



16th Open Symposium

Science Winning the Race

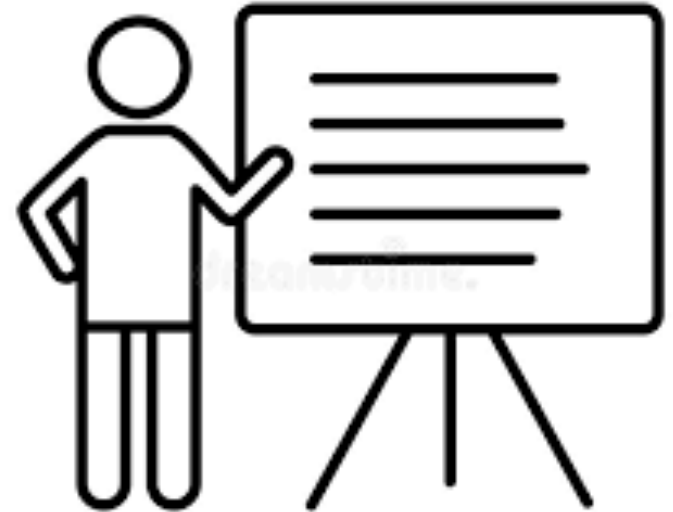
Moving into the cloud – Are we ready and what actions are needed ?

Cecilia Arfvidsson, on behalf of the EBF

15-17 November 2023, Barcelona

Presentation outline

- EBF and the strategic focus on the e-environment and Data Integrity challenges
- In 2023 ... Moving into the cloud...
- Finger on the Pulse (FotP) survey on implementation of cloud-based applications
- Zoom meeting with stakeholders
- Continued discussions during this EBF Open Symposium



EBF e-environment team focus for 2023

We see an increased interest and use of cloud-based applications in our bioanalytical labs



Organisation for Economic Co-operation and Development

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29 June 2023

ENVIRONMENT DIRECTORATE
CHEMICALS AND BIOTECHNOLOGY COMMITTEE

OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE
MONITORING

Advisory Document on GLP & Cloud Computing
Supplement 1 to Document Number 17 on Application of GLP Principles to Computerised
Systems

OECD Advisory Document on GLP & Cloud Computing

- Supplement 1 to Document Number 17 on Application of GLP Principles to Computerised Systems (issued in June 2023)



OECD Advisory Document on GLP & Cloud Computing

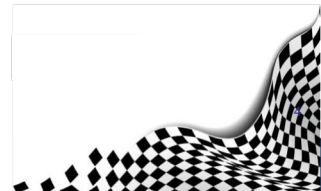


1. Background

The Good Laboratory Practice (GLP) Principles require that records and materials, including electronic records and data, necessary to reconstruct non-clinical safety studies meet the requirements for data quality, data integrity and data availability and are properly retained and archived.

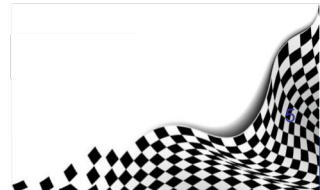
An increasing number of GLP test facilities use cloud applications to accommodate these requirements. However, the potential impact on GLP compliance should be considered when using cloud solutions. GLP test facilities have the ultimate responsibility for GLP compliance to assess risks to data integrity, data quality, data availability, data retention and data archiving.

Cloud refers to delivery of on-demand network access to a shared pool of configurable computing resources to users and can include software, networks/platforms or infrastructure. Cloud-based solutions in GLP could cover the external development, maintenance and hosting, inside or outside of the premises of the test facility, of computing resources such as:



2023 Finger on the Pulse Survey

- A Finger on the Pulse Survey (FotP) was sent out to EBF Core community in July 2023
 - to investigate the EBF community's interest in a zoom meeting for further discussion and interaction on the implementation of cloud-based applications
 - to collect some additional insight to what extent the bioanalytical community understands 'the cloud' and to what extent it has been implemented in our labs.
- The outcome from the survey was used as a starting point for the zoom meeting discussions and preparations of the EBF OS.
- Number of responders to the FotP survey = 23



What is the Cloud?

A service model.

