Enterprise User Experience Management for Life Sciences

New Technologies to Enhance Operations and Strengthen Compliance in Pharmaceutical, Medical Device, Insurance and Patient Care Delivery



Table of Contents

Executive Summary	3
Abstract	3
Life Sciences in Context	3
The Life Sciences Market	4
Pharmaceutical Industry	4
Medical Devices	5
Medical Insurance Industry	6
Patient Care (Health Care Systems)	6
Technology Trends in Life Sciences	6
Application Performance Management Market Overview	7
Market Size and Overview	7
Segmentation	8
Targeted Enterprise Applications for Life Sciences	8
Market Trends	9
User Experience Management Overview	9
Enterprise-class User Experience Management	9
Chart – User Experience Management Features by Tier	9
Category Definitions	10
Platforms	10
Basic User Experience Management	10
Advanced User Experience Management	10
Enterprise-class User Experience Management	10
Use Cases in Life Sciences	10
Use Case Area: User Education and Training	11
Use Case Area: Information Technology CIO Dashboard	12
Use Case Area: Help Desk Optimization	12
Use Case Area: Best Business Process / Compliance	13
Summary and Findings	14
The Opportunity For Life Sciences	15
Leading User Experience Management Vendors	14
Vendor Focus – Enterprise-class User Experience Management – Best in Class Product	14
About IdealNet, Inc.	15
About	15
Select Publications of Chris Biddle	15
Contact Information	16
Trademark Acknowledgements	16

Executive Summary

Abstract

Today, life sciences companies are faced with several major challenges with compliance and the information technology systems that serve as the backbone for these companies. These challenges remain unresolved using current approaches and cost life sciences companies many millions to tens of millions of dollars every year. For some, these numbers are in the hundreds of millions in penalties and opportunities lost. It is our view, based upon the review of available data, that a very significant opportunity may exist to mitigate these losses by utilizing new technology which is available to monitor user experience and then address identified issues.

This IdealNet report will examine the challenges, reveal the significant points of pain, and share a view for how specific new technologies in application performance management, particularly enterprise-class user experience management, can provide solutions for these challenges. We address both compliance and the optimization of user performance and believe that these technology sets can help deliver strong return on investment on a short-term basis. This is the first study that we are aware of that attempts to segment the user experience management (monitoring) market by specific use case for potential consumers of the technology.

IdealNet estimates that perhaps 30% to 35% of the potential return on investment has been realized by life sciences companies (and the global 1000 companies as a group) by optimizing infrastructure in support of major enterprise backbone applications and their underlying infrastructure. This leaves perhaps 50% to as much as 70% of the potential return on investment unrealized where a significant path to gaining access to this benefit is through the deployment of enterprise-class user experience management analytics. In the final analysis, the real determinant for the typical life sciences organization would be to identify those use cases for the technology that are applicable and then model the return on investment potential for the organization.

This opportunity is particularly compelling for life sciences companies on a global basis. This would include the top 100 pharmaceutical companies on a global basis and extend to the top 50 medical device manufacturers. There is a very substantial incremental opportunity for the top 100 to 300 global hospital (healthcare) systems and the top 30 insurers that service this life sciences ecosystem. For these companies the operational benefits seem very compelling, often with a return on investment in well under one year, with the potential savings of tens of millions of dollars and yet the risk of implementation seems almost nil. There are very few such opportunities for the CIO to consider of similar benefit yet with low attendant risk. We believe that this opportunity is particularly compelling for life sciences companies and that it should merit their immediate investigation.

IdealNet, Inc. regularly consults to some of the largest life sciences companies in the world. Please refer to our "About" statement at the back of this study for more information about the firm.

Life Sciences in Context

Information technology has focused for many years primarily on the efficiency and effectiveness of the infrastructure – the major enterprise applications, networks, storage and processors that enable organizations on a broad scale. Most of the technology within information technology is focused on these components from a systems point of view, not a user point of view. Further, very little attention is paid to the user. The user is, in fact, the most important system-level component. The user makes decisions about compliance, best practice, process and implementation every day and every hour they use the system. Yet, we know so little about their performance.

This raises many questions that, if we knew the answers, would enable a baseline for key performance indicators. If you can measure it, then you can improve it. You can compare it to industry metrics. You can determine what level is acceptable and what needs to be improved.

How effective are your users at utilizing your major enterprise applications? What problems are they having following best practice? How quickly and effectively can you remediate these problems? Are they following compliant behavior and how can you validate this? What is the view to every user's effectiveness and what levers does management have to optimize and improve this performance? Who should be trained and when? Do you know what your key performance indicators are for your major enterprise applications? Do you understand if these numbers should be improved? Could be improved? In context, it must be understood that life sciences is faced with a regulated environment which is not similar to any other industry. The mandate of legislation that wraps life sciences companies in a heavy and cumbersome burden of compliance seems to be increasing. Certainly this is the case in the United States and in the European community. Japan also has equivalent legislation. This compliance burden

creates in excess of one billion in penalties per year, for pharmaceutical companies in the United States. This includes the effects of legislation on both a countrywide and local basis.

The other significant challenge centers on the information technology and infrastructure those life sciences companies have already put in place to automate a very difficult and complex supply chain, and to create protective barriers and reporting to deal with the compliance burden. Not only must pharmaceutical companies, for example, implement heavily customized ERP and financial systems, but they also require extensive additional software systems for managing chargebacks, rebates, contract management, federal and state compliance and associated reporting.

