BRINGING THE ELECTRONIC LAB NOTEBOOK TO LIFE FOR ANALYTICAL SCIENTISTS

An ELN in Development provides a window into how scientists work and collates corporate knowledge to support process improvements.

- 2,000–3,000 experiments are added to the ELN each month
- 70% of new experiments in the ELN are cloned from previous experiments
- Captured information can be leveraged to streamline experimental documentation, identify bottlenecks, implement load sharing, and reduce cycle times

In 2006, Pfizer launched a project to bring an electronic lab notebook (ELN) to its scientists working in analytical, process, and formulation development. Today, the ELN is used by approximately 1,000 scientists in multiple locations. Scientists are now able to easily search the ELN to find experiments and build on work done previously by colleagues—over 70% of new experiments are rapidly cloned from previous experiments. This article describes the requirements for ELNs used in Development versus Research, discusses the specific needs identified by Pfizer’s analytical scientists in Development, and highlights some of the ways the system has streamlined scientific workflows and served as a hub for ongoing knowledge management initiatives at Pfizer.

ELNS IN D VERSUS R

Not that long ago, scientists and their organizations actively questioned the utility and applicability of ELNs. Many initial ELN deployments were in Research, and not surprisingly, early concerns with ELNs centered on data security and how implementing electronic systems would impact the generation and defense of intellectual property. The development of secure, reliable digital signatures was critical in the widespread adoption of ELNs in Research; today, most organizations have implemented ELNs in chemistry and, increasingly, in biology.

As in Research, ELNs in Development are primarily used to capture experimental data. But that captured data ultimately plays a different role in Development than it does in Research. Research, which is focused on candidate selection, uses data in an ELN to generate and defend intellectual property. Development, on the other hand, is focused on candidate progression. Consequently, data from Development-centered experiments is primarily used to efficiently build a story about the work carried out to develop a formulation, a process, a method, and inevitably, a drug. Electronic signatures and audit trails validate what work was done, when, by whom, how, and for what...
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purpose. The advantage of an electronic system is that much of this work is automated so that information is collected and stored at every point along the path from sample creation to testing to results interpretation and filing. However, complying with regulatory requirements such as 21 CFR Part 11 requires organizations to validate all processes, including the ELN’s ability to capture and store data accurately, consistently, and securely.

An ELN for Development scientists can be particularly challenging to validate because in order to enable reviewers to reconstruct the story behind any series of scientific activities within an organization, the system must capture data and context associated with work across a diverse set of scientific domains. At Pfizer, the ELN was adopted to support work including but not limited to:

- API and dosage forms development
- Packaging and device support
- Clinical supplies manufacturing and testing
- Regulatory submission content generation
- Manufacturing processes/technology development and transfer
- Product enhancement

To accommodate all of the ELN’s potential touch points, Pfizer worked to find a vendor that offered not only the core set of scientific support features, but also a rigorous, highly compliant audit trail with an emphasis on quality. This meant that after conducting an initial audit of the vendor’s application and design process, Pfizer could take a risk-based approach to system validation. Doing this required a level of confidence in the vendor’s process that allowed more rigorous validation efforts to focus on items not covered under the vendor’s “core” system as well as on items that were specifically configured for Pfizer scientists.

WHAT DO SCIENTISTS WANT FROM AN ELN?

Scientific software has no value if scientists won’t use it—and scientists will only use software if it helps them do their jobs better or faster. Pfizer’s Research IT group interviewed scientists in the various disciplines that would be using the ELN to find out what they expected from the system. Six themes emerged:

- **Usability.** The ELN should be as simple to use as a paper notebook. Data entry should be straightforward, and scientists should not have to struggle with a complicated or illogical interface. Further, because of its electronic nature, the ELN should provide additional efficiencies over a paper notebook, such as the ability to automatically complete calculations or provide prompts for missing data.

