european
pharmaceutical
review

INFORMATICS

IN-DEPTH FOCUS

Thermo SCIENTIFIC

You are compliant

Information is demanding. It has to be accurate and easy to share across your lab, or across the globe. To flow seamlessly into reports that ensure product safety, productivity, and compliance. In over 25 years of work with regulated industries, we've learned what you face today, and what's on the horizon. This is where you'll find sustainable, integrated **purpose-built LIMS** that withstand the test of time.

with informatics solutions ready for the future

• thermoscientific.com/informatics

Laboratory Information Management Systems
Designed to meet the flexibility demanded by today's laboratories

Chromatography Data Systems
Enterprise-level for global deployment and maximium instrument functionality

Document Management Systems
Compliant document management for mission critical information

Electronic Laboratory Notebooks
Secure documentation, enable collaboration and ensure traceability

Spectroscopy Software
Industry-leading solutions to visualize, process and manage data

INFORMATICS
IN-DEPTH FOCUS
INTRODUCTION

Michael H. Elliott
CEO, Atrium Research & Consulting

DEVELOPING INFORMATICS FOR THE PHARMACEUTICAL INDUSTRY

For the past 10 years, major pharmaceutical and biotechnology organisations have had an insatiable appetite for ELNs to improve operational effectiveness and achieve knowledge management strategies. Preliminary data gathered from our 2012 ELN study shows over 50 per cent of all biopharmaceutical companies have at least one system installed. For the top 25 companies, the percentage jumps to over 70 per cent. The installed based, however, has been primarily in discovery and early development. The use of the technology in quality assurance and control – where LIMS systems have traditionally held strength – is lower, at around 25 per cent, creating opportunities for new license sales. Forward-thinking companies are viewing ELN as a component of a larger informatics puzzle, rather than just a replacement of paper. In R&D, there is an increasing emphasis on services to expand capabilities and integrate with other systems. While licenses sales have slowed to about 15 per cent, the growth of professional services is over 30 per cent.

The trend seen over the last three years toward convergence of discrete informatics categories continues: LIMS systems taking experiment documentation characteristics of an ELN, ELN taking on LIMS-like sample tracking and workflow capabilities, both ELN and LIMS adding raw data management. There is a good reason why this continues. In every survey we have conducted in the last six years (including 2012), scientists' rate 'integrating data from multiple systems' as their top data and information management challenge. They do not want the pain of copying and pasting data from multiple systems and trying to make sense of it. The desire is for a holistic environment managing structured and unstructured data in such a way that it improves their ability to perform experiments and share data, not make their lives more difficult. When we asked prospective users for their perspective of an ELN, 'a portal into my lab's systems and databases' and 'for collaboration and knowledge sharing' are consistently at the top of the list.

The challenge for suppliers is to not add to the wanted features and capabilities in such a way that they make the product unwieldy and complex to deploy. In the early adopter phase of the market, clients asked for an increasing number of product extensions to address the requirements of domains like medicinal chemistry, drug metabolism, formulations and pharmacology. This resulted in converged solutions with increasing feature-rich products. Exploiting these productivity improving capabilities often meant increasingly challenging configurations and resource demanding deployments.

The pressure from management to show the results of major investments in a short timeframe is high, pragmatic companies in discovery are starting to trend back to a 'sticker book' or 'paper on glass' philosophy as their initial way to expand the user community as fast as possible. This deployment method targets intellectual property protection, knowledge management and collaboration but puts off workflow, structured data management and other sophisticated features to subsequent phases. In quality, the conversion of hundreds of validated methods to a procedure-execution ELN as well as the rationalisation of LIMS workflows (i.e., 'what do I do in LIMS versus ELN?') can be quite daunting, leading some to initially target GxP compliance; gains in lab efficiency gains through a truly automated environment will follow.

ELN has matured to the point that it is a necessary tool for any company who values knowledge preservation, collaboration and laboratory efficiency. There are now almost 40 suppliers representing any increasing number of niche applications; despite the healthy mergers and acquisitions of late. The product you select and how you will deploy it is highly dependent on the long term vision and direction of your organisation.

Wtah's miknag yuor dtaa so hrad to depecihr?

Whether you're managing it, searching through it, tracking it, analyzing it, collaborating with it, sharing it, reporting it or protecting it – you need simple ways to get clarity and add value to your data.

You'll find the solution at **IDBS**

www.idbs.com/epr

Enabling Science idbs

ROLLING OUT A BIOLOGY ELN AT UCB PHARMA

David Lee
Principal Scientist, Informatics, UCB

Electronic lab notebooks (ELNs) offer a solution to a number of the problems that bedevil drug discovery: efficiency, communication and knowledge management. Simply put, writing up experiments using an ELN should be faster and easier than a paper lab notebook. The data within it should also be a lot more accessible – Google-like searches (never mind advanced searches) will bring a list of hyperlinked hits, and away you go (that's the theory anyway). But how easy are they to implement? We are mid-way through an implementation project at UCB, and would like to describe what we have done and what we have learnt.