No other industry has the need for so many complex additional systems just to run the baseline business. No other industry has the need for such massive and complex software system deployments across hundreds, thousands, and even tens of thousands of seats of administrative, research & development, marketing and sales personnel. Life sciences is unique in many respects and these distinctions, in part, create the challenges which we will seek to better understand.

On the legislative side, penalties continue to increase annually, both civil and criminal, with associated cost and risk to leading pharmaceutical companies. It is very clear that expenses for U.S. pharmaceutical companies continue to skyrocket, and at a time when many of the key patents are expiring. Medical device companies also face a growing barrage of legislation and much higher costs for getting a new product to market.

In response to all of this, the focus in life sciences has moved from driving innovation in discovering new pharmaceuticals to driving and delivering operating excellence. A better balance must be maintained between the two. The next new wonder drug is farther away, and most likely not to be innovated in the largest companies.

The leaders need to be efficient and effective in managing their existing business. Portfolio growth comes at higher expense as single drug start-ups move into an M&A driven acquisition pipeline. Major traditional pharmaceutical companies must now compete with a barrage of Asian generics companies that are expanding their business from generics manufacture into the acquisition of unique new product lines. Challenges face companies providing products and services in pharmaceuticals manufacture and distribution, medical devices, medical insurance and patient care. Patient care is a very broad domain and includes many information technology and software infrastructure components on a global basis so the positive impact to operations can be very significant. These opportunity benefits potentially include reduction of risk, implementation of best compliant practice and a very substantial and rapid return on investment.

New technology sets such as enterprise-class user experience management offer very significant and positive opportunities for life sciences companies. They present these opportunities across a broad front of use cases, each presenting qualitative and highly strategic benefits, with the concurrent benefits of enhanced operational efficiency.

The Life Sciences Market

Every segment of life sciences is heavily regulated. There are unique considerations that affect the infrastructure that must be managed.

Pharmaceutical Industry

In the pharmaceutical industry, perhaps only one out of every ten thousand discovered compounds actually becomes an approved drug for sale. Tremendous expense is incurred in the early phases of development of compounds that will not become approved drugs. On average, it takes roughly 7 to 10 years to develop and approve a new drug. Yet only 3 out of every 20 approved drugs bring in revenue to cover the costs of development.

To make matters worse, perhaps 1 out of every 3 approved drugs generates enough money to cover the investments made in drugs that did not succeed. In essence, the major drug companies must deliver, or acquire, a drug that generates sales on a massive scale, every few years.

Drug discovery and development is very expensive; of all compounds investigated for use in humans only a small fraction are eventually approved. This approval comes after massive investment in clinical trials, as well as heavily regulated processes relating to safety monitoring. Drugs often fail in this process, generate huge costs, and yet generate no revenue in return. If the cost of all investment is taken into account, the cost of developing a successful new drug has been estimated over \$1 billion (to as much as \$1.5 billion) without the costs of bring the product to market. In context, the total industry-wide research and investment crested at a record \$65+ billion in 2009. Yet the risks associated with this endeavor are huge. They are made overly complex by legislation and regulation that affects pharmaceutical companies on a massive scale.

This is a list of the Federal statutes that affect the pharmaceutical industry and hence directly impact information technology operations and business best practice. The complexity of these statutes and regulations is immense and it directly affects the information technology infrastructure, compliant best practice and day-to-day operations on a broad scale. This partial list is as follows:

- Civil Monetary Penalties
- False Claims Act, 31 USC 3729
- Federal Anti-Kickback Law
- Federal Food, Drug, and Cosmetic Act, Section 352
- Federal Food, Drug, and Cosmetic Act, Section 355
- Federal Public Contract Anti-Kickback Act
- Health Care Fraud Statute
- Lanham Act
- Mandatory and Permissive Exclusion, 42 USC 1320a-7
- Medicaid Rebate Program Statute, 42 USC 1396r-8
- Public Health Services Act, 340B (42 USC 256b)
- Social Security Act, 1847A (42 USC 1395)
- Stark Law
- Veterans Health Care Act of 1992

Further, this is a list of Federal regulations that provide additional guidance:

- Anti-Kickback Regulatory Safe Harbors, 42 C.F.R. 1001.952
- ASP Data Elements Guide
- CMS Update to Information on Medicare Coding and Payment for Drugs and Biologicals
- CMS; DRA Policy Questions
- Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003)
- DRA Final Rule: 42 CFR Part 447 (39142-39190)
- DRA Policy Questions
- DRA: P.L. 109-171
- FDA Guidance (1997) on Medical Education
- FDA Guidance on DTC Broadcast Advertisement
- FDA Guidance on Off-label Drug Promotion
- Federal Sentencing Guidelines (complete)
- Federal Sentencing Guidelines 8B2.1, definition of an "effective [corporate] compliance program" (2007)
- General Instructions for Completing the Pharmaceutical Pricing Agreement
- Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New

Uses of Approved Drugs and Approved or Cleared Medical Devices, 73 Fed. Reg. 9342

- Guidelines for Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074
- Holder, Thompson, and McNulty Memos:
- Holder Memo
- Thompson Memo
- McNulty Memo
- HRSA's Patient and Contract Pharmacy Guidance Letter
- Medicaid Rebate Agreements:
- Medicaid Rebate Agreement
- Medicaid Rebate Agreement Attachment A
- OIG and Health Lawyers Association: An Integrated Approach to Corporate Compliance (July 2004)
- OIG and Health Lawyers Association: Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors (2007)
- OIG Compliance Guidance for the Pharmaceutical Industry
- OIG Fact-Sheet: Federal Anti-Kickback Law and Regulatory Safe Harbors (November 1999)
- OIG Response to Request for Guidance Regarding Certain Physician Investments in the Medical Device Industries (October 2006)
- Principles of Federal Prosecution of Business Organizations (August 2008)
- Sample Rebate Agreement between the Secretary of HHS and Manufacturer
- Submission of Manufacturer's Average Sales Price Data, 42 CFR Part 414 Sub-part J

The point of this data is to show that delivering information technology infrastructure and specific implementation business practice in a compliant way is essential to the survival and growth of any pharmaceutical company. This regulatory environment creates tremendous challenges both to the information technology infrastructure and to managing the behavior of the human capital in the organization.

