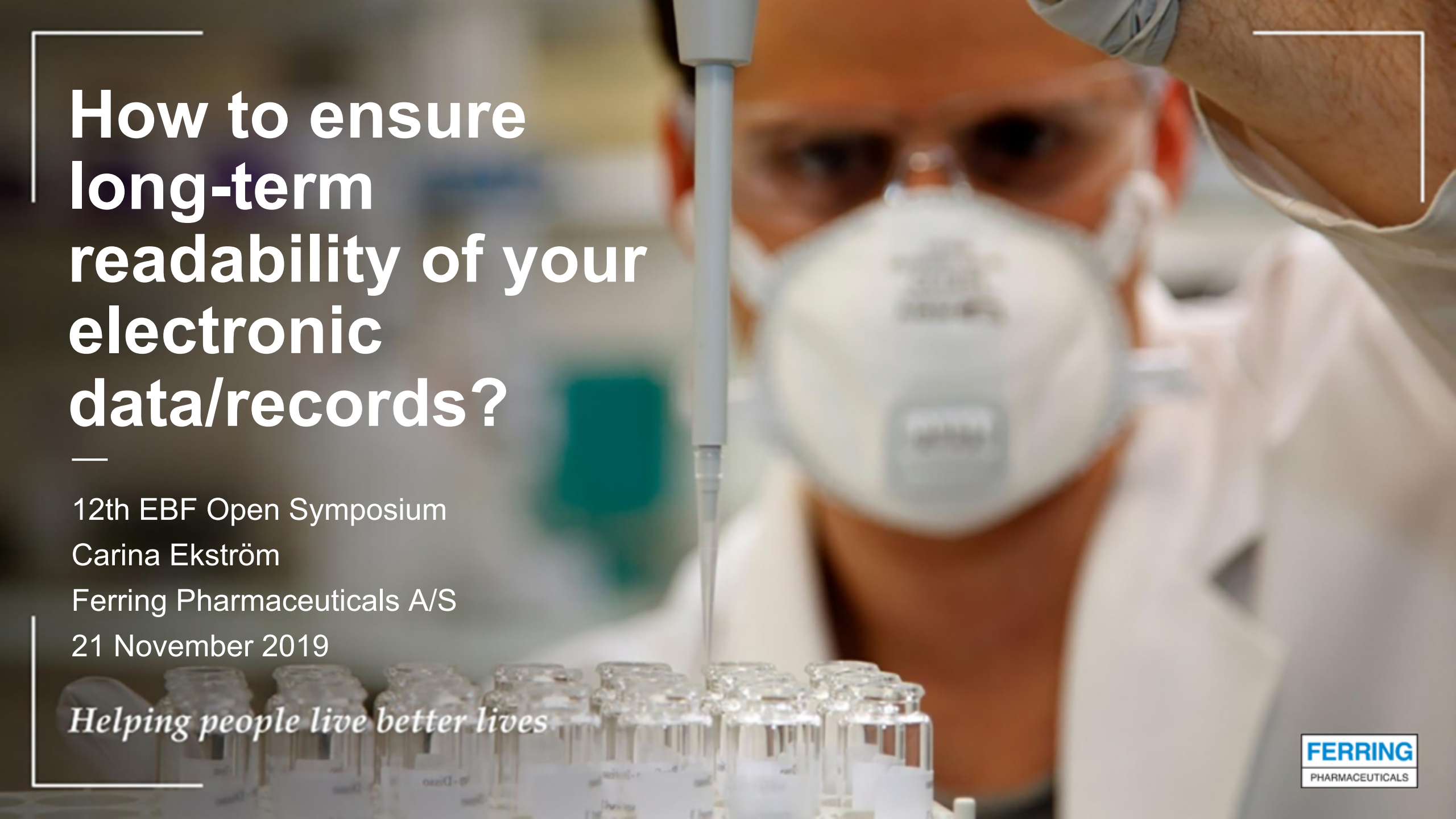
How to ensure long-term readability of your electronic data/records?



12th EBF Open Symposium

Carina Ekström
Ferring Pharmaceuticals A/S

21 November 2019

Helping people live better lives

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Back in the old days…..

