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ACCELERATE TIME TO MARKET WITH AN ELECTRONIC LAB NOTEBOOK

White Paper

Research organizations are challenged as never before to conceive and develop innovative scientific solutions rapidly and efficiently. Technology has made immense amounts of research information available at a keystroke—information that can spark creativity and new collaboration opportunities. However, scientists recording, managing and archiving research data in paper lab notebooks cannot keep up with this data deluge. Notes are illegible and data are lost, resulting in project teams having to repeat expensive experimentation because earlier work is difficult or impossible to find. Going paperless with a digital solution—specifically an Electronic Lab Notebook (ELN)—has provided the breakthrough many organizations required, yet failed implementations abound. A successful digital transition requires careful due diligence in assessing an organization's core requirements and available ELN technology in the context of a well defined implementation plan that includes a pilot program.

This white paper examines the challenges of managing research data today and what to look for in an ELN. The white paper also addresses key issues in selecting and deploying an ELN in today's digital research environment including the importance of seamlessly integrating ELNs with existing research workflows. The white paper concludes with a brief consideration of ELN costs, financial benefits and return on investment (ROI).

INTRODUCTION

Today research laboratories are leveraging advanced technology that allows them to generate "bigger data" that can be turned into actionable insights about lead products. This transformational technology brings with it a significant increase in the amount of available research and experiment data, making it increasingly challenging to isolate relevant data, understand it and act on it. Replacing traditional paper and spreadsheet-based processes involving manual transcription with a digital, end-to-end informatics solution accelerates data access and analysis, improving innovation and time-to-market.

Managing research and experiment data involves not just the traditional functions of a lab notebook but also the need to collaborate with other organizational functions. Efficiency is paramount; time management is critical. Recording ideas, inventions, experiments, observations and work details now must accommodate prior and concurrent research by others (both inside and outside of the organization). Collaboration is the new imperative. Hence, technology is driving a parallel evolution in research as manual processes are replaced with digital ones—which can be highly disruptive if not managed properly. Unfortunately there has been no clear path on how to implement a successful digital transition, and failed implementations cause resistance to change.

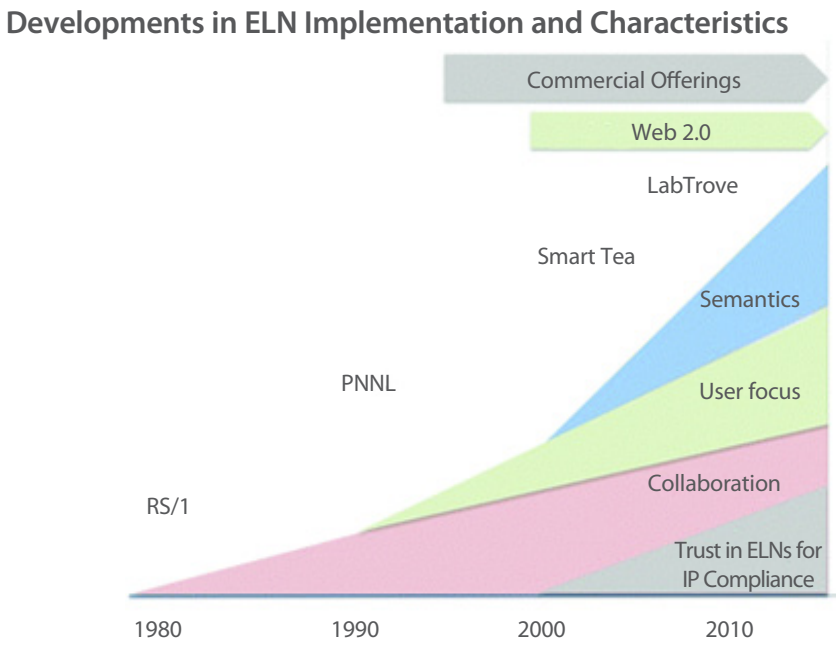


Figure 1: The evolution of ELNs since 1980, showing the growth in support for specific characteristics. (Source: Royal Society of Chemistry, http://pubs.rsc.org/en/content/articlehtml/2013/cs/c3cs60122f)

CHALLENGES OF MANAGING RESEARCH DATA

Research starts with an idea. The process involves recording that idea, developing an experiment based on the idea, tracking the experiment results and modifying the experiment until a successful outcome is achieved. Along each step of the way, data are recorded, analyzed and managed. Unfortunately, when this process is performed manually, data can be illegible; transcription errors can occur; paper notebooks can be poorly maintained, lost, destroyed or misplaced; exact details and dates of conception may not be clear.

