

LabArchives Quick Start Guide to Storage

In keeping with the Partners Electronic Lab Notebook (ELN) Policy, PIs of Clinical Research studies must use LabArchives Lab/Research Notebook (ELN) to document Research Data and other record keeping activities related to data manipulation and analytical procedures for active research projects as of their hospital's ELN implementation date (Oct. 1, 2019 for BWH and MGH; Jan. 1, 2020 for McLean, MEE, Spaulding and IHP).

The ELN Policy does not apply to

- Clinical research projects that utilize electronic lab or data management systems, processes, and ELNs that are 21 CFR Part 11 compliant, or
- Sponsor-initiated clinical trials that utilize sponsor systems and processes

As long as those systems and processes comply with the requirements of the [Mass General Brigham ELN policy](#).

21 CFR Part 11

Title 21 of the Code Federal Regulations. Part 11 contains the Food and Drug Administration (FDA) guidelines that define the criteria under which the FDA considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper. LabArchives maintains 21 CFR Part 11 Compliance.

If you're conducting a clinical trial and using computerized systems that contain any data that are relied on by an applicant in support of an FDA marketing application, your system must be 21 CFR Part 11 compliant.

More 21 CFR Part 11 Information: [ServiceNow 21 CFR Part 11 Knowledgebase Article](#)

Data Life Cycle and Clinical Research

Data associated with a research project follow a cycle from collection to destruction that includes use, sharing, storage, and archiving (the "Data Life Cycle"). **Data storage** and locations can change throughout the data life cycle and, as the table below indicates, you will need to document location whenever a change occurs.

Lifecycle Stage	Examples
Generating or Acquiring Primary Data: Storage of original source, or raw data.	Electronic Data Captures (EDC) Systems: REDCap, StudyTRAX, Sponsor-initiated systems.
Using Data: Storage of project data being regularly analyzed, processed and prepared for publication, grant submission, or provided to a sponsor.	Files saved to network storage options such as your 'H' drive, Shared File Areas (SFAs), Research Interactive Storage (RFA), Dropbox, Syncplicity, other Partners Secure Storage Solutions: https://rc.partners.org/storage
Archiving Data: Storage of data after a project is completed and/or is no longer being analyzed/used on a regular basis.	Clinical Research data is typically archived in the original EDC System or exported and archived to long term storage destination.

What Information is Documented in LabArchives ELN for Clinical Research?

You must document in LabArchives ELN where your **primary data storage** is located. For REDCap projects, include the Project Name, Project ID and the link to the REDCap project. You're not required to store all research data in LabArchives. REDCap, Dropbox, and other storage solutions are supported storage solutions for storing primary data.

You ARE required to document where/how data are generated, stored, accessed and analyzed in your ELN.

You must also use LabArchives ELN to document the **Statistical Analysis Plan**, to store versions of the statistical scripts/code used to generate the output files, and to store output files that will be used for publication. This includes standard operating procedures (SOPs), algorithms, analysis programs, or other information typically included in the materials and methods section of a manuscript. This is the information that gets you from raw data to finalized data and allows for reproducibility. This is the information that gets you from raw data to finalized data and allows for reproducibility.

REDCap

REDCap (Research Electronic Data Capture: <https://rc.partners.org/redcap/>) is a web-based application for electronic collection and management of research and clinical study data. It is recommended for Primary Data Storage and Archiving clinical research data.

REDCap has the technical features necessary to serve as the database / EDC component of a 21 CFR Part 11 compliant study. However, a project in REDCap must have policies, procedures, training, validation and documentation meeting the requirements of Part 11 and the predicate rules for the underlying legislation. If you are subject to an FDA Audit, an FDA inspector will review all project documentation to determine at the project level if a study is compliant.

More guidance on REDCap's Part 11 Compliance: https://partnershealthcare.service-now.com/kb_view.do?sysparm_article=KB0027911

REDCap & LabArchives Use Case

Life Cycle Stage & Storage	MGB Enterprise Solution
Generating or Acquiring Primary Data: Storage of original, REDCap source, or raw data.	REDCap
Using Data: Storage of project data being regularly analyzed, processed and prepared for publication, grant submission, or provided to a sponsor.	SAS, R, SPSS: Use REDCap API to pull source data directly from REDCap to analysis platform. Output Data Set Storage (Data in Use): Files can be saved to network storage options such as your 'H' drive, Shared File Areas (SFAs), Research Interactive Storage (RFA), Dropbox.



	LabArchives: Store, share and version algorithms, analysis programs, code, scripts, output files.
Archiving Data: Storage of data after a project is completed REDCap: data can remain in Partners REDCap and/or is no longer being analyzed/used on a regular basis.	REDCap: data can remain in MGB REDCap indefinitely.
Research Data Record Keeping Activities	MGB Enterprise Solution
Statistical analysis plan, standard operating procedures (SOPs), LabArchives algorithms, analysis programs, or other information typically included in the materials and methods section of a manuscript.	LabArchives

References:

GitLab: <https://rc.partners.org/gitlab>

GitLab is used to store, manage and version control code. It isn't just for software developers! Biostatisticians, data analysts and data scientists can use GitLab to manage their scripts and algorithms for their stats packages.

MGB Getting Started with LabArchives KB Article https://partnershealthcare.service-now.com/kb_view.do?sysparm_article=KB0034055

Partners Secure Storage Solutions: <https://rc.partners.org/storage>

Partners Enterprise Dropbox: https://partnershealthcare.service-now.com/kb_view.do?sysparm_article=KB0028677

Dropbox does not have a statement on 21 CFR Part 11 Compliance. It does comply with other data integrity requirements such as: revision history, authorization by Partners account, access controls. Acceptable for record keeping activities and data use storage if Part 11 compliance is not needed. Limitations may include data storage limits.

Veeva SiteVault eReg Binder: The eReg Binder assists sites with the electronic storage and maintenance of regulatory documents for Partners IRB approved protocols. Contact ceoffice@mgb.org

NEED HELP?

- **Email:** support@labarchives.com
- **Knowledgebase:** <https://www.labarchives.com/labarchives-knowledge-base/>
- **Free webinars and trainings:** <https://www.labarchives.com/webinars/intro-to-eln>
- **MGB Discussion List:** http://researchlistweb.partners.org/list/w/eln/subscribe_eln.aspx
- **MGB Help Desk:** labarchives@mgb.org

