

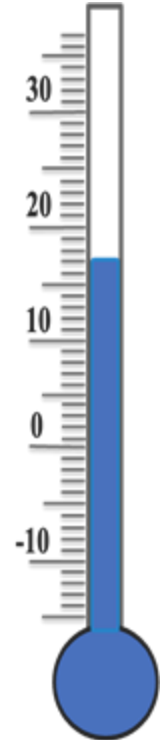
17th EBF Open Symposium

Taking the Temperature of Bioanalysis

E-environment Workshop

Upscaling of the archivist role and the archiving activities when transforming into a paperless and cloud-based lab

Cecilia Arfvidsson, on behalf of the EBF



Introduction

Paper-based workflows have been the standard for a very long time...

- The lab organization then manage all data within its own data centers and are responsible for all aspects of data security.

As labs now start to move their data infrastructure to the cloud and aim to become paperless, some aspects of these responsibilities shift to a cloud provider.

- GLP test facility continue to have the ultimate responsibility for GLP compliance and to assess the risks to data integrity, data quality, data availability, data retention and finally data archiving.



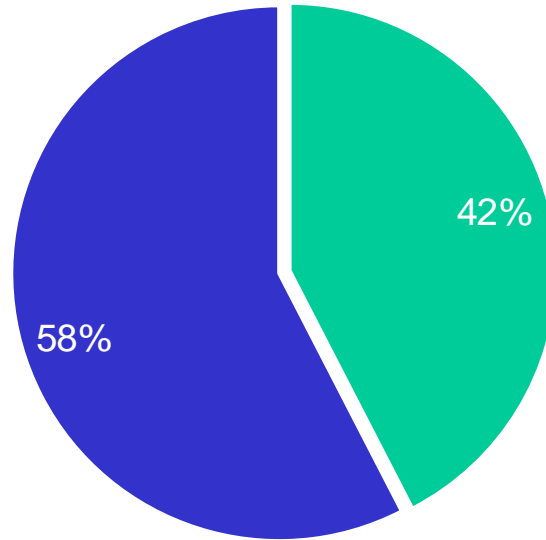
Finger on the Pulse Survey

- A Finger on the Pulse Survey was sent out to the EBF core community to collect some additional insights on where we are in the transition
 - into a paperless lab
 - into a cloud-based lab
- Survey also aimed to understand the BioA community's view on the potential changes/updates
 - in the archivist role and
 - in the archiving activities

when transforming into a paperless and cloud-based lab environment.