Medical Devices

The global market of medical devices is well over \$225 billion on a global basis and continues to grow. In the United States, the Food and Drug Administration has recognized and classified medical devices based on the level of control necessary to assure the safety and effectiveness of the device. This regulation requires complex information technology, compliant processes and a broad array of business process to implement. The classification procedures are described in the Code of Federal Regulations, Title 21, part 860 (usually known as 21 CFR 860). Class I devices have the least regulatory impact. Class II devices, however are those for which general controls alone are insufficient to assure safety and overall capability. A Class III device is one that needs premarket approval, a scientific review to ensure the device's safety and effectiveness, in addition to the general controls of Class I. Class III devices are usually those that support or sustain human life and prevent degradation of human health, risk of illness or injury. The regulatory framework in the United States is complex and this again impacts information technology infrastructure, compliant business process and more.

The European community is no different and perhaps even more complex for medical device companies. The European community has three core directives that include 90/385/ EEC regarding implantable medical devices, 93/42/EEC regarding medical devices and 98/79/EC regarding in-vitro diagnostic medical devices. These three core directives have been supplemented over time by several additional directives, including the last technical revision defined by 2007/47 EC. All of this adds complexity, puts tremendous emphasis on compliance and process, and creates additional challenges for information technology, both infrastructure as well as human capital.

Medical Insurance Industry

The United States health care system is centered on private health insurance, which is the primary source of insurance coverage for most Americans. Based upon publicly available data, IdealNet, Inc. estimates that perhaps 55% or more of Americans have private health insurance. Public programs provide the source of coverage for many senior citizens and for low-income segments of the population that meet eligibility requirements.

The primary public program is Medicare. This is a federal social insurance program for seniors and certain disabled individuals. Public programs also include military health benefits provided through TRICARE and the Veterans Health Administration. Some states have additional programs for low-income individuals.

Consider that the Medicare and Medicaid programs may soon account for 50 percent of all national health spending. All of this regulation has an attendant mix of compliance activity, reporting, and more for which failure to comply brings substantial penalty, both financial and potentially criminal.

Patient Care (Health Care Systems)

The largest healthcare systems in the United States are all multi-billion dollar ventures. Some are as large as \$40 billion per year in revenue or more. Practitioners in medicine, chiropractic, dentistry, nursing, pharmacy, allied health as well as other care providers deliver these healthcare services. There are over 15,000 hospitals worldwide with the top 500, on a global basis, representing business on a very significant and complex scale.

Health care can form a very large part of a developed nation's economy. In 2009, the health care industry consumed on average, approximately 9.0 percent of the gross domestic product across the most developed countries. The United States (16.0%), France (11.2%), and Switzerland (10.7%) were the top three spenders.

Health care systems also face a mix of the same regulatory environment, in part, associated with the insurance, pharmaceutical and medical device sectors. It is in this environment that all of these meet the patients and ultimate consumers of the technology. This brings the same levels of complexity in managing the information technology infrastructure and maintaining compliant and effective business process. In fact the convergence of these various regulatory pressures often create a greater challenges within the companies that deliver these services.

Technology Trends in Life Sciences

If you are a top 200 pharmaceutical company, there is no "off-the-shelf" set of software you can roll out to run your business. For the simplest scenario, you need a complex set of integrations across a diverse set of vendors such as SAP[®], ModelN[®], Revitas[®], Microsoft[®] and many, many others. Your relationships with trusted advisors such as IMS[®], Accenture[®], Deloitte[®] and others is critical to your business as complex integrations are a cornerstone of any operational deployment.

The requirements for government compliance are a core risk area for any CIO in life sciences. Operational requirements for systems to support reporting for government compliance are exacting and which must be managed 100% of the time to compliant practice. There is no room for error at any time. Anything below the acceptable threshold may result in the assessment of massive fines, penalties, and sometimes even criminal penalties. There are no shortcuts and errors at any level of scale can be career defining moments. All it takes is one person to create a pricing level outside of policy with a single transaction, to produce a potential penalty which could be unbounded and perhaps in excess of \$100 million or more.

Movement to the cloud certainly complicates the issue in the future – but this has not been a significant force for life sciences companies. Life sciences, primarily in the United States and Europe, are highly regulated and have been very slow to move into the cloud, if at all. The need to support complex compliance requirements, privacy and difficult supply chains has resulted in large data centers with very complex system integrations and a multitude of highly customized ETL interconnections. These are not easily unwound anytime soon.

Penetration by Salesforce[®] is often discussed but in terms of real seats in life sciences, has no significant impact yet. Penetration continues but albeit at a very slow pace. The bulk of the systems in these organizations are customized, heavily integrated and not yet well suited to cloud deployment.

The opportunity for benefit from new technology such as enterprise-class user experience management certainly easily reaches the top 100 pharmaceutical and related distribution companies on a global basis. It extends to the top 50 medical device manufacturers, top 100 to 300 hospital systems (easily the top 10% of the global hospital and clinic footprint in terms of revenue) and the top 30 insurers that are part of the life sciences ecosystem. Most of these are massive companies, easily within the global 1000, and they have many thousands of employees using key applications like, for example, SAP[®], Siemens Envision[®] and others to drive their business from end to end.

