Dotmatics
LabArchives

Protecting and Optimizing R&D at the National Institutes of Health

Why the NIH chose LabArchives to meet government electronic-records and data-sharing mandates and support its multidisciplinary research teams

Background

As the United States' official medical research agency, the National Institutes for Health (NIH) supports thousands of scientists undertaking basic, translational, and clinical research that will ultimately improve health and save lives. Subject to both the 2024 National Archives and Records Administration (NARA)/The Office of Management and Budget (OMB) federal electronic-records mandate and the 2023 NIH Data Management and Sharing Policy, these researchers are required to use only electronic resources to document their work and to share required research data.[1-3] Per the OMB, "By June 30, 2024, Federal agencies must manage all permanent records in an electronic format.[1]

To provide its multidisciplinary teams with viable options, NIH leadership set out to source solutions that would not only satisfy government mandates and budgets, but also empower researchers to work more efficiently, thoroughly, and collaboratively. With a long list of requirements, a specially formed NIH ELN Implementation Team (NEIT) vetted commercial options and assessed solutions that researchers had already been using before the mandates.

The rationale was that "Use of NIH-provided ELNs offers numerous benefits to the researcher such as in-platform collaboration, accelerated data sharing, and extensive capabilities for assuring data integrity. Further, use of centrally supported ELNs reduces operating costs and simplifies compliance with applicable regulations and Investigator responsibilities."[4]

CHALLENGE

The NIH needed to find a SaaS ELN to not only satisfy government electronic-records and data sharing mandates and budgets, but also sufficiently support the diverse needs of its multidisciplinary research teams.

SOLUTION

LabArchives was chosen as the NIH's multi-discipline ELN and now empowers 7,000 NIH researchers to work more efficiently, thoroughly, and collaboratively, while meeting policy requirements. The NIH licenses all LabArchives research products (ELN, Inventory, and Scheduler), enterprise-wide, for all researchers, across all of its 27 institutes and centers.

LABARCHIVES BENEFITS

Multidisciplinary Support:
- Support across scientific disciplines
- Approved for IP-generating work and GxP environments
- Specialty app integration (SnapGene, GraphPad Prism, ChemDraw)

Research Reproducibility:
- Complete central record hub
- Full experiment capture
- Instrument-sample data linking

Data Accessibility:
- Permission-controlled search across ELNs
- PI dashboards
- DOI sharing

Process Efficiency:
- Lab management tools
- Templates and widgets
- Microsoft (MS) Office 365 plug-in
- Upload for non-digital data/offline notes
- Integration-friendly architecture
- Centralized support
- Lower operating costs

Data Integrity and IP Protection:
- Safeguarded central data hub
- Role-based permissions
- FISMA moderate compliance
- FedRamp authorization on track

Vendor Reliability:
- History serving government and academia

Visit labarchives.com to learn more

LabArchives® cloud-based electronic laboratory notebook (ELN) and research workflow management solution quickly emerged as an ideal choice based on its proven record of providing multidisciplinary research groups at top research institutions with trusted functionality for collaboratively and securely managing their data, inventories, and resources.

On track for FedRamp authorization, LabArchives is now used institute-wide by up to 7,000 NIH researchers, who are enjoying a range of benefits, such as improved research reproducibility, process efficiency, data sharing, and IP protection. The transition has gone remarkably well, with LabArchives receiving an A+ support rating for its proven implementation support.

Challenge

The NIH had clear expectations in what it was looking for in an ELN, stating, "ELNs serve as the complete research record, documenting why specific experiments were initiated, how they were performed, what data and observations were produced, where the data are stored, and how the data were analyzed and interpreted, in sufficient detail so the research can be reproduced by others."[4]

NIH's Key Requirements

Any viable solution needed to meet key research needs, while working within the constraints of compliance demands, as detailed in Table 1.

Ideally, the NEIT hoped to settle on a very limited number of SaaS platforms that could serve as centrally-supported ELNs. This would not only help reduce operating costs and simplify compliance, but also streamline collaboration and data sharing, accelerate research, drive platform interoperability, and enhance efficiency.

Given the broad range of research that the NIH supports, the NEIT sought versatility and ease-of-use for meeting the unique needs of multidisciplinary teams working in different areas of science, as well as reliability in safeguarding data sharing and collaboration across specialties and locations. It seemed like a big ask, but as the largest biomedical research agency in the world, the NIH is used to challenging initiatives.