***IT resource** made
available via **Internet***

***Virtual server outsourced to a third-party** specialized
company that fulfills the 21CFR requirements*

*Rented electronic file and **data repository** as well as **software platform** outside the protected company IT environment*

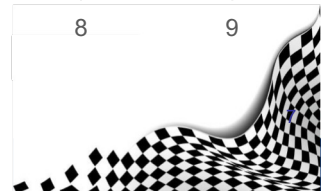
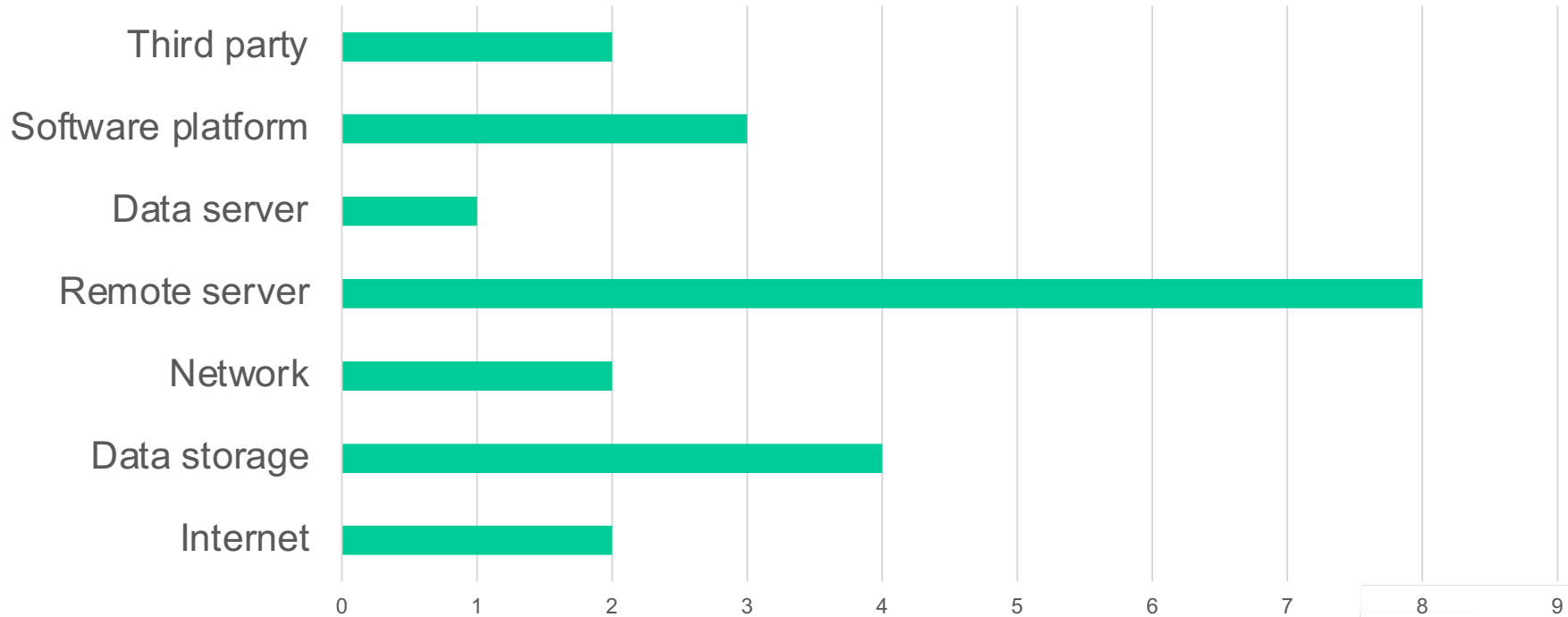
*A **server which can be used remote** for the saving of data
generated by computers and computerized systems.*

*Outsourcing own activities and responsibilities to a **third party**.*

*Public, **decentralised data storage area** accessible through the internet where
the physical servers are provided, monitored and administered by a third party*