The deployment of ELNs in UCB Discovery Biology stemmed from a project addressing data capture for *in vivo* experiments. Back in 2008, our existing assay data capture and analysis system (Quest) worked well: data from experiments was captured, integrated with data from other sources (molecule description systems for example) in a data warehouse then transformed into specific marts for delivery via query tools to project teams. But some types of data, for example *in vivo* data, did not enter this system. Existing data capture systems struggled to support the variability of *in vivo* experiments, where key parameters such as number of animals per group varied between experiments. The existing systems also struggled to build user friendly templates due to the volume of data, its complexity and the sophisticated charting and statistics required to analyse the data. In short, if tools were built, they were unpopular and no data was entered. Therefore *in vivo* data was not delivered to project teams via informatics tools, meaning project teams had to maintain this data manually which was laborious, error prone and often meant data was restricted to people 'in the know'.

An ELN was identified as the solution to this problem after a successful pilot project. The spread sheet functionality in particular delivered powerful charting and statistics as well as the flexibility required to handle the variability in these types of experiments. Project teams were formed and by 2010, the tool was live and integrated into Quest (though there is still a lot of work to be done before all *in vivo* experiments and all other types of data are captured by Quest).

Signing and witnessing

By 2010, all users had to print the experiment write-up to paper and glue it into a paper lab notebook (pLN), and from there get the pLN signed and witnessed and ultimately archived in the usual way. This process was laborious, inefficient and meant that the data was both restricted to people in the know and (if known about) it was very difficult to find.

We wanted to move to a fully electronic set up. We felt this would speed up write up times, freeing the scientists to do science. It would also make the data more accessible – with the ELN being an important conduit to data and knowledge. To go fully electronic we would have to, 1) identify a system to electronically sign &

witness the report, 2) store the witnessed document in a secure way and 3) convince the IP department that this was the way to go.

Luckily, number three was easy; the IP department were very supportive of this initiative. We had one shared concern though: we expected other functions at UCB to adopt ELNs, making it likely other ELN products would be chosen. Therefore, we decided to solve issues one and two outside of the ELN. This solution would be tested and implemented once, and then would integrate with many different ELNs if needs be. The tool we selected was PatentSafe (from Amphora Research Systems).

PatentSafe went live in 2011. Since then the users of the ELN have the ability to sign and witness their experiments electronically. But for some groups using the ELN for data capture, the change to using it as an ELN was not straightforward.

Building enthusiasm

The ELN, by mid-2011, was used by scientists with a range of behaviours. Some used it for all write ups, others only to record experiments generating assay data. The first group of scientists had no problems moving to fully electronic. The second group were harder to convince, the rest of the article focuses on them.

The use of an ELN as a data capture tool has spread to other groups. Almost all V-Region Discovery & Engineering group (VRDE) screening experiments were being captured by the ELN, but many other types of experiments (e.g. molecular biology etc.) were not. All ELN write-ups were still being printed to paper before being signed and witnessed. Some members of that group wanted to move to a fully electronic write up system.

We initially took a small pilot group, worked with them to develop templates for a range of common experiments and then asked them to test the system over a few weeks. Feedback was strongly positive. We discussed this with the whole group. There was reluctance in some members of the group, particularly the more senior members. They felt they were doing less routine science and that their experiments would be harder to write up. So we asked them to get involved in testing.

The testing period was extended and widened to include half the VRDE group. We also wanted the testing period to be shorter and to make sure all testers tried the system. To support this, we tried two things: 1) testing was to be carried out in the production system. Users would use the system to write up real experiments, the write-ups would be printed to paper and signed etc. using a pLN, and 2) we would radically increase the support available during the testing period to encourage more people into testing the system. This manifested itself as a half day training course run by the vendor using custom material, and on site consultants booking one on one sessions to gather feedback, solve issues and support the tech-phobic as they tried the system for the first time.

We wanted to move to a fully electronic set up to speed up write up times, freeing the scientists to do science

After two weeks of using the system, we gathered feedback – it was even stronger than before. Even after the training class, users who had been recalcitrant reported that they were 'getting it' and 'could see how it would work'. In fact, the training classes and testing period were the only in recent memory where scientists were asking to be involved. On the back of this strong support, we decided to roll out the system for all of biology. Rolling out to such a large number of scientists was going to offer different problems.

Mass roll out

At this stage, we had a small number of groups using the suite as an ELN in Slough and Braine. The challenge now was to develop a model to roll out to many more users using the same amount of informatics resource. The model that had worked for VRDE (initial requirement gathering with small set of key users, a short group wide training course backed up by on site consultancy support, and a short test period on the production system) was to be used again. Once the system was accepted by the group, PatentSafe training would be organised and the scientists would be fully electronic. The challenge was that many users had no experience with the ELN at all. We also needed to make sure we had enough resources to keep to a tight timeframe. To do this, we relied on the vendor consultancy team a great deal – they brought training and end user support expertise but also experience deploying to large groups of users.