Structured data (data residing in fixed fields within relational databases or spreadsheets that are easily stored, queried and analyzed) are entered manually or generated digitally and captured by software applications such as Laboratory Information Management Systems (LIMS). As the volume and complexity of digital data and documents increases today, so does the need to address *unstructured data* (data that does not have a predefined model). Systems that can handle unstructured data are becoming increasingly important, especially in Research and Development.

Electronic laboratory notebooks can be a direct replacement for paper lab notebooks, but valuable additional ELN functionality integrating with other organizational workflows to drive scientific innovation is required. Although best practices in ELN implementation and use are still evolving, currently there is a shift away from functionality-rich ELNs that can be tedious to implement towards ELNs that are easy to deploy and adopt. But still the ELN should readily integrate with other laboratory systems to eliminate time-wasting, error-prone manual data transfer and streamline data sharing across systems.

Many research organizations today are reviewing workflow processes to identify efficiencies and cost savings. Under this close scrutiny, the replacement of paper lab notebooks with ELNs requires not just the capital investment but also a shift in laboratory documentation policies and processes. As a result, the lab is being pulled closer to other business units to streamline workflows and integrate research processes with synergistic activities across the enterprise.

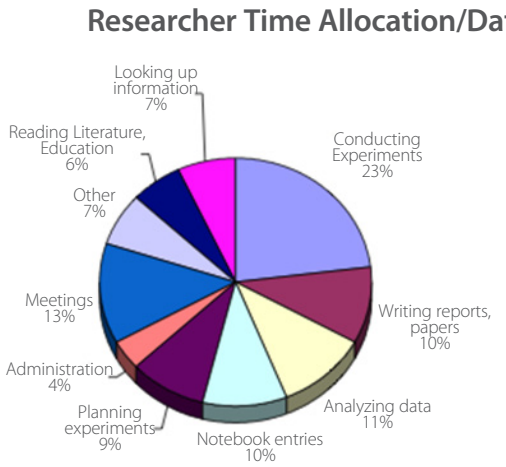


Figure 2

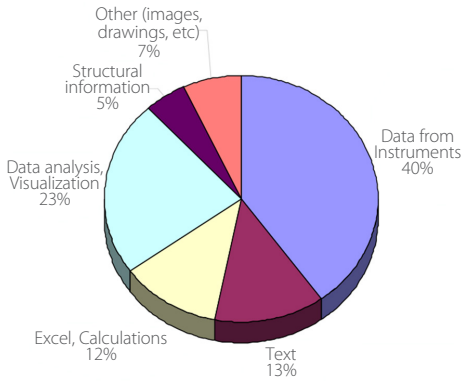


Figure 3

Figure 2 : Atrium Research has surveyed research chemists to determine how they spend their time. As the chart shows, only 23% of a typical researcher's time is spent conducting experiments. The rest of the time is spent on planning, administration, research and analysis activities. Streamlining activities frees up time for conducting experiments that can lead to development of new products and revenue streams. (Source: Atrium Research, 2012)

Figure 3: Laboratory notebooks contain a variety of content besides text. Scientists routinely include instrument data, spreadsheet calculations, structures, images and much more to support their research. Spending time cutting and pasting these materials into a paper lab notebook is inefficient. (Source: Atrium Research, 2012)

WHAT TO LOOK FOR IN AN ELN

In replacing paper notebooks with a digital solution, simplicity speeds user adoption but no commercial ELN stops there. ELNs need to be considered in the context of the critical business issues driving ELN adoption. The development and adoption of the ELN as an enterprise-integrated solution rather than a standalone, point solution has become a key strategic advantage helping laboratories move beyond paperless to a truly convergent, more collaborative and information-driven R&D environment.

Initially, life sciences companies were early adopters of ELNs, but digital notebook technology has now advanced to the early and late "majority" stages of the technology adoption lifecycle (Figure 4). Today many laboratories have a legacy system of some kind that digitally stores experimental and reaction data. A legacy ELN can be a database that includes anything from scanned PDF documents to word documents to spreadsheets. It can also be a commercial solution that is not fully leveraged because of useability or implementation issues. Many organizations that adopted early commercial ELNs now find themselves missing needed features with a system that is difficult to upgrade or has not been widely embraced by laboratory staff.

