

ELECTRONIC LABORATORY NOTEBOOKS

A PRISM FORUM WHITE PAPER
2004

Introduction

The laboratory notebook is the central repository of scientific research information. It captures the scientific process and gives meaning to a scientist's observations. Although scientific laboratory work today is highly computerized, electronic laboratory notebooks (ELNs) are infrequently used.

The PRISM Forum¹ ran a two-day workshop hosted by Eli Lilly in March 2004 to consider the challenges regarding Electronic Laboratory Notebooks & knowledge sharing in a research environment. 15 people that attended the workshop discussed and summarized various aspects of Electronic Laboratory Notebooks for two days. This white paper summarizes the outcome of that workshop.

ELN Definitions

What do we mean with an Electronic Laboratory Notebook? A consensus definition was once made by CENSA²:

"An electronic notebook is a system to create, store, retrieve and share fully electronic records in ways that meet all, legal, regulatory, technical and scientific requirements."

However, considering the current state of information technology we found it necessary to define something we name a hybrid ELN solution, a system that combines electronic data entry with traditional wet signatures and paper archiving. We made it clear that by implementing an ELN we should not neglect to solve the issue of archiving. To ensure archiving is addressed by currently accepted practices the hybrid ELN was defined:

"A hybrid electronic laboratory notebook is a system to create, store, retrieve and share electronic records, which uses printed copies with handwritten signatures for archiving and IP protection."

An attempt was also made to define what we mean by laboratory records, a term that remained unexplained in the CENSA definition:

"Records are the collection of information or data associated with an experiment to enable a suitably skilled person to repeat it. Records also contain a time and date-stamp."

¹ The PRISM Forum has an international membership of senior life science informaticians drawn from a number of biopharmaceutical organizations (<http://www.prismforum.org>).

² The Collaborative Electronic Notebook Systems Association (CENSA) is an international industry association (<http://www.censa.org>).

Expected benefits of an ELN

What are the key drivers for implementing an ELN solution? The workshop summarized the major expected benefits as:

- **IP protection improvement.**

The system has potential for improving quality of the records necessary for IP purposes by capturing ideas, and the entire creative process. ELN will ensure completeness of records and reduce litigation cost by improving access to the data. ELN can establish an earliest priority date.

- **Completeness and compliance.**

The system, if an integrated part of daily workflow, will improve record keeping compliance and provide legal evidence for patent protection with a higher quality than traditional paper notebooks. Records will be complete and information better structured. It will be easier to capture additional information and to include calculation possibilities. Audit trail possibilities can be introduced – electronic information can easily be replicated for recovery purposes.

- **Knowledge sharing**

Data can easily be found and re-used, which means a reduced repetition of failed activities by learning from others (capture best practice). New opportunities can be identified by mining and examining data in ways not previously possible. It will be easier to capture and maintain varied data types (you don't have to glue things into a paper lab notebook anymore) – no need to manage paper lab notebooks.

- **Personal efficiency**

ELN is available to all authorised users simultaneously and can be used to facilitate collaboration and workflow. ELN will facilitate the sharing of information among different business functions (e.g. Discovery to Process Development) and also facilitate packaging of information for 3rd parties.

By using forms and templates (iconic, reusable text) data entry will be easier. Reinvention of protocols is avoided. ELN will admit us to run parallel experiments. The time spent in the laboratory and in the office will be used without repeating administrative tasks. In fact, ELN will drive an improved workflow and a better experimental design. By the integration of other components a rational use of other components and services can be enabled.

- **Data capture and information management**

Manual errors will be avoided with an ELN. There will be no need for data to be retyped, which facilitates the discovery and exploitation of information. Other systems can be integrated with an ELN solution, as compound registration and management systems, as well as analytical systems and tools.

In contrast with the listed benefits, there are several concerns with paper notebooks, such as the problem with poor handwriting (sometimes barely legible), little or no indexing or search possibility, and a lack of awareness of lab book content between scientists. We concluded that paper laboratory notebooks no longer could hold sufficient information about experiments performed to fulfil all requirements from legal or quality points of view.

Paper laboratory notebooks are nearing obsolescence. It is merely a question of when to implement an ELN solution, not if.