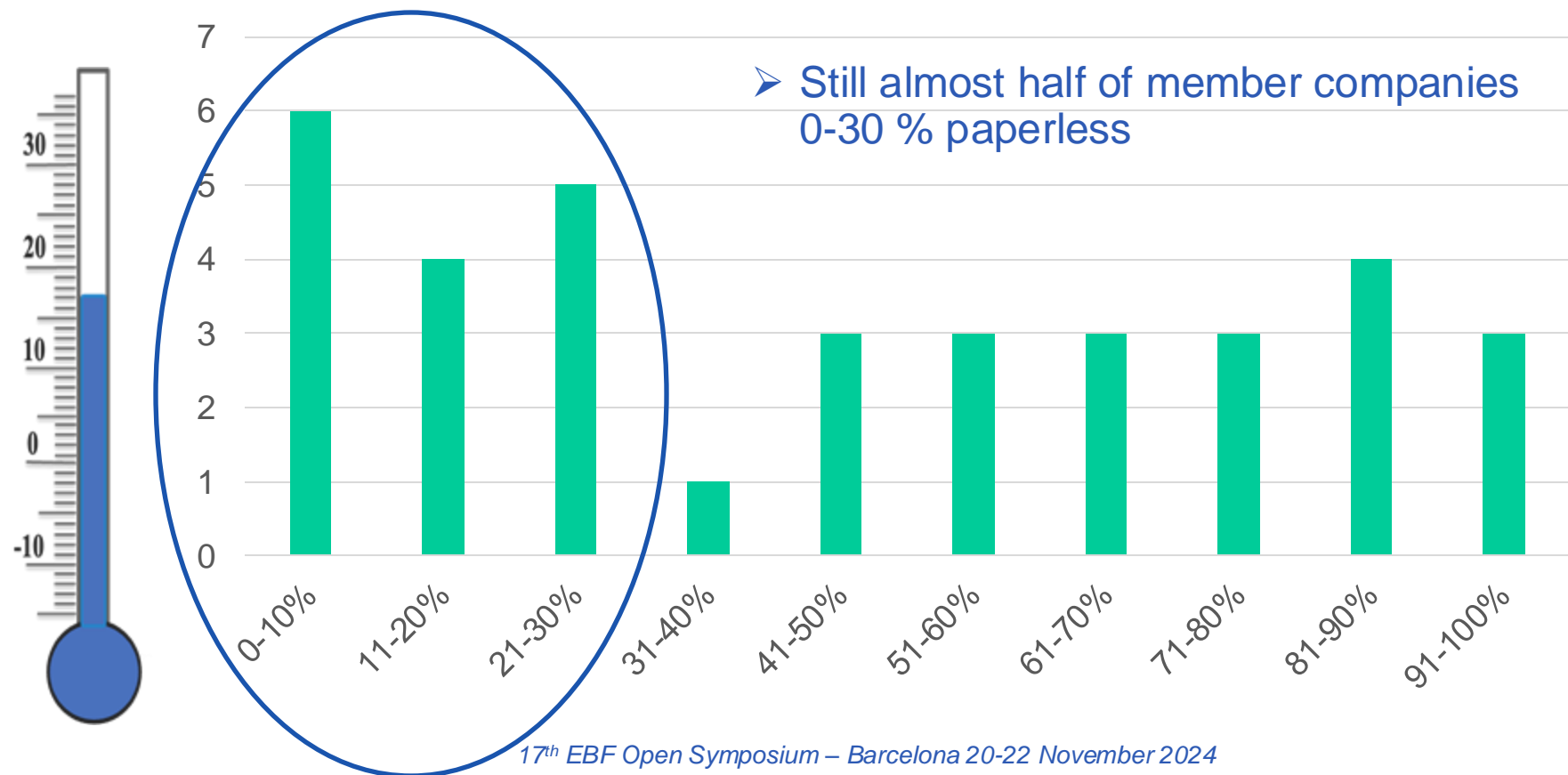
Q1 Do you represent Pharma or CRO?



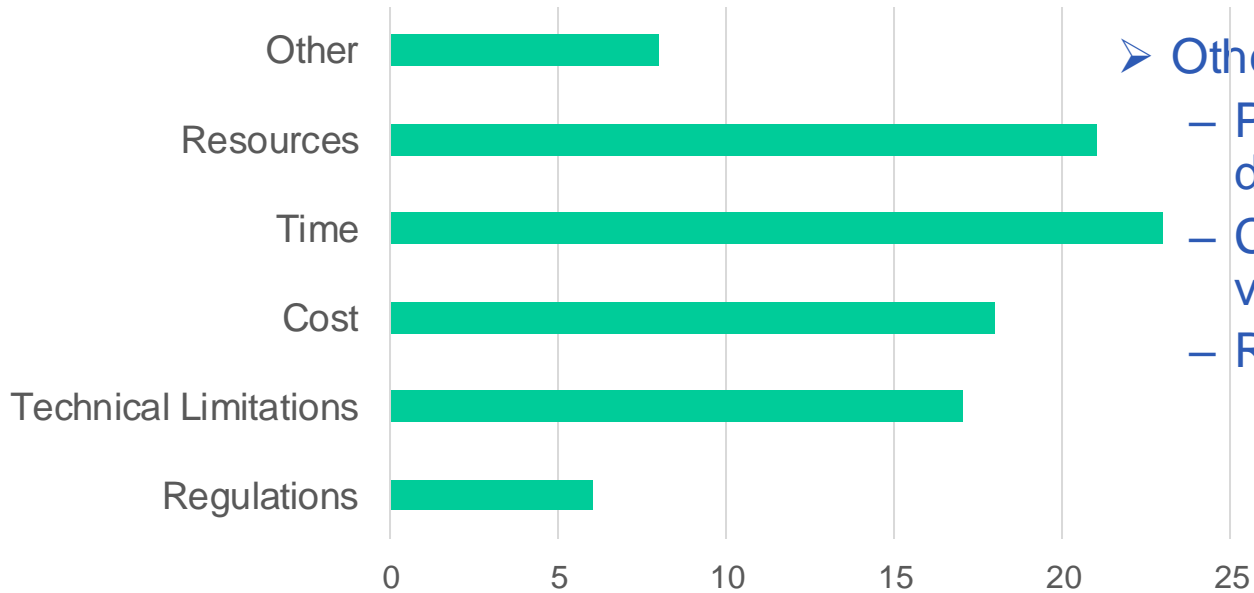
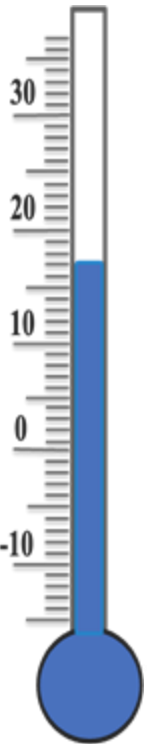
■ Pharma ■ CRO