In early 2012, we initiated the project and deployed the system to 50+ users in three months. The deployment coincided with an upgrade to a later version of the ELN that brought many long awaited new features (but also some new unwanted features). This made the support burden higher. Consultancy was used to both support existing users on the new version and ensure as many people took part in the testing period as possible. This amount of resource meant that feedback was still very good. Interestingly, the scientists who did not find the system very useful were often the tech-savvy kind who had independently developed word templates etc. to speed up their write up process. They found the new tool somewhat restrictive and so were less keen (at least initially).

Taking stock

By 2012, the ELN had been in use for a number of years, across two different sites and was being users for a variety of roles (data capture tool for *in vivo* experiments, production ELN, test adoption environment etc). The business rules that had been defined in 2008 were too loose and were being interpreted differently on each site. The hierarchy (folder structure) used to organise the experiments was different between groups and departments. The properties recorded by each group could also vary. Together this meant scientists from different groups found it hard to search for or browse

through data from other departments. The main goal of the ELN was being compromised. Also the different hierarchies required different access rights – administering this was proving to be a large support burden for informatics.

Clearly, in the long term, the only way the ELN was going to succeed was by revising the business rules. But users had been comfortable with the existing rules. Changing them successfully would require a lot of consultation. We selected a small group of key users from a range of groups and together reviewed access rights, hierarchy, experiment properties and the publishing workflow. The proposals were more radical than we anticipated. We simplified and standardised the experiment hierarchy, increased the number of mandatory experiment properties to improve querying and removed the ability to restrict access to data until it was published (now data was visible to all from the first save, but an experiment property flagged the data as being 'In-Progress' or 'Complete'). Gaining support for the new rules was easier than expected. Everyone understood the benefits of simplifying and standardising the set up but also agreed with making the data more available once properly flagged. Development is currently underway to support these new rules.

Support was also an issue. The informatics team within UCB is small. It was difficult to see how such an important tool, used by so many scientists, was going to be supported in the long-term. External consultancy was successful but there would be a loss of knowledge and efficiency with every change in consultant. Each department had been identifying key users (our ideal ratio was one key user for every 10 end users). The key users had had additional training in order to help them define requirements for their group. They were already acting as local experts, supporting other users. We decided to formalise this ad hoc group into a key user team who work together to support the system. Together we have built a library of 'how-to guides' and problem solving documentation. The team also has direct access to the ELN vendor's helpdesk and its knowledge base.

Writing up experiments using an ELN should be faster and easier than a paper lab notebook

Next steps

We are currently waiting for the development work supporting the new business rules to be completed before we roll out to another group. We will need to retrain existing users then restart the roll out. Deployment to new groups should be faster with the standardised business rules. Looking further ahead, we can see a number of ways to develop the ELN; by improving data capture using the spread sheet function, simplifying workflows by integrating external tools, and enhancing the ability to query and mine the data.

Conclusions

For me, the deployment of the ELN is one of the most rewarding informatics projects I've been involved in; the vast majority of scientists are keen to get involved and excited to use it. A clear, well defined set of business rules is needed to make sure the ELN is implemented in a best practice way, but we found that out second attempt was much better than our first. The ELN can support two modes of operation: 1) drag and drop existing files (e.g. Excel, Prism etc.) and 2) the spread sheet. The second mode gives us more value, saving the data in a structured way making querying and analysis easier. But it is much harder to implement and is a big step for scientists to make. The first mode (drag and drop) is easier to implement, easier for the scientists to learn meaning you get the ELN benefits fast. Key users have been invaluable – defining requirements, evangelising, and supporting the tool. Finally using the expertise of the vendor helped a lot, both increasing the expert resource available to the project and having the experience of rolling out to large numbers of users – fast!

BIOGRAPHY

David Lee is a principal scientist primarily focussed on systems capturing biological data. David has been with UCB for over eight years and held a variety of roles within UCB's Informatics Department. Previous to joining UCB has worked for a number of scientific software vendors in Europe and the U.S. His received his PhD from Imperial College, London. Currently David is leading a number of informatics initiatives including the deployment of an ELN in the UK and Belgium and the overhaul of UCB biologics registration system.

INFORMATICS
IN-DEPTH FOCUS
ASK THE EXPERT

Four informatics experts from the pharmaceutical industry pose one pressing question each for four leading vendor experts of informatics.

John Wise
Executive Director,
Pistoia Alliance

Q The increasing externalisation of drug discovery processes demands interoperability across their key supporting software applications. For example, in such an externalised research environment, chemists need to be able to share information between – and to conduct searches across – different brands of electronic laboratory notebooks without learning a plethora of search languages. What is the informatics software development community doing – or planning to do – to address this barrier to inter-operability of key research systems?