Application Performance Management Market Overview

Market Size and Overview

The application performance management (APM) is a market with about two billion in annual revenue. Industry analysts vary but in general the growth rate has increased recently from high single digits to very low double digits as of late. The tools are well established and most major analyst firms are concerned on reporting on the status quo – not the areas for innovation. The market is also sometimes referred to as application performance monitoring.

The APM market is characterized by legacy products. This is a legacy market. Most of the products have been around for a long time and are considered quite mature. They are regularly purchased by global 5000 organizations to complete the dashboard to the performance of information technology infrastructure and reporting.

The CIO very often uses these systems to establish baseline reporting back to the line of business with a focus on system performance.

Most of these are scripted and manually implemented. There is not much out of the box that provides other than very basic value as a dashboard to the technology infrastructure and perhaps an alert structure to manage it more successfully. There is some buzz around extending these legacy products to mobility, big data and more but mostly this is blocking and tackling for these vendors. Extending reports, primitive analytics and alerts to iPads and iPhones is just basic evolution, albeit welcome, but definitely not significant innovation.

Many of these legacy products have been around for years and started with support for client server architectures.

Patrol[®] was a start-up founded by an early executive from Oracle's telesales team. This particular gentleman self-funded Patrol[®], brought the company from fruition to a sale to BMC[®] for what was rumored to be less than \$50 million dollars. Today Patrol and related products from BMC[®] are core to the APM market, although they were really designed to solve the problem in the client server world.

We are addressing the overall APM as many analysts include basic user experience management in this market segment. The space is very confused and the definitions of user experience management have been polluted by very basic entries. In fact, there are so many basic entries that it confuses and sometimes diminishes the value of the enterprise-class user experience management products. The basic market for APM has always addressed infrastructure and the not the user!

The APM market today is best characterized roughly by several core capabilities wrapped around an information technology dashboard including the presentation of status, in a multitude of forms, of the hardware, network and software resources in an organization. Early on, the market valued the notion of alerts. These were console messages, emails, pager notifications (in the early days), SMS and phone calls notification when the performance off a targeted entity went below thresholds. Everything was about the infrastructure – the equipment, the resources and the software. These software applications track the execution of the components of software applications, report on the utilization of the hardware and software that are used by these software applications, determine if error conditions have happened and try to report on why the application has failed to execute properly. CA Technologies[®], IBM[®] and Hewlett Packard[®] all have excellent products that serve the APM market customers. There are many other players with varying sets of capability.

User experience management, at a very basic level, is bundled in by analysts who really don't want to take the time to understand it. They see two billion in expense for APM products and find order for their late adopter mainstream clients by aggregating it all together. Unfortunately, this view hides potential value for customers and fails to recognize the huge benefits associated with user experience management.

Segmentation

Our target segment, enterprise user experience management for life sciences, is at most today a \$100 to \$150 million dollar segment and hence under the radar of most large analyst firms. They cover this segment under the fold of APM. Yet, we believe that this segment presents more than five to ten times the opportunity for return on investment; far more than the other 90% of the software sold in the APM market. This can be validated fairly easily by each life sciences information technology team prior to implementation, but in general we are very enthusiastic about the potential we have identified by use case.

Most important, and we will raise this point more than once in this report, is that key features, which define as "enterprise-class," are offered by the vendor. Without these features and "basic" user experience management, you miss many of the opportunities to improve operations and compliance within your organization with the attendant return on investment. This is an even smaller segment yet offers the most potential value for life sciences customers.

Hence the notion of user experience management. It is the idea that by better understanding the performance of each user, and how the user experiences the performance of the infrastructure, we can provide a new set of business optimization by improving the user experience and targeting the problems they face. Now we can be more methodical in bringing the organization closer to best practice business process using the infrastructure that information technology and the line of business has provided. As a by-product, we enhance user satisfaction, provide dramatic reductions in expense and deliver strong return on investment. User experience management (or monitoring) has emerged as a new segment in APM that has left the early adopters and clearly moved into the early mainstream. Thousands of customers have used the technology, certainly at a basic level and have derived very good results for their investment.

User experience management (UEM) has been segmented by IdealNet into several tiers of technology. The greatest opportunity for strategic benefits and the broadest set of use cases come from what we define as Enterprise-class UEM.

Targeted Enterprise Applications for Life Sciences

In a typical large enterprise there are many applications. IdealNet would estimate between 150 to 500 applications may exist in various states of use in the global 5000 enterprise. There are likely some companies with thousands of applications. However, in general a few hundred receive most of the attention. This includes various browsers, applications purchased by department or section, and more than half of these applications are used by a small handful of people a small percentage of the time. Many are dormant, live on desktop systems and are eventually purged off due to disuse.

The core set of Enterprise Applications that form the backbone of an enterprise, are often easily counted on one to two hands by the CIO. Backbone applications are those that involve 500 to typically 5,000 to as many as 50,000 or even as many as 100,000 seats. These include enterprise resource planning (ERP), financials, customer relationship management (sales, marketing, customer support), Microsoft desktops, business intelligence and more. Applications like master data management (MDM) are really only IT centric in nature but still core to enterprise activity.

In life sciences it is clear that SAP[®] owns the enterprise backbone for ERP and financials in 95% or more of the leading pharmaceuticals on a worldwide basis. There are other legacy CRM environments such as Peoplesoft[®], Siebel[®] and more. They are followed by Oracle[®] more as a function of the database software infrastructure than key applications.