- Raw data on paper
- Long term storage in the physical archive

Today

In addition to the paper raw data we also have

Gigabytes of electronic data stored on servers

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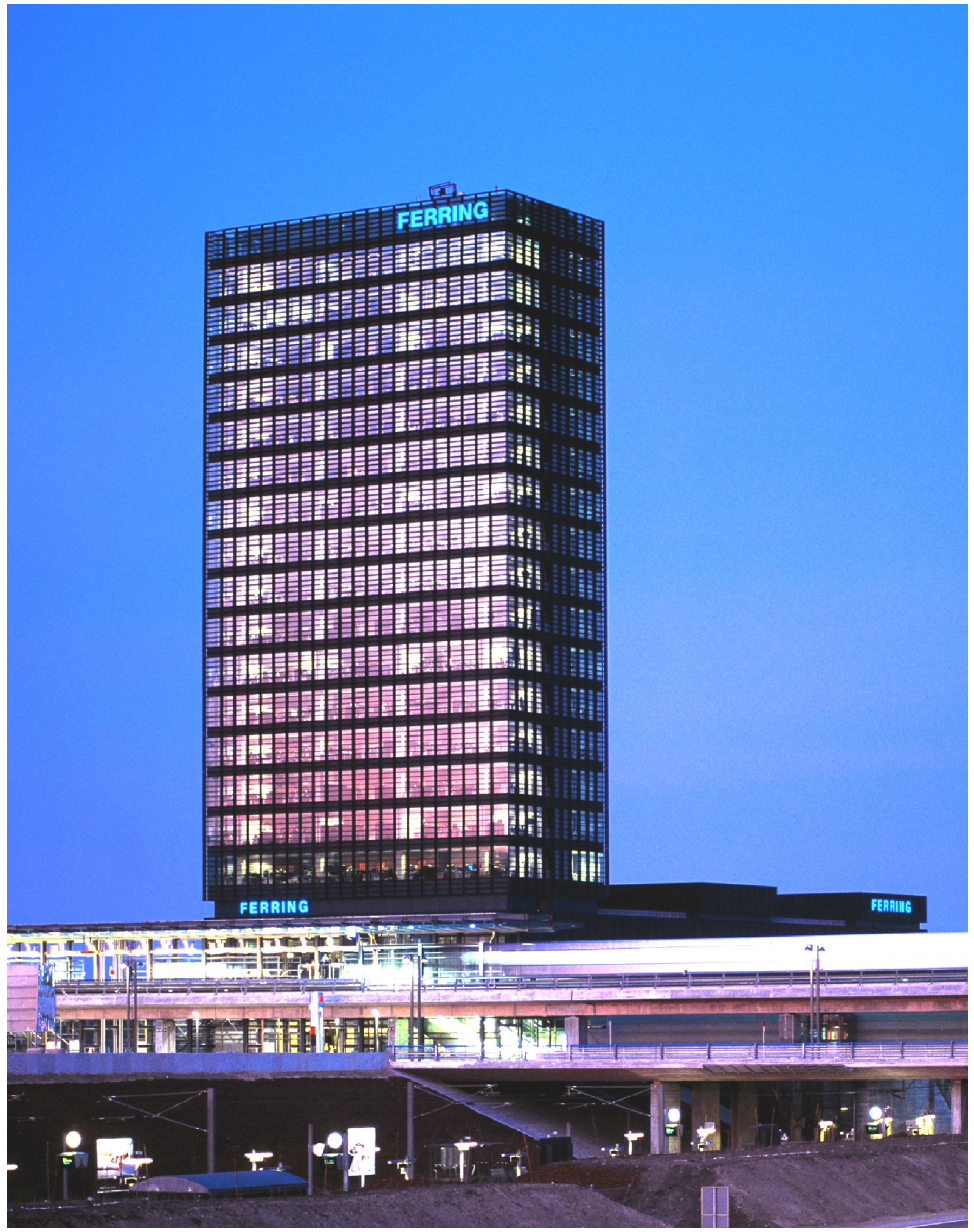
Archival of e-data records

After study finalisation:

- The folder with study related electronic data/records from lab equipment is zipped
- MD5 checksum of the folder calculated
- Zipped folder uploaded to the electronic archive
- Successful upload to e-archive is ensured by comparing MD5 checksum calculated before upload with MD5 checksum calculated in the e-archive upon upload



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De-archival

Study chosen for inspection or for periodic readability check:

- Export a copy of the file from the electronic archive
- Unzip and import to the software

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Background

Why now?