A The concept of the paperless lab has taken on new importance for pharmaceutical companies because in the current economic climate where every minute of research and scientific progress must be measured by a success factor, paper processes represent the antithesis of collaborative efforts. Today's pharmaceutical company works in collaboration with academia, CROs and partner biotechnology companies. Their data is spread across these organisations. Connecting these partners and integrating the flow of information between these groups requires fully integrated systems and far less reliance on paper-based processes.

The paperless lab concept has been talked about off and on for a number of years and each time it resurfaces, the technologies that support this movement are a little bit closer to fully achieving the goal. New technologies are now available that can fully integrate even the most heterogeneous of labs. This is an important distinction to make because most labs will have a fairly broad spectrum of vendors installed, something that in the past has been the perceived and sometimes practical obstacle for fully integrating the lab.

The problem, up until now, has been the cost to integrate different software systems and equipment from each of these independent instrument vendors, but newer technologies based on open standards have led to big opportunities for life sciences labs today. At Thermo Fisher, we've spent time developing Integration Manager and Data Manager, which transforms data from any instrument and delivers it to any source. While importing the final result is crucial, this solution takes it further by enabling scientists to see their real analytical data, chromatograms, mass spectra and results from other instrumentation regardless of the instrument supplier. This type of automated data acquisition and point-to-point data distribution across the enterprise is what is enabling today's paperless lab.

Trish Meek
Director of Product Strategy, Life Sciences, Informatics, Thermo Fisher Scientific

Gerhard Noelken
Pfizer

Q Electronic Lab Notebooks more and more become the central work environment for scientists in the labs. Good progress is made when it comes to the integration of balances and analytical instruments or systems from the same software vendor. Unfortunately, most pharmaceutical companies rely on software packages from several different vendors. How does your company support system and data integration across the boundary of different software vendors?

A The Waters NuGenesis ELN product utilises three interfacing mechanisms for interacting with balances and analytical instruments - a simple device interface (SDI), NuGenesis SDMS, and a software development kit (SDK). The SDI (a configurable software interface), allows NuGenesis ELN to connect directly to balances, pH meters, etc. in order to collect and store test readings.

For analytical instruments, NuGenesis ELN makes use of the integrated NuGenesis SDMS, a centralised data repository. The SDMS capability connects to analytical instruments through the network to capture data files and uses a library of data adapters in order to read instrument data files to extract meta-data that is then used to create a content index. Analytical instruments generally also print reports, and the SDMS capability utilises a print capture driver technology that is installed on the analytical instrument workstation to capture the print stream, convert the data to an enhanced meta-file, create an index, and then store the data. Once either the file or print data is captured within the SDMS repository, it can be transferred into the ELN. Approximately 90 - 95 per cent of analytical data can be captured by making use of the simple device interface or by using the SDMS data repository. The remaining analytical data that requires exchange into an ELN usually comes from another information system such as a chromatography data system (CDS), laboratory information management system (LIMS), or enterprise resource planning (ERP) system. For these types of systems, the ELN makes use of a comprehensive SDK. The SDK is a library of programing functions that facilitate the exchange of information between the ELN and the other system, e.g., pushing a completed chromatography sample set into the CDS for acquisition, data processing, and reporting followed by transferring the results back to the ELN.

Chris Stumpf
Senior Product Marketing Manager, Informatics, Waters

VLADGRIN / Shutterstock

Alexander Botzski
ELN Project Officer, VIB

Q Ultimately, the consumer electronics wave finds its entry in the lab and in the lab informatics solutions: fancier and more intuitive interfaces as well as web-based ELN and LIMS tools are on the way. When and how do you anticipate the complete entry of those second generation tools in conjunction with tablets in the lab? Would this also be the means of convincing more reluctant lab members to use ELN and LIMS tools more easily?

A Web and mobile are already here, at least for next generation ELNs such as IDBS' E-WorkBook Suite. The browser offers a range of attractive functions to naturally encourage faster uptake. An example is the 'social' tagging of experimental data in E-WorkBook's rich web interface that encourages collaboration.

The mobile environment is also important but laptops, and even ruggedised notebook PCs, have been around for many years and we must not fall into the trap of 'saving the world with the iPad'. The interface is really important but not as much as the functionality of your ELN. Used well, the ELN should enable data input and computation, access to secure internal and external research data (search IDBS ScienceLink for E-WorkBook) and bridge multiple disciplines. Using it simply as a digital replacement for paper dismisses the benefits of the interface itself.

Our belief is that an ELN is a data management system which should be accessible from a range of interfaces, each of which may reflect a different use:

- The desktop leverages local computational power for large locally produced datasets and is a tool of preference for those with inadequate bandwidth
- The web provides cross platform access and increasingly rich functionality for query, server-side analytics and widgets
- Mobile apps provide neat focused solutions for discreet workflows, data access and tasking

Importantly, all these applications should be working with the same data. Desktop-only ELNs are a legacy approach but web-only or mobile-only are also limiting. The multi-client approach, will appeal to a new – dare I say, younger - population of ELN users who are familiar with consumer devices and don't see any reason why they shouldn't form part of today's working environment. They allow flexibility and adaptability for multiple uses and for those provisioning the applications.