➤ In total 38 member companies responded to the survey

Q2. To what extent do you consider your lab paperless today?

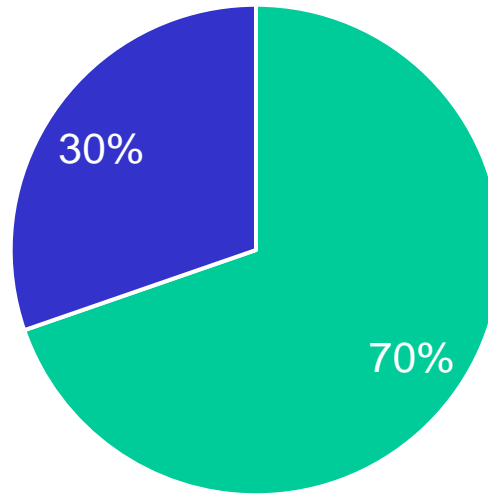
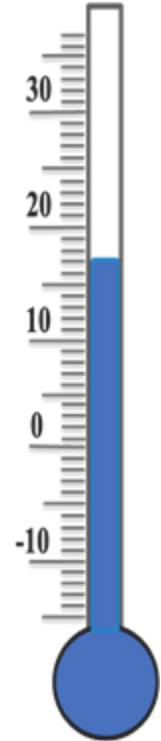


Q3. What are the key road blockers for a full transition into a paperless lab?



- Other being for example:
- Paper based external documentation
 - Computerised system validation efforts
 - Resistance (notebooks)

Q4. Do you feel equipped to estimate to what extent your lab workflows and applications have been transferred into the cloud (IaaS, PaaS or SaaS)?

