LabArchives Quick Start: Clinical Research

In keeping with the Partners Electronic Lab Notebook (ELN) Policy, PIs conducting Clinical Research studies must use LabArchives Lab/Research Notebook (ELN) to document Research Data and other records related to data manipulation and analytical procedures used in active research projects

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.

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.

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: https://rc.partners.org/kb/article/3073

LabArchives maintains 21 CFR Part 11 Compliance.

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. The chart below indicates times in the Data Life Cycle when you may expect the need to document location whenever a change occurs.

Data Life Cycle Stage	Examples
1. Generating or Acquiring Primary Data: Storage of original, source, or raw data.	Electronic Data Captures (EDC) Systems: REDCap, StudyTRAX, Sponsor-initiated systems.
2. 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
3. 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: include the Project Name and Project ID and a hyperlink for REDCap projects (if applicable). You're not required to store all research data in LabArchives. REDCap, Dropbox, and other storage solutions are supporting storage options for storing primary data. **At a minimum, document where/how data are generated, stored, accessed and analyzed.**

You must also use LabArchives to:

- Document the **Statistical Analysis Plan** and store versions of the statistical scripts/code that are used to generate the output files
- Capture the output files for publication (referencing the publication).
  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.

REDCap

REDCap (Research Electronic Data Capture): https://rc.partners.org/redcap/
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 and 21 CFR Part 11 Compliance

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://rc.partners.org/kb/article/2732

REDCap & LabArchives Use Case

Data Life Cycle Stage & Storage	Partners Enterprise Solution
1. Generating or **Acquiring Primary Data:** Storage of original, source, or raw data.	**REDCap**
2. **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.
3. **Archiving Data**: Storage of data after a project is completed and/or is no longer being analyzed/used on a regular basis.	**REDCap:** data can remain in Partners REDCap indefinitely.

Research Data Record Keeping Activities	Partners Enterprise Solution
Statistical analysis plan, standard operating procedures (SOPs), 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.

LabArchives Quick Guides: Storage https://rc.partners.org/eln

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

Partners Enterprise Dropbox: https://rc.partners.org/dropbox

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 for access and information.

Need Help?

Email: support@labarchives.com

Policy questions: labarchives@mgb.org

Knowledge: https://help.labarchives.com/hc/en-us