



Arxspan - Cloud-Based Electronic Notebooks The New Generation

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In the digital age of drug discovery, the practice of storing compound and testing information in electronic databases has been well-accepted by the Pharma industry. However, laboratory bench scientists have lagged and continue to rely on paper notebooks to serve as their primary data and observational storage tool. This reliance on paper notebooks, which continues to this day albeit at a diminishing frequency, persisted for several reasons including:

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

There are obvious significant limitations to hard copy notebooks that become ever more apparent 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 around the globe within corporate laboratories or by Contract Research Organizations (CROs). Over the past 10+ years the pharmaceutical industry has begun to adopt the use of electronic notebooks (ELNs). This adoption has resulted in some 'home-grown' electronic notebooks as well as ELNs from commercial software vendors. Most of these "first generation" notebooks are based on a locally maintained data storage server and installed software on each user's computer.

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 the first ELN candidate because of its associated high initial and maintenance costs, high IT infrastructure requirements and overall concerns pertaining to electronic records for IP.

Several years later, Sunovion made a transition from an internal drug discovery group to an outsource research organization. With that transition, the majority of research is now performed at CROs located primarily in Europe and Asia. 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 that demanded a better solution to manage information and IP.

Under the limitations of this diffuse system of CRO and internal research, Sunovion realized that an ELN would be the only way to gather and store information efficiently in real-time. A new search for possible ELN solutions was initiated.

The vetting process had the following guidelines:

- **Cloud-based Storage:** This 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.
- **User-friendly implementation:** Complicated user interfaces would necessitate multiple training sessions which are unfeasible for remote CROs, while lack of proper training could hamper end-user compliance that might jeopardize Sunovion's intellectual property.
- **Flexibility:** The ELN would need to incorporate Sunovion's current workflow in chemistry as well as other sciences while working with CRO systems.
- **Cost-effective:** The per-seat user cost, maintenance, and upgrade fees had to be controlled.

Over the course of six months, approximately 20 ELNs were evaluated as possible solutions, two were chosen for evaluation, 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.

"Sunovion's work environment relies heavily on CROs. Rapid deployment of the ELN to CROs was critical."

The initial focus served medicinal chemists, but the long-term goal was to expand the ELN to all sciences including biology, process chemistry, and analytical chemistry.

Besides the bench scientist's user-testing approval, 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. IT overhead was acceptable. 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. Sunovion has now migrated to a completely electronic ELN paradigm.

Installation and rollout with CROs took place over a year and was quite smooth. User scientists were located in Asia and Europe as well as the US. While there were a few minor issues during the rollout, the biggest problem 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 10 seconds became and are the norm.

"Arxspan worked around the clock to correct issues as they arose and to minimize any negative impact on our workflows."

In practice for the pre-clinical chemistry workflow, a Sunovion principal investigator (PI) creates a notebook containing the molecules requested for synthesis as well as 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 workers can work from the same notebook when needed; because the ELN is electronic, there are no size limitations. When complete, the notebook is closed.

"The paradigm of one chemist—one notebook is outdated"

With electronic record keeping, the ELN tracks the author's activities on each and every experiment. Multiple scientists may now work in a single notebook which helps organize project-related scientific content. This allows 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 on line. Biologists were pleased to find that the ELN provides excellent data storage with direct upload of their data and spreadsheet workups which avoids their old "copy and paste" workflow and saves time. In like fashion, the analytical group has become significantly more time-efficient. Because of the ELN's flexible design, it meets the varying requirements of the different scientific disciplines without complex software modifications.

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

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 the other informatics software already in use. The ELN has provided significant improvements in communication and time efficiencies that were required at the onset. There has been increased productivity, time-efficiency, and access to both current and archival records.



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