LC-MS/MS instruments from Vendor Blue

LC-MS/MS instruments from Vendor Green

Vendor Blue software can be decommissioned

But how do we then ensure readability of the archived e-data?

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Software decommissioned or format not supported any longer

OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING
Number 17

Advisory Document of the Working Group on Good Laboratory Practice

Application of GLP Principles to Computerised Systems

Section 3.2 Data and storage of data, point 75:

”When a system or software is updated, it must be possible to read data stored by the previous version or other methods must be available to read the old data”

”Software should be retained in the archive if necessary to read or reconstruct data”

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Software decommissioned or format not supported any longer

Archive the software

Are there not any alternatives?

* Long-term preservation of Analyst data using the AnIML format

David Van Bedaf, Janssen R&D

9th EBF Open Symposium, Barcelona

17 Nov 2016

Convert the data to a non-proprietary format

(e.g. AnIML*)

Yes, we believe there are!

The alternative is to virtualize the software

A feasibility study with virtualization showed that:

- It was possible to virtualize the two software, that control(led) our LC-MS/MS instruments, one on Windows XP virtual machine and the other on Windows 7 virtual machine
- It was possible to access the software via a secure remote desktop solution (portal)
- A copy of data could be viewed via the portal exactly as if it was viewed from the instrument PC
- It was confirmed from the vendors that we have the right to use our licenses for this purpose, i.e. off-premise software installation