Key Requirements for an ELN System

What do we expect from an Electronic Laboratory Notebook solution? Essential requirements may vary between different fields of research. Furthermore, an ELN system can mean different things if you are a scientist, a lawyer, regulatory specialist, an archivist or a manager. We have summarized key generic requirements for each of these user categories.

From the **scientist's** point of view, ELN system should...

- Capture information independent of source and format
- Clearly associate a record with the originator
- Have the possibility to both import and export data
- Support scientists' working practices, including re-use of procedures, calculations, text, data
- Be fully searchable
- Provide means of accessing and transferring data from other systems
- Retrieve and share records over time
- Support document life cycle stages: private (in progress), public (finalized) and archived
- Support element referencing within experiments
- Get user acceptance; the ELN should be more efficient to use than the paper counterpart

From **legal and regulatory** perspective, ELN should...

- Have evidentiary value in court proceedings (both records & audit trail)
- Support due diligence research
- Cover IP protection

- Support validated records when applied in regulated situations
- Produce non-deletable, non-editable completed records

From **archivist's** point of view we found that ELN should ...

- Be compatible with corporate archiving and records retention strategy and practices
- Support long-term retrievability of records
- Prove human readability over time

The **management** is likely to have the following additional requirements:

- Have the ability to generate business process metrics
- Improve quality
- Facilitate collaboration and information sharing
- Provide the ability to use, mine, extract and compile information
- Be compatible with corporate strategies
- Drive process improvement

ELN Challenges

We believe that delivering a system conforming to the requirements would leverage tremendous potential benefits listed earlier in this document. But there are also several challenges to look for. Broadly speaking, these can be grouped into four main categories:

- **Cultural aspects.**

Individuals and organizations vary in their inclination to share information. Feelings of proprietorship over data may be strong. Computer literacy problems may manifest themselves - there must be acceptance of the electronic paradigm across the business. A change of paradigm such as ELN is also likely to cause disruption or impose change of current work practices. In this area, ease of use and ease of adoption are prime considerations. The logistics of practical use in a laboratory setting must also be carefully considered.

- **Integration.**

The ELN is an integral part of everyday workflow and therefore must facilitate integration with existing data and systems. The integration strategy should be part of the buying/building strategy. System integration architecture is required.

- **Managing scope and expectations.**

Can a one-size electronic lab notebook suit all users in an organization?

How can ROI be measured? What are the essential functions and interfaces? Introduction of an ELN requires strong management commitment and consideration of overall business benefits. ROI, commitment to funding and cultural/process changes is essential ingredients of an ELN transition. We also advocate phased implementation to gather experience and manage expectations.

- **Technological challenges.**

Persistence of recorded information is required, which brings technical challenges to ensure long-term retrievability and readability of the information. Scalability towards future data sources and new ways of doing science is difficult to assess. Also, the marketplace does not seem to offer fully mature ELN products at this time. Considering the known strategic difficulties with systems integration and electronic archiving as well as dynamic development of science, the completely shrink-wrap ELN solution may not be available for some time to come. Companies will need to combine different solutions to manage lab notebook records throughout their lifecycle.

Options

When implementing a software portion of an ELN solution, a pharmaceutical company has to review a number of options. An important choice is deciding whether the organization should settle on a hybrid or a fully electronic ELN solution. Also, whether it is feasible to implement a general ELN for all users or settle on multiple discipline-specific systems.

The necessary software can be either purchased off-the-shelf or built for the purpose. To most companies, selecting an off-the-shelf product would be a natural first choice. However, tight integration of the ELN with a wider IT architecture and processes of the research organisation being a crucial requirement, some may choose to purpose-build the software or its portions to fit this and the other requirements more exactly.

When **buying** a system, the following key issues should be included in the evaluation programme:

- Does it really fit all requirements?
- Configurability
- Risk management
- Are the available products mature?
- Future vendor viability
- Integration challenges
- Support for industry standards
- Support for company technical standards
- Validation/compliance

When **building** a system, areas to be considered are:

- Return on investment
- Resource and skills required
- Support for functional and architectural requirements
- Risk management
- Plan for integration
- Support for company technical standards
- Future development and maintenance of the system
- Validation/compliance

Architecture

In terms of functionality, the ELN application is best described as the workspace for data assembly and record creation. It should enable creating laboratory records using data from a variety of sources, but should be separated from a records management function.