Scott Weiss
Director of Product Strategy, IDBS

Michael H. Elliott
CEO, Atrium Research & Consulting

Q One of the major restraints we see in the market is availability of IT and lab resources within customers' organisations to dedicate to an ELN or LIMS project. What is LabWare uniquely providing, both from a technology and services perspective, to simplify implementations, particularly a complex LIMS plus ELN deployment?

A From a product perspective, LabWare has been working hard to incorporate all the strengths of our previous implementations into pre-configured 'Templates' providing an 'out of the box' solution, within the given industry. For example, in the Petrochemical industry, our Template can be installed and implemented within weeks. Pharmaceuticals are often more challenging, but even so, our Pharmaceutical Template has been able to significantly reduce time and effort from many large scale projects. An area where this is most visible is in the validation process, where the use of the Template greatly reduces customer effort.

At the product level, LabWare LIMS and ELN have a similar 'look and feel' and single sign-on for the end-user. They share the same database, audit trail, compliance and configuration tools and can run on the same infrastructure thereby delivering significant cost savings and reduced resources required to install, integrate and support the two applications.

Back in the early 1990's, LabWare began to create a services team of laboratory software experts because we understand that a successful project depends on much more than providing great software. Over the years, we have witnessed how success is so often proportional to the timely availability of customer resources and expertise at key points in a project. Our services team has grown into a global organisation consisting of hundreds of experts, most of whom have dedicated their careers to working with laboratory software. They are capable of doing virtually of the activities normally expected of the customer, thereby providing the option to minimise the dependency on customer resources.

The comprehensive implementation and support systems that LabWare has developed and refined over 20 years for LIMS are now equally applicable to our ELN. Our customers benefit from a common help desk, online support systems, documentation, user meeting, IQ/OQ support materials etc.

Nick Townsend
Director Life-Sciences, LabWare Europe

www.labware.com

SELECTING AN ELN?

Be sure to choose the right partner

Implementing a seamlessly integrated end to end laboratory informatics solution can truly transform your business, and leading such a project is a big responsibility.

LabWare's experience at developing and delivering enterprise-wide LIMS and ELN solutions is unsurpassed making us a great partner, whatever the scale of your project.

For over 20 years LabWare has been leading the way in laboratory informatics through continuous innovation and powerful results. Contact us to discuss how we can help make your next project a success.

Offices worldwide
supporting customers
in more than 90 countries

LABWARE
Results Count

LABORATORY INFORMATICS – OUT OF THE FOG AND INTO THE CLOUD?

John Trigg
Director, phaseFour Informatics

The term Laboratory Informatics has been progressively creeping into the vocabulary of laboratory workers over the past decade, and has come to represent the field of information technology as it is applied to a wide range of laboratory processes and operations. Typically, it addresses the convergent field of laboratory data and information systems, which includes Laboratory Information Management Systems (LIMS), Electronic Laboratory Notebooks (ELNs), Scientific Data Management Systems (SDMS), Laboratory Execution Systems (LES) as well as the tools used for data acquisition and data processing.

There is a very good reason why the use of a generic term such as Laboratory Informatics is important: we need to get away from our traditional application-centric approach to laboratory computing and think in terms of the big picture, i.e. a fully integrated laboratory computing environment that embraces all aspects of the application of technology to laboratory operations and its interaction with other company systems. This has become increasingly important as the deployment of an ELN generally represents the final step in making a laboratory fully electronic and hence raises the demand for interconnection between all laboratory systems. In this sense, being fully electronic and being fully integrated are two different things. For most labs, the reality is that fully 'electronic' corresponds to an application-centric portfolio of 'systems' that were not necessarily designed to work together and for which interoperability is hampered by the lack of standards and is therefore dependent on custom solutions. What we aspire to is an 'integrated' laboratory that is modular, based on standards and is designed to facilitate connectivity, data sharing and collaboration.

> "Over the past two to three years, the informatics market has experienced two interesting developments"

The big question is how can we overcome some of the current limitations to achieving an integrated laboratory environment? Will the market provide this for us? Will informatics technologies naturally migrate with an emphasis on integration? Or will some other driving force help resolve the problem?

