



## Singapore Healthcare Management 2024

# DESTRUCTION OF STUDY DOCUMENT ARCHIVAL AFTER RETENTION PERIOD

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## INTRODUCTION

KK Research Centre (KKRC) has practiced archiving study documents at an off-site archival company at the end of the study, in line with Good Clinical Practice guidelines. Service Agreement with the archival companies specifies that the archived documents will be destroyed at the end of an agreed retention period. In 2022, we discovered that archival companies kept the study documents beyond the end of the retention period.

To address this problem, KKRC embarked on a QI Project with the aim to achieve end-to-end archival process.

## OBJECTIVE

To reduce the number of archived documents overdue for destruction from 100% to 30% or less by March 2024.

## METHODOLOGY

We conducted a Root Cause Analysis and took a review to address the problem statement.

A new workflow was introduced to ensure end-to-end archival process is achieved, including the proper disposal of archived documents where applicable.

## RESULTS

During the pilot phase of the new workflow (Aug-22 – Aug-23), the number of archived documents overdue for destruction dropped from 100% to 87%.

After the implementation of the updated workflow, the number of archived documents overdue for destruction further dropped to 27% by the end of February 2024.



## ANALYSIS

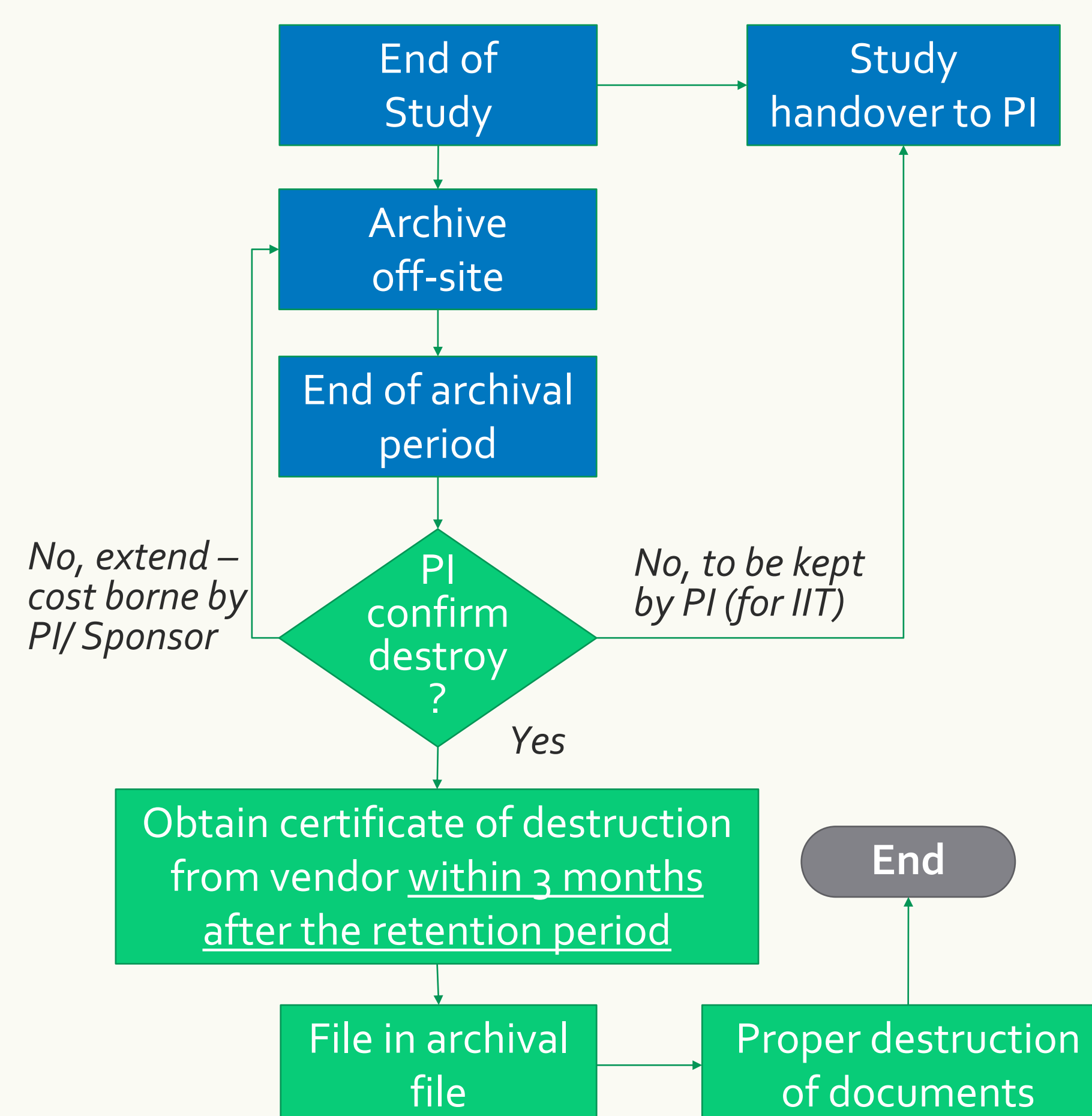
Through Root Cause Analysis, we concluded that there is lack of follow-up process to ensure study documents are destroyed at the end of the retention period.