New technology such as SAP's Hana[®] seems as if it is riding a new wave of innovation, especially for large pharmaceutical companies. We expect Hana[®] to rapidly deploy and dominate the pharmaceutical and medical device companies. Hana[®] clearly brings tremendous potential benefits to existing SAP[®] customers and seems a likely addition for them. In pharmaceuticals, based upon informal outreach, it is estimated that 75% to 90% or more of the existing SAP[®] customers will move to Hana[®]. Hana[®] is a production ready environment and a mature product in a leading edge market.

Oracle's Fusion[®] is facing many challenges. Oracle[®] is a fine company but their attempts to integrate a broad set of disparate client server applications with a broad set of new ones seems to be driving a product roadmap down a very long road. It seems obvious now, after several years of trying, that instead, they should be building new front ends to the massive customer bases that use Siebel[®], Peoplesoft[®] and other applications (solve the UI problem) and then take these customers to cloud infrastructure. On the other hand, Oracle's database remains the data storage infrastructure of choice for all legacy applications, with few exceptions. This positions Oracle[®] as a strategic vendor for life sciences companies in any scenario.

SAP[®] has done a good job evolving their core legacy applications with the addition of new ones, adding one at a time in a more thoughtful and well integrated way. Web portals have been thoughtfully integrated and all of it allows customers to maintain their massive legacy data sets, the complex and fragile integrations that drive them yet get the benefits of the browser based world. SAP's mid tier cloud strategies have floundered a bit, but this is not an issue for most leading life sciences companies.

BusinessObjects[®], now part of SAP[®], is also fairly ubiquitous in life sciences as in other industries. MicroStrategy[®] has found interesting niches as a function of their advanced capability and will continue to prosper in department applications that leverage the power of the system. Cognos[®], now part of IBM[®] also has some broad deployments but in general is behind BusinessObjects[®] in life sciences and we expect that trend to remain.

Other life sciences companies have made significant commitments to patient billing systems such as Siemens[®] Envision[®], Allscripts[®] and others. These use Oracle[®] database structures as well as Microsoft[®] SQL Server and IBM's DB2[®]. There are significant commitments to FDA submission/ approval systems; many are custom but there are standard platforms available from several vendors.

In conclusion, if you are a CIO in life sciences, we've told you what you already know. The largest enterprise is still very much run by major legacy applications that translate to CIO mindshare. If you successfully address compliance problems and identify user experience management opportunities in these 5 to 10 large applications, you have covered more than 80 to 90% of the available benefit for these corporations.

Market Trends

We believe, in summary, that enterprise-class user experience management and other ascending products in the same broad family (basic and advanced user experience management) will grow at a rate faster than the legacy APM market from 2013 through 2016. Penetration in the global 5000, now between 5% to 10%, will perhaps reach up to 50% at that time for one or more core enterprise backbone applications within such an enterprise.

Ultimately the feature sets required to compete will mandate full workflow capture and automated technologies that do not require legacy scripting techniques, either for out-ofthe-box functionality or for the accommodation of custom functionality. Mobility will be integrated, not for the executive dashboard within your firm, but more to extend the supply chain to your customer and this will create compelling incentives for enterprise-class user experience management.

Finally, we believe the true roadmap for innovation is to invest in the integration of new technologies that focuses on the closed loop process for the remediation of user driven error. This is the automation of techniques that both detect trends in user error and non-compliant behavior and then provide remediation, through software, to address and correct this behavior. This is the vision for the industry. This takes the current reactive state using actionable analytics to a proactive future state in which close loop process brings takes the user almost immediately to improved performance.

User Experience Management Overview

Enterprise-class User Experience Management IdealNet has defined our view of how to classify vendor capabilities in the user experience management space. In sorting out the benefits for life sciences companies, we have crisply categorized user experience management. The importance of this definition rests in the number and depth of use cases supported. Enterprise-class user experience management clearly supports the greatest number of use cases which ultimately delivers improved compliance and return on investment.

Chart – User Experience Management Features by Tier

This chart provides an overview of the technical components and the essential capabilities they provide:

Enterprise-class	Auto Remediation
	Full Functionality for Major Backbone Enterprise Applications
	Auto Learning for Customizations
	Full Workflow Capture by User
	BI Based Analytics
Advanced	Desktop Agent
	Scalable
	Proprietary Analytics
	Offline Users
Basic	Scripted
	Simulated or Server Measurement
	Designated Transactions
	Pre-Packaged Reports
	Alerts
Platforms	Network
	Storage
	Servers
	Thin Client (Citrix)
	Client Server
	Web
	Windows
	Mobile Devices
	In-House Data Center
	3rd Party Cloud

Category Definitions

Platforms

Platforms identify the structures which are both monitored and which are then used for delivery of user experience monitoring reporting and analytics. Global 5000 legacy environments are replete with thin clients (Citrix®) and often times this is an essential component. At the same time a broad tier of mobile devices is proliferating, usually driven not by monitoring, but for delivery of reports and analytics on the monitoring activity, certainly in 2012. Mobility is not an innovation, but merely evolutionary, as an extension to platform support for user experience management.

Basic User Experience Management

Basic user experience management includes the legacy scripted capability to identify and measure response for

any portion of your key application. Your organization may define a few key transactions, end to end, and then script the system to monitor these and report on their status. To the extent these are not scripted, the data may be server-based and derive report data from the web based packets traffic. Reporting is usually prepackaged and may be customized, although you are using a proprietary interface. Alerts are an essential part of the mix usually delivered through email, pager or SMS interfaces.