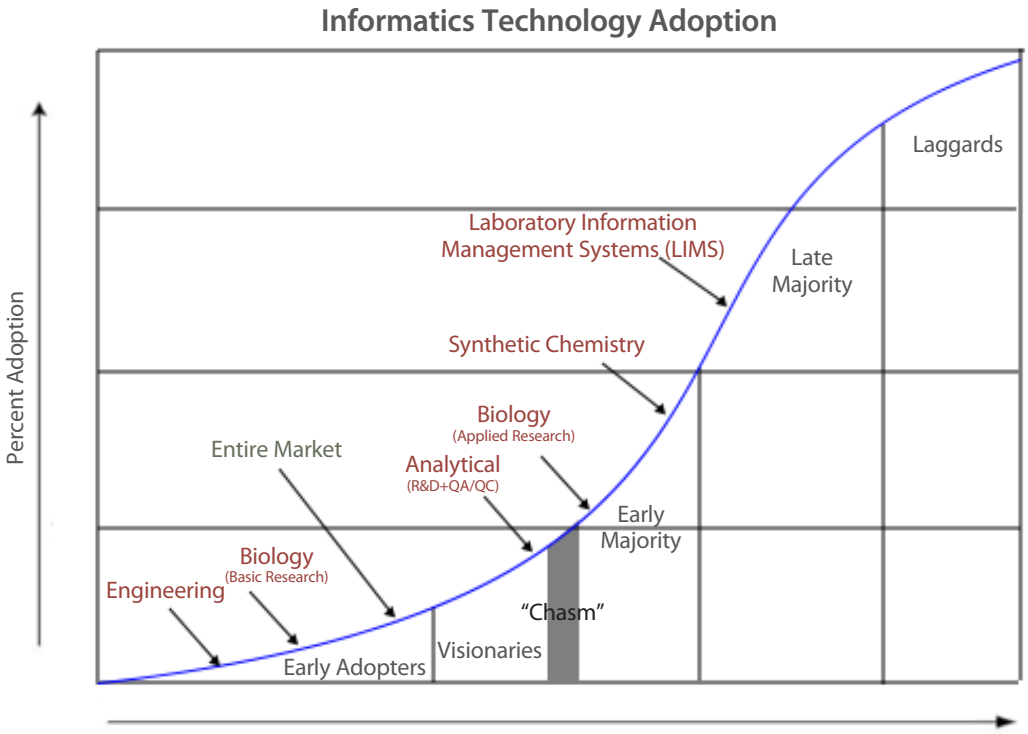


Figure 4: ELN technology is in the early market stage, but it is beginning to leap the "chasm" and move beyond early adoption to greater market acceptance. (Source: Michael Elliot, Atrium Research, 5th Electronic Laboratory Notebook Survey © 2012)

Fortunately, ELN technology has evolved to the point where initially customized or extensively configured (and extremely expensive) solutions can be replaced by more affordable, easier-to-implement, off-the-shelf systems. The long implementation cycles that typically accompany these customized or highly configured electronic solutions are disappearing with the introduction of multi-disciplinary, generic ELNs offering both fast deployment and low total cost of ownership (TCO).

Organizations looking to deploy an ELN for the first time or upgrade an existing legacy ELN should consider the following notebook capabilities in assessing today's available technology.

Easy Data Capture, Search and Reuse

To accelerate time-to-value for scientists, the ELN needs to be intuitive and easy to use. Data must be easy to enter, find and reuse with all experimental data and notes stored in a single location that can be accessed by everyone based on permissions.

Indexing solves the challenge of finding and reviewing recorded experiment data. Make sure the ELN efficiently indexes text, data and graphics enabling scientists to quickly and easily search the entire notebook for a specific procedure, citation, research idea or data item. An extended search that includes group notebooks with appropriate accessibility settings can also be beneficial in making information broadly available to many stakeholders in a collaborative research environment.

Section templates should be easily configurable to support standard operating procedures. Easy-to-use, standardized templates ensure that experimental workflows and research data are captured and presented consistently. Encouraging scientists to perform tasks in a uniform manner improves process consistency while also encouraging ELN adoption.