Over the past two to three years, the informatics market has experienced two interesting developments; firstly, the previously separate LIMS and ELN sub-markets have started to overlap, causing a certain amount of confusion as a consequence of our application-centric mind-set. And secondly, a number of

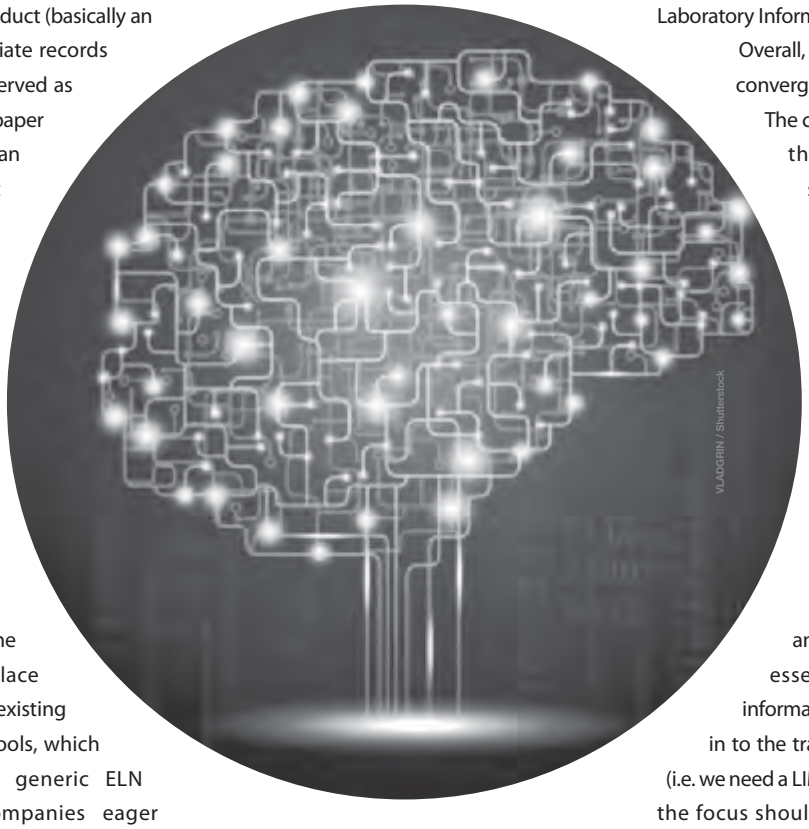
merger and acquisition activities have reshaped the vendor line-up, specifically in the ELN field. So what do these developments mean? Do they represent something more fundamental than just functional and commercial opportunism and present some tentative steps towards addressing the integration problem?

Confusion in the market place?

The Electronic Laboratory Notebook (ELN) market has evolved over the past decade, driving improvements in laboratory productivity, efficiency, IP protection, information sharing and collaboration. Two types of products dominated the early phase of the ELN market; one was a generic product (basically an authoring tool with appropriate records management facilities) that served as a direct replacement for the paper lab notebook. The other was an integrated chemistry-centric product serving the requirements of small molecule chemistry. There was considerable debate about how to address the biology market, a concern that has subsequently been addressed by a number of vendors, but broadly speaking, there was little interest from the Analytical or Quality Assurance sectors. The key players in the market place were either companies with existing chemistry centric software tools, which could be extended with generic ELN functionality, or new companies eager to exploit the potential of developing an ELN. Somewhat surprisingly, none of the established Laboratory Information Management Systems (LIMS) vendors chose to enter the ELN space.

As the ELN market took shape, there were a few other products that were broadly categorised as ELNs but which are now identified as Laboratory Execution Systems (LES). These systems were considered to be somewhat LIMS-like since they captured and recorded test results and measurements, but they did so from a process or procedure-centric (SOP) approach, rather than a sample-centric approach. As such, these systems achieved some success in regulated (QMP) labs where they offered an alternative to a conventional LIMS.

Since 2008, the ELN market has continued to mature, specifically in the area of small molecule chemistry and has gained better traction with regard to biology, but the waters have been muddied somewhat by some LIMS companies adding ELN functionality to their products. Prior to 2008, the ELN and LIMS markets seemed to be quite independent of each other. However, the success of the products that fell in the LES category were starting to be seen as an increasing threat to the LIMS market,



and as a consequence, some of the LIMS vendors started to develop 'ELN modules' to address either an additional capability to handle unstructured data, or to provide a procedural-driven approach to data input.

> "Overall, there has been a trend towards convergence in the ELN market place"

TABLE 1 Core differences in informatics

ELN	Experiment-centric, unstructured data, generic and specific functionality
LES	Procedure or experiment-centric, structured data
LIMS/ELN	Sample-centric, structured data, batch operations and workflow
SDMS/ELN	Data-centric, structured data and files

A further level of complexity in the marketplace has evolved with the prospect of Scientific Data Management Systems (SDMS) being identified as ELNs by virtue of the fact that the databases upon which these systems are built can readily accommodate documents, e.g. a document containing an experiment write-up can be associated directly with the underlying data. Two examples are (a) the transcript of an interview with Joseph Kofman (R&D Information Systems Director, Allergan), on 'Exploring and Adopting an SDMS as an ELN Generic Substitute'[1], and (b) 'Enhancing the Value of Laboratory Information'[2].