Advanced User Experience Management

Advanced user experience management must include a desktop-based agent to truly experience and measure the user experience. These systems must exhibit large enterprise scale and often come with proprietary analytics in addition to canned reports. Some systems offer support for offline users in environments such as Oracle[®] Siebel[®]. This is a critical requirement in these environments given the extreme number of offline users in a typical Siebel implementation.

Enterprise-class User Experience Management

Enterprise-class user experience management enables the full compliment of potential use cases for user experience management technology. The capabilities of this set are only possessed by a very few vendors and represent the leading edge of innovation and potential for the industry. In this class all reporting and analytics are based upon standard BI platforms. Full workflow capture is available for every user, which shows system errors, user errors, and all activity, screen by screen, field by field, button by button. Deployment is done without scripting, out-of-the-box for the major enterprise applications and includes all functionality. The systems can auto learn your customizations and adapt and report on them – without further customization.

The vision for the future is wrapped around autoremediation. Auto-remediation takes the notion of identified user error and immediately brings compliant best practice back to the user to correct the errors as the problem develops. This is the future of the industry – the volumes of return on investment possible will potentially drive user experience management, as a market segment, to an aggregate size larger than the rest of the application performance management space.

Use Cases in Life Sciences

We have identified the enterprise-class user experience management software capabilities. It is important now to understand the target use cases of importance in life sciences and tie them back to the functionality in the software. First, we need to identify the departments that may participate in the various use cases. They include IT systems support and application development, user support and help desk, line of business management, center of excellence, and education/training.

Then we need to examine each use case, what user experience management functionality is required to support it, and the potential for economic benefit.

Clearly, with low risk, a rapid implementation, and an attendant review of the potential high rewards and return on investment potential prior to implementation, we feel the use cases become quite compelling.

Use Case Area: User Education and Training

The user education departments are often staffed around the major enterprise applications. These include SAP[®], Siebel[®], PeopleSoft[®], and many others. These major enterprise backbone applications are complex, often customized and map in fine detail to compliance and best practice in the life sciences industry.

The complexity cannot be emphasized enough. For example, it is extremely difficult to train users in buy side or sell side administration of the supply chain. Areas like government compliance, chargebacks and rebates make the life science dashboard of required proficiency very difficult to master. At the end of the quarter, adjustments need to be entered into the systems by various departments and there is no room for error. One mistake in price point in any transaction could result in massive fines under the "Best Price" clause. For this reason it takes many months for new users to come "up to speed" and compliant proficiency. To make matters more difficult, there is only a very subjective assessment on management's part as to this proficiency.

More often than not, given turnover, brand new users are trained with a set curriculum. There is little dashboard to the proficiency of the users beyond "tests" which are designed for course support. But in terms of specific transaction implementation with live systems there is almost usually no data. Vendors and education teams implement tests which are more question and answer oriented, as opposed to measuring the correct path to success navigating specific tasks through the required application screens, modules, fields and buttons.

Enterprise-class user experience management brings the full potential for measuring performance both during and after

training. Because you can see the errors and delay, versus the rest of your population, you can zero in on the best areas for which you can target and optimize that user's performance. There are many paths sometimes to complete transactions. Your organization already has likely defined a best practice path either for reasons of efficiency, risk reduction, compliance or all of the above. So you have the unique ability to see immediately how your users map to these best practice executions, both in terms of how they navigated the system, as well as how quickly they did it. You can explicitly see immediately which groups of trained users represent your best users (your center of excellence) and which need remediation.

Advanced user experience management can define the categories of opportunity for training to target as these vendor platforms are agent based – they are taking the user's view of interaction and response. Unfortunately, without full automation (which nets out to full workflow capture and full application coverage) they cannot provide the captured workflow or metrics to understand the performance of a single user, only the users in aggregate.

Advanced user experience management tools can still be effective in targeting training, albeit without the full potential for return on investment.

Basic user experience management does provide a dashboard to basic application performance parameters, but doesn't really tell you about the actual user experience nor does it record any data at the desktop level, as experienced by the user. Further, these environments are often instrumented just for web-based server connection and cannot extract meaningful data from complex environments that use combinations of client server, thin clients like Citrix[®] and web-based clients nor can they handle offline users so typical of Siebel[®] legacy installations. For these reasons, we believe the training use case is not materially available to users of legacy user experience management technology at all.

The hard cost return on investment vests around the elimination of an endless repetition of training, sometimes by decree, for your entire user base. Now you can apply training strategically based upon clearly quantified need. There is soft cost return on investment around enhanced user efficiency in execution, which reduces time and cost for your work teams, and perhaps in other areas in which revenue is limited by timely execution of transactions and process on a daily basis.

Use Case Area: Information Technology CIO Dashboard

(Includes Alerts, Application Development Deployment, Custom Application Development and Systems Support)

Information technology teams, both within centralized and the line of business organizations have been the earliest consumers of basic user experience management. The use case started early as one of many additional tools to provide visibility to the operation, performance and status of the vast array of networks, storage, servers and applications that must be supported for life sciences customers. The array of legacy application performance management tools is guite daunting and the implicit business case was always that the IT team, and more specifically the CIO, needed to understand problems before they escalated, or at least diagnose and understand them as they escalated, as the soft cost to the business for lack of access to these systems was substantial. Further, the CIO needs to know more about problem states and potential solutions, all of the time, than any constituent organization.

