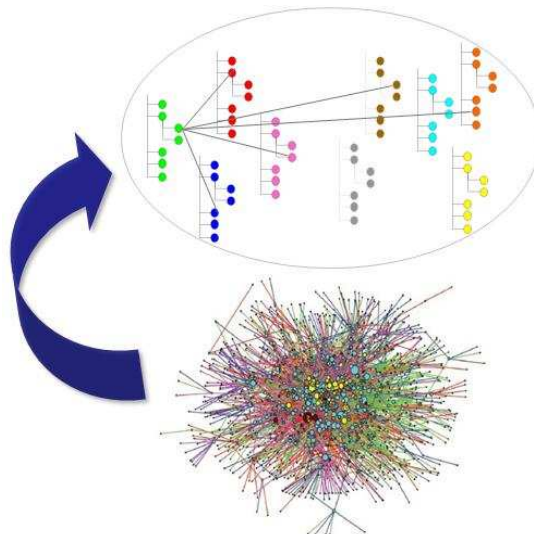


Figure 2: With proper contextual relationships, data is transformed from ‘spaghetti and meatballs’ into something entirely different: knowledge

The Relationship between the Past and the Future

Pharma companies spend billions of dollars a year on clinical trials. The data from these costly trials are usually released in the form of scientific reports issued at the end of the trial, and then they are retired to gather virtual dust in a database. The substances of successful trials go on to become marketable drugs, while the failures get scrapped, along with the millions of dollars that were invested in them.

But to an R&D scientist, last year’s failure can be just as valuable as last year’s success. Information about which compounds, under which circumstances, failed versus those that succeeded is a goldmine of data that can be extrapolated to predict future results with similar substances. Used creatively, yesterday’s dust-gathering data can help fill this year’s pipeline with more successes and fewer failures.

By analyzing historical clinical and non-clinical data with a variety of flexible parameters, hidden patterns and relationships from disparate information sources can be revealed.

With this newfound ability, pharma companies can predict those substances that are most likely to produce scientific and economic success, and prioritize those substances in their pipeline. By prioritizing sleeper hits over promising duds, they are essentially reducing the time to market of a successful drug by months or years.

The other side of the coin is the saved opportunity cost: pharma companies can save millions, even billions, of dollars by removing predicted failures from their pipeline and avoiding going down the costly road of clinical trials. Instead of scientists spending years to find out that a drug will

Companies can now analyze the likely success of their competition's pipeline before they enter into expensive mergers.

Knowledge is dynamic, spilling across rigid structures. Employees need a way to share knowledge that is as dynamic and organic as their knowledge itself.

have an adverse effect in Phase III, they may be able to, within a certain margin of error, discern early indicators in a few days or weeks providing opportunity for early culling or changes in product direction.

Pharma companies equipped with this technology can make predictions not only for their own substances, but for other companies' pipelines, too. They can make more informed decisions, entering into multi-billion dollar mergers, joint ventures, and acquisition or in-licensing agreements after they have analyzed the likely success of their competition's pipeline. Companies should keep in mind that if they don't start using the knowledge that is out there, eventually their competition will – and they will use it against them.

It should be noted that while Contextual Knowledge Environments can provide scientists with the tools for predictive analytics, R&D scientists and pharma leadership must – and should – always make the ultimate call on which substances to pursue in their pipeline. This is why the combination of contextualized tacit and structured knowledge is so powerful: it holistically combines hard scientific evidence and patterns with R&D scientists' intuitive, educated hypotheses.

PEOPLE RELATIONSHIPS

The Pitfalls of Silos

While Sir Isaac Newton was writing the *Principia Mathematica* at Halley's request, he did not know that another mathematician named Gottfried Leibniz was also inventing calculus hundreds of miles away in Germany.

Most scholars today agree that Newton arrived at calculus first, but because he buried his notes for several years before Halley convinced him to publish, Leibniz published

his proofs first. The *Mathematica Principia* came out shortly afterward, and a bitter fight ensued on both sides of the continent as to which man invented calculus.

Although some pharma execs may take from this story the importance of IP protection, the more interesting point is that two brilliant men spent years of their lives inventing the exact same thing. If Sir Isaac Newton and Gottfried Leibniz can do it, so can pharma employees.

Three hundred years later, with the advent of the telephone, the Internet, and the 24-hour news cycle, we have little justification for being in the same spot, but sadly we often are. Today's pharmaceutical employees do not need to be separated by a continent to be clueless as to what their colleagues are working on. Usually a cubicle wall will suffice.