Table 1: Key SaaS-ELN Requirements for NIH Use

Need	Solution Must:
Record Log	Record permanent log of all entries, edits, and deletions, including authorized users and date/time
Federal Record Retention and Backup	Retain records of sufficient detail for required amount of time (e.g., 30 years for patent support, 7 years for non-FDA/IRB intramural research, indefinitely for scientific reference), with sufficient back-up (at least daily), and clear documentation of any external storage platforms utilized for large data files (e.g., genomics, imaging, radiology, microscopy data)
Paper-Record Capture	Capture and add images of paper-dependent data sources (e.g., notes compiled while working offline, written math equations, instrument printouts)
Security Controls and Access Tracking	Provide mechanism to control data access, protect sensitive data, and ensure data are not altered after entry (e.g., CFR Part 11 compliant signatures, page locking, versioning, time stamps, audit trails, deletion controls, and FISMA moderate compliance for protecting sensitive data, such as personally identifiable information and protected health information)
Role-based Permissions	Enable role-based granular access controls to define and manage rights and responsibilities across teams, from Primary Investigators to research team members to interns
FedRamp Authorization	Meet the standards of the Federal Risk and Authorization Management Program (FedRamp), a standardized, risk-oriented assessment framework developed by the United States federal government for authorizing the use of cloud-based products to handle unclassified government information

Solution

The NEIT hoped to select one main SaaS ELN for institute-wide use, as well as provide recommendations regarding the use of solutions that teams had been using prior to the mandates, as well as those needed for special circumstances. After thoroughly vetting several options, the key recommendations were:

- **LabArchives ELN, Inventory and Scheduler software-** First-choice solution for agency-wide use across all research domains
- **Signals -** Limited option for special medicinal and synthetic chemistry needs only
- **MS Documents stored on SharePoint -** Strictly for IP-free research at Investigator's discretion and responsibility

> Selecting commercial software approved by NIH for use as an ELN can greatly simplify assuring compliance with IT system requirements and execution of Investigator responsibilities and is encouraged whenever possible."
>
> — Excerpt from the NIH Intramural Electronic Lab Notebook Policy[4]

The NIH's approved platform comparison chart is presented in Appendix A.

NIH's Key Requirements

LabArchives stood out as a great option for several reasons. Not only did LabArchives ELN meet all baseline SaaS-ELN functionality and security requirements for NIH use (see Table 1), but it also offered robust inventory and resource scheduling functionality, as well as a number of other benefits that made it the ideal choice for multi-discipline use across the institute, such as:

- SnapGene integration for molecular biology capabilities
- GraphPad Prism integration for statistical analysis capabilities
- ChemDraw availability for enhanced chemistry capabilities with a low learning curve
- Microsoft Office 365 plug-in for compatibility with MS documents
- Unrivaled usability, including:
  - Browser access for any authorized user on any device with a web browser, including personal, as well as communal, computers, workstations, tablets, and iPads
  - Composite dashboard view, activity feed, and advanced search capabilities across all ELNs for which a user is authorized
  - In-platform collaboration with authorized internal and external users
  - Flexibility to support individual ELNs for highly independent work, project-based ELNs for collaborative work, or a mixture of both
  - External data sharing capabilities via persistent digital object identifiers (DOIs)
  - Widget-based creation of databases (coming fall 2024)
  - In-platform access to PubMed and full journal articles covered by NIH licenses
  - Camera app for uploading data captured offline/non-digitally without physical retention on the device used (e.g., hand-written notes, formulas and math equations, instrument printouts)
  - Exportable PDF or HTML daily summary of ELN entries
  - Migration of Benchling ELNs into the system with relative ease
- Outstanding support, including documentation and user training

Key Limitations of Other Options

In comparison to LabArchives, other options vetted had some key limitations.

- **Signals:** With a set-up and training process that is considerably more extensive than LabArchives, Signals is an approved option, but its recommended use is limited to synthetic and medicinal chemistry teams who require advanced in-platform chemistry intelligence. Availability is currently capped at 1000 licenses.
- **Github/Jupyter:** GitHub and Jupyter are both FedRamp authorized and, therefore, it is feasible to document the complete research record using GitHub to store versions of analytic code and Jupyter notebooks. Detailed guidance on complaint use is forthcoming from the NEIT. LabArchives includes an integration with Jupyter notebooks.
- **Microsoft Documents stored on SharePoint (not OneNote):** Microsoft Documents, such as Word or Excel, are acceptable options strictly for research that is **not** expected to produce IP. This qualification is based on key limitations, such as the lack of capabilities for validated signatures, risk for accidental deletions, and limited immutable versioning functionality, which is only possible when documents are properly stored on NIH SharePoint or Teams sites and marked with the Active ELN Record Retention Label. Investigators wishing to use MS Documents must assume the risks and responsibilities for managing them.
- **Research-specific electronic systems:** Use of electronic systems necessary for highly specialized research needs (e.g., clinical trials research, epidemiology, computational biology, and engineering) may be acceptable if used in a manner that meets the reproducibility standard for documenting the complete research record and if the system meets IT System Requirements for ELN. Details on approved approaches for doing such are forthcoming from the NEIT.
- **OneNote (NOT approved):** Lacking any immutable versioning or signature-validation capabilities, OneNote is not approved for any use as an ELN at the NIH, whether general purpose or for research producing IP. Microsoft has advised that they do not have plans to include either capability in the future. The NEIT notes, “Given that meeting NIH ELN requirements is expected to be cumbersome and resource intensive, ICs are urged to weigh the feasibility [of] implementing any such proposals against the perceived benefits of using OneNote rather than using the NIH-funded commercial ELNs…”[4]
- **Benchling (NOT approved):** Benchling is not an approved ELN option at the NIH for a variety of reasons, including the inability to grant enterprise ownership over free versions of Benchling; capabilities in the enterprise version that are incompatible with many of the NIH’s legacy data system and models; high costs that can reach 10-times similar options; no federal security-requirement authorization and no expressed interest gaining approval.