In the simple case, basic user experience management allows you to identify and prioritize some classes of application performance issues, on a broad scale. IT teams can identify root cause analysis for system errors, but not for user errors. This is a hugely important distinction which we discuss elsewhere. Basic user experience management, in fact, rarely views the problem set from the real user perspective. Basic user experience management does not view the problem from the desktop, but from a simulation of a user or from an http server or other server perspective. Given this perspective IT teams have reasonable access to aggregate system level data, application problems and a simulated or server level view of what the average user is experiencing. The deployment and roll-out of new applications or new releases of major enterprise backbone releases is another area of opportunity. You can evaluate the performance, both of the applications and infrastructure (system errors and performance) as well as the user interaction (user error and user performance). This is most important during the HYPERCARE window for most organizations, the term HYPERCARE applies to the first 30 days of rollout to the user community. This is the time when you need visibility to both what is being reported as wrong, and what is actually wrong, before it is reported.

You can also use user experience management in the design of new customizations. Very often the user community, with tremendously good intentions, will design a new customization based upon their perceptions. Now you have the actual data and you can validate what you hear with empirical data before you design and implement. Further you can test these customizations afterwards to see how users actually interact with them. This sort of application development, called user experience driven design and validation, is a fairly hot new trend in Silicon Valley and getting quite a bit of momentum.

In addition, an excellent niche application for the IT team is in resource utilization and planning. Notwithstanding many of the tools in your existing application performance management arsenal, for your major life sciences applications, such as SAP[®], it is not always clear how much of what functionality you are using. For some IT organizations, user experience management is the best way to understand what in your SAP[®] or Siebel[®] system is really being used, and what isn't. This can lead you to remove functionality from your system with resultant savings for storage, maintenance and support. CIO's know the economics of this can be amazing. This may be worth a look.

Finally, user experience management can do an amazing job of supporting service level agreements. It can tell you everything about each user's time on the system, system errors versus user errors (often a problem area) and much more. It is absolutely the best dashboard to use when presenting to your line of business.

Use Case Area: Help Desk Optimization (Applies to User Support Functions / Help Desk / IT Service Desk / Center of Excellence)

This use case applies broadly and easily to most organizations. Generally the larger the scale, the more impressive the results. Life sciences companies have very complex application stacks and hence have a multitude of escalation issues and usually quite a few centers of excellence, or equivalent, where the "black belt" users for a given application help support the user community.

Every CIO knows that help desks, IT service desks and the development of the centers of excellence are a tremendously expensive process. The expenses can be distributed both within and without IT. The basic help desk, via a system such Remedy[®], lives in IT and the center of excellence for SAP[®] may live within one or more lines of business. It varies by organization.

Most of the life sciences organizations we talk to deal with anywhere from a thousand to several tens of thousands of help desk calls on a monthly basis. The areas of opportunity include reduction in the number of calls to resolve a specific issue, reduction in the length of calls for any single issue.

In a typical call cycle, the user has experienced the problem 6 to 7 times before they call the help desk. Once on the help desk call, they have to explain the problem usually at least two times, go through the escalation, try to determine how to provide "screen shots" or evidence of the problem and more in support of the help desk process. This process is replete with the necessity for "call back" as the evidence gathered is insufficient and requires additional work by the user. The user generally dislikes this process and because of avoidance, user errors are generally propagated for a long time with resultant reductions in operational efficiency, user satisfaction, perceptions of IT and much more. In the final analysis, neither the help desk nor the user understand precisely, most of the time, what went wrong especially when it was the result of user error.

Enterprise-class user experience management fully captures 100% of the user workflow and interaction, without exception, for everything in the target application system. At the time of help desk call, this data is immediately visible to the help desk team. They can see system errors, user errors, field by field what happened, and then can direct the user immediately. Further, this data can be clipped and copied to the report should escalation be required. For major enterprise backbone applications, the impact to the help desk operations can be quite large. Most organizations are fairly excited about reductions on the order of .5% or perhaps 1%.

These can bring major impact to short-term return on investment. User experience management can bring reductions of 5% to 20% to operational costs associated with the length of calls and the number of calls. The financial impact of this huge percentage is rather startling and this simple application becomes the easiest way to both build the financial model to acquire the technology, acquire the consultants to apply the best practice implementation, and then return investment within the first year of deployment. The rest of the use cases and all the attendant benefits can come along for the ride and usually add additional layers of return on investment.

Beyond the basic metrics for help desk infrastructure you have the ability to impact customer satisfaction (the help desk customers) and to attack problems on a pro-active basis, before they are reported. This is similar to the HYPERCARE window process in that you are reviewing the analytics to see clusters areas of user error, excessive times, or even system error.

There are also soft cost benefits we can also find beyond the hard cost benefits we have identified also. How much more productive is the user community and how does this improve the benefits to your organization? In conclusion, call times and volumes are reduced, time to resolution is improved, customer (line of business) satisfaction generally improves and the financial impact of this materially improves operational efficiency.

Use Case Area: Best Business Process / Compliance

This is a remarkable capability which can be derived from using the data stored by enterprise-class user experience management systems. It is far from the original dashboard capability of application performance management and may turn out to be the "killer application" for the technology, certainly in life sciences, in addition to IT service desk call time/frequency reduction.

As it turns out, if you look at software in the compliance space, there is almost no software available that takes the keystrokes, transactions, field, screens, movements from what your employees do in major applications such as SAP[®] and Oracle[®] Siebel[®]. We found one vendor, Knoa Software[®], which delivers this enterprise-class capability. It seems almost essential to several important use cases.

It is not always a question of what your users should be doing or what they say they are doing – life sciences liability in compliance question of exactly what they are doing. Most of the enterprise systems in place in pharmaceutical companies and medical device companies do not, and cannot enforce the best practice necessary to maintain compliance. They rely on training and expect the best outcomes with minimal enforcement. There are billions in fines levied against U.S. pharmaceutical companies that indicate that the best outcomes did not happen and reinforce the conclusions that the systems in place are not yet adequate to drive the best and desired outcomes.