The true cost of a siloed organization is immeasurable, and duplicate efforts of brilliant minds are only minor contributors. The greatest cost is one of opportunity: millions of missed connections, innovative half-ideas waiting to meet and spark. Just as data without context is meaningless, an individual's knowledge is piecemeal and requires collaboration to flourish.

Your People Are Not An Org Chart: The Living, Breathing Organization

One of the best things a pharmaceutical company can do to foster a culture of innovation is to enable real-time, context-based collaboration among its employees.

In most organizations scientists build professional relationships based on incidental factors: geography, projects, common interests and org charts. But a company's intellectual capital cannot be described by org charts. Knowledge is dynamic, spilling

Unlike old, static corporate networks, contexts flow organically across continents and projects to create new centers of ideation.

Suddenly R&D scientists can congregate around contexts like virtual ‘water coolers’, but instead of discussing last night’s ball game, they’re discussing the cure for cancer.

across rigid structures. Employees need a way to share knowledge that is as dynamic and organic as their knowledge itself.

The answer is in corporate social networks built around ideas, or contexts. If employees are able to build relationships based on contexts – i.e. therapeutic areas, indications, specific molecules or problems – they would have the opportunity to share knowledge with colleagues across continents and projects and bring to the surface patterns and new insights that they would not otherwise. Unlike old, static corporate networks, contexts flow organically across traditional organizational structures to create new centers of ideation. Knowledge growth is also automatic: with every relevant email or report or trial study, scientists add their knowledge to a given discipline, making a Contextual Knowledge Environment the living, learning brain of the organization.

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ORGANIZATIONAL RELATIONSHIPS

Partnerships are important

One trend that is unmistakable in the industry is the increasing number of relationships between pharma companies and external partners and stakeholders. Pharma companies need a better way to manage these increasingly complex relationships while maintaining proper security and compliance. Contextual Knowledge Environments can be set up with the appropriate security measures, either within a company’s firewall or in a cloud environment, to host these intra- and inter-organizational collaborations.

M&A, JVs | With the growing rate of industry consolidation and partnerships, and the shrinking financial resources to invest in them, it is crucial that pharma companies understand the real value and likely success of potential mergers and joint ventures. This entails taking stock of both parties’ ‘hard’ and ‘soft’ assets. Pharma companies can perform a basic level of predictive analysis on a potential partner’s pipeline (their ‘hard’ assets) before investing in them. Just as important, in the case of a merger, are their ‘soft’ assets – the people, methodologies, and tacit knowledge. With CKEs, pharma companies can create ‘maps’ of both companies to determine complementary assets.

Open Source & PPPs | Two million heads are better than one. Pharma companies are discovering new channels of innovation and collaboration by throwing a spotlight on specific diseases, and opening them up to the entire company, or the larger scientific community, for contribution and stimulation of new ideas. This will become an increasingly important channel for innovation in the future.

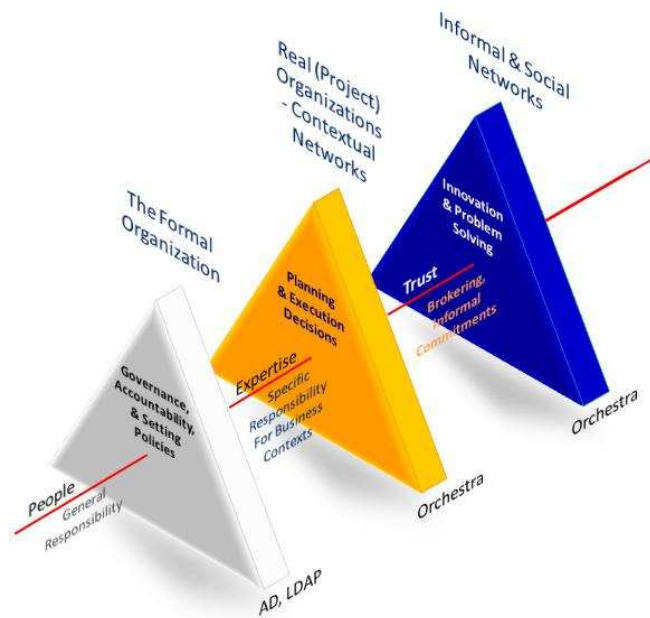


Figure 3: Beyond the Org Chart: Every company has 3 organizations; innovation comes from the elusive 3rd org: Corporate Social Networks.

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The same technology that enables organizations to share knowledge also needs to have the intelligence, business rules, and fool-proof security to protect an organization's precious knowledge.