- **Portability.** This is one area where user expectations differed somewhat from the actual need. Initially, scientists conceived of the ELN as a “magic tablet” that they would carry around with them. But in reality, most scientists worked in their notebooks in two locations: at their office desks and at the lab bench. The ELN was ultimately implemented in a variety of ways tailored to specific lab needs. Some scientists access the ELN on docked laptops shared with other scientists; a single laptop may be shared in smaller labs; dedicated PCs are used in sterile labs; and laptops are also used to interface with balances.

- **Accessibility.** Scientists should be able to access the system, securely, from the office, the lab, the home, or while traveling.

- **Searchability.** Scientists familiar with the power of Google to find information on demand recognized the advantage of being able to search on words, numbers, and structures to locate experimental data in an ELN rather than tediously scanning a table of contents or flipping through pages in a paper notebook. And this potential has been realized in the system implemented—the ability to search and clone experiments is one of the primary efficiencies of Pfizer’s ELN.

- **Collaboration.** One drawback of a paper notebook is its physicality. A paper notebook in a specific office, site, or country is hard to share across an ocean with a collaborator—and sharing it carries the risk of damaging or losing data. An electronic system outfitted with the proper security settings enables data to be instantaneously available anywhere it might be needed.

- **Integration.** Electronic systems are proliferating across all areas of pharma R&D, and it is essential that these systems play well together. This is particularly true for an ELN, given its ability to compile and aggregate data and information. The ELN should work with those tools already in the lab and with any new systems that scientists may adopt in the future.
Based on these themes, Pfizer Pharmaceutical Sciences defined the ELN as a highly flexible, electronic replacement to paper notebooks that would enable scientists to access empirical data, capture laboratory activities, and design and execute experiments. The ELN would provide speed and efficiency gains to help overcome daunting internal and external challenges at Pfizer and achieve key strategic objectives, particularly those associated with knowledge management. The project goals and metrics were organized in three areas:

- **Business goals**: Measure increased documentation efficiency, reduced cycle times, and increased global workload sharing.
- **Technical goals**: Meet the expectations and requirements set forth by scientists (as discussed previously).
- **Human goals**:
  1) Observe that scientists use the ELN to document experiments, search the notebook repository prior to initiating new experiments, and use the ELN collaboratively.
  2) Determine that the ELN eliminates transcription errors and reduces the documentation load to make scientists more efficient and avoid issues that could complicate candidate progression.

**DOING ANALYTICAL SCIENCE WITH THE ELN**

One thing that drives efficiency and consistency in the analytical lab is the ability to connect the tools analytical scientists use every day with the ELN. Pfizer’s ELN balance interface illustrates the power of this type of connectivity. Scientists working completely within the ELN have the ability to browse available balances. Once connected to a balance, scientists can avoid common transcription errors by automatically capturing the tare weight and actual weight for materials within the ELN. The ELN then automatically calculates concentrations and provides information associated with the balance (who the technician was, what method was used, when the weight was taken, etc.) to ensure consistent and accurate documentation (see Figure 1). This connection between the ELN and balances was one of the key pieces of functionality requested by Pfizer Pharmaceutical Sciences, and the result has such broad utility that the vendor has made the functionality a standard part of its core ELN product.

The materials import wizard in the Pfizer ELN provides scientists with other connections to vital data. Scientists can search for sample information residing in remote systems using any number of synonyms (the compound name, the generic name, or the marketed name are all acceptable search terms). Once scientists have selected a lot to use, information on that lot and associated sample metadata is automatically imported into the analytical materials table in the notebook experiment so that scientists can quickly link, relate, and document their work.

The ELN also includes various sections for managing different types of analytical preparations (see Figure 2).

![Figure 1: The balance interface in the Pfizer ELN streamlines information capture and eliminates transcription errors.](image1)

![Figure 2: Sections within the Pfizer ELN enable scientists to manage different types of preparations.](image2)
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The goal with all of the interfaces in the ELN is to minimize data entry and streamline the way scientists interact with the system. More importantly, the system also supports the creation of a fully electronic experiment write-up that tracks experiments from inception to completion and incorporates all sign-offs required by an organization’s procedures or regulatory requirements (see Figure 3).