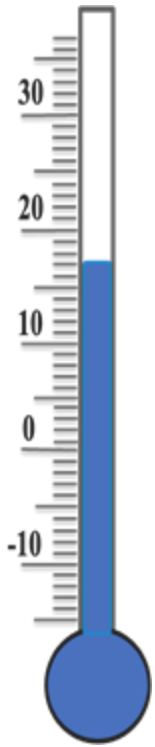
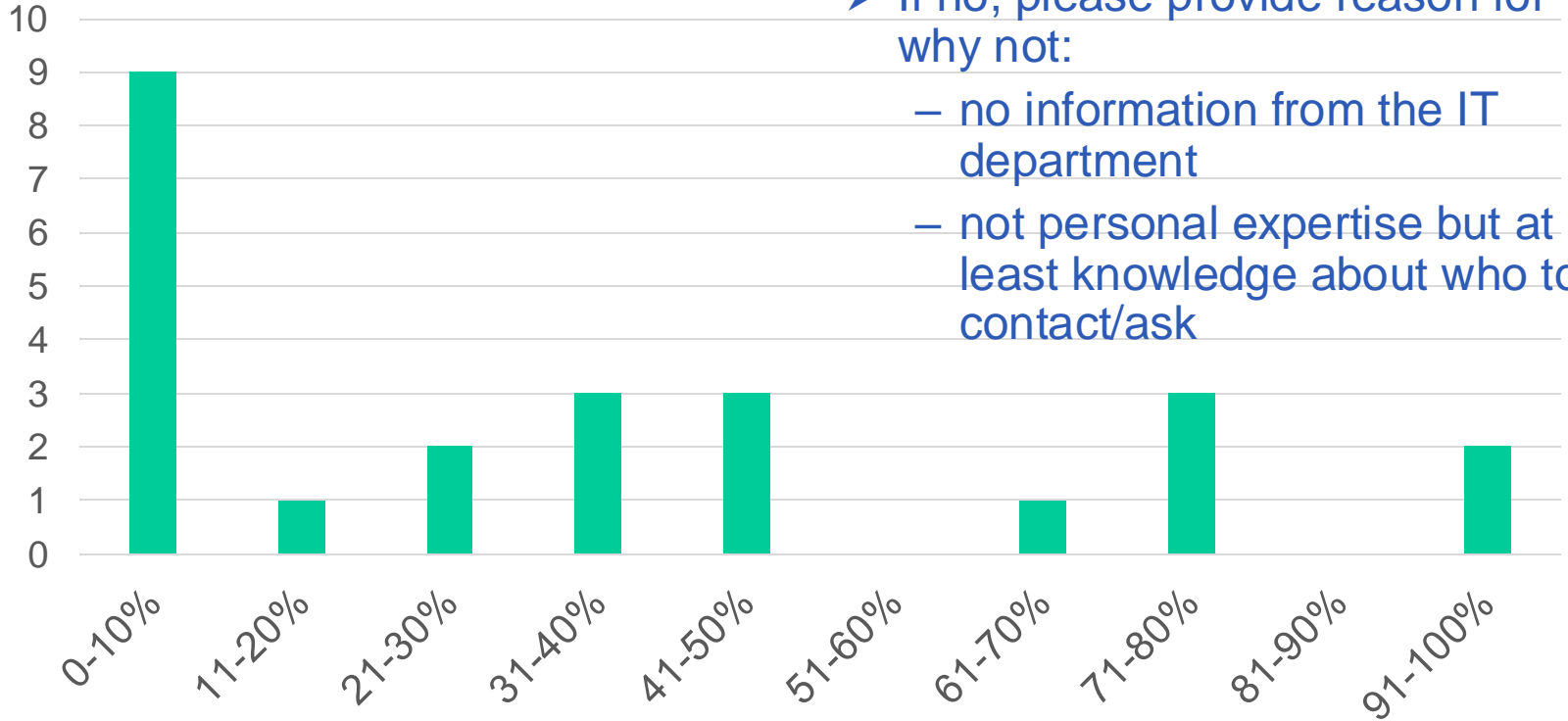


■ Yes ■ No

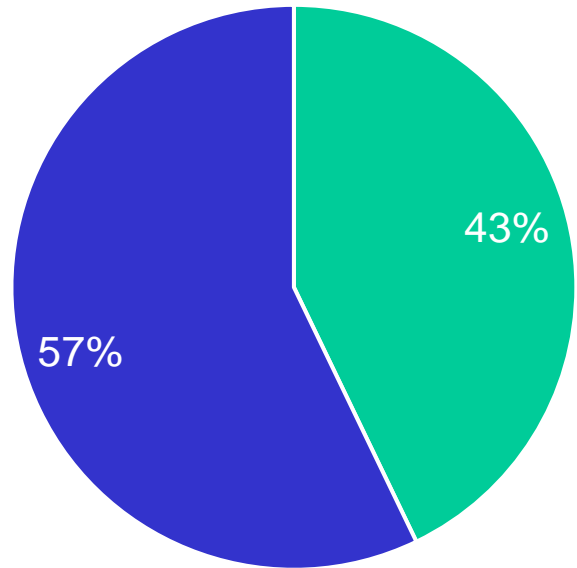
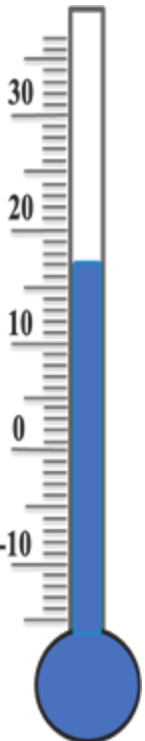
Q4. If yes, please provide best estimate percentage (0-100%):