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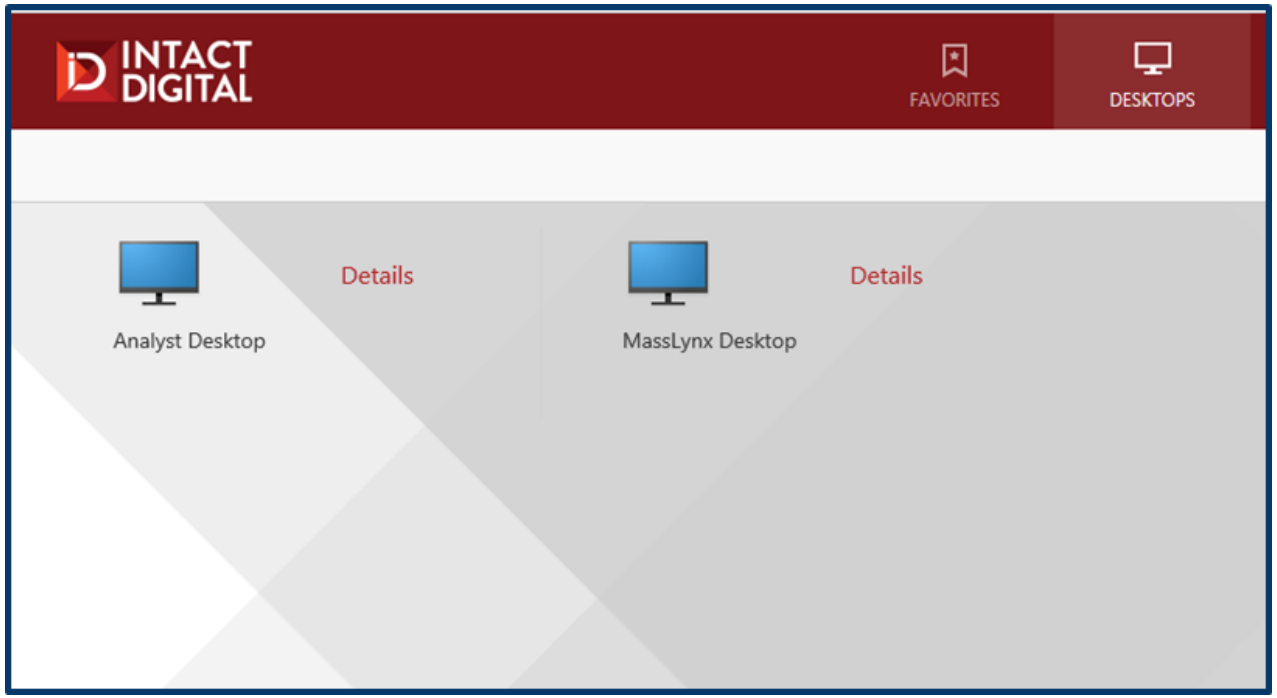
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Analyst Desktop
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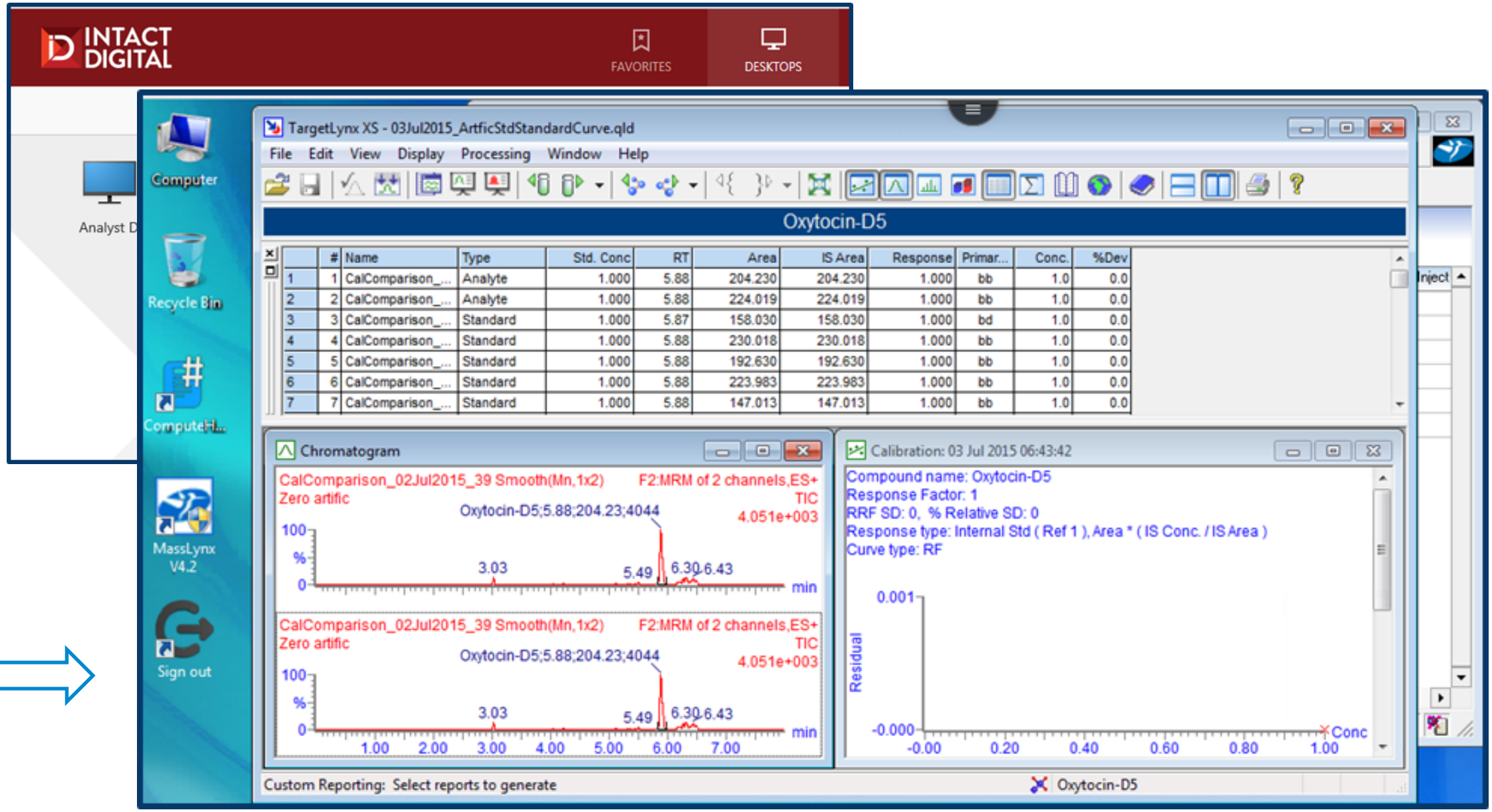
MassLynx Desktop