In the near term, this sort of capability allows you to build out rule sets or filters against the data and know, definitively, not only what people did in the system, field by field, but even what they viewed. This deep compliance machinery is exactly what life sciences requires – it is perhaps an overkill for other industries but given the state of fines in life sciences it is a timely and apt fit to bring the solution set at the hands of the CIO much closer to what is required.

Build out is required on a customized basis either as a standalone application or with an interface to perhaps a commercial compliance platform. Given the nature of the huge enterprise backbone applications, IdealNet submits that special implementations for systems like SAP[®] and Siebel[®] make much more sense as their transaction volumes define the bulk of the critical enterprise.

Deep compliance issues aside, there is always best practice for transaction and activity execution. There are many ways through an ERP or financial system to get the same or similar result, but one or two ways define best practice. User experience management provides a dashboard, by user, by group, by geography, by department or by almost any other measure to exactly how transactions and activities are being carried and the paths being used. Which of your users represent best practice? Which don't and why? How can this lead to non-compliant behavior?

Summary and Findings

The Opportunity For Life Sciences

This IdealNet report has overviewed the challenges, revealed the significant points of pain, and shown how enterpriseclass user experience management can provide solutions for these challenges. We address compliance, the optimization user performance and believe that these technology sets can help deliver strong return on investment on a short term basis. As we mentioned earlier in this report, this is the first study that we are aware of that attempts to segment the user experience management (monitoring) market by specific use case for potential consumers of the technology.

This opportunity is particularly compelling for life sciences companies on a global basis. This would include the top 100 pharmaceutical companies and extend to the top 50 medical device manufacturers. There is a very substantial incremental opportunity for the top 100 to 300 global hospital (healthcare) systems and the top 30 insurers that service this life sciences ecosystem. For these companies the operational benefits seem very compelling, often with a return on investment in well under one year, with the potential savings of tens of millions of dollars and yet the risk of implementation seems almost nil. There are very few such opportunities for the CIO to consider of similar benefit yet with low attendant risk. We believe that this opportunity is particular compelling for life sciences companies and that it should merit their immediate investigation.

IdealNet believes that the call to action for life sciences organizations would be to identify those use cases for the technology that are applicable to your organization and then model the return on investment potential for your organization. A proof of concept, pursuant to a strong economic analysis, provides a very low risk, potentially high reward way to proceed. We recommend identifying a vendor in the category that meets your needs although we do emphasize the use case benefits of enterprise-class user experience management.

Leading User Experience Management Vendors

Hewlett Packard[®], CA Technologies[®], SAP[®] and IBM[®] all provide world-class basic user experience management products that enable basic infrastructure reporting and alerting. They user server or simulated technologies and generally require scripting where specific transaction measurement is required, especially for major legacy applications.

SAP[®] also resells SAP UEM by Knoa[®] which is an enterpriseclass user experience offering side by side with their other infrastructure products. This is discussed below.

IdealNet, Inc. did identify a small Boston based vendor with development facilities in Israel, which we were unable to interview prior to the finalization of this report. They did provide an advanced agent technology, superior to most of the legacy vendors, but still required scripting and extensive work by the user to accommodate major legacy applications. We believe that they will vest as advanced user experience management and we will watch their capability.

Vendor Focus – Enterprise-class User Experience Management – Best in Class Product

We recommend a close look at Knoa Software[®]. Their EPM product for SAP[®] and for Siebel[®] maps to our recommendations for an enterprise-class offering. They have several hundreds of licensee's, a global reference base and a major channel through SAP[®].

Their automation is 100% complete for major enterprise applications out-of-the-box without any scripting. This

capability, along with their full capture of all user workflow, sets them apart and enables use cases that other vendors cannot support.

Knoa also has single customers with as many as 70,000 licensed users – this places them successfully in the largest corporations in the world.

Knoa Software is a market visionary in the developing segment of user experience management. Their view of overall direction and capability sets them apart and positions them to continue success as the user experience market develops.

About IdealNet, Inc.

About

The IdealNet[®], Inc. team provides expert business and technical strategy analysis for rebate utilization and prescription level scrubbing and data validation including Commercial, Medicaid, Medicare Part D, Tricare and Medical Claims.

We address a broad array of contract management challenges to include Chargeback processing, Rebate processing, Medicaid processing and all facets of Government pricing. This can include complete package selection and related analysis and support, definition and full documentation sets for commercial and regulatory compliance procedures and definition and implementation of contracting and pricing strategy and best practices by product and across your entire portfolio of pharmaceuticals.

On a broader scale, we can integrate your systems with a comprehensive data warehouse architecture, implementation and integration with an enterprise wide implementation of master data management and other internal complex supply chain, operational, compliance and planning systems. This includes the necessary data transformation, conversion and reporting to support compliant practices on a global basis.

Select Publications of Chris Biddle

Chief Executive Officer, IdealNet, Inc.

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Contact Information

Siebel®

Siemens® Envision®

IdealNet, Inc. 2933 W. Germantown Pike Bldg. 2, Suite 204 Fairview Village, PA 19409, USA Toll Free (US/Canada): 800-618-0836 Phone: 484-681-4086 Fax: 610-666-1006 info@idealnetinc.com

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IdealNet, Inc. 2933 West Germantown Pike Building 2, Suite 204 Fairview Village, PA 19409 USA Sales: 800 618 0836 Fax: 610 666 1006 email: info@idealnetinc.com www.idealnetinc.com

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