➤ If no, please provide reason for why not:

- no information from the IT department
- not personal expertise but at least knowledge about who to contact/ask

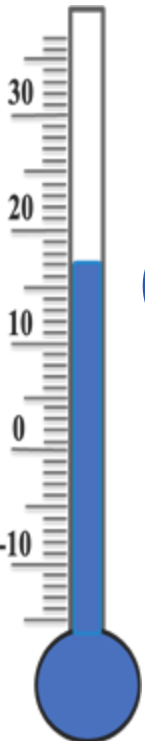


Q5. Does your process/SOP on archiving also consider when your data is stored/archived in the cloud?

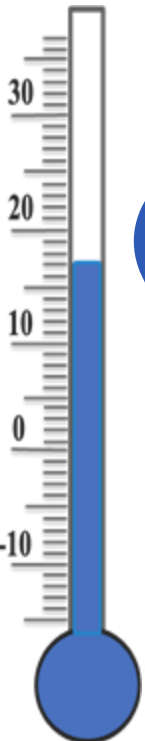


■ Yes ■ No

Q6a If yes, What extra measures are in place when data is archived in the cloud?

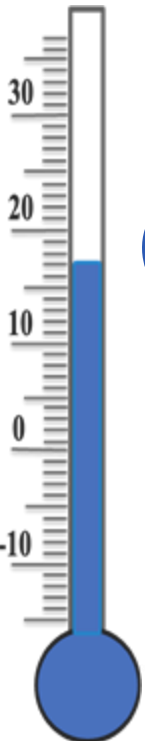
- 
- *Supplier qualification and monitoring*
 - *Service Level Agreements with Cloud provider*
 - *GDPR coverage if SAAS comes from outside the EU.*
 - *Storage location review/risk analysis.*

Q6a If yes, What extra measures are in place when data is archived in the cloud?



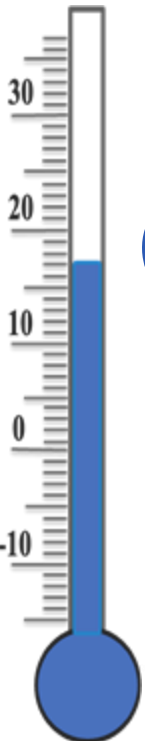
Considering risk assessment and control on data file migrations. Ensuring access control of archived data files. Considering when/where we electronically sign for confirmation of move/copy of archived data and how much we can automate. Defining in our system descriptions and SOPs where our true copies are.

Q6a If yes, What extra measures are in place when data is archived in the cloud?



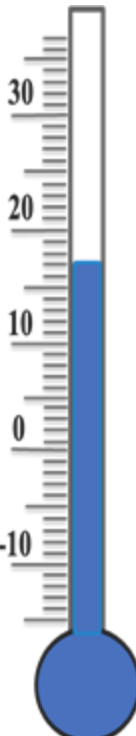
When archiving or retaining electronic records, specific requirements described in SOPs must be followed to ensure data integrity, retrievability and readability during the archive phase.

Q6a If yes, What extra measures are in place when data is archived in the cloud?