### ROOT CAUSES

**Q: Why are study documents kept past the date of archival period?**

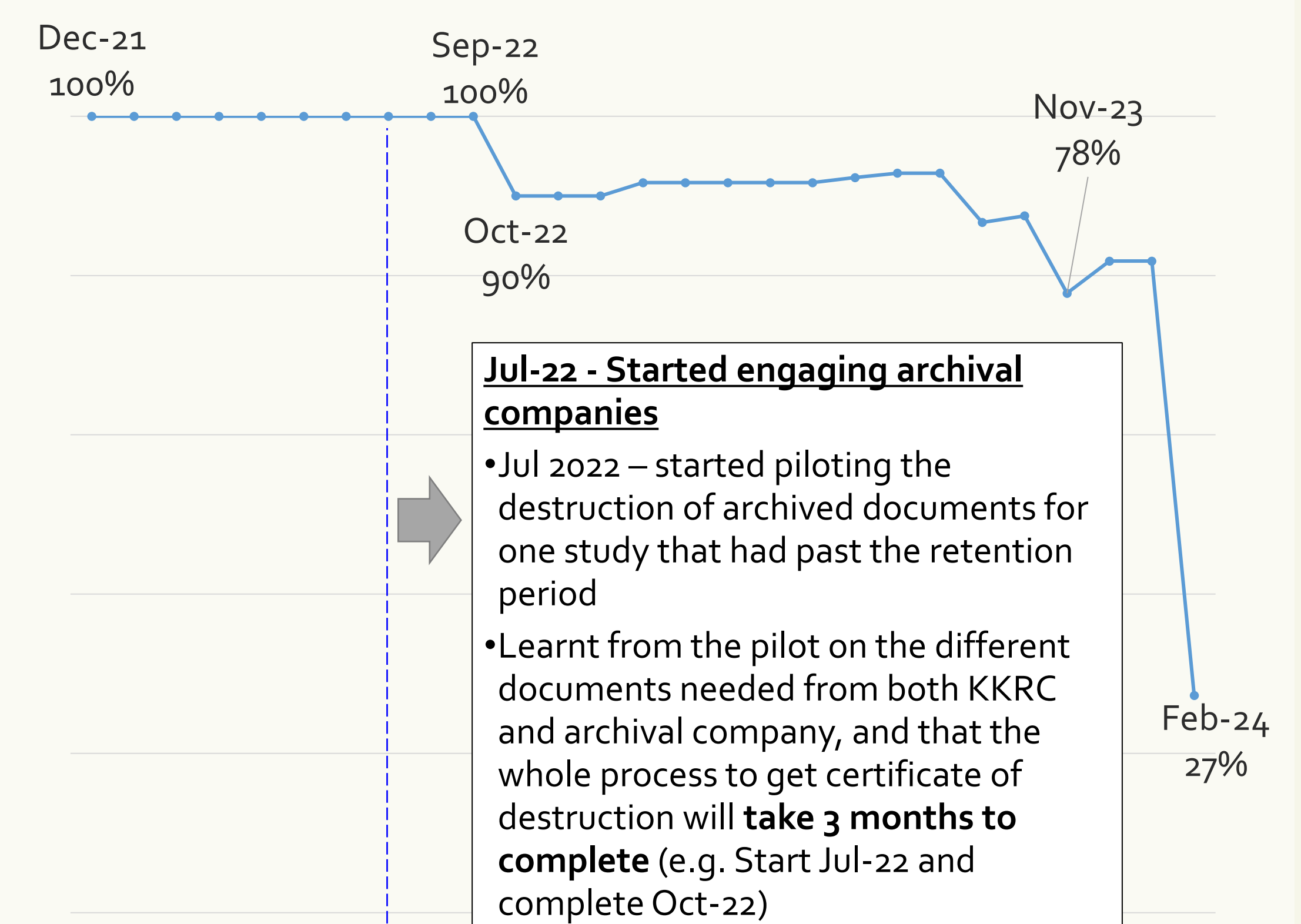
- No follow-up with the archival company after the agreed archival period is over
- No communication with the Principal Investigator (PI) on the status of the archived documents
- No follow-up process after study documents are archived

### NEW PROCESS FLOW (FROM OCT 2022)



### VERIFY IMPROVEMENTS WITH DATA

% Archived Studies Overdue for Destruction (more than 3 months after the retention period).



## CONCLUSION

Introduction of the new workflow successfully reduced the number of archived documents overdue for destruction to less than 30% by March 2024, indicating end-to-end archival process is achieved.