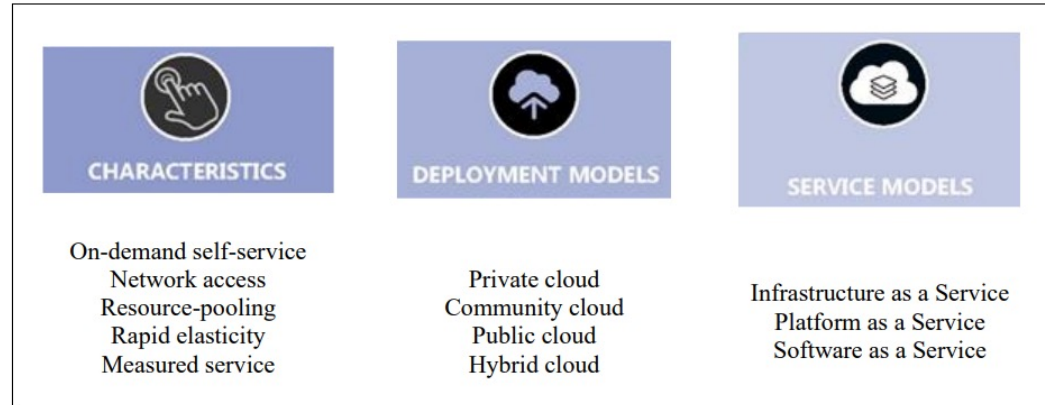
Key words used in the "Cloud" definition



Cloud definition – in OECD

The US National Institute of Standards and Technology (NIST)¹ defines cloud computing as:

“A model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g. networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction.”

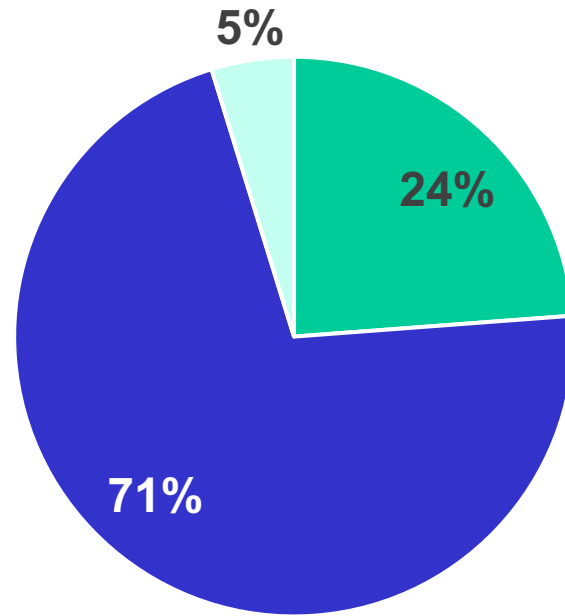


Source: Crisanto, J. et al. (2018), FSI Insights on policy implementation No. 13, Regulating and supervising the clouds: emerging prudential approaches for insurance companies,

¹Peter Mell, T. (2011), The NIST Definition of Cloud Computing, NIST

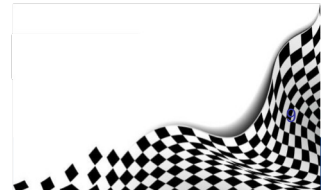


Do you think that you know enough about cloud-based services and applications?