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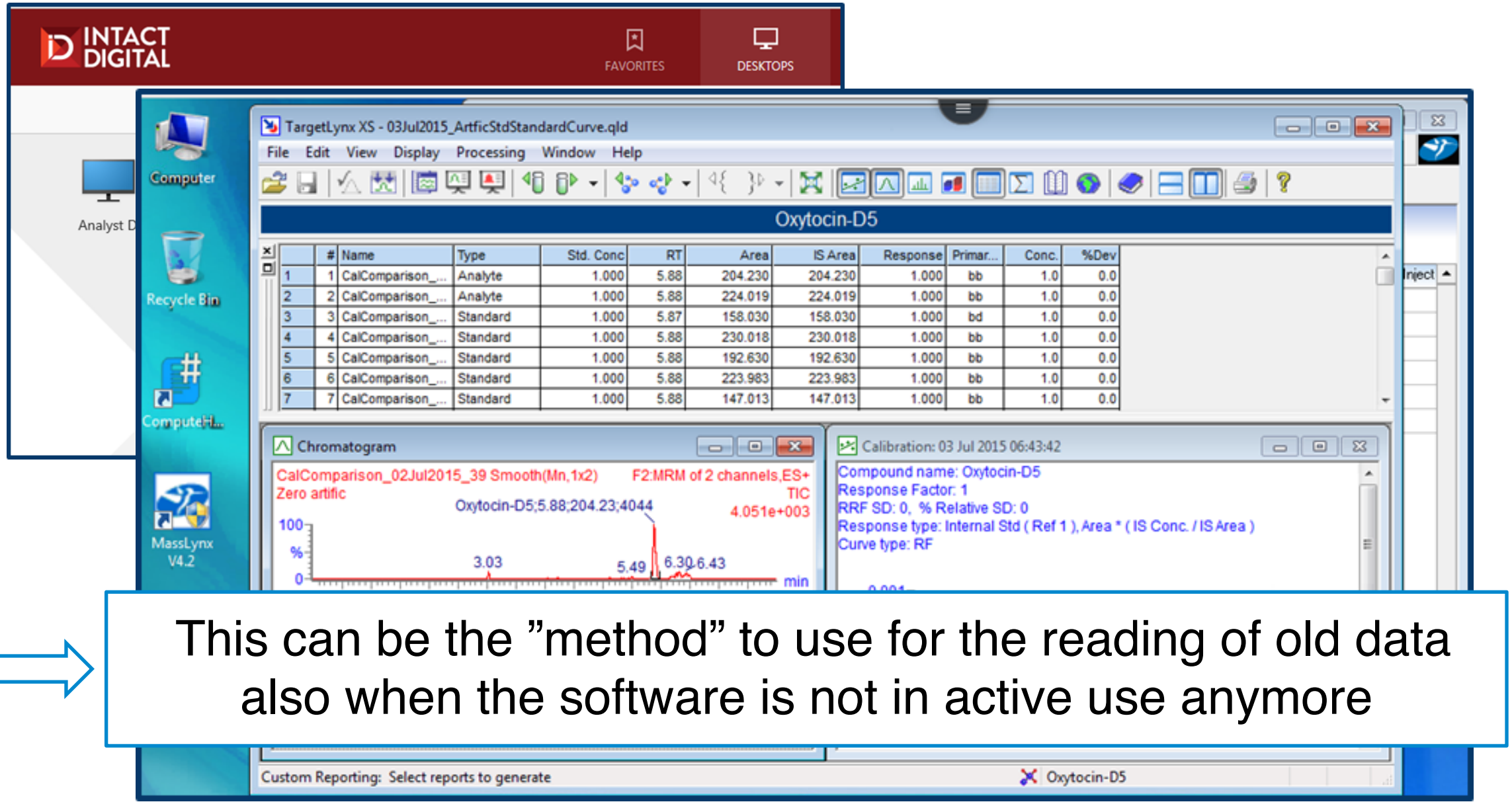

This can be the ”method” to use for the reading of old data also when the software is not in active use anymore

Software Library: Keep the ”software as a reader”

How will it work?