> The U.S. federal government has incredibly high security standards for cloud technologies, which is why the FedRAMP Marketplace is the sole source for all federal agencies seeking authorized solutions. FedRAMP authorization for LabArchives will mean that our ELN, Inventory, and Scheduler products meet all FedRAMP requirements and demonstrates Dotmatics’ commitment to the highest standards of security and reliability.”
>
> — Kiptyn Locke, President, LabArchives

Results

LabArchives is the **one multi-discipline ELN recommended NIH-wide.**

- **All NIH Institute and Centers** (ICs) can obtain access to LabArchives.
- **GxP validated** research environments are supported by LabArchives.
- **IP-producing** research environments are supported by LabArchives.
- **Chemistry** research is supported by LabArchives plus ChemDraw.
- **7,000 NIH researchers** are already using LabArchives.

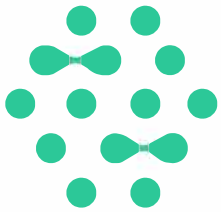
The NIH licenses all LabArchives research products, enterprise-wide, for all researchers across all of its 27 institutes and centers; this includes:

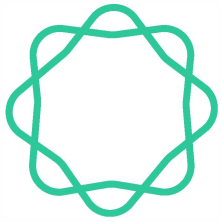
- **LabArchives ELN:** a digital notebook and workspace for improved productivity, data management, connectivity, and collaboration (including a 16GB individual file upload limit and unlimited overall storage)
- **LabArchives Inventory:** software for the organization, usage, tracking, and ordering of inventory items with an integration with the ELN
- **LabArchives Scheduler:** easy-to-use calendar and scheduling tools for the management and scheduling of laboratory equipment and resources

The transition to LabArchives has gone remarkably well thanks to LabArchives' stellar support. In fact, LabArchives received an A+ support rating in year two, when the NIH scaled from 1,000 to 4,000 users. That number has since grown to 7,000 users.

LabArchives: Now Available NIH-Wide at No Additional Cost!

All NIH Investigators, or their designees, can now directly request LabArchives accounts for their group members at no additional cost to their team.





Significance

As detailed in Table 2, by using LabArchives as its primary ELN for multi-discipline research, the NIH has seen a range of benefits, including improved research reproducibility, process efficiency, data sharing, and IP protection.

Table 2: Impact of LabArchives Across the NIH	
Area of Benefit	**Examples:**
Multidisciplinary Support	• Better support for diverse research on a unified platform thanks to a broad range of functionally and integrated specialty tools (e.g., SnapGene, GraphPad Prism, ChemDraw) • Easier collaboration with an institute-wide Saas platform • Support for preclinical studies
Research Reproducibility	• Improved research reproducibility with full experimental design capture, master file linking to experiments, and complete central record hub
Data Accessibility	• Enhanced data access controls via advanced settings • Advanced search across all ELNs to which a user has appropriate permissions • Faster public sharing of unique data via DOIs directly from the ELN • Easier management with always-available PI dashboards for viewing and managing ELNs
Process Efficiency	• Easier lab management with features such as reagent tracking and scheduling for equipment and procedure rooms • Simpler submission to core facilities thanks to data templates and sample manifests • Streamlined linking of sample-level data to instrument data • Lower operating costs and consolidated support with a centralized SaaS solution • Faster creation of longitudinal relational databases using widgets and templates (coming fall 2024) • Smoother integration with instruments, HPC, data systems, and other components of the data environment
Data Integrity and IP Protection	• Simplified compliance with an authorized single solution that meets all necessary federal requirements • Improved in-platform data validation • Greater reassurance of data integrity with features such as page locking, witnessing, time stamps, and complete audit trails • More control of data access with granular permissions at both the page and entry-level

What's Next?