Overall, there has been a trend towards convergence in the ELN market place. The consequence of convergence is that the ELN market is now somewhat confusing for potential customers since the term ELN is used in a very liberal sense. Most of the confusion is related to the analytical and QA market segments where the differences between ELNs, LIMS and SDMS are becoming less clear. **Table 1** identifies the core differences.

Unravelling the functional and business requirements is an essential first step in any informatics project and it is easy to fall in to the trap of focusing on the solution (i.e. we need a LIMS, we need an ELN, etc.) when the focus should really be on the problem. Although the convergence issue in the ELN market creates some confusion, it also highlights the fact that there are a number of viable alternatives to replacing a paper lab notebook. By fully understanding the problem and identifying the functional needs of the laboratory, the solution may be found in alternative informatics applications; the challenge is to find the best overall fit for the laboratory's workflow.

Mergers and acquisitions

The second development in the market is a significant increase in M&A activity, which has resulted in some major vendor realignments. The incorporation of the Analytical/QA domain

in the ELN market seems to suggest that the major players are now taking a more holistic view of laboratory informatics. The rationale behind the merger and acquisition activity is partly commercial, which doesn't always translate into benefits for customers, but the underlying purpose is to address the laboratory integration issue, albeit through proprietary means, and subject, of course, to customers being happy with a single-vendor solution. As such, the challenge of interoperability may well be addressed by selecting from a single vendor's portfolio of informatics products.

Technology to the rescue?

Whilst the informatics market is reshaping itself somewhat to address integration issues, other more general developments in technology may offer an alternative path forward. To understand this we have to look at the emergence of social, or consumer technologies that are revolutionising our day-to-day computing experiences. In particular, the growing emphasis on the use of tools for sharing and collaboration, the ease of data capture, and the development of gesture-based interfaces have added a different 'social' dimension to everyday computing that has had a profound effect on the underlying communication processes. 'Apps', the 'Cloud' and mobile devices are redefining consumer technologies. Is this of any relevance to laboratories? First and foremost, laboratory computing generally lags behind the consumer experience due to various constraints such as compliance concerns, internal IT policies and legacy systems. But is there a tipping point? In particular, the Cloud may prove to be the catalyst. From a business perspective, the Cloud offers an effective solution to the increasing demand for the deployment of collaboration tools across multiple departments, multiple sites and different geographies. Furthermore, it lends itself well to collaboration with outsourced operations where the practicalities of deployment are largely limited to configuration, rather than physical installation of hardware and software. The benefits of a thin client, access from anywhere, low deployment costs and centralised support has both financial and functional attractions. Pitted against this are concerns about access control, security and data integrity. Choosing the Cloud is a risk-based decision, but if confidence grows sufficiently, then it is a path likely to be adopted on a wide scale.

> "The underlying issues of data interchange standards and open source represent an opportunity to resolve long-term challenges of integration"

The Cloud, however, is generally defined as Software as a Service (SaaS); i.e. the remote deployment of software applications, but already there are expectations that 'Platform as a Service' (PaaS) will develop into a more integrated provision for businesses to support collaboration, web service integration, database integration, security, storage, etc. Any progress in this direction will be dependent on a far greater level of commonality than is evident in current laboratory informatics and may lead towards more fundamental changes by bringing open source and data standards into the equation. From the laboratory's perspective, this would have some distinct business benefits and could be the precursor to a more modular approach to meeting functional requirements.

One of the consequences of the ubiquitous nature of the internet is the way it can disrupt established business models. So the tipping point for laboratory informatics could be aligned to the Cloud, and may prove to be a challenge to those vendors not prepared to adapt quickly enough.

The underlying issues of data interchange standards and open source represent an opportunity to resolve long-term challenges of integration. Ideally, separating the content (data) from the application would allow vendors to be innovative and competitive in terms of functionality, but would avoid locking the data in to a specific vendor or specific application. This would seem to be a win-win situation that could be further advanced by a modular, open-source approach to building informatics functionality.

Mobility

One of the practical consequences of Laboratory Informatics that can present a problem to some users is the loss of the sheer convenience of paper. Portability and mobility are two of paper's strong points, and it's not an uncommon argument with the introduction of an informatics system that user access is often restricted the physical locations where the computer sits. For this reason, there is considerable interest in mobile devices such as smart phones and tablets that offer a far more portable and mobile approach. However, they also bring along some concerns, particularly in terms of the risk of loss or damage. Screen size and data input may, in certain circumstances also be a concern, but there is enough development underway with regard to virtual keyboards and flexible screens to expect that it's just a matter of time before these limitations can be addressed and mobile devices become common place in a laboratory environment.