- Software will be installed and hosted in a virtual machine (e.g. with Windows XP or Windows 7)
- Access to software will be via a remote desktop solution (portal)
- Data/records will be kept in our electronic archive
- A copy of the data will be uploaded via the portal when needed, e.g. during inspection
- The software will be used to view the data
- Once the session is over, the copy of the data will be deleted from the Software Library machines

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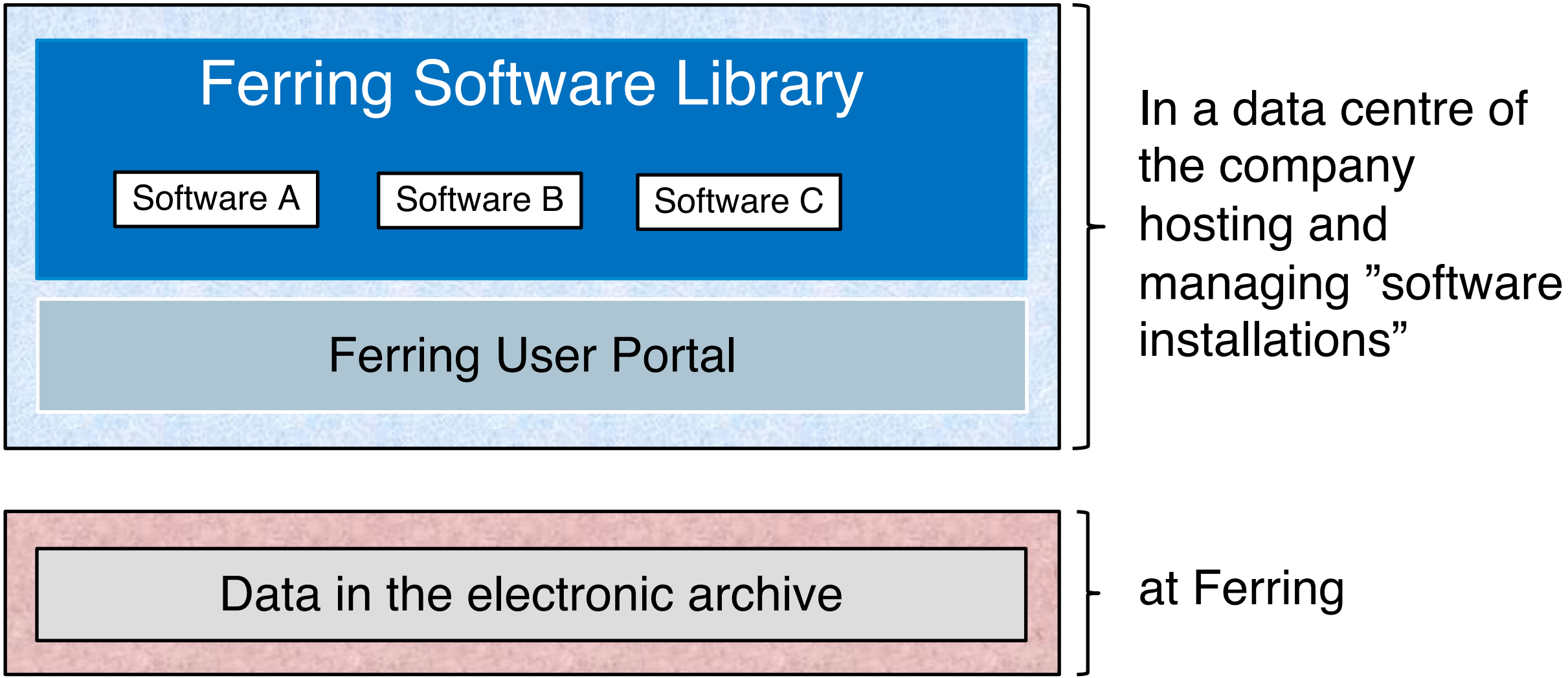
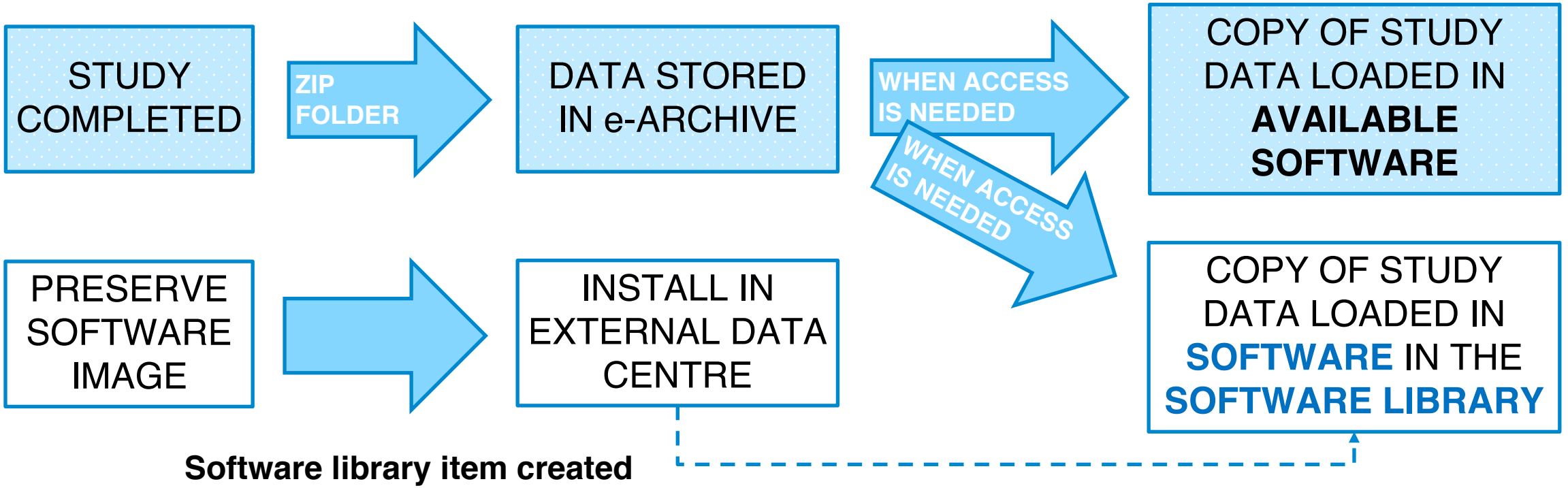
Software library setup