With LabArchives now available as the one multi-discipline ELN chosen for cross-institute use, all NIH Investigators, at all ICs, are encouraged to request accounts for their teams and to learn more about the solution via training sessions. As the use of LabArchives grows, so will its positive impact on research reproducibility, process efficiency, data accessibility, and IP protection.

Learn More about LabArchives

With SOC 2 Type II and ISO 27001 certifications already secured, and FedRAMP and StateRAMP authorizations on track, LabArchives is the perfect solution for government and academic researchers looking to collaborate and innovate in the face of burdensome and costly security, research integrity, and data-sharing requirements.

Have a member of our team contact you to discuss an NIH-style program for your institution.

1. Executive Office of the President, Office of Management and Budget. Memorandum for the Heads of Executive Departments and Agencies: Update to Transition to Electronic Records. December 23, 2022.

2. Executive Office of the President, Office of Management and Budget. Memorandum for the Heads of Executive Departments and Agencies: Transition to Electronic Records. June 28, 2019.

3. National Institutes of Health (2023). Data Management and Sharing Policy. NIH Publications.

4. Intramural Electronic Lab Notebook Policy. NIH web page. https://oir.nih.gov/sourcebook/intramural-program-oversight/electronic-lab-notebooks/intramural-electronic-lab-notebook-policy (accessed 2024-08-29).

5. Frequently Asked Questions About the Use of ELNs at NIH. NIH web page. https://oir.nih.gov/sourcebook/intramural-program-oversight/electronic-lab-notebooks/frequently-asked-questions-about-use-elns-nih (accessed 2024-08-29).

Appendix A:

Comparison of NIH-Approved Platforms for ELN Use[4]

LabArchives	Signals	MS Documents Stored on SharePoint *(non-IP only)*	Features and Capabilities	
Multi-discipline	Chemistry	Multi-discipline	ELN research domains	**General**
$0	$0	$0	Cost to NIH users	
1/24	3/24	6/24	Accounts available for new ELN users	
✓	✓	✓	Security: FedRAMP certification (completed or on track & ready to use)	**Core Security & Records Management Requirements**
✓	✓	Immutable versioning is enabled when the ELN RRL is applied. Versions must be created by the user.	Permanent Log: all entries, edits, deletions, with authorized user & date/ time	
✓	✓		Immutable timestamps for all entries - easily accessible / visible	
✓	✓		Identification of author for all entries - easily accessible / visible	
✓	✓		Controls preventing permanent deletion of individual entries	
✓	✓	ELN RRL	Controls preventing permanent deletion of notebooks	
✓	✓	If on SharePoint	Frequent (at least daily) back-ups (ELN or NIH back-up service)	
✓	✓	If on SharePoint	PI-level control of user authorization (usually via role-based permissions)	
✓	✓	✓	Institutional-level ownership of notebooks	
✓	✓	✓	Institutional-level view of authorized users	
✓	✓	✓	Institutional-level rapid access to content & control of user authorization	
✓	✓	✓	Compliance with NARA Universal Electronic Records Management standards	
✓	✓	✗	21 CFR Part 11 compliant electronic signatures	**Specialized RM**
✓	✓	✗	Page-locking, witnessing, timestamps, audit trails	
✓	✓	✗	GxP compliant-ready, suitable for user validated GxP environments	

LabArchives	Signals	MS Documents Stored on SharePoint *(non-IP only)*	Features and Capabilities	
✓	✓	✓	Access outside the NIH network	**Key User-Facing Features**
✓	✓	✓	Automatic file upload	
✓	✓	✓	Microsoft Office integration	
16GB	2GB	250GB	Max file upload size	
Unlimited		25TB	Storage limit per account	
✓	✓	✓	External collaborator access	
✓	✓	✓	Access for a mobile device	
✓	✗	+/- if on SharePoint	PI Dashboard view of all ELNs	
✓	✗	On SharePoint	Advanced search across all PI notebooks	
✓	✓	✓	Metadata tags, annotations	
✓	✓	✗	Indexing & advanced search of attachment contents	
✓	✓	✗	Image annotation	
✓	✓	✗	Granular content-based permissions	
✓	✗	✗	Public data sharing via DOIs & Figshare integration	
6/24	✓	✗	Database creation	
✓	✗	✗	PubMed references & full papers	
ChemDraw (3/24)	✓✓✓	✗	In platform support for chemistry or integrations	
SnapGene	SnapGene	✗	Integrated support for molecular biology	
GraphPad Prism	Spotfire	✗	In platform support for statistics or integration	
✓	✓	✗	Inventory / reagent tracking	
✓	✗	Teams / Outlook	Scheduler (e.g., shared equipment)	
✓	✓	Teams	Activity feed	