Summary

Following in the wake of the advances in consumer technologies is it conceivable that Laboratory Informatics will follow suit in order to address evolving business requirements? When it comes to interoperability, the limitations of our current systems are becoming increasingly visible. The lack of standards, the lack of interoperability and the high cost of proprietary solutions do not compare well with the experience in other domains. As laboratories become increasingly dependent on collaborative and outsourced approaches to conducting their business, are the current tools and implementation strategies adequate? We can interpret the market response through convergence and M&A activities as recognising the problem, but the question remains whether a single-vendor solution is compatible with the laboratory's traditional best-of-breed attitude towards meeting their requirements. Or is the answer in the technology itself? As Cloud computing, open source and mobile devices become increasingly dominant, can we assume that Laboratory Informatics will follow suit?

> "One of the practical consequences of Laboratory Informatics that can present a problem to some users is the loss of the sheer convenience of paper"

REFERENCES

1. Will SDMS Become ELN of the Future? http://www.pharma-iq.com/informatics/articles/will-sdms-become-eln-of-the-future
2. Enhancing the Value of Laboratory Information: http://www.scientificcomputing.com/articles-In-Enhancing-the-Value-of-Laboratory-Information-033010.aspx

Date
25 – 27 September 2012
Venue
Milan, Italy

Pharma IQ recently published the results of an industry-wide laboratory informatics report conducted among 6,000 pharmaceutical laboratory informatics specialists. Entitled 'Laboratory Informatics: Current Trends & Predictions for 2015', the report was created as a part of the pre-conference research for the 11th Annual ELNs & Advanced Laboratory Solutions conference, taking place between 25 – 27 September 2012 in Milan, Italy.

Specialists were asked to take a step back and consider what the lab of the future is going to look like. Each organisation is on its own unique journey in building an informatics system. "The corporate laboratory of the future will be adaptive and continuously optimised. Winners will dynamically alter operations to changing business needs based on operational analytics and leverage of institutional knowledge," predicts Michael Elliot, CEO of Atrium Research & Consulting.

Seventy-five per cent of Laboratory Informatics users listed technology investment and implementation as their number one priority between 2012 and 2015, with only 8.3 per cent using the 'Cloud'. Seth Pinsky, VP Research & Development at Abbott Labs argues that "the cloud hasn't helped things to be fundamentally different."

Peter Boogaard, Founder of Industrial lab Automation suggests: "A lack of SaaS or alternative license structures to support new customers may limit the utilisation of the current infrastructure."

Results from the survey indicate that the implementation of laboratory informatics systems in pharmaceuticals is mature, as almost 55 per cent of respondents implemented their major piece in the last 7-11 years, with 30 per cent having one in place for 11 years or more. There was a flattening-off over the last two to seven years, with only 4.2 per cent having implemented an informatics system in the last year.

Pharma IQ asked users what the three biggest obstacles were in the day-to-day experience of laboratory informatics; the results indicated some joint contenders. The top two challenges included data mining and a lack of knowledge around the standardisation of regulatory requirements, both 41.7 per cent. Integration with other non-informatics software systems and a lack of industry standards were also high on people's agendas, at 37.5 per cent, while data migration into a new system received 25 per cent of total responses. Conversations with industry experts also back these results up, with the McKinsey & Company Report – Big Data: The next frontier for innovation, competition and productivity stating: 'As computers and cell phones continue to pervade our daily activities and as millions of networked sensors are being embedded in these devices, the amount of data available for analysis is exploding. The scale and scope of the changes that such 'big data' are bringing about have reached inflection point.'

The full report can be downloaded free of charge at www.elnforum.com/report or by requesting a copy at enquire@iqpc.co.uk.

The results of the survey report have helped to shape the agenda and final speaker line-up for 11th Annual ELNs & Advanced Laboratory Solutions, which features John Trigg, Director of phaseFour Informatics leading the session 'Un-blurring the Lines: The Evolving Laboratory Ecosystem' and Daniel Domine, Head of Research Informatics from Merck, presenting the case study 'A Single ELN Across Biology: From Dream to Reality'.

Other important topics expressed by survey respondents to be discussed at the event include:

- Case Study: Bridging the Chemical and Biological Space – Cross-Functional ELNs (Ralph Haffner, Local Head Research Informatics, Roche)
- A Single ELN Across Biology: From Dream to Reality (Daniel Domine, Head of Research Informatics, Merck)
- Case Study: Replacing an Existing System with a New More Integrated Platform (Frank Klöck, Project Manager, Bayer)
- Case Study: (NIBR Digital Notebook Initiative – Extending ELNs beyond Chemistry, (Mohit Agnihotri, Associate Director, IT Project Management, Novartis (NIBR))
- Systems Evolution: Getting Much More out of Your Informatics (Edward Reilly, Systems Consultant, Baxter)
- Storing and managing legacy data to keep it accessible while working with or implementing a newer system (Eric Rulier, Senior IT Labs Project Leader, UCB Pharma)

FOR MORE INFORMATION

www.elnforum.com/report
Email: joanna.checinska@iqpc.co.uk
Tel: +44 (0) 207 368 9421