> "The new ELN system will help Heinz bring innovation to the market quicker by upgrading the experimentation process across R&D."
>
> – Jim Matthews, Vice President of R&D, Heinz North America

Flexibility

The ELN needs to accommodate a variety of formats and content including text, tables, images and spreadsheets. Flexible notation capabilities are also important, so that researchers can annotate experiment data with new findings. Supervisors should be able to add notes throughout the document and tag relevant data. Reviewers should be able to countersign experiments. The ELN should support both *ad hoc* and template-based reporting capabilities..

Flexibility is closely associated with simplicity and ease of use. According to Atrium Research (Figure 3), researchers typically spend only 23% of their time actually performing experiments, the rest is spent on support activities. Allowing scientists to spend more time on scientific experimentation can accelerate innovation and productivity, moving products to market faster.

> "[The ELN has been] very useful for me. It is the first time in 1.5 years in the company that I have an updated lab notebook. It is very simple to add all the information about the products, the instruments used, to add Excel worksheets. I don't want to go back to the paper notebook."
>
> – Scientist, Leading Consumer Packaged Goods Corporation

Assured IP Protection

Intellectual property (IP) protection and electronic witnessing are extremely important features for an ELN in Research. Workflows with electronic signatures and countersignatures allow researchers to move forward quickly. The recent change in U.S. patent law from first-to-invent to first-to-file has increased the importance of comprehensive, accurate experimental history records. In fact, the ability to rapidly extract data in case of legal conflicts is more important than ever. Electronic records and signatures are legally acceptable and defensible, and can actually be more credible and reliable than records from paper-based systems that typically offer relatively few safeguards. The ELN should substantiate exact research details including conception, reduction to practice, diligence, corroberation and witnessing by capturing these critical inventive acts with time and date stamp functionality.

> "Patent infringement ... is a huge issue in the industry, so you have to be sure that you are protecting your intellectual capital and doing it in a good way."
>
> – Brian Patrick Carman, R&D Manager, Heinz North America

Enhanced Collaboration

Collaboration should be a key capability of any ELN system—enabling scientists to work together more effectively, both internally and externally, to exchange ideas and accelerate experiment success. Collaboration can go well beyond communication to sharing protocol design and execution. ELNs allow scientists to automate the process of accessing, analyzing and reporting scientific data. Workflow protocols that can be saved in a library, searched and accessed by authorized users will be useful. Sharing of protocols saves time and helps scientists leverage the core competencies of others.

Better Data Quality

Digital research and experiment data comes with greater detail, context and legibility than is possible with annotated paper notebooks. ELN transparency makes it possible to track errors, changes and updates with significantly greater accuracy. Improved visibility means enhanced research quality and compliance.

Improved Regulatory Compliance

Any ELN should easily accommodate today's regulatory compliance requirements with full support for current Good Practice (GxP) specifications, secure audit trails to prove data integrity and 21 CFR Part 11-compliant electronic and digital signatures. In addition, all laboratories are subject to environmental regulations such as the US Environmental Protection Agency's EPCRA rule and 29 CFR 1950 that cover a number of regulatory criteria from process safety management to the handling of hazardous substances.

IT Considerations

IT considerations for an ELN system include security, integration with other enterprise systems and support. Due diligence requires making a list of other lab and corporate systems, from registration databases to inventory and data management systems, to ensure that the ELN can connect to these systems seamlessly. Data security is critical and typically addressed with role-based permissions similar to the permission levels used by other corporate information and data systems. Continuing vendor support for the ELN is also extremely important. The ELN vendor should be experienced with a record of continuous system improvements and upgrades to ensure system sustainability.

ELNs that deliver these capabilities can radically improve laboratory workflows, reduce costs and spark scientific innovation. Moving research and experiment data out of filing cabinets and into an enterprise information system liberates scientists to focus on mission-critical research in a more productive and collaborative work environment.

WHAT TO CONSIDER IN SELECTING AND DEPLOYING AN ELN

To ensure a successful digital transition, organizations must carefully define the ELN functionality they require and put a comprehensive deployment plan in place. When assessing your organization's ELN requirements, it is very important to keep in mind that a wish list of every capability should not be used as the basis for an RFI/RFP. This will evolve into an unmanageable installation that will be impossible to roll out within the original project scope, as well as being difficult to maintain. Instead, consider the current workflows that the ELN will replace at your laboratory as well as your desired future workflows from an overall perspective. Then define the project scope based on the ELN capabilities that these core workflows require.

