

# Current practice of archiving e-data in the GLP environment at SANOFI

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# Situation before global e-Archiving initiative

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- Data stored in a GxP and non-GxP system / application:
  - in databases and data can be locked
  - in databases and data can be locked with internal archive tool
  - in databases in native format
  - on secured long term storage
  - on secured file share
  - on unsecured file share [non-GxP]
  - on qualified acquisition PC secured [non-GxP]
  - on qualified acquisition PC unsecured [non-GxP]

What condition do we want



or



for our data

# Global e-Archiving initiative

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- **Strategy**

- **Define Storage and e-Archive options available today**

- Discuss and agree with QA GLP acceptable options.
- Create Quality Document(s) about e-Archive and Long Term Storage strategy and procedures for GLP Test Facilities.

- **Survey of current environment**

- Risk assessment with results in a position paper.

- **Gap analysis between strategy and current environment**

- Validate that Quality Documents are feasible and/or adapted
- Prioritize gaps based on risk assessments stated in the position paper
- Define tasks and budget needed to close priority gaps

- **Finalize Quality Documents and define IS project(s) needed**

- **Start implementation**

# Output of the global e-Archiving initiative

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- Final defined global e-Archiving tool
  - PReSERVE - **P**latform for **R**etention and **S**afety of **E**lectronic **R**ecords, leveraging their **V**alue for the **E**nterprise
- Platform
  - ECM Documentum based System
- File format
  - GLP facilities archive files in human readable format like \*.xml; \*.pdf and ASCII

# Output of the global e-Archiving initiative

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- A global SOP about electronic archiving is released.
- As a supporting document, an assessment form, was created and shall be used by the users to determine the following information per system/application:
  - Do electronic data exists that needs to be stored or archived
  - What is the format of these electronic data
  - Which storing- or archive system has to be used
  - What is the current status
  - What are the gaps between current and proper archiving/storing
  - How can these gaps be closed
- Access to global e-Archiving tool (PReSERVE) is under implementation
- A slide deck to train users is available
- Some systems were already assessed.  
Assessment of remaining systems/applications is ongoing.

# Output of the global e-Archiving initiative

## Archiving vs Long Term Storage

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- File/Data in human readable format
  - Should always be archived in global e-Archiving tool (PReSERVE)

# Output of the global e-Archiving initiative

## Archiving vs Long Term Storage

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- File/Data in native format

- The files not needed for potential future reprocessing and which can be extracted/converted completely (incl. audit trail) into a human readable format should always be archived in global e-Archiving tool (PReSERVE).
- The files needed for potential future reprocessing should be stored in long term storage solution (e.g. OpenLab, NuGenesis or a system-specific internal archive tool)
- If this is not possible for any reason, then an automated process using a file capture system (e.g. AllSync) or a similar tool has to be created to store the electronic data on a secured file share.
- Manual moving data from the working file share to secured file share should be prevented due to security reasons.

# Output of the global e-Archiving initiative

## Archiving vs Long Term Storage

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- **File/Data in native format**

- **A final archiving solution has to be found during decommissioning of the source system / application.**
  - All electronic data stored in native format needs to be converted into a human readable format that can be archived in the global e-Archiving tool (PReSERVE).
  - If this is not possible, the vendor of the source system has to be asked to do that.
  - If this is not possible:
    - For a non-GxP system/application it has than to be decided if the data can be deleted.
    - For a GxP system/application the source system/application has to be kept for the retention period of the electronic data.



# Output of the global e-Archiving initiative

## Archiving vs Long Term Storage

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- Mixture of files (some in human readable format, some in native format)
  - All files of one study or test should be kept together.
  - A mixture of files should be handled in the same way as files in native format, described in the workflow slide.

# Output of the global e-Archiving initiative

## Electronic data from an external provider

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- **Electronic data from an external provider in human readable format**
  - **Will be directly archived in global e-Archiving tool (PReSERVE)**
    - Can we check completeness ?
    - For example:
      - Acquisition method included?
      - Audit Trail included?
      - Processing Quantification Method included?

# Output of the global e-Archiving initiative

## Electronic data from an external provider

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- **Electronic data from an external provider in native format**
  - It will be not possible neither to store the native data in a long term solution nor in the global e-Archiving tool (PReSERVE) at Sanofi.
  - It will be also not possible to view and check completeness and/or to show the electronic data in native format to the authorities.
  - If the external provider is not able to convert the electronic data into a human readable format that can be archived in the global e-Archiving tool (PReSERVE), then the electronic data needed be stored at the external provider for the retention period.

# Output of the global e-Archiving initiative

## Electronic data from an external provider

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- For the future Sanofi expects:
  - To get all electronic data back from an external provider in a human readable format which can be archived in the global e-Archiving tool (PReSERVE).
  - If the provider cannot deliver the data in such a format, then a case to case decision is needed to define how to proceed with the electronic data.
  - The responsible outsourcing manager, study director or head of the test facility, e-archivist and the external partner have to come to an agreement what to do to meet the retention period for electronic data in native format.



# Process of e-Archiving or secured storing

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- Electronic data will be archived or stored secured close to the study end.
- Time Trigger
  - Start of the e-Archiving or secured storing of electronic data after finalization of the study (signature of the study report, sending the results to the requester)
- Grace Period
  - Time period between start of archiving process (study end) and the time when data have to be archived or secured stored (same process as for paper based data)

# Process of e-Archiving or secured storing

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- **Archivist**

- The archivist is designated by the test facility management and ultimately responsible for the archiving/long term storage of the electronic data.
- The archivist may delegate technical aspects and activities to test facilities members, who will be appointed as e-Archivists or e-Records manager, if needed.

# Process of e-Archiving or secured storing

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- **Responsibilities**

- **Study Director or Study Conductor**

- The study director can delegate the activities to the study conductor, but will be ultimately responsible.
    - Study Director is responsible to start the process after the study is finalized and to this he/she will inform the e-Archivist (or e-Record manager) to archive/securely store the electronic data in parallel to archiving the paper based data.

- **Principal Investigator (PI)**

- Unless it is defined in the study plan, the PI will inform the e-Archivist (or e-Record manager) of the test site to archive/securely store the electronic data.
    - Unless it is written in local SOPs, the PI will delete the data from the source system/application after the electronic data are successfully archived/securely stored.



# Process of e-Archiving or secured storing

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## ● Responsibilities

### ● Nominated e-Archivist (or e-Record manager)

- The e-Archivist will, depending of the result of the assessment of the specific system or application:
    - archive the electronic data in the global e-Archiving tool (PReSERVE)  
or
    - store the electronic data in a long term storage system  
or
    - store the electronic data in a secured file share
  - Immediately after the archiving/long term storage, the e-Archivist will check that the archiving/storing was successful.
  - After a positive result of this check, the e-Archivist will delete the archived/securely stored electronic data from the source system/application to prevent duplicates that can be edited by default.
  - Depending on local SOPs, the e-Archivist will inform the study director and/or the archivist that the data are archived and been removed from the production environment.
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Thanks for your attention

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