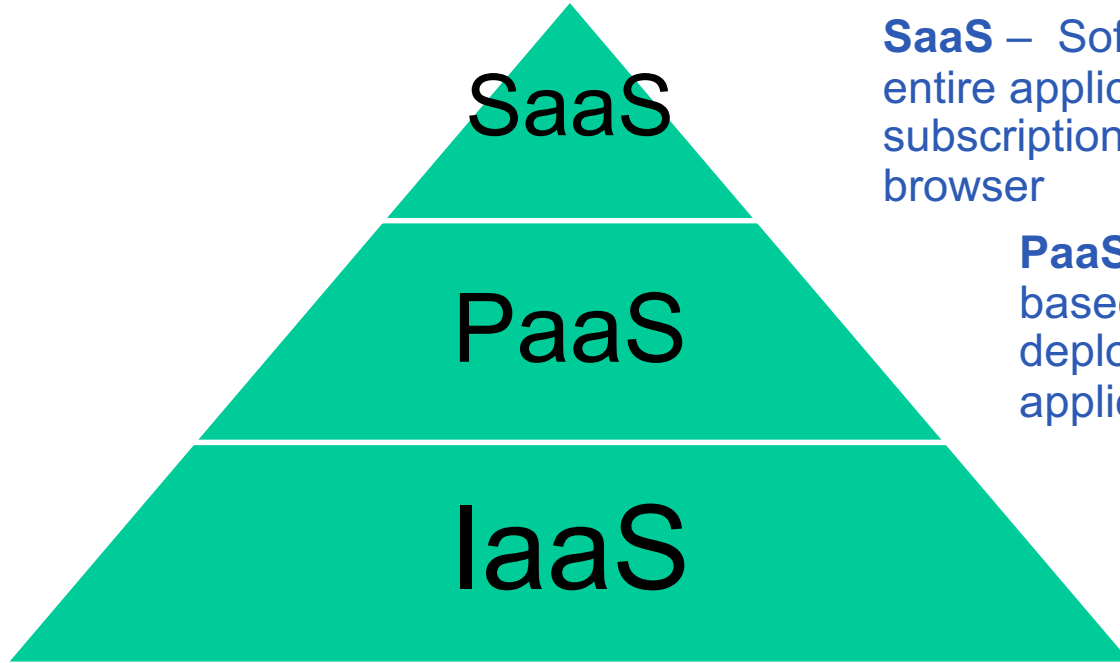
■ Yes ■ No ■ I do not know

- 90% of the responders agreed a zoom meeting would be beneficial to discuss details and share experiences



Cloud service models

“As a service” - a business consumes IT resources owned, managed and maintained by a third-party cloud service provider.



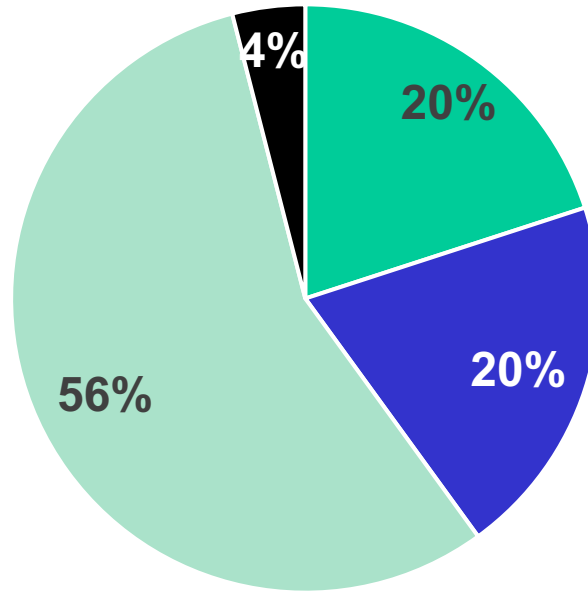
SaaS – Software as a service. Delivers entire applications as a service on a subscription basis. Accessed through a browser

PaaS – Platform as a service. Cloud based platform for developing, deploying running and managing applications

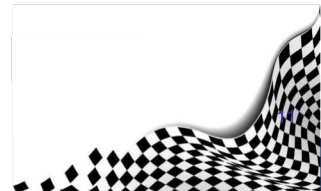
IaaS – Infrastructure as a service. Most like traditional IT infrastructure, but leased, not owned.



To what (maximum) extent (level) has your company/lab implemented cloud-based applications?

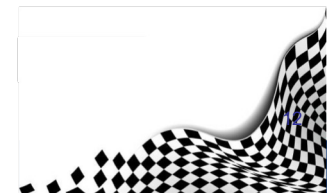


■ IaaS ■ PaaS ■ SaaS ■ I do not know

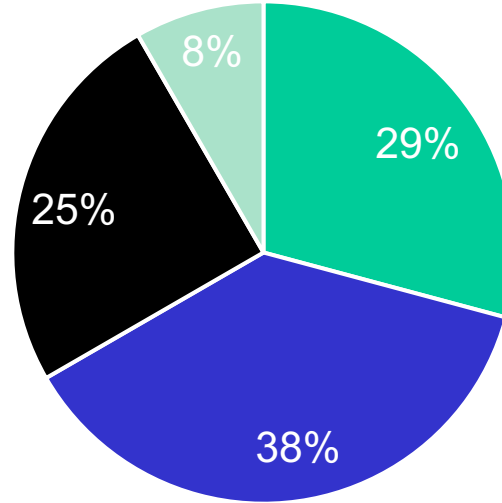


Where are cloud-based applications implemented in your lab?