In implementation, this means that scientists should not have to retype data that can be collected or calculated automatically. It assumes that the electronic system can check for the inclusion of mandatory information and prompt scientists if necessary fields are blank. It includes notifications that can remind authors and reviewers of deadlines set for signing off on work or reviewing write-ups. And the ELN can facilitate collaboration by providing check in/check out systems so that collaborators can work together to update experiments with their latest project results or accomplishments.

ELN RESULTS AND IMPACTS

Currently, about 1,000 scientists across the Pfizer Pharmaceutical Sciences business lines use the ELN. Of these, about 90% generate content with the system; the remaining 10% include quality assurance staff and managers who primarily review data already entered in the system by others. Content generators add between 2,000 and 3,000 experiments each month to the system. Of most significance, greater than 70% of these new experiments are created by cloning an existing experiment. This validates several metrics. Clearly, scientists are able to easily search the system to find experiments and build on work already done by colleagues. And looking at the time it once took to ask employees to pull a
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From a survey of Pfizer ELN users

““The day after the ELN was rolled out, I closed out every paper notebook I have because I never want to go back to a paper system again.”

notebook, scan the index, and flip through the pages, it’s readily apparent that the electronic system is much more streamlined and saves enormous resources—time, people, and money.

Certainly Pfizer scientists have been pleased with the system. The following quotes were collected from user surveys after the ELN was implemented:

“The day after the ELN was rolled out, I closed out every paper notebook I have because I never want to go back to a paper system again.”

“Wow, it’s really nice to see a system that looks like it will actually work, this is going to be great day-to-day”

“The ELN was well received in my group and is highly utilized. Not only does it save time documenting experiments, it creates better documentation that is more accessible.”

In addition to streamlining scientific workflows, the ELN has also aggregated data in a way that provides a window into how scientists work and makes it possible for organizations to better understand existing processes and retool to make operations more efficient. By leveraging consistently captured information and processes, the ELN has helped identify bottlenecks and areas where changes or load sharing could be employed to make processes more streamlined and efficient.

The ability to link key pieces of data and mine experiments captured in the ELN moves organizations toward true knowledge management. A well-structured ELN is a perfect source for an analysis or reporting tool to mine, provided that critical fields are available for searching. In a development setting, that might mean collecting data describing materials (e.g., reactants, products, impurities, or solvents) and properties of those materials (e.g., name, structure, sample/lot ID, or protocol). Any number of experiments may ultimately contain the information needed to facilitate Development decisions, reports, or dossiers, and this information can be used by pipelining tools to create a detailed, actionable report that collates data from multiple sources across disciplines. Previously manual, error-prone, and laborious paper-based tasks can be streamlined through electronic workflows or processes. For example, a scientist might enter a structure or product name and then receive back a summary of product yield and associated impurities generated for that compound overall range of reaction solvents analyzed in multiple experiments (see Figure 4). Reports of this type provide the knowledge to streamline or justify further experimentation or summarize project progress in presentations or team meetings.

Figure 4: This report illustrates how pipelining tools and an ELN can be used together to create actionable knowledge to drive decisions in pharmaceutical development.
CONCLUSION

The Pfizer ELN does more than merely streamline workflows. By serving as both a producer and a consumer of information, the ELN serves as a hub for data aggregation and knowledge management, enabling analytical scientists to process information and make better decisions faster.

ABOUT THE AUTHOR

Stan Piper is a Principal Scientist specializing in informatics projects in Pfizer’s Pharmaceutical Sciences division. Stan has been with Pfizer since 1998. He began as an analytical lab scientist, and for the past 10 years Stan has worked as a member of several Business Systems and Integration teams, evaluating and implementing laboratory solutions including: LIMS, CDS, ELN and Lab Data Archive applications. He is currently serving as Business Lead for several global informatics initiatives. Stan received his BSc in Chemical Biology from Stevens Institute of Technology in 1998, and his MBA from Rensselaer Polytechnic Institute in 2006.

To learn more about the benefits of electronic lab notebooks, go to accelrys.com/eln

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