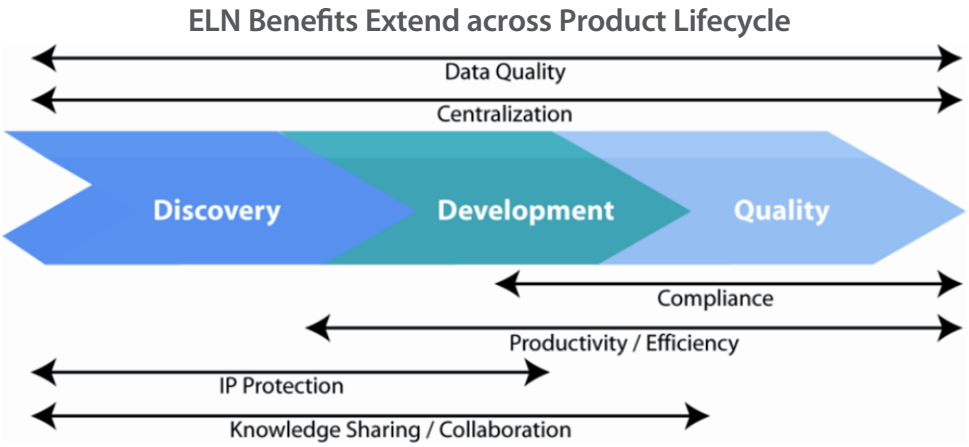


Figure 5: ELN benefits vary from stage to stage across the discovery to commercialization continuum. (Source: What are the Benefits of ELN? by Michael Elliott, published by Scientific Computing, Jan/Feb 2010)

Begin by surveying your scientists and technicians to determine what functions will achieve enthusiastic buy-in and subsequent use, emphasizing features that optimize research and laboratory workflows such as calculations, experiment cloning and synchronization with spreadsheets. Carefully define and document user requirements before looking at available ELN functionality. This will help you identify the ELN that best fits your lab's needs without being distracted by ELN capabilities that appear attractive but do not offer real value to the organization.

The ELN selection project will involve close scrutiny of available commercial ELNs. Third-party research from independent sources can help you focus and further refine your requirements prior to commencing the RFI or RFP process. Once you have defined the ELN features and capabilities you require, the same third-party research can help you create a short list of ELN vendors whose systems match your needs. Then you can develop an RFI or an RFP and send it to those vendors.

Based upon the vendor responses to the RFI/RFP, invite vendors with the best fit to demonstrate their notebook capabilities and explain how they address your defined use cases. Keep an eye on system ease of use, information capture/accessibility and system extensibility. Take care not to be swayed by features shown during a vendor demo that are attractive but out of the scope of your ELN project, and be sure to look beyond the capabilities of the ELN product alone. Select an experienced vendor that is able to support your solution to the extent required. Verify what kind of organization stands behind your ELN. What is their primary focus—small software packages, enterprise solutions or non-software offerings? What is their strategy and mid- to long-term vision? Does their approach match your vision?

Once you've made your selection, deploy a pilot installation so that ELN users and IT can verify that the ELN meets their technology needs. Pilot project feedback will be very important in fine-tuning your ELN system capabilities and implementation project plan.

Full-scale deployment should be accomplished according to a defined project plan agreed upon by your project team and the ELN vendor. There is a perception that labs can experience a 15-20% reduction in efficiency during the transition to a new notebook; this does not have to be the case. A pilot project that monitors and optimizes user adoption can ensure an ELN roll-out that does not adversely impact lab operations during implementation. Roll-outs can be particularly smooth when you implement an ELN with an easy-to-use, intuitive interface.

User training is a critical phase in any ELN implementation. Ensuring that users understand the benefits of the new ELN can accelerate adoption. Many labs discover that not all scientists are using the new ELN during the rollout period, and you will need to determine why this is and how to get over the hump. One tactic that can drive ELN adoption is the involvement of super-users to assist others. Further, individual department-specific training—including building specific workflow templates—can also increase adoption by showing scientists how they can tailor the system to their needs and save time with the ELN.

For more information on how to select an ELN, please request our white paper "Selecting an Electronic Lab Notebook: 7 Things You Must Know" at http://accelrys.com/resource-center/white-papers/selecting-an-eln-request.html.