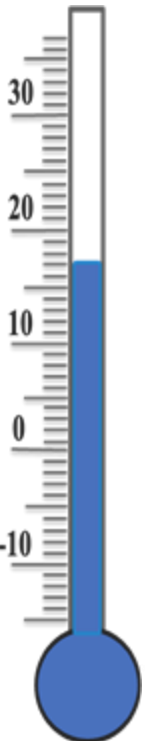


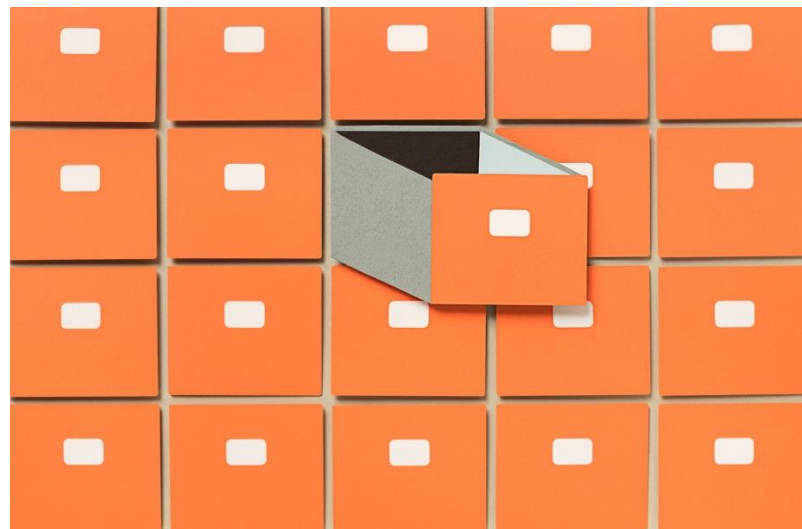
We have leveraged to the Vendor documentation and description of the system and the cloud solution. We receive notifications on upgrades and changes that are reviewed and approved by System Owner and this documentation is locked.

Q6a If yes, What extra measures are in place when data is archived in the cloud?

- 
- *Archiving managed by IT department*
 - *Not very detailed*
 - *Not fully aware of, being in the scope of RIM Team (Regulatory Information Management)*

Q6b If yes, are there any differences in the definition of the archivist role?

- 
- **NO!**
 - *The archivist role should be defined the same for e-Data as for physical data.*
 - *Archivist role within a SaaS set-up needs clear testing and also associated processes to ensure database administrators have limited access to archived study files.*



Q6b If yes, are there any differences in the definition of the archivist role?



➤ *We would define individual archivists per system which could be the same person(s) as our IT manager/system manager/system admin (or which terminology fits best). These e-archivists will be responsible to ensure SLA access/vendor management at the contracted vendor as well as access control of the archived data.*

➤ *A system Archivist role has been defined by the GLP archivist and applied to the SaaS solution by specific description of the roles in the Adm SOP. However, the GLP archivist role has not changed, and this may cause some issues because the use of the cloud has an imbedded deviation from the OECD definition of a GLP archivist.*

Q7. How do you secure long term access of your data in the cloud??

Contracts

Vendor contract and Master Subscription Services Agreement

I don't know

It's something that we are still evaluating

Virtualized computer systems



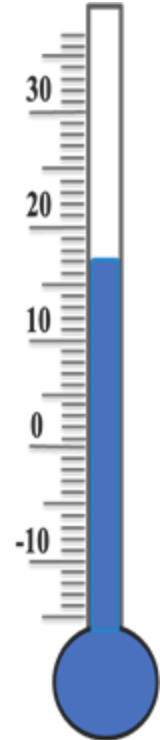
To store the data at a renowned cloud provider.

Periodical verifications

Amazon Web Services (AWS) stores data in multiple centers

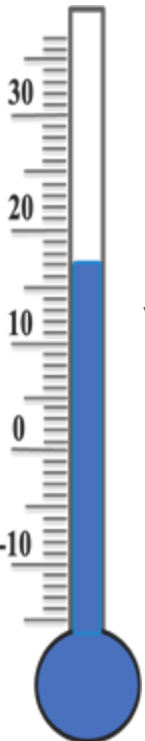
Contractual agreement; define exit strategy

By the company owning the servers in the cloud-solutions for archiving and retention of data, and through contracts with external vendors.