Function	IaaS	PaaS	SaaS	NONE (=Facility IT)	Do not know
Storage deposit	22%		11%	61%	6%
Equipment software		6%	13%	81%	
LIMS/ELN system(s)	11%	5%	26%	53%	5%
Storage of study data	6%		6%	88%	
Archiving of data	6%		13%	81%	



What external cloud vendors are currently being used?



Others being:

- ZenQMS
- Kneat
- Simplicia
- Pharmacloud
- Rackspace
- Veeva

■ Amazon ■ Microsoft ■ Google ■ Other ■ I do not know



What questions do you have on cloud-based implementation?

Qualification / validation

Vendor qualification?

How do you ensure read/change access to the data?

How can such a process with an external service provider be controlled?

Who monitors and records access to the data?

Compliance of the Cloud-based IT system with the regulations of GLP / GCP studies?

Archiving

Backup and archival process?

How to handle the GLP archivist role in a Cloud solution when you do not know where your data are?



Regulations

Server location?

Experiences with audits of cloud service providers?

GLP status of provider?

What are the specific guidelines for the use of cloud applications?

Technical

How to get information about encryption in the cloud?

What are the risks using cloud-based data tools?

What software used in the industry is hosted on the cloud?

Data Integrity

How do you handle security breaches?

How to demonstrate integrity backup-and restore?

What type of security standards are put in place to ensure data stored in the cloud is secure?

Responsibilities, access and security issues?

Data Privacy/GDPR

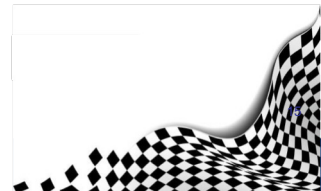
Data Privacy, Service Level Agreements?

How cloud-based services can insure General Data Protection Regulation (GDPR) for the stored data?



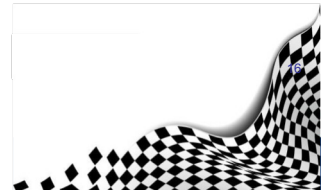
Implementation of Cloud Based Applications – Zoom meeting

- What are the bioanalytical labs' responsibilities in the interfaces with other collaborating expertise functions?
 - Engage with these interfaces and expertise functions
 - Collect their feedback on the role of the BioA lab and what responsibilities they see lay with the BioA lab
- Is there a role for EBF to facilitate in the implementation of cloud-based applications?



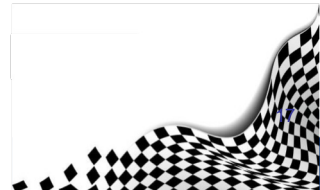
Community feedback from zoom meeting

- The regulators are waiting for the industry to lead the way
- Someone needs to go first ...
- End to end cloud-based implementations are still very unusual BUT cloud-based applications are already implemented in our labs
- An impact assessment is critical (as called out in OECD guidance)
- Country specific regulations/expectations on data privacy (where the data is stored) may occur

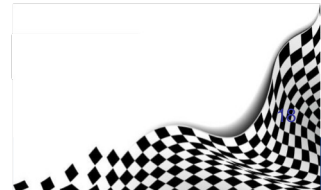


EBF OS – continued discussion in Pitlane 3

- Illustrate the current cloud applications in a few examples
 - On-Premise vs. SaaS – what are the true differences?
 - What actions are needed?
 - Points to consider
 - Lab equipment and data collection vs supporting functions in the cloud – what are the differences?
- Is there a role for EBF to facilitate in the implementation of cloud-based applications?

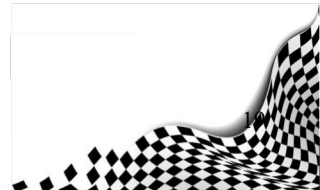


Any Questions?



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