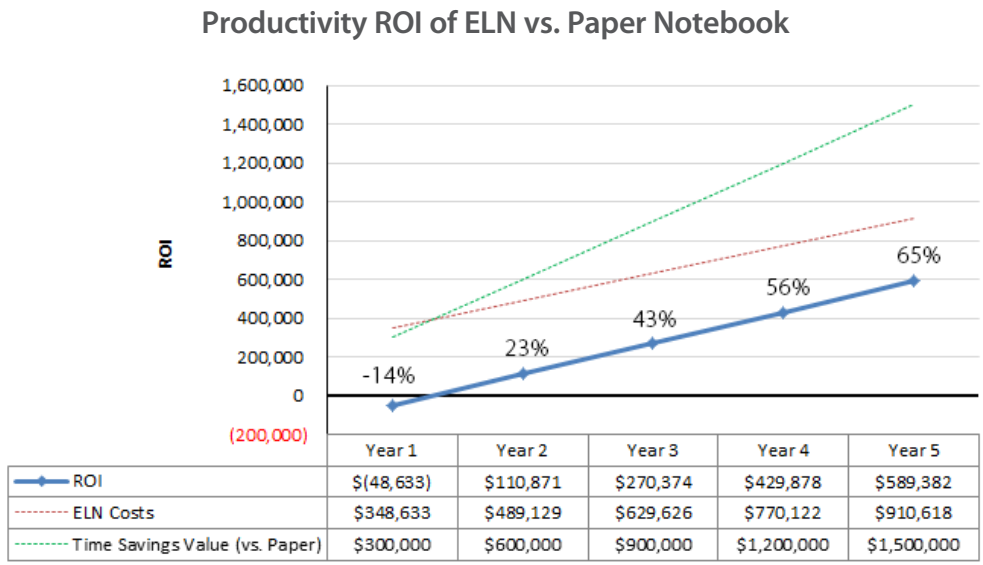
"Companies that implement ELNs are experiencing tangible benefits."

– Michael Elliott, Atrium Research, "Electronic Laboratory Notebooks", 2004

ELN COSTS, FINANCIAL BENEFITS AND ROI

Surveys by leading industry analysts show that ELN deployments can result in significant process efficiencies and time savings. As with any large-scale system implementation, there will be a number of costs to consider to gain a true picture of the Total Cost of Ownership (TCO). Once the TCO associated with the specific ELN proposal is known, a projected Return on Investment (ROI) can be calculated.

An ELN financial benefits analysis must address both hard and soft costs. Hard costs are those



	Year 1	Year 2	Year 3	Year 4	Year 5
ROI	$(48,633)	$110,871	$270,374	$429,878	$589,382
ELN Costs	$348,633	$489,129	$629,626	$770,122	$910,618
Time Savings Value (vs. Paper)	$300,000	$600,000	$900,000	$1,200,000	$1,500,000

Figure 6: ROI of ELN vs. Paper Notebook. (Source: BIOVIA ELN ROI Calculator, © 2013)

associated with capital equipment, system purchase and maintenance costs. Soft costs are those associated with time-saving efficiencies achieved from more efficient laboratory operations and data management. Based upon your defined list of ELN requirements, each ELN vendor under consideration should provide a list of hard costs required to implement the system. Figure 6 projects the ROI based upon a medium-sized ELN system costing $104,000; a payback of the investment is achieved within 18 months and continues to deliver savings in subsequent years.

ELN ROI is calculated based upon time savings. The greater the time savings, the higher the ROI. Atrium Research estimates that the average time savings after implementing an ELN versus continued use of paper-based notebooks is 20%.[1]

The ELN consolidates information from multiple systems and eliminates the "arts and craft" projects common in paper-based labs, which can consume upwards of four hours/week per scientist. Eliminating this non-value-added work can result in substantial savings. The example below shows how the ROI associated with saving one hour/week can exceed 3 million dollars.[2]

- Number of users: 500
- Hourly Rate: $125
- Time Saved: One hour/week over 50 weeks
- 500 x $125 x 1 x 50 = $3.125 million

[1]Market Report: 2012 Electronic Laboratory Notebook Survey, Atrium Research, October 2012

[2]Implementing Electronic Lab Notebooks Part 5, Bennett Lass, PhD, PMP, Scientific Computing, October 2011

An ELN deployment buys considerable time savings that can be further quantified through:

