

Adoption of Cloud-Based Electronic Notebooks to Collect, Store and Share Information Efficiently, In Real-Time

Customer Success Story:
Sunovion Pharmaceuticals

Adoption of Cloud-Based Electronic Notebooks to Collect, Store and Share Information Efficiently, In Real-Time.

While the practice of storing compound and testing information in electronic databases has been well-accepted by the pharmaceutical industry, reliance on paper notebooks as a primary data and observational storage tool continues. This dependency on paper has persisted for several reasons including:

- Historical experience with an accepted process for capturing data
- Ready availability and ease of implementation
- Concerns about intellectual property (IP) protection of records captured in an electronic format
- Cost

Despite these perceived advantages to paper, there are significant limitations to hard copy notebooks that are evident when data must be searched, retrieved, or shared across departments and over the years for archival purposes. These limitations are further exacerbated as research at most organizations is now conducted at corporate locations around the world or by contract research organizations (CROs).

Over the past decade, the pharmaceutical industry has increasingly adopted use of electronic notebooks (ELNs), both 'home-grown' solutions as well as ELNs from commercial software vendors. In most cases, "first generation" notebooks have been based on a locally maintained data storage server and installed software on the computers of each user.



"The ability to have real-time evaluation and improved communication has led to great time-savings and improved QA for the entire scientific enterprise."

Jason Newcom, Ph.D.

Director, Business Development & Alliance Management
Sunovion Pharmaceuticals Inc.

The Situation

In 2005, Sepracor Inc. (now Sunovion Pharmaceuticals, Inc.) performed its first evaluation of an ELN system. At that time, Sunovion ultimately rejected a proposal to purchase and locally install an ELN candidate because of its high initial and maintenance costs, extensive IT infrastructure requirements and concerns pertaining to IP protection.

Several years later, the company transitioned their drug discovery from internal teams to CROs, effectively shifting the majority of research to Europe and Asia. Unfortunately, records from these laboratories became difficult to access due to their geographical separation. The immediate result was a loosely organized and inefficient system for collecting, storing and retrieving data of all types.

Identifying a new ELN Solution

As Sunovion's work environment increasingly relied on a diffuse network of contractors in Europe and Asia, a new ELN solution to effectively manage information and IP was sought along with rapid deployment to the CROs.

The vetting process identified several critical success factors:

- Cloud-based storage was required to allow for global rollout. Because the CRO-focused user groups were geographically diverse and project needs and personnel changed rapidly, the ELN had to allow easy addition and removal of access to multiple users at multiple sites.
- The solution and implementation had to be user-friendly. Complicated user interfaces would necessitate multiple training sessions which were not feasible for remote CROs, while lack of proper training could hamper end-user compliance that might jeopardize Sunovion's intellectual property.
- Flexibility was essential to incorporate Sunovion's current workflow in chemistry as well as other disciplines while working with systems used by the CROs.
- The solution had to be cost effective. The per-seat user cost, maintenance and upgrade fees had to be controlled.

Over the course of six months, approximately twenty ELN solutions were evaluated and, ultimately, the Arxspan notebook was selected to meet the needs of the company. Arxspan provided a strong core ELN product as well as a flexible framework and willingness to collaborate on modifications that would allow for easy adaptation into the existing Sunovion workflow. The initial focus served medicinal chemists, but the long-term goal was to expand the ELN to all disciplines including biology, process chemistry, and analytical chemistry.

ELN Implementation

In addition to user-testing approval from bench scientists, implementation at Sunovion required buy-in from the IT group and corporate lawyers. The cloud-delivered ELN is web-based and requires only a small IT footprint without local software installations on user computers. The IT group successfully ran stress testing of the Arxspan servers for scale-up capability. In addition, the legal team approved the ELN for several reasons including that it was 21CFR11 compliant, it had versioning/history controls and it allowed for e-signatures. Initially Sunovion used the ELN in a "print-sign-bind" mode to create a hard copy archive.

Installation and rollout with CROs in Europe and Asia took place over the course of one year and was quite smooth. While there were a few minor issues during the rollout, the biggest obstacle resulted from external CRO firewalls that slowed response time. Once the firewall problem was identified and rectified, fully acceptable page refresh times of less than ten seconds became and remain the norm.

When managing pre-clinical chemistry workflows, a Sunovion principal investigator creates a notebook containing the molecules requested for synthesis and a work order which are then uploaded to the ELN server. CRO managers use the uploaded notebook to assign work and track synthesis progress. Multiple team members can work from the same notebook when needed; because the ELN is electronic, there are no size limitations. When complete, the notebook is closed.

With electronic record keeping, the ELN tracks the author's activities on every experiment. Multiple scientists may now work in a single notebook which helps organize project-related scientific content, allowing project managers to easily review newly recorded data. Likewise, the ELN is searchable by either text or structure resulting in highly efficient data retrieval.

Six months after the highly successful ELN rollout to chemists, the biology and analytical chemistry groups also came online, creating greater efficiencies. For example, the ELN provides excellent data storage with direct upload of data and spreadsheet workups which avoids the old "copy and paste" workflow and saves time. Because of the ELN's flexible design, it meets the varying requirements of the different scientific disciplines without complex software modifications.

The Results

The cloud-based, web-delivered Arxspan ELN is now nearly fully deployed across the scientific community at Sunovion and its CROs. Arxspan worked to integrate the ELN with other informatics software already in use. There has been increased productivity, time-efficiency, and access to both current and archival records. Importantly, the ELN has provided significant improvements in communication and time efficiencies that were identified as critical success factors at the onset.