The flow when the software is to be decommissioned



The technique is available and found feasible for the software we will decommission

How can we ensure compliance?

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We will validate each installation in the Software Library

e.g. for the software we are about to decommission:

- that data can be read (viewed) and re-evaluated
- that the re-evaluation gives the same results as the original evaluation by the validated software on the equipment in the lab
- compare the ”results” by spot checks according to pre-set protocol, e.g.
    - peak area for a specific sample
    - peak area before and after a manual reintegration
    - who performed the reintegration and when

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When the software is decommissioned:

Before each use (e.g. during inspection) and for periodic readability check of archived e-data:

Check suitability of the software in the Software Library by:

- evaluating a test data set
- spot checking the ”results” according to a pre-set protocol
  e.g. from:
  - integrated chromatograms (manually and automatically integrated)
  - the result file

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In the archive we will keep:

- The software package
- The validation documentation
- Installation specifications and –settings
- The test data set needed for
  - periodic testing
  - test in case of inspection

Things to consider:

- Validation status of the virtual software – formal system review?
- Licences
- Access control
- What to do if the ”software hosting” company goes out-of-business

Conclusion and future work

- Based on the results of the feasibility study we regard this approach as a way to ensure continued readability of electronic data from decommissioned software

- The implementation project is ongoing

- Planned to be in production Q1 2020

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Thanks to:

Julien Marchand	Ferring Project Manager
Natasa Milic-Frayling	CEO and Founder of Intact Digital Ltd
Magnus Knutsson	Project Representative from Bioanalysis

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Questions?

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