- **Improved Productivity**: An ELN empowers scientists to work smarter and faster. This increased productivity impacts the organization's bottom line directly and positively. First, calculate an average hourly rate for scientists, as well as the amount of time they spend each week updating their paper notebooks. If this time can be reduced by even 10%, a cost savings can be achieved, often totaling tens of thousands of dollars per researcher per year due to improved workflow efficiencies.
- **Prevention of Duplicate Experiments**: IDC Manufacturing Insights estimates that 30% of all experiments are repeated because prior data cannot be found.[3] Eradicating such duplicate experiments can deliver substantial time and cost savings. Scientists working with electronic records can search the database to verify if similar research or experimentation has already been performed.
- **Enhanced Knowledge Management**: As leveraging "Big Data" becomes a central activity of research laboratories, the ELN enables laboratories to structure their unstructured data, leveraging *ad hoc* lab data and processing it in unanticipated ways. Unlike paper lab notebooks, most ELNs enable Big Data analysis of notebook contents, a capability that can be a key differentiator in accelerating scientific innovation and new product commercialization.

These benefits are not just process improvements; they represent real dollar savings. The ultimate goal is for tasks to be "self-documenting," never requiring scientists to step outside of the work they are doing to tell a notebook or other informatics system what they have done.

A case study of a small business healthcare company using an ELN rated the technology as beneficial for collaboration, workflow support and regulatory compliance with investment payback achieved in 6-9 months.[4]

As more and more laboratory activities are supported by digital systems, ELNs are becoming "the center of the universe" for research scientists in the digital lab and a key enabling technology in speeding products to market across a range of industries.

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[3]IDC Manufacturing Insights,"Accelerating Science-Led Innovation for Competitive Advantage," Joe Barkai, February 2012

[4]Research by TechValidate, TVID: 6E1-6D4-89E, published March 30, 2015

APPENDIX 1

Paper Lab Notebooks vs. Electronic Lab Notebooks

	Recording Data	Searching Data	Analyzing Data	Managing/ Reporting Data
BEFORE ELN: Disconnected research data with paper notebooks	• Multiple notebooks • Time-consuming • Inefficient • Frequently illegible • Manual cut-and-paste • Difficult to update and annotate data • Inconsistent data recording methodology • Difficult to maintain, store and access notebooks/data • Slows lab productivity • Poor IP protection	• Time-consuming manual search through multiple notebooks • Critical experiment data buried in filing cabinets • Data often lost, Damaged or destroyed • Prior research often repeated	• Difficult to collect data from different sources • Time-consuming • Difficult to compare and analyze data • Difficult to re-purpose data • Isolated silos of scientific knowledge	• Inconsistent data archiving processes • Time-consuming • Difficult to share data • Large physical footprint; many notebooks require large storage space • Lack of integration with digital lab systems • Need to manually transcribe data to compile reports • Manual audit trails • Difficult to ensure regulatory compliance
AFTER ELN: Centralized, integrated, shareable research data with ELNs	• Single/centralized ELN • Easily record structured and unstructured data • Standardized templates • Consistency across experiments • Completely legible • Automates and expedites data entry • Minimized transcription errors • Efficiency gains with common workflows • Improved data quality • Easy to locate, re-use and reference prior experiment data • Easily clone experiments and workflows • Improved lab productivity • Enhanced IP protectection • Enhanced regulatory compliance	• Real-time data access • Easy to search and manage research data • Consolidate data from multiple sources • Accessible anytime, anywhere • Easy to search across multiple data repositories • Easier access to/sharing of data across enterprise • IP data electronically time/date stamped • Reduced experiment duplication	• Easy to gather data from different sources • Easy to drag and drop data into multi-dimensional analytical tools • Rapidly optimize and validate methods and recipes • Built-in calculations • Fast/flexible report generation • flexible experiment editing/annotation • Integrated with tools and dashboards for data exploration and analysis • Better collaboration across multiple scientific disciplines • Improved knowledge management	• Streamlined lab operations • Fast, easy report generation using standard report templates • All research data in a single digitally-accessible location • Small physical footprint • Integrates with IS infrastructure • Integrates with other corporate digital systems • Digital time/date stamped audit trails with rev. history/e-signatures • Data inherently mobile • Accessible anytime, anywhere • Role-based permissions protect sensitive data • Reduced research costs

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