Thus, ELN can become an enabler and productivity tool for investigators. It can be used operationally in a changing context and have flexibility to adapt to future requirements through integration with other tools and integration of data.

In most companies, record management is a corporate service maintained independently of the ELN system. Paper or electronic, this infrastructure has been built with focus on longevity and secure maintenance of records. It is advisable for the implementers of ELN to deliver records into that infrastructure rather than building a completely new records management solution exclusively for ELN records.

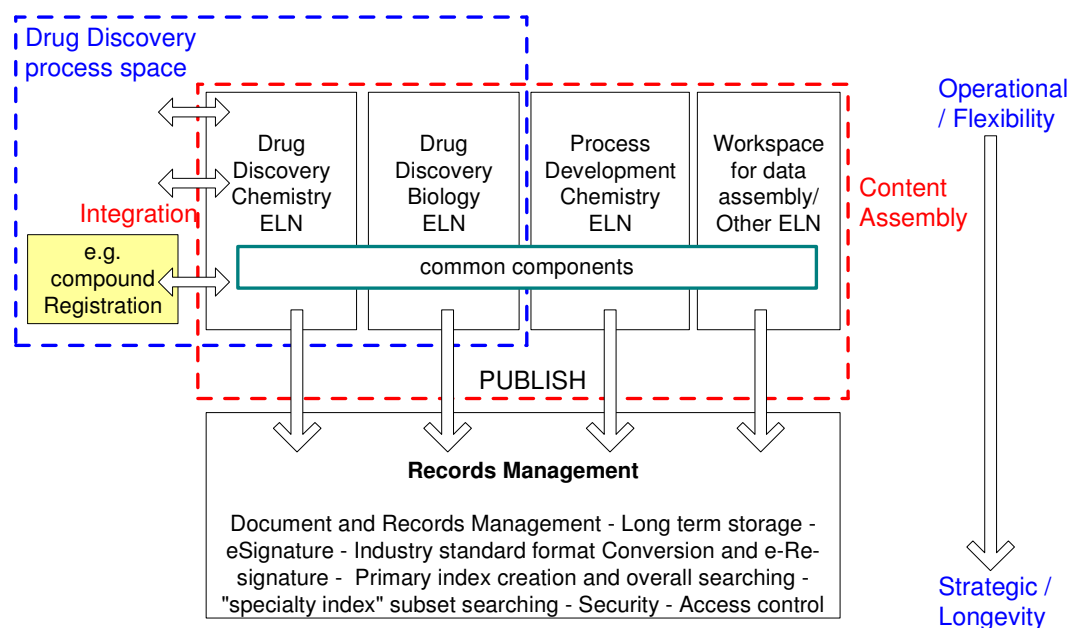


Figure 1. Architectural overview.

The architectural overview of an ELN system is shown in Figure 1.

Steps towards an ELN implementation

To avoid the common pitfalls and summarize the workshop's advice for an ELN implementation:

- **Define what other systems exist or should be created first**

Avoid wrong expectations. ELN may not be your biggest problem. Perhaps what you need more is the compound registration database, sample logistics, and chemical inventory...

- **Establish and maintain the scope**

Define ELN strategy to establish what the ELN records should contain. Manage the scope of requirements to stay focused on your main objectives throughout the project.

- **Define IT architecture for data sharing**

Use it as a requirement for ELN procurement or in-house development project

- **Create a master plan for desired final system**

Keep in mind that the ELN system is more than a software application. Consider systems, processes and data that are in scope: applications, metadata, database and records management. Use component architecture to break down the system into manageable parts.

- **Set realistic scope for pilot implementation**

Avoid solving all problems at once. Identify driving forces and plan for iterative improvements. Allow for experience gathering and refinement before all-out implementation. When scaling up, stick to the same core architecture in all implementations.

Conclusion

We believe that paper laboratory notebooks will be replaced by electronic systems in the near future and that business drivers will support this change. It is a challenging but a mission-critical necessity. Companies need to start defining ELN strategies now.