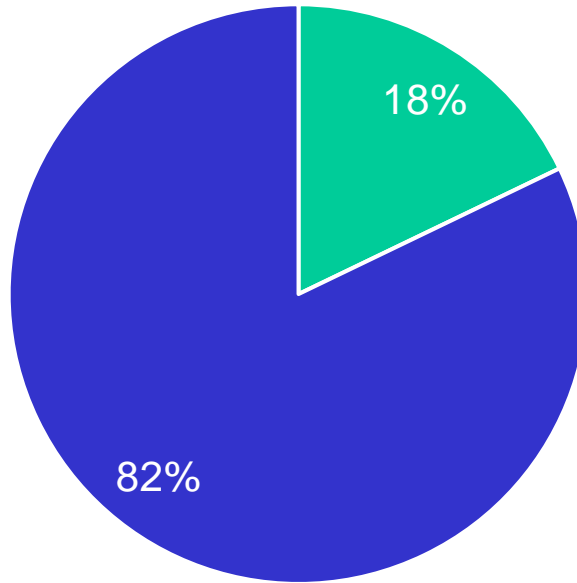
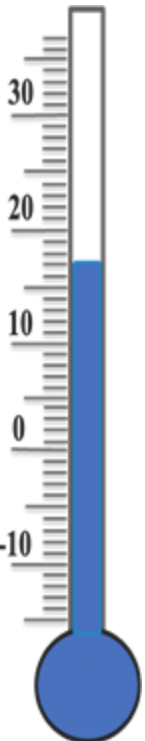


Q8. How do you maintain full control of your archived data in the cloud?

- Other being for example:
- Back-Up Strategy
 - Disaster Recovery
 - Exit strategy
 - SLA with Corporate IT
 - Departments specialized in administering the business with the XaaS-vendors.



Q9. Have you ever been audited / received questions from health authorities on your cloud archiving process?



■ Yes ■ No

Case Study 1 – Experiences from 8 years being a paperless laboratory (David P, Lablytica)

➤ Paperless since 2016

- The role of the archivist has been changed after almost each regulatory inspection....
 - No archivist named at test site for the electronic archiving system (2016)
 - IT system administrators need to be the archivist (2017)
 - No archivist named at test site for the electronic archiving system (2022)
- Changes have only been semantic and have not had any practical impact.
- Would not change when moving into the cloud.



OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING, No 17



ENV/JM/MONO(2016)13

Unclassified

English - Or. English
9 November 2022

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY ON
CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

Cancels & replaces the same document of 22 April 2016

OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE
MONITORING

Number 17
Advisory Document of the Working Party on Good Laboratory Practice
Application of GLP Principles to Computerised Systems

3.11 Archiving

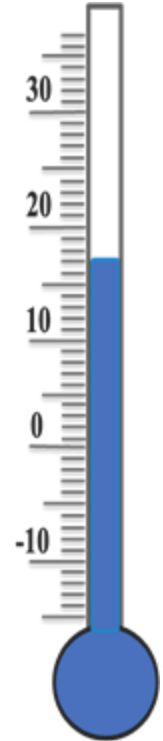
Any GLP-relevant data may be archived electronically. The GLP Principles for archiving must be applied consistently to electronic and non-electronic data.....

*Electronic archiving should be **regarded as an independent procedure** which should be validated appropriately. A risk assessment should be applied when designing and validating the archiving procedure.....*

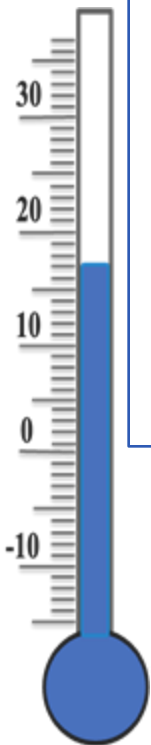
*The **archivist**, who holds sole responsibility, may **delegate tasks during the management of electronic data** to qualified personnel or automated processes (e.g. access control).*

Case Study 2 - Questions from German authorities when moving into the cloud (Tobias H, Abbvie)

- Application (Nugensis) moving into the cloud
- Questions received from the German authorities on the implementation of a cloud-based application included requests for:
 - Contractual documentation/SLAs with the software vendor that outlines the contract term, data integrity responsibilities, and data ownership/data access arrangements
 - The archive transfer and migration plans
 - SOPs with defined procedures with which fifteen-year storage even after the contract has ended can be guaranteed
 - Compilation of the types of raw data to be archived in the cloud
 - Risk assessment with reference to data integrity in the planned external electronic archiving



OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING - Advisory Document on GLP & Cloud Computing, Supplement 1 to Document No 17



6.3 Electronic archives in cloud solution

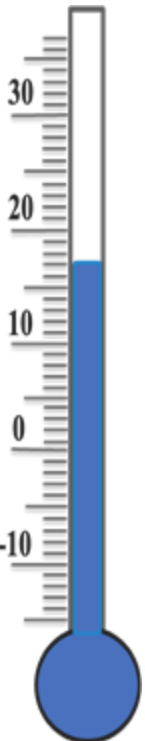
Cloud service providers may act as a contract archive by providing services or components to retain and archive GLP relevant data and records...


*Electronic archives should comply with the applicable **GLP Principles** (including OECD Document No. 15) and TFM must ultimately ensure that this occurs.....*

...some GLP compliance monitoring authorities require details on location of a cloud archive for physical verification, which excludes the use of servers with unknown location for the hosting of electronic archives.....

*Information on the computerised systems and cloud service providers that support logical and technical integrity should be available. This would include **proves of full control by archivist, access control, inventory for indexed orderly storage, record retrievability, evidence of record integrity and traceability** from raw data to final report*

Case Study 3 - Considerations for a GCP lab when moving into the cloud (Anna L, Minervax)

- 
- Focus on building a system for GCP support
 - OECD GLP guidelines not relevant but rather EMA Guideline on computerised systems and electronic data in clinical trials
 - GCP aspects to be considered:
 - Data confidentiality
 - Data integrity
 - Data availability
 - ...
 - Is the archiving requirement of source data from a lab supporting clinical studies any different from eTMF source data requirements/ common clinical practice?



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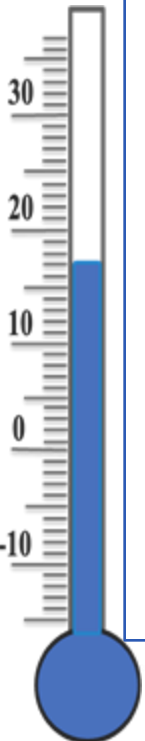
9 March 2023
EMA/INS/GCP/112288/2023
Good Clinical Practice Inspectors Working Group (GCP IWG)


Guideline on computerised systems and electronic data in clinical trials

Adopted by GCP IWG for release for consultation	4 March 2021
Start of public consultation	18 June 2021
End of consultation (deadline for comments)	17 December 2021
Final version adopted by the GCP IWG	7 March 2023
Date of coming into effect	6 months after publication

This guideline replaces the 'Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials' (EMA/INS/GCP/454280/2010).

EMA - Guideline on computerised systems and electronic data in clinical trials





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6.11 Archiving

*The investigator and sponsor should be aware of the required retention periods for clinical trial data and essential documents, including metadata.It should be clearly defined which data are related to each clinical trial activity and **where this record is located and who has access/edit rights** to the document. Security controls should be in place to **ensure data confidentiality, integrity, and availability**....*

*Suitable archiving systems should be in place to **safeguard data integrity** for the periods established by the regulatory requirements*

*Source documents and data should always **be available***

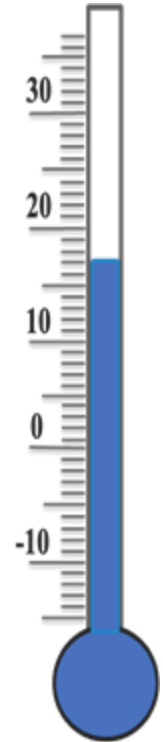
*Data should be **maintained in a secure manner***

To summarise

An archivist is an information professional who assesses, collects, organizes, preserves, maintains control over, and provides access to records and archives determined to have long-term value - Wikipedia



- Are there any true changes in the archivist role when moving all data into the cloud?
- What are the key changes in the archiving activities when moving all data into the cloud?



Acknowledgements

- EBF core members for valuable input into the survey
- EBF e-environment team for valuable input into the archiving discussions





More information on the EBF: www.e-b-f.eu

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