Public Private Partnerships are also increasingly popular for their low investment, high flexibility, and nimble ability to go after neglected therapeutic areas. They have the benefit of buying goodwill with the public, and they allow R&D scientists a mental 'workout'. Brilliant minds need the opportunity to stretch their boundaries, and contributing part of their time to open ventures in an open model allows their genius free reign.

CROs, Regulatory Agencies, & Customers | Pharmaceutical companies' relationships with other external stakeholders are changing as well. Contract Research Organizations have proven their ability to handle not only repetitive clinical trial work (which frees up in-house R&D scientists to do more innovative research), but also the more innovative research in the discovery phase, which opens an opportunity for more strategic relationships and the need for better knowledge sharing.

If pharma companies and regulatory agencies are going to succeed in streamlining the approval process, especially with stricter regulation, increasingly global product releases, new processes for biologics, and the emergence of pharmacogenomics as a cornerstone of personalized medicines, they too will need to share knowledge more effectively and efficiently than they have so far.

Thanks to pharmacogenomics, adaptive trials and other advances, there is likely to be a growing need to monitor and communicate directly with customers as well, which pharma companies are ill-equipped to do at present. This, too, is likely to be a requirement, rather than an option, in the future.

But Don't Share Everything: Roles in Context

The growing rate of collaboration between organizations and individuals in the pharma industry requires not only the ability to effectively share knowledge but also, most importantly, the ability to restrict certain knowledge. In this global, online, collaborative new industry, information security, including IP protection, is more important, and elusive, than ever.

The same technology that enables organizations to share knowledge also needs to have the intelligence, business rules, and fool-proof security to protect an organization's precious knowledge, both within an organization and with its partners. The business rules that dictate how much knowledge is shared need to be flexible, dynamic, and easy to change by the knowledge owner.

This requires a special kind of information security. Many companies have tried to restrict and protect information on the basis of org charts and roles, but roles do not adequately reflect the nuances of a user's interests and 'need to know'. This is where contexts again offer ideal flexibility. CKEs determine a user's access at the context level first, and roles and responsibilities within those contexts, thereby simplifying how security rules can be uniformly applied to information assets.

Pharma companies should also be aware of who is securing their data. Companies are rightfully protective of their IP and other knowledge, and yet they allow sensitive information to be accessed by anyone in IT who is an administrator of the system. Security of data should be controlled by business rules in a secure environment where only those who are authorized can see and control sensitive information.

CONCLUSION: FALLING APPLES

For all the things that Sir Isaac Newton accomplished in his life, the most famous story about him is simply not true: Newton did not discover the universal law of gravity because he was struck on the head by a falling apple.

Likewise, pharmaceutical companies cannot rely on ‘falling apples.’ Companies need to realize that it is not too expensive to invest in knowledge and collaboration; it is too expensive *not to*. The companies that emerge winners from the innovation crisis will be those that proactively find and nurture relationships between knowledge and knowledge partners. They will be the ones that learn from their past to predict their future, and transform their current closed environments into open, collaborative networks of knowledge both within and across company borders that can address key industry challenges and the broader challenge of emerging global healthcare needs.

To paraphrase Newton, if we are to see further, it will be because we stand upon each other’s shoulders.

ABOUT POINTCROSS

PointCross is a global provider of advanced strategic business solutions to knowledge-rich markets, including the pharmaceutical industry.

Our Integrated Drug Development Suite (IDDS) specifically addresses the pharmaceutical industry’s innovation crisis. At the heart of IDDS is Orchestra+Solo™, an

adaptive, contextual knowledge environment and personalized client that orchestrates core business processes. Among its diverse capabilities, IDDS delivers:

- ☑ Single point of access to contextualized tacit and structured knowledge across the enterprise, with search and Orienting within and across contexts;
- ☑ Flexible, fool-proof IP security based on contexts and roles, determined by business rules;
- ☑ Predictive analytics for clinical and non-clinical data;
- ☑ Secure multi-party workflows for knowledge sharing and corporate social networks within and across companies;
- ☑ Solutions for business development, acquisitions and licensing, e-discovery, audit, regulatory submissions and compliance, and more;
- ☑ Scalable architecture and development toolkits for additional capabilities.

PointCross represents a new way of doing business. We deliver business-ready solutions in 1/10th the time and a fraction of the cost compared to standard technologies, while offering strategic advice from experts who understand the business challenges of knowledge-intensive industries.

We are headquartered in the California Bay Area, with a development and support center in Bangalore, India.

For more information, visit us at www.pointcross.com and call us at (650) 350-1900.

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